UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: ELMIRON (PENTOSAN POLYSULFATE SODIUM) PRODUCTS LIABILITY LITIGATION	MDL No. 2973 Case No. 2:20-md-02973(BRM)(ESK)
SAMANTHA PADELFORD, Plaintiff, vs. JANSSEN PHARMACEUTICALS, INC., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.; ORTHO-MCNEIL PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a Johnson & Johnson Research & Development, L.L.C.; JANSSEN ORTHO LLC; ALZA CORPORATION and JOHNSON & JOHNSON, Defendants.	JUDGE BRIAN R. MARTINOTTI JUDGE EDWARD S. KIEL DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO 6 Civil Action No: 2:23-cv-265

COMPLAINT

Plaintiff Samantha Padelford ("Plaintiff"), by and through her undersigned attorneys, for her Complaint 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 & Johnson Research & Development, L.L.C.; Janssen Ortho LLC; Alza Corporation and Johnson & Johnson (collectively "Defendants") alleges as follows:

INTRODUCTION

1. This is an action for damages caused by Defendants' wrongful conduct in developing, designing, testing, labeling, packaging, promoting, advertising, marketing,

distributing and/or selling pentosan polysulfate sodium ("PPS") as Defendants' prescription drug Elmiron® ("Elmiron").

2. Defendants manufacture, promote and sell Elmiron as a prescription drug treating insterstitial cystitis. Elmiron is manufactured as a capsule for oral consumption.

3. Elmiron injured Plaintiff by causing harmful, but latent, retinal damage, ultimately resulting in impaired vision.

4. Defendants knew or should have known Elmiron causes harmful retinal damage when taken as prescribed and intended.

5. Numerous patient reports, scientific studies and alerts by governmental agencies establish that Elmiron causes retinal damage.

6. Defendants nonetheless failed to warn, advise educate or otherwise inform Elmiron users, prescribers, or governmental regulators in the United States regarding the risk of pigmentary maculopathy caused by Elmiron or the need for medical and/or opthalmological monitoring. At all times relevant herein, the U.S. label for Elmiron made no mention of risk to patients' eyes or vision.

7. As a proximate result of Defendants' wrongful acts and omissions, Plaintiff was injured and suffered damages caused by her use of Elmiron.

8. Plaintiff seeks, inter alia, compensatory damages, statutory damages, punitive damages, attorneys' fees and costs.

THE PARTIES

9. Plaintiff Samantha Padelford is an Arkansas resident residing in Izard County, Arkansas. Plaintiff was diagnosed with interstitial cystitis and took Elmiron as prescribed by her physician from approximately 2001 to 2008. Plaintiff was given no warning and had no

knowledge of the serious risk of retinal damage and vision loss posed by Elmiron. As a result of her use of Elmiron, Plaintiff now suffers from substantially impaired vision, among other symptoms.

10. Upon information and belief, defendant Janssen Pharmaceuticals, Inc., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Janssen Pharma") is a corporation organized and existing under the laws of the State of Pennsylvania with its principal place of business in New Jersey. Janssen Pharma has held the U.S. Food and Drug Administration New Drug Application for Elmiron since approximately August 2008.

11. Upon information and belief, defendant Ortho-McNeil Pharmaceuticals, Inc. ("Ortho Pharma") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in New Jersey. Ortho Pharma held the New Drug Application for Elmiron from approximately July or August 2004 until August 2008.

12. Upon information and belief, defendant Janssen Research & Development LLC, f/k/a Johnson & Johnson Research & Development L.L.C. ("Janssen R&D") is a limited liability company organized and existing under the laws of the State of New Jersey with its principal place of business in New Jersey. Janssen R&D's sole member is Centocor Research & Development, Inc., a corporation organized and existing under the laws of the State of Pennsylvania with its principal place of business in Pennsylvania. Janssen R&D held the New Drug Application for Elmiron from approximately August 2002 until July or August 2004.

13. Upon information and belief, defendant Janssen Ortho, LLC ("Janssen Ortho") is a limited liability corporation organized and existing under the laws of the State of Delaware with its principal place of business in Puerto Rico. Janssen Ortho's sole member is OMJ PR Holdings, a corporation organized and existing under the laws of the Republic of Ireland with its

principal place of business in Puerto Rico. Janssen Ortho manufactures and packages Elmiron for Janssen Pharmaceuticals, Inc.

14. Upon information and belief, defendant Alza Corporation is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in California.

15. Upon information and belief, defendant Johnson & Johnson is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business in New Jersey.

16. Upon information and belief, at all relevant times herein, Janssen Pharma, Ortho Pharma, Janssen R&D and Janssen Ortho have been wholly-owned subsidiaries of Johnson & Johnson, with their profits inuring to Johnson & Johnson's benefit.

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

JURISDICTION AND VENUE

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

19. Venue is proper in this Court pursuant to 27 U.S.C. § 1391 because Defendants transact business in this District and a substantial portion of the practices, events, acts and omissions complained of herein occurred in this judicial district. Defendants Janssen Pharma, Ortho Pharma, Janssen R&D, Alza and Johnson & Johnson are at home in this forum.

20. Any and all conditions precedent to this action have occurred, been performed or have been waived.

FACTUAL BACKGROUND

21. In September 1996, the FDA approved Elmiron for the treatment of interstitial cystitis, a diagnosis applicable to patients with chronic bladder pain in the absence of other explanatory etiologies or causes.

22. Under the American Urological Association's interstitial cystitis treatment guidelines, Elmiron is not a "first-line" treatment. Elmiron is instead one of ten suggested "second-line" treatments, including three other oral medications: amitriptyline, cimetidine and hydroxyzine. The guidelines include numerous third, fourth, fifth and sixth-line treatments.

23. Defendants market or marketed Elmiron as "The Only Oral Medication Approved to Treat Bladder Pain or Discomfort of Interstitial Cystitis (IC)."[1] Elmiron is not the only oral medication approved by the FDA that can be used to treat interstitial cystitis and it is not the only interstitial cystitis treatment.

24. Despite one or more studies providing clear evidence of the dangers of PPS, Defendants have failed to investigate adequately the threat PPS poses to patients' vision. Defendants have failed to warn patients of the risk they would suffer retinal injury and vision impairment as a result of Elmiron use.

25. A physician's usage study of PPS conducted in the late 1980s and early 1990s noted adverse effects affecting vision, including optic neuritis and retinal hemorrhage.

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[1] https://www.orthoelmiron.com/patient/about-elmiron

Defendants relied upon this study when seeking FDA approval for Elmiron, and therefore had direct knowledge of said adverse effects.[2]

26. The reported adverse effects included:

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

b. "Filmy Sensation Over Left Eye" Possible Left Optic Neuritis: A 21 year old white female without any history of ophthalmological problems, head trauma, diabetes, or any previous neurological symptoms experienced a "filmy sensation over the left eye."[3]

27. Almost immediately after the FDA approved Elmiron, patients and doctors began reporting serious complications relating to eye and vision problems in patients taking Elmiron.[4]

28. Nearly 150 cases of eye disorders were reported to the FDA as adverse effects of Elmiron, ranging from blurred vision to maculopathy and blindness. Other reported symptoms include visual impairment, halo vision and reduced visual acuity.[5]

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[2] A Statistical and Medical Review of an Amendment to the New Drug Application for Elmiron® (Pentosan Polysulfate), NDA #20193, Appx. D (Jan. 1996).

[3] *Id*.

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

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

29. In 2018, researchers from the Emory Eye Center published in the Journal of Ophthalmology their concerns about the presentation of a unique eye disease they were seeing in patients taking Elmiron.[6]

30. The Emory Eye Center researchers summarized their findings in a letter to the editor of the Journal of Urology:

> We wish to alert readers to a concerning new observation of vision threatening retinal changes associated with long-term exposure to [Elmiron]. We recently reported our findings of retinal pigmentary changes in six patients undergoing long-term therapy with [Elmiron]. These patients primarily described difficulty reading and/or trouble adjusting to dim lighting. Each patient had received a standard dosage of [Elmiron], ranting from 200 to 400 mg daily, for a median duration of 15.5 years. . . . Examination findings in patients with this condition are suggestive of injury to the retina and the underlying retinal pigment epithelium. . . . After extensive investigations, which included molecular testing for hereditary retinal disease, we found these cases to resemble no other retinal disease.[7]

31. Researchers encouraged "drug cessation in affected patients," and recommended "that any patient with suggestive visual symptoms undergo a comprehensive ophthalmic examination."[8]

32. The Interstitial Cystitis Network, a health publishing company dedicated to interstitial cystitis, launched its own patient survey following the Emory Eye Center findings. As

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

[7] William A. Pearce, Adam M. Hanif and Nieraj Jain, Letter to the Editor Re: *FDA BRUDAC 2018 Criteria for Interstitial Cystitis / Bladder Pain Syndrome Clinical Trials*, 200 UROLOGY 1122 (2018).

[8] *Id*.

of April 2019, the Interstitial Cystitis Network had nearly 1,000 participants, with 53% reporting eye disease.

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

34. Despite numerous signs of the potential for severe retinal side effects, multiple studies conducted, research published in peer-reviewed journals and public warnings from the European Medicines Agency, Defendants failed to investigate the issue reasonably and have been silent as to the harm caused by Elmiron.

35. Defendants have not alerted patients of the need for ophthalmological monitoring while taking Elmiron or differentiated whether risks increase with higher doses or longer duration, despite these types of warnings being normal industry practice.

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

37. At relevant times herein, the labeling for Elmiron does not list vision-threatening retinal changes as a side effect.

38. At relevant times herein, the patient materials for Elmiron, including the Patient Education Flyer and ELMIRON Patient Brochure, do not mention vision threatening visual changes or the need for ophthalmological monitoring.

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

40. At relevant times herein, Janssen Pharma maintains a website promoting Elmiron, ww.orthoelmiron.com which has included, among other things, "About Elmiron," "How Elmiron Works," "Important Safety Information" and "Patient Information." At relevant times herein, the website has failed to mention the potential for vision-threatening retinal changes associated with Elmiron use.

41. As a result of the acts and omissions of Defendants, Plaintiff could not have discovered, through the exercise of reasonable diligence, that exposure to Elmiron was associated with increased exposure to vision-threatening retinal changes. The applicable limitations periods therefore did not begin to accrue until Plaintiff discovered, or through the exercise of reasonable diligence should have discovered, Defendants' wrongful acts and omissions.

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

43. Defendants are under a continuing duty to disclose the true character, quality and nature of Elmiron to Plaintiff. Defendants have nevertheless failed to inform patients and doctors regarding the vision-threatening retinal changes associated with Elmiron.

44. Plaintiff reasonably relied upon Defendants' knowing, affirmative or active concealment when she continued to use Elmiron as prescribed. Defendants are therefore estopped from relying on any statute of limitations defense.

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

omissions about the safety of Elmiron and the vision-threatening retinal changes associated with it.

COUNT I
Strict Liability – Design Defect and Failure to Warn

46. The allegations set forth in paragraphs 1 through 45 are incorporated by this reference as if fully set forth herein.

47. Defendants had a duty to provide adequate warnings and instructions for Elmiron, to use reasonable care to design a product that is not unreasonably dangerous to users and to adequately test their product.

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

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

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

51. The Elmiron supplied to Plaintiff by Defendants was defective due to inadequate warnings or instructions concerning the true risks of its use.

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

53. The Elmiron supplied to Plaintiff by Defendants was defective, dangerous and had inadequate warnings or instructions at the time it was sold. Defendants acquired additional knowledge and information concerning the defective and dangerous nature of Elmiron. Despite their knowledge and information, Defendants at relevant times herein failed and neglected to issue adequate warnings or post-sale warnings that Elmiron causes serious and potentially irreversible vision issues and retinal harm.

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

55. By failing to test and research harms associated with Elmiron use adequately, and by failing to provide appropriate warnings about Elmiron use, patients and the medical community, including prescribing doctors, were not adequately informed about the true risk / benefit profile of Elmiron and were not sufficiently aware that serious and potentially irreversible vision issues and retinal harm might be associated with Elmiron use. Nor were the medical community, patients, patients' families or regulators appropriately informed that serious and potentially irreversible vision issues and retinal harm might be a side effect of Elmiron use and should or could be reported as an adverse event.

56. As a direct and proximate result of Defendants' acts and omissions, including inadequate warnings, dilution or lack of information, lack of adequate testing, lack of adequate

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

WHEREFORE, plaintiff Samantha Padelford prays this Court enter judgment in her favor and against Defendants on Count I of her Complaint and award her compensatory damages, punitive damages, pre-judgment interest, post-judgment interest, attorneys' fees, costs and such other and further relief as the Court determines necessary and just.

COUNT II
Breach of Express Warranty

57. The allegations set forth in paragraphs 1 through 45 are incorporated by this reference as if fully set forth herein.

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

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

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

WHEREFORE, plaintiff Samantha Padelford prays this Court enter judgment in her favor and against Defendants on Count II of her Complaint and award her compensatory damages, punitive damages, pre-judgment interest, post-judgment interest, attorneys' fees, costs and such other and further relief as the Court determines necessary and just.

COUNT III
Breach of Implied Warranty

61. The allegations set forth in paragraphs 1 through 45 are incorporated by this reference as if fully set forth herein.

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

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

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

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

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

67. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss

of capacity for the enjoyment of life, expense of hospitalization, medical and/or nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses and aggravation of previously existing conditions. Plaintiff's losses are either permanent or continuing, and Plaintiff will suffer said losses in the future.

WHEREFORE, plaintiff Samantha Padelford prays this Court enter judgment in her favor and against Defendants on Count III of her Complaint and award her compensatory damages, punitive damages, pre-judgment interest, post-judgment interest, attorneys' fees, costs and such other and further relief as the Court determines necessary and just.

COUNT IV
Negligence

68. The allegations set forth in paragraphs 1 through 45 are incorporated by this reference as if fully set forth herein.

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

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

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

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

a. Negligent and careless research and testing of Elmiron,

b. Negligent and careless design or formulation of Elmiron,

c. Negligent and careless failure to give adequate warnings that would attract the attention of Plaintiff, Plaintiff's physicians and the public in general of the potentially dangerous, defective, unsafe and deleterious propensity of Elmiron and of the risks associated with its use,

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

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

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

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

73. As a direct and proximate result of Defendants' negligence, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and/or nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses and aggravation of previously

existing conditions. Plaintiff's losses are either permanent or continuing, and Plaintiff will suffer said losses in the future.

WHEREFORE, plaintiff Samantha Padelford prays this Court enter judgment in her favor and against Defendants on Count IV of her Complaint and award her compensatory damages, punitive damages, pre-judgment interest, post-judgment interest, attorneys' fees, costs and such other and further relief as the Court determines necessary and just.

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

74. The allegations set forth in paragraphs 1 through 45 are incorporated by this reference as if fully set forth herein.

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

76. By reason of their acts and omissions alleged herein, Defendants violated provisions of statutes and regulations, including but not limited to the following:

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

b. Defendants violated 21 C.F.R. § 201.56 by failing to follow the "[s]pecific requirements on content and format of labeling for human prescription drugs,"

c. Defendants violated 21 C.F.R. § 201.57 by failing to follow the "[s]pecific requirements on content and format of labeling for human prescription drugs,"

d. Defendants violated 21 C.F.R. § 202.1 by the manner in which they advertised and promoted Elmiron and

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

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

78. Defendants' violations of the foregoing statutes and regulations constitute negligence per se.

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

WHEREFORE, plaintiff Samantha Padelford prays this Court enter judgment in her favor and against Defendants on Count V of her Complaint and award her compensatory damages, punitive damages, pre-judgment interest, post-judgment interest, attorneys' fees, costs and such other and further relief as the Court determines necessary and just.

COUNT VI
Negligent Misrepresentation

80. The allegations set forth in paragraphs 1 through 45 are incorporated by this reference as if fully set forth herein.

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

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

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

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

85. At the time the aforesaid representations were made, Defendants intended to induce Plaintiff and/or Plaintiff's physicians to rely upon said representations.

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

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

WHEREFORE, plaintiff Samantha Padelford prays this Court enter judgment in her favor and against Defendants on Count VI of her Complaint and award her compensatory damages, punitive damages, pre-judgment interest, post-judgment interest, attorneys' fees, costs and such other and further relief as the Court determines necessary and just.

JURY TRIAL DEMAND

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

Dated: January 16, 2023

RESPECTFULLY SUBMITTED,

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Attorneys for Plaintiff