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

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

AUDREY L. HOWELL	)	
	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
JANSSEN PHARMACEUTICALS, INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA INC.; ORTHO-MCNEIL PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT, LLC, f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC; JANSSEN ORTHO, LLC; JOHNSON & JOHNSON; TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.; TEVA PHARMACEUTICALS USA, INC.; and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	JURY TRIAL DEMANDED
	)	
Defendants	)	

COMPLAINT

Plaintiff Audrey L. Howell states the following for her causes of action against Defendants Janssen Pharmaceuticals, Inc., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.; Ortho-McNeil Pharmaceuticals, Inc.; Janssen Research & Development, LLC, f/k/a Johnson and Johnson Pharmaceutical Research and Development, LLC; Janssen Ortho, LLC; Johnson & Johnson, Inc; Teva Branded Pharmaceutical Products R&D, Inc.; Teva Pharmaceuticals USA, Inc.; and Teva Pharmaceutical Industries LTD., (hereinafter collectively referred to as "Defendants"), and allege as follows:

BACKGROUND

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' wrongful conduct in connection with the prescription drug, Elmiron®, which is indicated for the treatment of the bladder pain and/or the discomfort associated with interstitial cystitis (IC).

2. At all relevant times, upon information and belief, Elmiron was designed, developed, tested, manufactured, packaged, distributed, labelled, promoted, marketed, and/or sold by Defendants pursuant to a joint venture licensing agreement.

3. At all relevant times, Defendants conducted business throughout the State of Alabama, Elmiron was sold and marketed throughout the State of Alabama, and Defendants' wrongful conduct occurred, in part, in the State of Alabama.

PARTIES

I. PLAINTIFF

4. Plaintiff Audrey L. Howell is now and was at all times relevant a resident of Jefferson County, Alabama.

II. DEFENDANTS

Teva Branded Pharmaceutical Products R&D, Inc.

5. 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.

6. 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 Alabama, and was 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.

7. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware Corporation with a principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454.

8. At all relevant times, Defendant Teva Pharmaceutical USA, Inc. regularly and continuously did business in the United States, including in the State of Alabama, and was 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 Pharmaceutical Industries Ltd.

9. Defendants Teva Branded Pharmaceutical Products R&D, Inc. and Teva Pharmaceuticals USA, Inc. are subsidiaries of the parent company Defendant Teva Pharmaceutical Industries Ltd. with Global Headquarters at 5 Basel Street, Petach Tikva 49131, Israel, and U.S. Headquarters at 400 Interpace Parkway, #3, Parsippany, New Jersey 07054.

10. Upon information and belief, Defendant Teva Pharmaceutical Industries Ltd., 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, individually and/or through or with its partners and joint venturers.

11. Upon information and belief, Defendant Teva Pharmaceutical Industries Ltd.'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 Alabama.

Janssen Pharma

12. 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.

13. 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, including in Alabama.

14. 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.

Ortho Pharma

15. Defendant Ortho-McNeil Pharmaceuticals, Inc. ("Ortho Pharma") is a corporation organized under Delaware law with its principal place of business in 1000 US Highway 202, Raritan, New Jersey 08869.

16. 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, including in Alabama.

Janssen R&D

17. 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 and Johnson Plaza, New Brunswick, New Jersey 08933.

18. 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.

19. Upon information and belief, Defendant Janssen R&D has transacted and conducted business within the State of Alabama and has derived substantial revenue from goods and products disseminated and used in the State of Alabama.

20. 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.

21. 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.

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, on behalf of Janssen Pharma, for sale throughout the United States and in Alabama specifically.

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.

Johnson & Johnson

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

28. Upon information and belief, at all relevant times, Defendants Janssen Pharma, 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.

29. 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.

30. 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.

31. 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 Alabama.

Jurisdiction and Venue

32. This Court has subject matter jurisdiction over this action by virtue of 28 U.S.C. §1332, in that the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00) exclusive of interests and costs and because there is a complete diversity of citizenship between Plaintiff and Defendants. Venue is proper in this Court pursuant to 28 U.S.C. §1391, as a substantial part of acts and omissions complained of occurred in this District. Specific personal jurisdiction is present by virtue of the fact that Defendants are doing business in this District and are purposefully availing themselves of the benefits and protections of the District. Plaintiff's claims arise directly from Defendants' contacts with this District, subjecting Defendants to specific personal jurisdiction in this action.

33. At all relevant times, Defendants expected or should have expected that their acts would have consequences within the United States of America.

FACTUAL ALLEGATIONS

I. Brief History of Elmiron

34. 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 with interstitial cystitis.

35. Defendants' fraudulent and illegal conduct with respect to Elmiron caused thousands of individuals, including Ms. Howell, to develop severe injuries, including but not limited to, pigmentary maculopathy.

36. 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.

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

38. IC is known to affect more women than men.

39. 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 pentosane poly sulfate (Elmiron). Elmiron is not the best nor the only option for treating interstitial cystitis.

40. There is no known cause of interstitial cystitis.

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

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

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

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

45. According to the U.S. Food and Drug Administration ("FDA"), "the documentation required in a 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.

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

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

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

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

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

51. On September 26, 1996, FDA approved Elmiron for relief of pain or discomfort associated with IC.

52. 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.

53. Beginning in approximately 1996, when Elmiron was first approved by 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.

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

55. Upon information and belief, in approximately 1997, Baker Norton was subsequently purchased by Teva Pharmaceutical Industries, Ltd., and/or Teva Pharmaceuticals, Inc.

56. Upon information and belief, as part of that transaction, Teva Pharmaceutical Industries, Ltd., and/or Teva Pharmaceuticals, Inc. purchased the assets and liabilities of Baker Norton.

57. Upon information and belief, 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.

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

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

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

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

62. 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.

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

II. Defendants Knew of the Elmiron Defect but Failed to Warn or Test

64. From approximately 1997 to the present, Defendants have received multiple Adverse Event Reports (“AER”) from medical professionals concerning Elmiron. These AERs included serious visual complication believed to be associated with Elmiron use, ranging from retinal hemorrhage to macular degeneration to even unilateral blindness.

65. 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 and recorded in other AER databases around the world, where Elmiron was sold, like EudraVagilance, the European Medicines Agency's ("EMA") adverse event database.

66. 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.

67. More recently, since approximately 2018, outside, independent studies and reports, documented in medical literature raise similar concerns regarding Elmiron's safety and propensity for causing serious visual complications including, but not limited to, pigmentary maculopathy.

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

69. 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.

70. 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.

71. 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 believed associated with Elmiron exposure.

72. 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.

73. A Harvard Medical School case study, published in 2019, 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.

74. 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.

75. 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.

76. 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:

77. Post-market cases of pigmentary maculopathy have been reported with chronic use of pentosane polysulfate sodium (PPS). Visual symptoms in these cases included difficulty reading and prolonged dark adaptations. All patients should have regular ophthalmic examinations for early detection of pigmentary maculopathy, particularly those with long-term use of PPS. If pigmentary maculopathy is confirmed, treatment discontinuation should be considered.

78. 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.

79. 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.

80. The Elmiron label used in EMA countries further admits that "eye disorders", like pigmentary maculopathy "might not be easily recognized by the urology community".

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

82. 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.

83. 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.

84. 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.

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

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

87. 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.

88. 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.

89. 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.

90. 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.

91. 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.

92. 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.

93. 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.

94. Upon information and belief, Defendants 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.

95. 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.

96. 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.

97. 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.

98. 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.

99. 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.

100. 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.

101. 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.

102. 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.

103. 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.

104. Today, Defendants' U.S. Elmiron does 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.

105. To this day, upon information and belief, Defendants have made no attempt to warn U.S. healthcare professionals and/or consumers of the risks of serious visual complications, including, but not limited to, pigmentary maculopathy associated with long-term Elmiron use.

III. Plaintiff-Specific Allegations

106. Plaintiff, Audrey Howell, brings this case for damages associated with her use of the pharmaceutical drug Elmiron, which was designed, manufactured, marketed, sold and/or distributed by Defendants. Specifically, Ms. Howell suffered various injuries, serious physical pain and suffering, medical, and hospital expenses as a direct result of her use of Elmiron.

107. Upon information and belief, at the direction of her physician, Plaintiff, Ms. Howell, began taking Elmiron continuously and daily from approximately 1997 to 2004 and 2016 to 2018 for the treatment of her IC-related pain.

108. In approximately April 2020, Plaintiff was diagnosed with vision-related injuries, including, but not limited to, macular degeneration.

109. It was only about two months prior to 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.

110. 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.

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

112. As a direct and proximate result of Ms. Howell being prescribed Elmiron from approximately 1997 to 2004 and 2016 to 2018, Plaintiff suffered significant injuries, such as those described above.

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

114. By reason of the foregoing acts and omissions, Plaintiff has 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.

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

116. Plaintiff accordingly seeks damages associated with these injuries.

117. Ms. Howell would not have used Elmiron had any or all of Defendants' properly disclosed the risks associated with its use.

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

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

119. 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.

120. 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.

121. 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.

122. 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.

123. 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.

124. Further, Defendant actively concealed the true risks associated with the use of Elmiron, particularly as they related 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 warning required to safely prescribe and take Elmiron and no vision-related adverse side effects associated with use of Elmiron.

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

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

127. 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.

CAUSES OF ACTION

COUNT 1: Negligence

128. Plaintiff incorporates by reference paragraphs 1 through 127 of this Complaint as if fully set forth herein and further alleges as follows:

129. Defendants, directly or indirectly, caused Elmiron to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Elmiron within this judicial district and aimed at a consumer market within this district.

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

131. 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.

132. Defendants failed to exercise reasonable care in the marketing of Elmiron 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.

133. Defendants knew or, in the exercise of reasonable care, should have known that use of Elmiron could cause or be associated with Plaintiff's injuries, and thus, create a dangerous and unreasonable risk of injury to the users of these products, including Plaintiff.

134. Defendants also knew or, in the exercise of reasonable care, should have known that users and consumers of Elmiron were unaware of the risks and the magnitude of the risks associated with use of Elmiron.

135. 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 pigmentary maculopathy, permanent eye damage, 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.

136. 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.

137. 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.

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

WHEREFORE, Plaintiff respectfully prays for judgment in Count I against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

COUNT II: Strict Liability – Defective Design

139. Plaintiff incorporates by reference paragraphs 1 through 127 of this Complaint as if fully set forth herein and further alleges as follows:

140. 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 the 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.

141. At all times relevant herein, Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Elmiron.

142. Elmiron is defective in its design or formulation in that it is not reasonable fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design.

143. At all times relevant herein, Elmiron was expected to reach, and in fact did reach, consumers in the State of Alabama and throughout the United States without substantial change in the condition in which it was sold.

144. 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.

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

146. At all times relevant herein, Defendants intended for its Elmiron to be used 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.

147. 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.

148. 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.

149. 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 than an ordinary consumer would expect and more dangerous than other methods of treatment for IC-related pain.

150. 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.

151. 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 FDA, that had FDA known of such facts, Elmiron would have never been approved and no physician would have been able to prescribe Elmiron to Plaintiff.

152. Defendant 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 FDA, that had 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.

153. 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.

154. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has lost past earning and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff respectfully prays for judgment in Count II against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

COUNT III: Strict Liability – Manufacturing Defect

155. Plaintiff incorporates by reference paragraphs 1 through 127 of this Complaint as if fully set forth herein and further alleges as follows:

156. At all times relevant herein, the Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Elmiron.

157. At all times relevant herein, Elmiron was expected to reach, and did reach, consumers in the State of Alabama and throughout the United States without substantial change in the condition in which it was sold.

158. Elmiron use by Plaintiff for IC was reasonably foreseeable and was used in the manner for which it was intended by the Defendants.

159. At all times relevant herein, Elmiron was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, Elmiron contained manufacturing defects which rendered the product unreasonably dangerous and subjected Plaintiff to risks that exceed the benefits of Elmiron, including but not limited to the risks of developing serious and dangerous side effects, and other severe and permanent health consequences;

b. Elmiron manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. Elmiron was not made in accordance with Defendants' specifications or performance standards; and

d. Elmiron manufacturing defects existed before it left the control of Defendants.

160. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured and will continue to endure substantial pain and suffering. She has incurred significant expenses for medical care and treatment

and will continue to incur such expenses in the future. Plaintiff has lost past earning and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff respectfully prays for judgment in Count III against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

COUNT IV: Strict Liability – Failure to Warn

161. At all relevant times, 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 design and/or manufacturing defects.

162. 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.

163. 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.

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

165. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has lost past earning and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff respectfully prays for judgment in Count IV against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

COUNT V: Breach of Implied Warranties

166. Plaintiff incorporates by reference paragraphs 1 through 127 of this Complaint as if fully set forth herein and further alleges as follows:

167. 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 FDA, health care professionals and consumers, including Plaintiff, or person responsible for consumer.

168. Defendants are merchants with respect to consumer medication like Elmiron and impliedly warranted their Elmiron which they manufactured and/or distributed and sold, and which Plaintiff purchased and ingested, to be of merchantable quality and safe and fit for the use for which they were intended; specifically, as consumer medication.

169. Defendants failed to disclose that Elmiron has dangerous propensities when used as intended and that use of Elmiron carries an increased risk of developing severe injuries, including Plaintiff's injuries.

170. Plaintiff was an intended beneficiary of the implied warranties made by Defendants to purchasers of Elmiron.

171. Elmiron was expected to reach and did in fact reach consumers and users, including Plaintiff, without substantial change in the condition in which they were manufactured and sold by Defendants.

172. Defendants intended that Elmiron be used in the manner in which Plaintiff, in fact, used it and which Defendants impliedly warranted to be of merchantable quality, safe, and fit for this use, even though Elmiron was not adequately tested or researched.

173. In reliance upon Defendants' implied warranty, Plaintiff used Elmiron as instructed and labeled and in the foreseeable manner intended, recommended, promoted, and marketed by Defendants.

174. Plaintiff could not have reasonably discovered or known of the risks of serious injury associated with Elmiron.

175. Defendants breached their implied warranty to Plaintiff in that Elmiron was not of merchantable quality, safe, or fit for their intended use, or adequately tested. Elmiron has

dangerous propensities when used as intended and can cause serious injuries, including those injuries complained of herein

176. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has lost past earning and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff respectfully prays for judgment in Count V against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

COUNT VI: Breach of Express Warranties

177. Plaintiff incorporates by reference paragraphs 1 through 127 of this Complaint as if fully set forth herein and further alleges as follows:

178. 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 FDA, health care professionals and consumers, including Plaintiff, or person responsible for consumer.

179. Defendants had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of Elmiron, including a duty to:

a. ensure that their products did not cause the user unreasonably dangerous side effects;

b. warn of dangerous and potentially fatal side effects; and

c. disclose adverse material facts, such as the true risks associated with the use of and exposure to Elmiron, when making representations to consumers and the general public, including Plaintiff.

180. At all relevant times, Defendants expressly represented and warranted to the purchasers of their products, by and through statements made by Defendants in labels, publications, package inserts, and other written materials intended for consumers and the general public, that Elmiron was safe to human health and the environment, effective, fit, and proper for their intended use. Defendants advertised, labeled, marketed, and promoted Elmiron, representing the quality to consumers and the public in such a way as to induce their purchase or use, thereby making an express warranty that Elmiron would conform to the representations.

181. The representations about Elmiron, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

182. 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 warranties made, directly or indirectly, to Plaintiff concerning Elmiron sold to Plaintiff.

183. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has lost past earning and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff respectfully prays for judgment in Count VI against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

COUNT VII: Fraudulent Concealment

184. Plaintiff incorporates by reference paragraphs 1 through 127 of this Complaint as if fully set forth herein and further alleges as follows:

185. At all times, during the course of, dealing between Defendants, Plaintiff, and Plaintiff's healthcare providers, Defendants misrepresented the safety of Elmiron.

186. Defendants knew or was reckless in not knowing that its representations were, in fact, false.

187. In representations to Plaintiff and Plaintiff's healthcare providers, Defendants fraudulently concealed and intentionally omitted material information, including but not limited to, the fact that:

a. Elmiron was not as safe as other similar drugs and medications indicated for the treatment of IC;

b. Elmiron was defective, and it caused dangerous side effects;

c. Elmiron was manufactured negligently;

d. Elmiron was manufactured defectively;

e. Elmiron was manufactured improperly;

f. Elmiron was designed negligently;

g. Elmiron was designed defectively;

h. Elmiron was designed improperly.

188. Defendants were under a duty to disclose to Plaintiff and Plaintiff's healthcare providers the defective nature of Elmiron including but not limited to the risk of developing vision loss.

189. Defendants had sole access to material facts concerning the defective nature of Elmiron and its propensity to cause vison damage and/or loss.

190. Defendants' concealment and omissions of material facts concerning, *inter alia*, the safety of Elmiron was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and Plaintiff's physicians, hospitals and healthcare providers into reliance on the use of the Elmiron, and to cause them to purchase, prescribe, dispense and/or use the product.

191. Defendants knew that Plaintiff and Plaintiff's healthcare providers had no way to determine the truth behind Defendants; concealment and omissions, as set forth herein.

192. Plaintiff, as well as Plaintiff's physicians, hospital and healthcare providers, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

193. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff has lost past earning and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff respectfully prays for judgment in Count VII against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

DAMAGES

194. Plaintiff respectfully requests the following damages be considered separately and individually for the purpose of determining the sum of money that fairly and reasonably compensates Plaintiff:

a. Medical Expenses;

b. Pain and Suffering;

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

d. Physical Impairment;

e. Loss of Enjoyment of Life;

f. Pre and Post Judgment Interest;

g. Exemplary and Punitive Damages; and

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

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury in this case as to such issues so triable.

Respectfully submitted,

Dated: July 13, 2020

/s/ F. Jerome Tapley
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