IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

LYNN BREWER and WILLIAM BREWER, Plaintiffs, v. JANSSEN PHARMACEUTICALS, INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA INC.; ORTHO-MCNEIL PHARMACEUTICALS, LLC; JANSSEN RESEARCH & DEVELOPMENT, LLC, f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC; JOHNSON & JOHNSON; JANSSEN ORTHO, LLC; TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.; TEVA PHARMACEUTICALS USA, INC.; and ABC CORPORATION 1-20, Defendants.	Case No.: **JURY DEMAND**

COMPLAINT

Plaintiffs, LYNN BREWER and WILLIAM BREWER, (hereinafter "Mrs. Brewer" and "Mr. Brewer", respectively), by and through undersigned counsel, hereby complains against Defendants, JANSSEN PHARMACEUTICALS, INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA INC.; ORTHO-MCNEIL PHARMACEUTICALS, LLC; JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON & JOHNSON RESEARCH & DEVELOPMENT, L.L.C.; JOHNSON & JOHNSON; JANSSEN

ORTHO LLC; TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.; TEVA PHARMACEUTICALS USA, INC.; and ABC CORPORATION 1-20, (hereinafter collectively referred to as "Defendants"), and allege as follows:

A. PRELIMINARY STATEMENT

1. As a result of Defendants' wrongful and tortious conduct with respect to the prescription drug, Elmiron®[1]—which is indicated for the treatment of the bladder pain and/or the discomfort associated with interstitial cystitis (IC)—Plaintiff, Lynn Brewer, has suffered serious and permanent vision-related injuries.

2. At all relevant times, upon information and belief, Defendants were involved in the pre- and post-market testing, development, labeling,[2] marketing and/or sale of Elmiron. During the more than two decades that Elmiron was available in the United States, Defendants knew (or should have known) of a causal association and/or causal relationship between Elmiron use and an increased risk of developing serious vision-related injuries, like those suffered by Mrs. Brewer.

3. But, upon information and belief, rather than attempt to study this potential safety concern, to change the formulation or administration of Elmiron, or to change the Elmiron drug label to warn the public of the risk of serious, permanent vision-related injuries, instead, Defendants did nothing. Instead, Defendants affirmatively represented that Elmiron was a safe and effective treatment for

[1] Elmiron is the brand name for pentosan polysulfate sodium and will be referred to hereinafter as simply "Elmiron".

[2] In the context of a pharmaceutical sold in the United States, the term "label", according to Federal and FDA regulations, includes the product's package insert (and Medication Guide, if applicable), package labeling, and container label. It is this definition of "label" or "labeling" that is intended throughout this Complaint.

interstitial cystitis.

4. As a direct and proximate result of Defendants' misconduct, Plaintiffs have brought the instant suit and claims under the New Jersey Products Liability Act (Count I), consumer fraud (Count II), negligence (Count III), breach of express warranty (Count IV), breach of implied warranty (Count V), common law fraudulent misrepresentation and fraudulent concealment (Count VI), and loss of consortium (Count VII).

B. PARTIES

a. PLAINTIFFS

5. Plaintiff, Lynn Brewer, is a citizen of the state of Alabama and currently resides in Centre, Alabama.

6. Plaintiff, William Brewer, is a citizen of the state of Alabama and currently resides in Centre, Alabama.

b. DEFENDANTS

JANSSEN PHARMA

7. Defendant JANSSEN PHARMACEUTICALS, INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA INC., ("Janssen Pharma") is a New Jersey corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

8. Upon information and belief, Defendant Janssen Pharma made consequential decisions and/or took significant actions concerning, *inter alia*, the

design, testing, marketing, promotion, labeling and/or regulatory approval of Elmiron in the United States, which necessarily includes New Jersey.

9. Upon information and belief, as part of its business, Defendant Janssen Pharma engages in the design, testing, labeling, packaging, marketing, advertising, distributing and/or selling of pharmaceutical products, including Elmiron, throughout the United States, which necessarily includes New Jersey.

ORTHO PHARMA

10. Defendant ORTHO-MCNEIL PHARMACEUTICALS, LLC ("Ortho Pharma") is a corporation organized under Delaware law with its principal place of business in 1000 US Highway 202, Raritan, New Jersey 08869.

11. Upon information and belief, Defendant Ortho Pharma made consequential decisions and/or took significant actions concerning, *inter alia*, the design, testing, marketing, promotion, labeling and/or regulatory approval of Elmiron in the United States, which necessarily includes New Jersey.

JANSSEN R&D

12. Defendant, JANSSEN RESEARCH & DEVELOPMENT, LLC, f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC, (hereinafter "Janssen R&D") is a limited liability company under the laws of New Jersey, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

13. Upon information and belief, Defendant Janssen R&D 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, which necessarily includes New Jersey.

14. Upon information and belief, Defendant Janssen R&D has transacted and conducted business within the State of New Jersey and has derived substantial revenue from goods and products disseminated and used throughout the United States, which necessarily includes New Jersey.

15. Upon information and belief, as part of its business, Defendant Janssen R&D is involved in the research, development, sales, and/or marketing of pharmaceutical products, including Elmiron, throughout the United States, which necessarily includes New Jersey.

16. Upon information and belief, and at all relevant times Defendant, Janssen R&D, was in the business of and, indeed, did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute the drug Elmiron.

JOHNSON & JOHNSON

17. Defendant Johnson & Johnson (hereinafter collectively referred to as "J&J") is a New Jersey corporation, which has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

18. Upon information and belief, at all relevant times, Defendants Janssen Pharma, Ortho Pharma, and Janssen R&D have been wholly owned subsidiaries of Defendant J&J, with the profits of each inuring to Defendant J&J's benefit.

19. Upon information and belief, as part of its business, Defendant J&J, and its "family of companies," is involved in the research, development, sale, and/or marketing of pharmaceutical products, including Elmiron, in the United States, which necessarily includes New Jersey.

20. Upon information and belief, Defendant J&J made consequential decisions and/or took significant actions concerning, *inter alia*, the design, marketing, promotion, labeling and/or regulatory approval of Elmiron in the United States, which necessarily includes New Jersey.

21. Upon information and belief, Defendant J&J's 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, including in New Jersey.

JANSSEN ORTHO

22. Defendant JANSSEN ORTHO, LLC ("JANSSEN ORTHO") is a limited liability company organized under Delaware law with its principal place of business in Gurabo 00777, Puerto Rico.

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

24. Upon information and belief, Defendant Janssen Ortho made consequential decisions and/or took significant actions concerning, *inter alia*, the design, testing, marketing, promotion, labeling and regulatory approval of Elmiron.

25. Upon information and belief, Defendant Janssen Ortho manufacturers and/or packages Elmiron for sale in the United States, which necessarily includes New Jersey, on behalf of Janssen Pharma.

26. Upon information and belief, and at all relevant times, Defendant, Janssen Ortho, was in the business of and, indeed, did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute the drug Elmiron.

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.

27. Defendant TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. is a Delaware corporation with a principal place of business located at 41 Moores Rd., Frazer, PA 19355.

28. At all relevant times, Defendant TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. regularly and continuously did business in the United States, including in the State of New Jersey, and, also, engaged in the design, testing, labeling, packaging, marketing, advertising, distribution and/or sale of Elmiron, individually and/or through or with its partners and joint venturers.

TEVA PHARMACEUTICALS USA, INC.

29. Defendant TEVA PHARMACEUTICALS USA, INC. is a Delaware Corporation with a principal place of business located at 400 Interpace Parkway, Parsippany, NJ 07054.

30. At all relevant times, Defendant TEVA PHARMACEUTICALS USA, INC. regularly and continuously did business in the United States, including in the

State of New Jersey, and also engaged in the design, testing, labeling, packaging, marketing, advertising, distribution and/or sale of Elmiron, individually and or through its partners and joint venturers.

ABC CORPORATION 1-20

31. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of ABC CORPORATION 1-20, inclusive, are unknown to Plaintiff at this time, who, therefore, sues these Defendants by such fictitious names.

32. Plaintiff is informed and believes, and thereon alleges, that each defendant designed herein as a ABC CORPORATION 1-20 caused injuries and damages proximately thereby to Plaintiff as hereinafter alleged, and that each ABC CORPORATION 1-20 Defendant is liable to the Plaintiff for the acts and omissions alleged herein below, and the resulting injuries to Plaintiff, and damages sustained by the Plaintiff.

33. Plaintiff will amend this Complaint to allege the true names and capacities of said ABC CORPORATION 1-20 Defendants when the same is ascertained.

34. Plaintiff is informed and believes, and thereon alleges, that at all times herein mentioned, each of the ABC CORPORATION 1-20 Defendants were the agents, servants, employees and/or engaged in a joint venturers of the other co-defendants and other ABC CORPORATION 1-20 Defendants, and each of them, and at all said times, each Defendant and each ABC CORPORATION 1-20 Defendant was

acting in the full course, scope and authority of said agency, service, employment and/or joint venture.

35. ABC CORPORATION 1-20 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.

36. ABC CORPORATION 1-20 Defendants directly or through their agents or employees designed, manufactured, marketed, and sold Elmiron in the United States, which is used to manage symptoms of interstitial cystitis and painful bladder syndrome.

37. At all times relevant hereto, ABC CORPORATION 1-20 Defendants worked in conjunction with each other and they were affiliated, related, jointly owned, and/or controlled entities or subsidiaries during the researching, analyzing, licensing, designing, testing, formulating, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising and/or selling the prescription drug known as Elmiron.

38. At all times alleged herein, ABC CORPORATION 1-20 Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and/or organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

39. At all times herein mentioned, each of ABC CORPORATION 1-20 Defendants were the agents, servants, partners, predecessors in interest, and/or joint venturers of each of the remaining Defendants herein and were, at all times, operating and acting within the purpose and scope of said agency, service, employment, partnership, and/or joint venture.

40. At all times relevant, ABC CORPORATION 1-20 Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, which necessarily includes New Jersey, directly or indirectly through partners, servants, subsidiaries and/or related entities acting in concert, the pharmaceutical product, Elmiron.

C. JURISDICTION AND VENUE

41. This court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy as to Plaintiffs exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than Alabama, where the Plaintiffs are citizens.

42. This Court has supplemental jurisdiction over the remaining common law and state law claims pursuant to 28 U.S.C. § 1367.

43. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2), because many of the Defendants reside there, all Defendants transact and conduct business in New Jersey, and a substantial part of the acts and omissions giving rise to this Complaint occurred in New Jersey.

D. NATURE OF THE CASE

44. Plaintiffs bring this case against Defendants Janssen Pharma, Ortho Pharma, Janssen R&D, J&J, Janssen Ortho, Teva Branded Pharmaceutical Products R&D, Inc., Teva Pharmaceuticals USA, Inc., and ABC Corporation 1-20 for damages associated with Mrs. Brewer's use of the pharmaceutical drug Elmiron, which was designed, manufactured, marketed, sold and/or distributed by Defendants. Specifically, Mrs. Brewer suffered various injuries, serious physical pain and suffering, medical, and hospital expenses as a direct result of her use of Elmiron.

45. At all relevant times, all Defendants were in the business of and, indeed, did design, research, manufacture, test, advertise, promote, market, sell and/or distribute Elmiron for the treatment of the bladder pain and/or discomfort associated with interstitial cystitis.

46. Defendants' fraudulent and illegal conduct with respect to Elmiron caused thousands of individuals, including Mrs. Brewer, to develop severe injuries, including but not limited to, maculopathy.

E. RELVANT FACTUAL BACKGROUND

INTERSTITIAL CYSTITIS

47. Interstitial cystitis ("IC")—which is also sometimes referred to as "painful bladder syndrome"—is a chronic bladder condition in which individuals experience bladder pain, pelvic pain, urinary frequency, urinary urgency, and/or nocturia.

48. According to the U.S. Centers for Disease Control, IC may impact as many as 5.1 out of every 100,000 Americans and up to 12% of U.S. women may have early symptoms of IC.[3]

49. IC is known to affect more woman than men.[4]

50. The American Urological Association (AUA) established guidelines, separating treatment options into six (6) tiers of increasingly invasive therapies for the treatment of IC. The treatments listed range from minimally invasive interventions, like simple lifestyle changes, to increasingly more invasive interventions, like invasive diagnostic studies or surgery. AUA recommends second-line treatment of IC to incorporate multi-modal pain management approaches including manual therapy and oral therapy options such as pentosan polysulfate (Elmiron). Elmiron is not the best nor the only option for treating interstitial cystitis.

51. There is no known cause of interstitial cystitis.

52. There is no known cure for interstitial cystitis and the condition is permanent or chronic.

FDA APPROVAL OF ELMIRON

53. On approximately June 11, 1991, Baker Norton Pharmaceuticals, a division of Ivax Pharmaceuticals, ("Baker Norton") submitted a New Drug Application ("NDA") for pentosan polysulfate sodium (NDA: 020193) (hereinafter "original NDA").

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[3] *See* Centers for Disease Control website, "What is Interstitial Cystitis (IC)?", available online at: https://www.cdc.gov/ic/index.html.
[4] *Id.*

54. Pentosane polysulfate sodium is a semi-synthetically produced heparin-like macromolecular carbohydrate derivative.

55. Pentosane polysulfate sodium is sold under the brand name Elmiron.

56. According to the FDA, "the documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged."[5]

57. Upon information and belief, FDA deemed the original NDA non-approvable in approximately 1993.

58. Upon information and belief, in response, Baker Norton submitted additional materials, in support of the application, for FDA review.

59. Upon information and belief, FDA issued a second non-approvable letter in approximately 1994.

60. Upon information and belief, Elmiron was granted an Orphan Drug designation in 1995.

61. Upon information and belief, Baker Norton, again, submitted additional materials, in support of the application, for FDA review.

62. On September 26, 1996, the U.S. Food and Drug Administration (FDA) approved Elmiron for relief of pain or discomfort associated with IC.

[5] *See* FDA Website, "New Drug Application (NDA)", available online at: https://www.fda.gov/drugs/types-applications/new-drug-application-nda.

63. The proposed label, approved by FDA, included a Package Insert—directed at physicians and other healthcare providers—as well as a Medication Guide—directed at patients.

64. Beginning in approximately 1996, when Elmiron was first approved by the FDA, neither its Package Insert, nor its Medication Guide contained any warnings or information regarding the risk of serious visual complications, including, but not limited to, pigmentary maculopathy.

HISTORY OF ELMIRON NDA AND TRADEMARK OWNERSHIP

65. Upon information and belief, from approximately 1996, when the NDA was approved, until approximately 1997, Baker Norton owned the trademark for Elmiron.

66. Upon information and belief, in approximately 2005, Teva Branded Pharmaceutical Products R&D, Inc., Teva Pharmaceuticals USA, Inc., and/or Teva Pharmaceuticals, Inc., purchased Ivax Pharmaceuticals.

67. Upon information and belief, as part of that transaction, Teva Branded Pharmaceutical Products R&D, Inc., Teva Pharmaceuticals USA, Inc., and/or Teva Pharmaceuticals, Inc., purchased the assets and liabilities of Ivax Pharmaceuticals, including, but not limited to Baker Norton.

68. Upon information and belief, Elmiron is a Registered Trademark of Teva Branded Pharmaceutical Products R&D, Inc., Teva Pharmaceuticals USA, Inc., and/or Teva Pharmaceuticals, Inc., under license to Defendant Janssen Pharma.

69. Alternatively, upon information and belief, Elmiron is a Registered Trademark of Janssen Pharma, Ortho Pharma, Janssen R&D, J&J, Janssen Ortho, Teva Branded Pharmaceutical Products R&D, Inc., Teva Pharmaceuticals USA, Inc., and/or ABC Corporation 1-20.

70. Upon information and belief, from approximately August 2002 until August 2004, Defendant Janssen R&D held the NDA for Elmiron.

71. Upon information and belief, from July 2004 until August 2008, Defendants Ortho Pharma held the NDA for Elmiron.

72. Upon information and belief, since August 2008, Janssen Pharma, had held the NDA for Elmiron and continues to manufacture, sell, and/or distribute Elmiron in the United States.

73. Alternatively, upon information and belief, since approximately 1997, Janssen Pharma, Ortho Pharma, Janssen R&D, J&J, and/or ABC Corporation 1-20 have held the NDA for Elmiron and continue to manufacture, sell, and/or distribute Elmiron in the United States.

74. There is no generic, non-bioequivalent form of Elmiron sold in the United States.

75. Upon information and belief, given the chronic and permanent nature of IC, Defendants anticipated (or reasonably should have anticipated), that patients taking Elmiron would likely do so indefinitely.

76. Upon information and belief, sales of Elmiron generate approximately $150M in annual revenue in the United States.

DEFENDANTS' INDIFFERENCE TO INCREASING SAFETY CONCERNS

77. From approximately 1997 to the present, Defendants—including, but not limited to, specifically, Janssen Pharma, Ortho Pharma, Janssen R&D, Janssen Ortho, and/or J&J—have received multiple Adverse Event Reports ("AER")[6] from medical professionals concerning Elmiron. These AERs included serious visual complication believed to be associated with Elmiron use, ranging from retinal haemorrhage to macular degeneration to, even, unilateral blindness.

78. Indeed, the reports of serious visual complications were not unique to the United States and, upon information and belief, serious visual complications were reported to Defendants—including, but not limited to, specifically, Teva Branded Pharmaceutical Products R&D, Inc. and/or Teva Pharmaceuticals USA, Inc.—and recorded in other AER databases around the world, where Elmiron was sold, like Health Canada[7] Vigilance Adverse Reaction Online Database[8] and EudraVigilance[9].

79. It is widely recognized and accepted in the pharmaceutical industry that reported AERs represent only a small fraction of adverse events associated with and/or caused by a particular drug.

80. More recently, since approximately 2018, outside, independent studies and reports, documented in medical literature raise similar concerns regarding

[6] An adverse drug event is an event—usually, a negative event—or occurrence believed to be associated and/or caused by a drug.
[7] Health Canada is the Canadian health authority and a roughly equivalent body to the U.S. FDA.
[8] Canada Vigilance Adverse Reaction Online Database is Health Canadian's adverse event database.
[9] EudraVigilance is the European Medicines Agency's ("EMA") adverse event database.

Elmiron's safety and propensity for causing serious visual complications including, but not limited to, pigmentary maculopathy.

81. In approximately May 2018, Emory Eye Center in Atlanta, Georgia, published a case study of six adult patients, who were treating their IC symptoms with Elmiron. The Emory physicians observed and documented significant pigmentary maculopathy in all six patients, who each had a long-history of Elmiron use.

82. In approximately April 2019, the Emory Eye Center published a further case study of ten patients. The doctors reported that over the last four years, patients who did not treat IC with pentosane polysulfide sodium were not experiencing pigmentary maculopathy.

83. The first clinical population-based study came from Kaiser Permanente in 2019. Kaiser Permanente conducted a study based of 4.3 million patients. Patients showed clear evidence of this specific maculopathy, which was believe was associated with Elmiron exposure.

84. The Kaiser Permanente research was presented at the "AAO 2019"—the annual meeting of the American Academy of Ophthalmology at Moscone Center, San Francisco. The study revealed that eye damage increased with the quantity of Elmiron intake.

85. A Harvard Medical School case study, published in 2019, examined a female with a history of eighteen years of Elmiron use at a low dose of 200mg/day. She initially presented with symptoms that included blurry vision, difficulty seeing

at night, and pigmentary changes in the retina. Two years later, she returned for evaluation; her eye examination revealed more extensive eye damage, consistent with pigmentary maculopathy. The Harvard physicians concluded that long-term Elmiron use results in progression of pigmentary maculopathy, even if the drug is stopped.

86. A study published in April 2020 by the Canadian Ophthalmological Society concluded, *inter alia*, the prevalence of Elmiron-induced macular toxicity posed a "significant risk" to patients taking Elmiron.

DEFENDANTS' INTERNATIONAL MISINFORMATION CAMPAIGN

87. Upon information and belief, beginning in approximately 2019, Defendants took steps to warn consumers and physicians in other countries of the risk of serious visual complications, including pigmentary maculopathy, associated with the extended use of Elmiron.

88. For instance, in approximately September of 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.

89. Likewise, in approximately 2019, Defendants "agreed" with an EMA Committee's recommendation that Elmiron's label be changed to warn of the risk of serious visual complications, including pigmentary maculopathy, associated with long-term use of Elmiron.

90. The Elmiron label in EMA 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.

91. The Elmiron label used in EMA countries further admits that "eye disorders", like pigmentary maculopathy, are "uncommon" undesirable effects of the medication.

92. In approving these changes to the Elmiron label, the EMA Committee for Medicinal Products for Human Use (CHMP) created a report, which, upon information and belief, Defendants received. As relevant, here, the CHMP in its report 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".

DEFENDANTS HAD A DUTY TO PROTECT U.S. CONSUMERS, BUT DID NOT

93. At all relevant times, Defendants had a duty to craft an adequate label with respect to Elmiron.

94. At all relevant times, Defendants had a duty to ensure that the warnings in the Elmiron label were adequate, at all times, for as long as the drug remained

available for sale in the United States.

95. At all relevant times, Defendants had a responsibility to conduct post-marketing surveillance and to continue to study the safety and efficacy of Elmiron, after the Elmiron NDA was approved, for as long as the drug remained available for sale in the United States.

96. At all relevant times, Defendants had a duty to revise the Elmiron label to include a warning regarding the risk of serious vision-related injuries as soon as there was reasonable evidence of a causal association between vision-related injuries and Elmiron use.

97. Upon information and belief, by approximately 2001, Defendants had reasonable evidence of a causal association between serious vision-related injuries and Elmiron use.

98. Upon information and belief, by approximately 2001, Defendants learned Elmiron use could cause serious vision-related injuries.

99. Upon information and belief, despite reasonable evidence of causal association, Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA NDA regulations, concerning the safety and efficacy of Elmiron, including, but not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Elmiron users suffering vision-related injuries as a result of their Elmiron use. Such information was material and relevant to the risk of patients, like Plaintiff, developing serious vision-related injuries as a result of taking Elmiron.

100. Upon information and belief, despite understanding Elmiron could cause vision-related injuries, Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA NDA regulations, concerning the safety and efficacy of Elmiron, including, but not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Elmiron users suffering vision-related injuries as a result of their Elmiron use. Such information was material and relevant to the risk of patients, like Plaintiff, developing serious vision-related injuries as a result of taking Elmiron.

101. Accordingly, pursuant N.J.S. §2A:58C-5(c), Defendants are liable to Plaintiffs for punitive damages.

HOW DEFENDANTS' MISCONDUCT ENDANGERED U.S. CONSUMERS

102. Upon information and belief, had Defendants exercised reasonable care in testing and studying Elmiron, they would have discovered prior to seeking FDA approval, that long-term Elmiron use can cause serious visual injuries, including, but not limited to, pigmentary maculopathy.

103. Upon information and belief, despite understanding patients taking Elmiron would likely remain on the medication for long periods of time, Defendants' failed to test and study the long-term safety and efficacy of the drug, prior to seeking FDA approval.

104. Upon information and belief, had Defendants exercised reasonable care in testing and studying Elmiron's long-term effects, they would have discovered prior to seeking FDA approval, that long-term Elmiron use can cause serious visual

injuries, including, but not limited to, pigmentary maculopathy.

105. Upon information and belief, despite post-approval adverse event reports and other clinical evidence, Defendants failed to continue to test and study the safety and efficacy of Elmiron, particularly in patients who used the drug for long periods of time.

106. Upon information and belief, from the date all Defendants received FDA-approval to market Elmiron in the United States, Defendants each of them made, distributed, marketed, and sold Elmiron without adequate warning to Plaintiff's prescribing physicians or Plaintiff that Elmiron was associated with and/or could cause retina damage in patients who used it, and that all Defendants had not adequately conducted complete and proper testing and studies of Elmiron with regard to retina damage.

107. Upon information and belief, Elmiron concealed and/or failed to completely disclose their knowledge that Elmiron was associated with and/or could cause retina damage as well as their knowledge that they had failed to fully test or study said risk.

108. Upon information and belief, all Defendants ignored the association between the use of Elmiron and the risk of developing permanent and disfiguring visual complications, including, but not limited to, pigmentary maculopathy and retina damage.

109. Upon information and belief, all Defendants failed to warn Plaintiff and Plaintiff's healthcare providers regarding true risk of retina damage of Elmiron, but

similar efficacy compared to less potent products.

110. Upon information and belief, all Defendants failed to provide adequate instructions to U.S. healthcare professionals and patients regarding how to safely monitor and identify signs of potentially serious visual complications associated with long-term Elmiron use.

111. Upon information and belief, all Defendants failed to warn U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely monitor and identify signs of potentially serious visual complications associated with long-term Elmiron use.

112. Upon information and belief, all Defendants failed to warn U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, that the risk of potentially serious visual complications increases the longer a patient continues to use Elmiron.

113. Upon information and belief, all Defendants failed to warn and/or to provide adequate instructions to U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely stop taking Elmiron in the event that potentially serious visual complications developed while using Elmiron.

114. Upon information and belief, all Defendants failed to warn U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, of the true risk of retina damage to patients taking Elmiron as to compared to other similarly efficacious pharmaceutical products.

115. All of Defendants' failures to provide adequate instructions and/or disclose information—which Defendants each possessed regarding the failure to adequately test and study Elmiron for the risk of serious visual complications—further, rendered the Elmiron Package Insert, Medication Guide, and other educational and/or promotional materials inadequate.

116. Despite AERs from healthcare professionals and consumers around the world, from approximately 1997 until approximately September 2019, Elmiron never warned—in any country or market—of the risk of serious visual complications, including, but not limited to, pigmentary maculopathy.

ELMIRON U.S. LABEL CHANGE

117. From when Elmiron was first sold in the United States until June 16, 2020, Defendants' U.S. Elmiron did not warn U.S. healthcare professionals and/or consumers of the risk of serious visual complications, including, but not limited to, pigmentary maculopathy associated with long-term Elmiron use.

118. Indeed, from when Elmiron was first sold in the United States until June 16, 2020, upon information and belief, Defendants made no attempt to warn U.S. healthcare professionals and/or consumers of the risk of serious visual complications, including, but not limited to, pigmentary maculopathy associated with long-term Elmiron use.

119. Upon information and belief, beginning on June 16, 2020, Defendants' Elmiron label contained the following language as to the risk of serious, vision-related complications:

WARNINGS
Retinal Pigmentary Changes

Pigmentary changes in the retina, reported in the literature as pigmentary maculopathy, have been identified with long-term use of ELMIRON® (see ADVERSE REACTIONS). Although most of these cases occurred after 3 years of use or longer, cases have been seen with a shorter duration of use. While the etiology is unclear, cumulative dose appears to be a risk factor.

Visual symptoms in the reported cases included difficulty reading, slow adjustment to low or reduced light environments, and blurred vision. The visual consequences of these pigmentary changes are not fully characterized. Caution should be used in patients with retinal pigment changes from other causes in which examination findings may confound the appropriate diagnosis, follow-up, and treatment. Detailed ophthalmologic history should be obtained in all patients prior to starting treatment with ELMIRON®. If there is a family history of hereditary pattern dystrophy, genetic testing should be considered. For patients with pre-existing ophthalmologic conditions, a comprehensive baseline retinal examination (including color fundoscopic photography, ocular coherence tomography (OCT), and auto-fluorescence imaging) is recommended prior to starting therapy. A baseline retinal examination (including OCT and auto-fluorescence imaging) is suggested for all patients within six months of initiating treatment and periodically while continuing treatment. If pigmentary changes in the retina develop, then risks and benefits of continuing treatment should be re-evaluated, since these changes may be irreversible. Follow-up retinal examinations should be continued given that retinal and vision changes may progress even after cessation of treatment.

H. PLAINTIFF'S USE OF ELMIRON

120. Upon information and belief, at the direction of her physician, Plaintiff, Mrs. Brewer, began taking Elmiron continuously and daily from approximately 2005 to 2019 for the treatment of her IC-related pain.

121. In approximately April 2005, Plaintiff was diagnosed with vision-related injuries, including, but not limited to, maculopathy.

122. It was within two years of the date of the filing of this Complaint that

Plaintiff first knew, or had any reason to know, that her vision-related injuries, including, but not limited to, macular degeneration could have been caused by Elmiron.

123. As a direct result of her long-term exposure to Defendants' Elmiron product, Plaintiff suffered serious visual injuries, including, but not limited to, macular degeneration, changes in eye color pigment, severe vision degradation, loss of night vision, and pigmentary maculopathy.

124. Upon information and belief, Plaintiff's ingestion of Elmiron caused her injuries.

125. As a direct and proximate result of Mrs. Brewer being prescribed Elmiron, Plaintiff suffered significant injuries, such as those described above.

126. As a direct and proximate result of Defendants' misconduct, as described herein, Plaintiff suffered serious vision-related injuries, due to Plaintiff's exposure to Elmiron.

127. By reason of the foregoing acts and omissions, Plaintiffs have suffered serious visual injuries, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, and medical treatment.

128. By reason of the forgoing acts and omissions, Plaintiffs have suffered damages and harm, including, but not limited to, emotional distress, medical expenses, other economic harm.

129. Plaintiffs accordingly seek damages associated with these injuries.

130. Mrs. Brewer would not have used Elmiron had any or all of Defendants'

properly disclosed the risks associated with its use.

131. Mrs. Brewer's injuries could have been avoided or would have been less severe had had any or all of Defendants properly disclosed the risks associated with its use.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

132. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to withhold information from the Plaintiff, her healthcare providers, and the general public concerning the known hazards associated with the use of, and exposure to, Elmiron, particularly over extended periods of time.

133. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to withhold safety-related warnings from the Plaintiff, her family members, and the general public concerning the known hazards associated with the use of, and exposure to, Elmiron, particularly over extended periods of time.

134. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to withhold instructions from the Plaintiff, her family members, and the general public concerning how to identify, mitigate, and/or treat known hazards associated with the use of, and exposure to, Elmiron, particularly over extended periods of time.

135. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to ignore relevant safety concerns and to deliberately not study the long-term safety and efficacy of Elmiron, particularly in chronic users of Elmiron.

136. Defendants failed to disclose a known defect and, instead, affirmatively

misrepresented that Elmiron was safe for its intended use. Defendants disseminated labeling, marketing, promotion and/or sales information to Plaintiff, her healthcare providers, and the general public regarding the safety of Elmiron knowing such information was false, misleading, and/or inadequate to warn of the safety risks associated with long-term Elmiron use. They did so willfully, wantonly, and with the intent to prevent the dissemination of information known to them concerning Elmiron's safety.

137. Further, Defendant actively concealed the true risks associated with the use of Elmiron, particularly as they relate to the risk of serious vision-related injuries, by affirmatively representing in numerous communications, which were disseminated to Plaintiff, her healthcare providers, and which included, without limitation, the Package Insert and the Medication Guide, that there were no warnings required to safely prescribe and take Elmiron and no vision-related adverse side effects associated with use of Elmiron.

138. Due to the absence of any warning by the Defendants as to the significant health and safety risks posed by Elmiron, Plaintiffs were unaware that Elmiron could cause serious vision-related injuries, as this danger was not known to Plaintiff, her healthcare providers, or the general public.

139. Due to the absence of any instructions for how to identify and/or monitor Elmiron patients for potential vision-related complications, Plaintiffs were unaware that Elmiron could cause serious vision-related injuries, as this danger was not known to Plaintiff, her healthcare providers, or the general public.

140. Given Defendants' conduct and deliberate actions designed to deceive Plaintiff, her healthcare providers, and the general public with respect to the safety and efficacy of Elmiron, Defendants are estopped from relying on any statute of limitations defenses.

COUNT ONE: PRODUCTS LIABILITY

A. Defective Design, Manufacture, and Inadequate Testing

141. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

142. At all times relevant herein, Defendants placed Elmiron into the stream of commerce with disregard for the public safety in that no adequate testing or other reasonable steps were taken to assure their products were safe and/or efficacious for their intended purpose. Insofar as Elmiron could not be used safely without the unreasonable risk of harm, it was ineffective for the purpose for its intended use, *i.e.*, the treatment of IC-related pain.

143. Upon information and belief, at all times relevant herein, Janssen Ortho was the exclusive manufacturer of Elmiron and manufactured Elmiron consistent with the design specifications, manufacturing standards, and/or other similar requirements set by Defendants. As the exclusive manufacturer of Elmiron, at all times relevant herein, Janssen Ortho is strictly liable to Plaintiff for placing it into the stream of commerce.

144. Alternatively, upon information and belief, Defendants were the designers, manufacturers and/or suppliers of Elmiron and are strictly liable to

Plaintiff for designing, manufacturing, distributing, marketing, selling and placing it into the stream of commerce.

145. The Elmiron manufactured, designed, marketed and/or supplied by Defendants was defective in design, manufacture or formulation, in that, when it left Defendants' control, the harm of said products outweighed any benefit derived therefrom, which rendered it inherently dangerous and/or defective, thereby causing serious harm to the Plaintiff.

146. The Elmiron designed, marketed, manufactured and/or supplied by Defendants was defective in design or formulation in that, when it left the control of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

147. The Elmiron designed, marketed, manufactured and/or supplied by Defendants were defective due to inadequate pre-market and post-market testing.

148. At all times relevant hereto, Defendants encouraged the use of Elmiron as a superior form of treatment for IC, despite their failure to test or otherwise determine the safety and efficacy of such use. As a direct and proximate result of Defendants' widespread promotional activity, physicians began commonly prescribing Elmiron as a safe and effective treatment for IC-related pain.

149. A reasonable pharmaceutical company would understand that reported AERs represent only a small fraction of adverse events associated with a particular drug.

150. A reasonable pharmaceutical company would understand that reported

AERs represent only a small fraction of adverse events caused by a particular drug.

151. A reasonable pharmaceutical company would continue to study a drug—even after it was commercially available for sale—to distinguish between undesirable effects caused by the drug and undesirable effects associated with the drug.

152. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries that are permanent and continuing in nature, which required medical treatment and will require on-going medical treatment, resulting in significant past and future medical expenses. Additionally, Plaintiff has suffered and will continue to suffer economic losses, loss of normal life, and physical and mental pain and suffering.

153. Alternatively, the Elmiron designed, marketed, manufactured and/or supplied by Defendants were defective in design, for the intended patient population, due to the low bioavailability of the drug.

154. Alternatively, Elmiron that was manufactured, marketed, supplied and/or sold by Defendants and prescribed to and used by Plaintiff was defective in design, manufacture or formulation in that when it left the hands of the manufacturer and/or supplier/seller, it was unreasonably dangerous, and was more dangerous that an ordinary consumer would expect and more dangerous than other methods of treatment for IC-related pain.

155. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to ignore relevant safety concerns, including adverse event reports—both in the United States and around the world, where Elmiron was sold—and to

deliberately not study the long-term safety and efficacy of Elmiron, particularly in chronic users of Elmiron.

156. Defendants improperly, negligently falsely and deceptively misrepresented or knowingly omitted, suppressed, or concealed facts of such materiality regarding the safety and efficacy of Elmiron to and/or from the FDA, that had the FDA known of such facts, the Product would have never been approved and no physician would have been able to prescribe Elmiron to Plaintiff.

157. Defendants improperly, negligently, falsely, and deceptively misrepresented and/or knowingly omitted, suppressed, and/or concealed facts of such materiality regarding the safety and efficacy of Elmiron to and/or from the FDA, that had the FDA known of such facts, Elmiron would have never been approved with the warnings and instructions for use that accompanied Elmiron and/or were provided to prescribing physicians and the public, so that Elmiron would not have been prescribed to nor used by Plaintiff.

158. Because Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA regulations, which information was material and relevant to the harm in question, no statutory presumptions in favor of Defendants are warranted.

B. Failure to Warn

159. At all relevant times hereto, Defendants advertised and promoted the use of Elmiron as a safe method of treatment for IC despite the lack of adequate testing for either safety or efficacy and after it knew or reasonably should have known

that Elmiron suffered from a design and/or manufacturing flaw.

160. A reasonable pharmaceutical company would understand that reported AERs represent only a small fraction of adverse events associated with a particular drug.

161. A reasonable pharmaceutical company would understand that reported AERs represent only a small fraction of adverse events caused by a particular drug.

162. A reasonable pharmaceutical company would have recognized an emerging safety signal relative to the risk of vision-related injuries and would have changed the Elmiron label to reflect, at a minimum, that Elmiron use was associated with serious, vision-related complications.

163. Despite the fact that evidence existed that the use of Elmiron was dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Elmiron and in fact, acted to deceive the medical community and public at large, including all potential users of Elmiron by promoting it as a safe and effective method of chemotherapy, when, in fact, it was unsafe and alternative and safer methods for pharmacological treatment existed.

164. Elmiron designed, marketed, manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions because Defendants knew or should have known that Elmiron created, among other things, a significantly increased risk of permanent and disfiguring eye damage by consumers and Defendants failed to adequately warn of said risks and the severity of such

adverse effects, resulting in harm to Plaintiffs, as set forth, herein.

165. Defendants failed to warn physicians and users of Elmiron of the aforementioned dangers and adverse side effects.

166. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries that are permanent and continuing in nature, which required medical treatment and will require on-going medical treatment, resulting in significant past and future medical expenses. Additionally, Plaintiff have suffered and will continue to suffer economic losses, loss of normal life, and physical and mental pain and suffering.

WHEREFORE, Plaintiff respectfully prays of this Court and demands of Defendants, jointly and severally, as follows: (1) all damages available to Plaintiff under the law, including, but not limited to, past and future medical, lost wages in the past, loss wage-earning capacity in the future, pain and suffering in the past and future, mental anguish, loss of consortium, and disfigurement and statutory treble damages; (2) punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing; (3) an award of attorneys' fees and costs; (4) prejudgment interest and the costs of suit; and (5) such other relief as this court may deem just and proper.

COUNT TWO: CONSUMER FRAUD

167. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

168. Knowing the falsity and/ misleading nature of their claims, Defendants

engaged in unconscionable commercial practices, deception, fraud, false promise, misrepresentation and/or the knowing concealment suppression or omission of material facts relative to the safety and efficacy of Elmiron.

169. Defendants intended such actions to mislead patients, healthcare providers, and the general public with respect to the safety and efficacy of Elmiron.

170. Such actions did, in fact, mislead patients, healthcare providers, and the general public with respect to the safety and efficacy of Elmiron.

171. Reliance of information, labeling, and/or statements made by Defendants with respect to the safety and efficacy of Elmiron, by patients, including Plaintiffs, healthcare providers, and the general public, was reasonable.

172. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries that are permanent and continuing in nature, which required medical treatment and will require on-going medical treatment, resulting in significant past and future medical expenses. Additionally, Plaintiff have suffered and will continue to suffer economic losses, loss of normal life, and physical and mental pain and suffering.

173. Plaintiff suffered an ascertainable loss of money or property as a result of Defendants' use or employment of unconscionable commercial practices as set forth above, and seeks treble damages, attorney's fees and costs of suit.

WHEREFORE, Plaintiff respectfully prays of this Court and demand of Defendants, jointly and severally, as follows: (1) all damages available to Plaintiff under the law, including, but not limited to, past and future medical, lost wages in

the past, loss wage-earning capacity in the future, pain and suffering in the past and future, mental anguish, loss of consortium, and disfigurement and statutory treble damages; (2) punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing; (3) an award of attorneys' fees and costs; (4) prejudgment interest and the costs of suit; and (5) such other relief as this court may deem just and proper

COUNT THREE: NEGLIGENCE

174. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

175. A reasonable pharmaceutical company would understand that reported AERs represent only a small fraction of adverse events associated with a particular drug.

176. A reasonable pharmaceutical company would understand that reported AERs represent only a small fraction of adverse events caused by a particular drug.

177. A reasonable pharmaceutical company would continue to study a drug—even after it was commercially available for sale—to distinguish between undesirable effects caused by the drug and undesirable effects associated with the drug.

178. At all relevant times, Defendants had a responsibility to conduct post-marketing surveillance and to continue to study the safety and efficacy of Elmiron, after the Elmiron NDA was approved, for as long as the drug remained available for sale in the United States.

179. Defendants willfully, wantonly and intentionally conspired, and acted

in concert, to ignore relevant safety concerns, including adverse event reports—both in the United States and around the world, where Elmiron was sold—and to deliberately not study the long-term safety and efficacy of Elmiron, particularly in chronic users of Elmiron.

180. At all relevant times, Defendants had a duty to craft an adequate label with respect to Elmiron.

181. At all relevant times, Defendants had a duty to ensure that the warnings in the Elmiron label were adequate, at all times, for as long as the drug remained available for sale in the United States.

182. At all relevant times, Defendants had a duty to revise the Elmiron label to include a warning regarding the risk of serious vision-related injuries as soon as there was reasonable evidence of a causal association between vision-related injuries and Elmiron use.

183. Upon information and belief, by approximately 2001, Defendants had reasonable evidence of a causal association between serious vision-related injuries and Elmiron use.

184. Upon information and belief, by approximately 2001, Defendants learned Elmiron use could cause serious vision-related injuries.

185. A reasonable pharmaceutical company would have recognized an emerging safety signal relative to the risk of vision-related injuries and would have changed the Elmiron label to reflect, at a minimum, that Elmiron use was associated with serious, vision-related complications.

186. Upon information and belief, despite reasonable evidence of causal association, Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA NDA regulations, concerning the safety and efficacy of Elmiron, including, but not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Elmiron users suffering vision-related injuries as a result of their Elmiron use. Such information was material and relevant to the risk of patients, like Plaintiff, developing serious vision-related injuries as a result of taking Elmiron.

187. Upon information and belief, despite understanding Elmiron could cause vision-related injuries, Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA NDA regulations, concerning the safety and efficacy of Elmiron, including, but not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Elmiron users suffering vision-related injuries as a result of their Elmiron use. Such information was material and relevant to the risk of patients, like Plaintiff, developing serious vision-related injuries as a result of taking Elmiron.

188. Defendants owed a duty to the general public, and specifically to the Plaintiff and her healthcare providers, to exercise reasonable care in the design, study, testing, development, manufacture, labeling, promotion, sale, marketing, and distribution of their prescription medications, including Elmiron, at issue in this lawsuit.

189. Defendants failed to exercise reasonable care in the design of Elmiron,

because as designed, it was capable of causing serious and permanent personal injuries such as those suffered by Plaintiff during foreseeable use.

190. Defendants also failed to exercise reasonable care in the marketing of Elmiron, and/or its generic non-bioequivalent form, because they failed to warn, that as designed, Elmiron, was capable of causing serious and permanent personal injuries such as those suffered by Plaintiff during foreseeable use.

191. Defendants breached their duty and were negligent by, but not limited to, the following actions, misrepresentations, and omissions toward Plaintiff:

a. By failing to use due care in developing, testing, designing and manufacturing Elmiron so as to avoid the aforementioned risks to individuals when Elmiron was being used for treatment;

b. By failing to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of Elmiron and the comparative severity and duration of such adverse effects;

c. In disseminating information to Plaintiff and Plaintiff's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;

d. By failing to accompany their products with proper or adequate rate of incidence or prevalence of eye damage;

e. By failing to provide warnings or other information that

accurately reflected the symptoms, scope, and severity of the side effects and health risks;

f. By failing to conduct adequate pre-clinical and clinical testing and post- marketing surveillance to determine the safety of Elmiron;

g. By failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff and other consumers;

h. By failing to provide adequate training or information to medical care providers for appropriate use and handling of Elmiron, and patients taking Elmiron;

i. By failing to adequately test and/or warn about the use of Elmiron, including, without limitations, the possible adverse side effects and health risks caused by the use of Elmiron;

j. By failing to design and/or manufacture a product that could be used safely;

k. In designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable use, which Defendant knew or should have known could cause injury to Plaintiff;

l. By failing to remove Elmiron, from the market when Defendants' knew or should have known of the likelihood of serious and

permanent side effects and injury to its users;

m. By failing to adequately warn users, consumers and physicians about the severity, scope and likelihood of permanent hair loss and related conditions to individuals taking Elmiron; and

n. In representing to physicians, including but not limited to Plaintiff's prescribing physicians, that this drug was safe and effective for use.

192. The Elmiron that injured Plaintiff was in substantially the same condition when Plaintiff used Elmiron as it was in when it left the control of Defendants. Elmiron's ability to cause serious and permanent personal injuries and damages such as those suffered by Plaintiff was not due to any voluntary action or contributory negligence of Plaintiff. Plaintiff used Elmiron as directed and without change in its form or substance.

193. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Elmiron was a proximate cause of Plaintiff's injuries and damages.

194. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

WHEREFORE, Plaintiffs respectfully pray of this Court and demand of Defendants, jointly and severally, as follows: (1) all damages available to Plaintiffs under the law, including, but not limited to, past and future medical, lost wages in the past, loss wage-earning capacity in the future, pain and suffering in the past and future, mental anguish, loss of consortium, and disfigurement and statutory treble

damages; (2) punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing; (3) an award of attorneys' fees and costs; (4) prejudgment interest and the costs of suit; and (5) such other relief as this court may deem just and proper.

COUNT FOUR: BREACH OF WARRANTY—
BREACH OF EXPRESS WARRANTY

195. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

196. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce Elmiron in the course of same, directly advertised or marketed the product to the FDA, healthcare professionals and consumers, including Plaintiff, or persons responsible for consumer.

197. Elmiron, materially failed to conform to those representations made by Defendants in Package Inserts, and otherwise, concerning the properties and effects of Elmiron respectively manufactured and/or distributed and sold by Defendants, and which Plaintiff purchased and used with in direct or indirect reliance upon these express representations. Such failures by Defendants constituted a material breach of express warranties made, directly or indirectly, to Plaintiff concerning Elmiron sold to Plaintiff.

198. As a direct, foreseeable and proximate result of Defendants' breaches of express warranties, Plaintiff suffered permanent and grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's physician,

in reasonable reliance upon such express warranties, prescribed for Plaintiff the use of Elmiron, Plaintiff purchased and used Elmiron as prescribed and instructed by Plaintiff's physician, leading to Plaintiff's injuries.

WHEREFORE, Plaintiff respectfully prays of this Court and demand of Defendants, jointly and severally, as follows: (1) all damages available to Plaintiff under the law, including, but not limited to, past and future medical, lost wages in the past, loss wage-earning capacity in the future, pain and suffering in the past and future, mental anguish, loss of consortium, and disfigurement and statutory treble damages; (2) punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing; (3) an award of attorneys' fees and costs; (4) prejudgment interest and the costs of suit; and (5) such other relief as this court may deem just and proper.

COUNT FIVE: BREACH OF WARRANTY – BREACH OF IMPLIED WARRANTY

199. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

200. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce Elmiron in the course of same, directly advertised or marketed the product to the FDA, health care professionals and consumers, including Plaintiff, or persons responsible for consumer.

201. Defendants impliedly warranted their Elmiron which they manufactured and/or distributed and sold, and which Plaintiff purchased and

ingested, to be of merchantable quality and fit for the common, ordinary, and intended uses for which the product was sold.

202. Defendants breached their implied warranties of Elmiron sold to Plaintiff because this product was not fit for its common, ordinary, and intended use.

203. As a direct, foreseeable and proximate result of Defendants' breaches of implied warranties, Plaintiff suffered permanent and grievous bodily injury and consequential economic and other losses, as described above, when Plaintiff used Elmiron in reasonable reliance upon the implied warranties.

WHEREFORE, Plaintiff respectfully prays of this Court and demand of Defendants, jointly and severally, as follows: (1) all damages available to Plaintiff under the law, including, but not limited to, past and future medical, lost wages in the past, loss wage-earning capacity in the future, pain and suffering in the past and future, mental anguish, loss of consortium, and disfigurement and statutory treble damages; (2) punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing; (3) an award of attorneys' fees and costs; (4) prejudgment interest and the costs of suit; and (5) such other relief as this court may deem just and proper.

COUNT SIX: COMMON LAW FRAUDULENT MISREPRESENTATION AND FRAUDULENT CONCEALMENT

204. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

205. Defendants, having undertaken the manufacturing, design, marketing, prescription, dispensing, distribution and promotion of Elmiron described herein,

owed a duty to provide accurate and complete information regarding its product.

206. Defendants' fraudulently misrepresented information regarding Elmiron including, but not limited to, their propensity to cause serious physical harm.

207. At the time of Defendants' fraudulent misrepresentations and omissions, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

208. Defendants breached their duties to Plaintiff by providing false, incomplete, and misleading information regarding Elmiron in direct to consumer advertising on their web sites and indirectly, through prescribing physicians.

209. Defendants had a duty and obligation to disclose to Plaintiff, individually and by and through her treating physicians, that Elmiron was dangerous and likely to cause health consequences to users.

210. Neither Plaintiff nor Plaintiff's prescribing and/or treating physicians were aware of the facts set forth, above, and, had they been aware of said facts, would not have prescribed Elmiron.

211. Neither Plaintiff nor Plaintiff's prescribing and/or treating physicians were aware of the facts set forth, above, and, had they been aware of said facts, would have more closely monitored Plaintiff and discontinued Elmiron once her ophthalmological symptoms appeared.

212. Plaintiff, individually and by and through Plaintiff's physicians, reasonably relied upon Defendants' deceptive, inaccurate, and fraudulent misrepresentations.

213. As a proximate result of Defendant's fraudulent misrepresentations, Plaintiffs have suffered physical, pecuniary, and emotional harm.

WHEREFORE, Plaintiff respectfully prays of this Court and demand of Defendants, jointly and severally, as follows: (1) all damages available to Plaintiff under the law, including, but not limited to, past and future medical, lost wages in the past, loss wage-earning capacity in the future, pain and suffering in the past and future, mental anguish, loss of consortium, and disfigurement and statutory treble damages; (2) punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing; (3) an award of attorneys' fees and costs; (4) prejudgment interest and the costs of suit; and (5) such other relief as this court may deem just and proper.

COUNT SEVEN: LOSS OF CONSORTIUM

214. Plaintiff William Brewer incorporates by reference all preceding paragraphs as if fully set forth herein.

215. At all times relevant to this action, Mr. Brewer was the lawful husband of Plaintiff, Lynn Brewer.

216. As a result of the injuries and harm sustained by Mrs. Brewer as a result of the acts and omissions of Defendants described above, Mr. Brewer has suffered and will continue to suffer the loss of his wife's services, society and companionship.

WHEREFORE, Plaintiff respectfully prays of this Court and demands of Defendants, jointly and severally, as follows: (1) all damages available to Plaintiff under the law for his loss of consortium; (2) an award of attorneys' fees and costs; (3)

prejudgment interest and the costs of suit; and (4) such other relief as this Court may deem just and proper.

DAMAGES

161. Plaintiffs respectfully request the following damages be considered separately and individually for the purpose of determining the sum of money that will fairly and reasonably compensate plaintiff:

a. Medical Expenses;

b. Pain and Suffering;

c. Mental Anguish, Anxiety, and Discomfort of Plaintiffs;

d. Physical Impairment;

e. Loss of Enjoyment of Life;

f. Pre and post judgment interest;

g. Exemplary and Punitive Damages;

h. Treble damages;

i. Reasonable and necessary attorneys fees, costs, pre-judgement interest; and

j. Such other relief to which Plaintiff may be justly entitled.

WHEREFORE, the Plaintiffs demand judgment of and from Defendants in an amount for compensatory damages against all Defendants for pain and suffering actual damages; consequential damages; exemplary damages, jointly and severally against all Defendants; interest on damages (pre- and post-judgment) in accordance with the law; Plaintiffs' reasonable attorney's fees, as well as costs of court and all

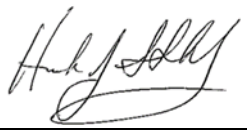
other costs incurred; and such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

The Plaintiff hereby demands a trial by jury on all counts and as to all issues.

Dated: June 24, 2020

Respectfully submitted,



By: _____

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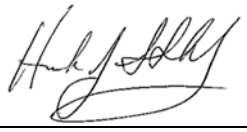
DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, HUNTER J. SHKOLNIK, is hereby designated as trial counsel in this matter.

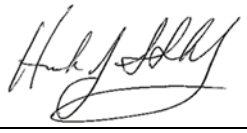


Hunter J. Shkolnik

CERTIFICATION

Plaintiff certifies that the foregoing action is not the subject of any other action pending in any other court or arbitration proceeding and that no other action or arbitration proceeding is contemplated at this time. Plaintiff further certifies that no other persons are known to them who should be joined as parties at this time. Plaintiff is aware that if the statements contained within this certification are knowingly false, that she may be subject to punishment.

Dated: June 24, 2020



Hunter J. Shkolnik