JS 44 (Rev. 02/19)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Hoppe, Joyce A.

(b) County of Residence of First Listed Plaintiff Waukesha County, WI
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Sol H. Weiss, Esq., Anapol Weiss, One Logan Square, 130 N. 18th Street, Suite 1600 Philadelphia, PA (215) 735-1130

DEFENDANTS

Janssen Pharmaceuticals, Inc. and Johnson & Johnson

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 151 Medicare Act ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans) ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholders' Suits ☐ 190 Other Contract ☐ 195 Contract Product Liability ☐ 196 Franchise	**PERSONAL INJURY** ☐ 310 Airplane ☐ 315 Airplane Product Liability ☐ 320 Assault, Libel & Slander ☐ 330 Federal Employers' Liability ☐ 340 Marine ☐ 345 Marine Product Liability ☐ 350 Motor Vehicle ☐ 355 Motor Vehicle Product Liability ☐ 360 Other Personal Injury ☐ 362 Personal Injury - Medical Malpractice	**PERSONAL INJURY** ☐ 365 Personal Injury - Product Liability ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability ☐ 368 Asbestos Personal Injury Product Liability **PERSONAL PROPERTY** ☐ 370 Other Fraud ☐ 371 Truth in Lending ☐ 380 Other Personal Property Damage ☐ 385 Property Damage Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881 ☐ 690 Other **LABOR** ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Management Relations ☐ 740 Railway Labor Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Employee Retirement Income Security Act	☐ 422 Appeal 28 USC 158 ☐ 423 Withdrawal 28 USC 157 **PROPERTY RIGHTS** ☐ 820 Copyrights ☐ 830 Patent ☐ 835 Patent - Abbreviated New Drug Application ☐ 840 Trademark **SOCIAL SECURITY** ☐ 861 HIA (1395ff) ☐ 862 Black Lung (923) ☐ 863 DIWC/DIWW (405(g)) ☐ 864 SSID Title XVI ☐ 865 RSI (405(g))	☐ 375 False Claims Act ☐ 376 Qui Tam (31 USC 3729(a)) ☐ 400 State Reapportionment ☐ 410 Antitrust ☐ 430 Banks and Banking ☐ 450 Commerce ☐ 460 Deportation ☐ 470 Racketeer Influenced and Corrupt Organizations ☐ 480 Consumer Credit ☐ 485 Telephone Consumer Protection Act ☐ 490 Cable/Sat TV ☐ 850 Securities/Commodities/ Exchange ☐ 890 Other Statutory Actions ☐ 891 Agricultural Acts ☐ 893 Environmental Matters ☐ 895 Freedom of Information Act ☐ 896 Arbitration ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision ☐ 950 Constitutionality of State Statutes
REAL PROPERTY	**CIVIL RIGHTS**	**PRISONER PETITIONS**	**IMMIGRATION**	**FEDERAL TAX SUITS**	
☐ 210 Land Condemnation ☐ 220 Foreclosure ☐ 230 Rent Lease & Ejectment ☐ 240 Torts to Land ☐ 245 Tort Product Liability ☐ 290 All Other Real Property	☐ 440 Other Civil Rights ☐ 441 Voting ☐ 442 Employment ☐ 443 Housing/ Accommodations ☐ 445 Amer. w/Disabilities - Employment ☐ 446 Amer. w/Disabilities - Other ☐ 448 Education	**Habeas Corpus:** ☐ 463 Alien Detainee ☐ 510 Motions to Vacate Sentence ☐ 530 General ☐ 535 Death Penalty **Other:** ☐ 540 Mandamus & Other ☐ 550 Civil Rights ☐ 555 Prison Condition ☐ 560 Civil Detainee - Conditions of Confinement	☐ 462 Naturalization Application ☐ 465 Other Immigration Actions	☐ 870 Taxes (U.S. Plaintiff or Defendant) ☐ 871 IRS—Third Party 26 USC 7609	

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 USC 1332

Brief description of cause:
This action involves an injury claim from a pharmaceutical arising out of the use of Elmiron.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Hon. Beetlestone DOCKET NUMBER 2:20-cv-02147

DATE 09/30/2020

SIGNATURE OF ATTORNEY OF RECORD S/ Sol H. Weiss - PA #15925

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM

(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: Joyce A. Hoppe, N91W16151 Junction Way #108, Menomonee Falls, WI 53051

Address of Defendant: Janssen Pharmaceuticals Inc. - 800 Ridgeview Drive, Horsham, PA 19044

Place of Accident, Incident or Transaction: Multiple Jurisdictions

RELATED CASE, IF ANY:

Case Number: 2:20-cv-02147 Judge: Hon. Beetlestone Date Terminated: _____

Civil cases are deemed related when ***Yes*** is answered to any of the following questions:

1.	Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?	Yes ☐	No ☑
2.	Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?	Yes ☑	No ☐
3.	Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court?	Yes ☐	No ☑
4.	Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?	Yes ☐	No ☑

I certify that, to my knowledge, the within case ☉ **is** / ☐ **is not** related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 09/30/2020 /s/ Sol H. Weiss 15925

Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

CIVIL: (Place a √ in one category only)

A. Federal Question Cases:

- ☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts
- ☐ 2. FELA
- ☐ 3. Jones Act-Personal Injury
- ☐ 4. Antitrust
- ☐ 5. Patent
- ☐ 6. Labor-Management Relations
- ☐ 7. Civil Rights
- ☐ 8. Habeas Corpus
- ☐ 9. Securities Act(s) Cases
- ☐ 10. Social Security Review Cases
- ☐ 11. All other Federal Question Cases
  (Please specify): _____

B. Diversity Jurisdiction Cases:

- ☐ 1. Insurance Contract and Other Contracts
- ☐ 2. Airplane Personal Injury
- ☐ 3. Assault, Defamation
- ☐ 4. Marine Personal Injury
- ☐ 5. Motor Vehicle Personal Injury
- ☐ 6. Other Personal Injury *(Please specify):* _____
- ☑ 7. Products Liability
- ☐ 8. Products Liability – Asbestos
- ☐ 9. All other Diversity Cases
  (Please specify): _____

ARBITRATION CERTIFICATION

(The effect of this certification is to remove the case from eligibility for arbitration.)

I, Sol H. Weiss, Esq., counsel of record *or* pro se plaintiff, do hereby certify:

☑ Pursuant to Local Civil Rule 53.2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs:

☐ Relief other than monetary damages is sought.

DATE: 09/30/2020 /s/Sol H. Weiss 15925

Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

Joyce A. Hoppe	:	CIVIL ACTION
v.	:	
Janssen Pharmaceuticals, Inc. and Johnson & Johnson	:	NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ( )

(f) Standard Management – Cases that do not fall into any one of the other tracks. (x)

09/30/2020	Sol H. Weiss, Esq.	Joyce Hoppe
Date	**Attorney-at-law**	**Attorney for**
(215) 725-2098	(215) 735-7701	sweiss@anapolweiss.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JOYCE A. HOPPE	)	**CIVIL ACTION NO.**
v.	)	
JANSSEN PHARMACEUTICALS, INC.	)	**COMPLAINT**

Now comes Plaintiff by and through the undersigned counsel, and for her Complaint hereby avers and states as follows:

NATURE OF THE ACTION

1. This is a product liability action for damages suffered as a direct and proximate result of Plaintiff's use of Defendant's defective and unreasonably dangerous prescription drug, Elmiron (pentosan polysulfate sodium or PPS).
2. At all times relevant hereto, Defendant developed, manufactured, designed, formulated, tested, labeled, packaged, produced, created, made, promoted, advertised, marketed, distributed and/or sold Elmiron in the United States.
3. Plaintiff was prescribed Elmiron for the treatment of interstitial cystitis and/or bladder pain.
4. As a result of her use of Elmiron, Plaintiff suffered injuries including harmful, but latent, retinal damage and maculopathy, which ultimately resulted in impaired vision because of Elmiron.

5. Defendant knew, or should have known, of the significant risks for visual symptoms and retinal changes associated with the use of Elmiron when taken as prescribed and intended.
6. Despite knowing about these significant risks, Defendant did not disclose these significant risks to the medical and healthcare community, including Plaintiff's prescribing doctor and the Food and Drug Administration ("FDA"), until June 2020.
7. Despite knowing about these significant risks, Defendant did not disclose these significant risks to Plaintiff or the public in general, until June 2020.
8. Despite knowing about these significant risks, Defendant did not provide adequate warnings of the risks associated with using Elmiron to patients, the medical and healthcare community, Plaintiff's physician, or the public in general, until June 2020.
9. Throughout the time Defendant marketed Elmiron, Defendant withheld material adverse events from the public, medical and healthcare community, and the FDA.
10. Defendant failed to disclose the serious link between Elmiron use and significant visual damage, including pigmentary maculopathy.

PARTIES

11. At all times relevant hereto, Plaintiff was a resident and citizen of Wisconsin.
12. Plaintiff was prescribed Elmiron in Wisconsin.
13. Plaintiff began experiencing visual symptoms in Wisconsin.
14. In approximately 2019, Plaintiff was diagnosed with a possible toxic maculopathy in Wisconsin.
15. Defendant Janssen Pharmaceuticals, Inc, is a Pennsylvania corporation with a principal place of business located at 800 Ridgeview Drive, Horsham, Pennsylvania 19044.

16. At all relevant times, Defendant was engaged in the business of developing, designing, licensing, manufacturing, distributing, marketing, promoting, selling, and/or introducing into interstate commerce, either directly or indirectly through third parties, subsidiaries or related entities, the prescription drug Elmiron.

17. Defendant's Elmiron is used to manage symptoms of interstitial cystitis and painful bladder syndrome.

JURISDICTION AND VENUE

18. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendant, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

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

20. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendant Janssen Pharmaceuticals is a Pennsylvania corporation.

21. Defendant currently transacts business within this District by selling its products within this District and throughout the United States.

22. Defendant expected or should have expected that its business activities could or would have consequences within the State of Pennsylvania, as well as throughout the United States.

FACTS

Background

23. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

A. Interstitial Cystitis

24. Interstitial cystitis is a chronic medical condition that causes a patient to experience bladder pressure and/or pain, and/or urinary urgency, and sometimes pelvic pain.

25. This pain can range from a mild discomfort to a severe pain.

26. There is no known cure for interstitial cystitis or painful bladder syndrome.

27. Elmiron is used to treat patients with interstitial cystitis.

B. Elmiron

28. Elmiron (pentosan polysulfate sodium) was granted an Orphan Drug designation in 1995.

29. Elmiron was first approved in September 1996 as a treatment for interstitial cystitis and painful bladder symptoms.

30. Upon information and belief, Alza Pharmaceuticals purchased Elmiron in 1997 from Ivax and Baker Norton Pharmaceuticals, the initial sponsor of the New Drug Application (NDA).

31. Upon information and belief, Janssen Pharmaceuticals has been the NDA sponsor and holder since 2002, when Alza was acquired by McNeil Pharmaceuticals, Ind., a subsidiary of Janssen Pharmaceuticals.

32. At all relevant times, the label and prescribing information that accompanied Elmiron when prescribed to patients contained the following: "Warnings: None."

33. In addition, according to the Drugs@FDA website, the label for Elmiron had been updated on approximately five occasions, prior to June 16, 2020, and at no time prior to June 16, 2020, did it contain any information about vision loss, including pigmentary maculopathy, in any section of the label.

34. On June 16, 2020, the label for Elmiron was updated to include information regarding retinal pigmentary changes for the first time.

35. Elmiron is a low molecular weight heparin-like compound. It has anticoagulant and fibrinolytic effects, but the mechanism of action of pentosan polysulfate sodium in interstitial cystitis is not known.

36. Patients who are prescribed Elmiron are advised to take the drug for at least six months in order to determine if there is an effect.

37. For those patients who take the drug, the drug is known to be used for long-term use and in many patients use is expected to last years, if not decades.

C. Elmiron-Induced Macular Toxicity

38. In 2018, researchers from the Emory Eye Center published *Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium* in the Journal of Opthalmology ("Pearce article").[1]

39. In the *Pearce* article, researchers identified concerns regarding a unique eye disease they were seeing in patients taking Elmiron.

40. The researchers concluded that patients taking Elmiron were experiencing structural changes to the retina.

41. Further studies from Harvard Medical School suggest that the damage caused by Elmiron continues to progress even after the patient stops taking Elmiron.[2]

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

[2] Rachel M. Huckfeldt and Demetrios G Vavvas, Progressive Maculopathy After Discontinuation of Pentosan Polysulfate Sodium, 50 OPHTHALMIC SURGERY, LASERS AND IMAGING RETINA 656– 59 (2019), ncbi.nlm.nih.gov/pubmed/31671200.

42. Defendant made changes to Elmiron's label in other countries to warn users of the risks of visual injuries, including pigmentary maculopathy.

43. For example, Defendant changed the Elmiron label in Canada in September 2019.

44. Defendant did not update the label for Elmiron to include a warning for "retinal pigmentary changes" in the United States until June 16, 2020.

45. The relevant portion of Defendant's June 16, 2020 U.S. label update stated as follows:

> Pigmentary changes in the retina, reported in the literature as pigmentary maculopathy, have been identified with long-term use of ELMIRON® (see ADVERSE REACTIONS). Although most of these cases occurred after 3 years of use or longer, cases have been seen with a shorter duration of use. While the etiology is unclear, cumulative dose appears to be a risk factor. Visual symptoms in the reported cases included difficulty reading, slow adjustment to low or reduced light environments, and blurred vision. The visual consequences of these pigmentary changes are not fully characterized. Caution should be used in patients with retinal pigment changes from other causes in which examination findings may confound the appropriate diagnosis, follow-up, and treatment. Detailed ophthalmologic history should be obtained in all patients prior to starting treatment with ELMIRON®. If there is a family history of hereditary pattern dystrophy, genetic testing should be considered. For patients with pre-existing ophthalmologic conditions, a comprehensive baseline retinal examination (including color fundoscopic photography, ocular coherence tomography (OCT), and auto-fluorescence imaging) is recommended prior to starting therapy. A baseline retinal examination (including OCT and auto-fluorescence imaging) is suggested for all patients within six months of initiating treatment and periodically while continuing treatment. If pigmentary changes in the retina develop, then risks and benefits of continuing treatment should be re-evaluated, since these changes may be irreversible. Follow-up retinal examinations should be continued given that retinal and vision changes may progress even after cessation of treatment.

46. During all relevant times to Plaintiff's claim, the label did not contain any mention of retinal pigmentary changes.

47. Defendant also updated Elmiron's Patient Leaflet on June 16, 2020.

48. The relevant update can be found in a box titled "What is the most important information I should know about Elmiron?" and states as follows:

> Pigment changes in the retina of the eye (also referred to as pigmentary maculopathy in medical journal articles) have been reported with long-term use of ELMIRON® . While the cause of the pigmentary changes is unclear, continued long term dosing with ELMIRON® may be a risk factor. The consequences of these pigmentary changes in the retina are not fully understood. Visual symptoms that have been reported include: difficulty reading, slow adjustment to low or reduced light environments, and blurred vision. If you already have retinal pigment changes from other causes, it may be difficult to distinguish future retinal pigment changes if they occur. Call your doctor (including your eye doctor) if you notice any changes in your vision. Throughout your treatment, regular eye examinations that include retinal examinations are suggested for early detection of retinal/macular changes. Your doctor will discuss with you when to get your first eye examination and follow up exams, and whether the treatment should be continued since these changes may be irreversible and may progress even after stopping treatment.

49. During all relevant times to Plaintiff's claim, the Patient Leaflet did not contain any mention of pigment changes to the retina.

D. Plaintiff Specific Facts

50. Plaintiff was diagnosed with interstitial cystitis and/or painful bladder in approximately 2003.

51. Defendant represented Elmiron to be an appropriate and suitable product for treatment of the symptoms of interstitial cystitis and painful bladder.

52. Plaintiff's treating medical physician prescribed Elmiron to Plaintiff in approximately 2003 due to her interstitial cystitis diagnosis.

53. Plaintiff continued to take Elmiron until approximately October 2018.

54. In approximately early 2018, Plaintiff began to experience visual symptoms that progressively worsened.

55. Plaintiff has been diagnosed with a possible toxic maculopathy given her long-term Elmiron use.

56. Defendant ignored reports regarding Elmiron's failure to perform as intended, and injuries associated with long-term use from patients and health care providers throughout the country. This lead to injuries to Plaintiff and numerous other patients.

57. Defendant did not conduct adequate testing to determine the cause of the reported injuries, nor did it rule out Elmiron's design as the cause of the reported injuries.

58. Instead, Defendant continued to market Elmiron as a safe and effective prescription drug for interstitial cystitis.

59. Despite having knowledge that Elmiron was associated with visual symptoms following use, Defendant failed to timely or adequately notify the public and physicians, including Plaintiff and her physician, of these adverse effects and/or defects in Elmiron.

60. Defendant also failed to timely or adequately inform the public and physicians, including Plaintiff and her physician, that Elmiron users should monitor their vision and eyes with regular examination.

61. Defendant actively concealed the true and significant risks associated with Elmiron from Plaintiff and her physicians.

62. At the time of use, Plaintiff was unaware, and could not have reasonably known or have learned through reasonable diligence, of the concealed information concerning the safety and efficacy of Elmiron, including, but not limited to, the risk of retinal changes, maculopathy, vision loss, and other various visual symptoms, and had no way to determine the truth behind defendant's concealment and omissions.

63. As a result of Defendant's actions and inactions concerning Defendant's Elmiron product, and as a result of her use of Elmiron, Plaintiff suffered serious injuries including, but not

limited to, various visual symptoms, changes to her retina, and the possibility of continuing progression of her toxic maculopathy despite cessation of her Elmiron treatment.

64. As a direct and proximate result of her Elmiron prescription and consumption, Plaintiff has been permanently and severely injured, having suffered serious consequences.

65. Plaintiff seeks damages associated with these injuries.

EQUITABLE TOLLING

66. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

67. Defendant failed to disclose a known defect and affirmatively misrepresented that Elmiron was safe for its intended use. Further, Defendant actively concealed the true risks associated with the use of Elmiron. Neither Plaintiff nor the prescribing physician had knowledge that Defendant was engaged in the wrongdoing alleged herein.

68. Because of Defendant's concealment of and misrepresentations regarding the true risks associated with Elmiron, Plaintiff could not have reasonably discovered Defendant's wrongdoing at any time prior to the commencement of this action.

69. Thus, because Defendant fraudulently concealed the defective nature of Elmiron and the risks associated with its use, the running of any statute of limitations has been tolled. Likewise, Defendant is estopped from relying on any statute of limitations.

70. Additionally, and alternatively, Plaintiff files this lawsuit within the applicable limitations period of first suspecting that Elmiron caused the appreciable harm sustained by Plaintiff. Plaintiff did not have actual or constructive knowledge of acts indicating to a reasonable person that Plaintiff was the victim of a tort. Plaintiff was unaware of the facts upon which

a cause of action rests until less than the applicable limitations period prior to the filing of this action. Plaintiff's lack of knowledge was not willful, negligent, or unreasonable.

CAUSES OF ACTION

COUNTS I & II
STRICT LIABILITY: DESIGN DEFECT
STRICT LIABILITY: FAILURE TO WARN

71. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

72. Defendant had a duty to use reasonable care to design a product that was not unreasonably dangerous to users.

73. Defendant had a duty to adequately test Elmiron.

74. Defendant had a duty to provide adequate warnings and instructions for Elmiron.

75. At all relevant times, Elmiron was defective in design or formulation because, when it left the hands of the manufacturer or supplier:

    a. Elmiron was in an unreasonably dangerous and defective condition for its intended use;

    b. Elmiron posed a risk of serious and potentially irreversible vision issues and retinal harm to Plaintiff and other consumers;

    c. The foreseeable risks of harm posed by Elmiron could have been reduced or avoided by the adoption of a feasible reasonable alternative design by Defendant;

    d. The omission of the alternative design rendered Elmiron not reasonably safe;

    e. Elmiron had not been adequately tested;

    f. Elmiron had inadequate warnings or instructions concerning the true risks of its use;

g. The foreseeable risks of harm posed by Elmiron to Plaintiff could have been reduced or avoided by the provision of reasonable instructions or warnings by Defendant;

h. Defendant's omission of reasonable instructions or warnings rendered Elmiron not reasonably safe.

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

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

78. The Elmiron supplied to Plaintiff by Defendant was defective, dangerous, and had inadequate warnings or instructions at the time it was sold, and Defendant also acquired additional knowledge and information confirming the defective and dangerous nature of Elmiron.

79. Despite this knowledge and information, Defendant failed and neglected to issue adequate warnings or post-sale warnings that Elmiron causes serious and potentially irreversible vision issues and retinal harm.

80. Defendant 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.

81. By failing to adequately test and research harms associated with Elmiron use, and by failing to provide appropriate warnings about Elmiron use, patients and the medical community, including prescribing doctors, were inadequately informed about the true risk-benefit profile of Elmiron and were not sufficiently aware that serious and potentially irreversible vision issues and retinal harm might be associated with Elmiron use. Nor were the medical community, patients, patients' families, or regulators appropriately informed that serious and potentially irreversible vision issues and retinal harm might be a side effect of Elmiron use and should or could be reported as an adverse event.
82. The defective condition of Elmiron existed at the time Elmiron left Defendant's control.
83. Elmiron reached Plaintiff, as the user and/or consumer, without substantial change in the condition in which Elmiron was sold.
84. Plaintiff did not misuse, alter, or modify the Elmiron she consumed.
85. Upon information and belief, Elmiron's defective condition is the cause of Plaintiff's damages.
86. Elmiron's defective condition was not an inherent characteristic of Elmiron and would not be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes Elmiron.
87. As a direct and proximate result of Defendant's conduct, including the inadequate warnings, dilution or lack of information, lack of adequate testing and research, and the defective and dangerous nature of Elmiron, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn

money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT III
NEGLIGENCE

88. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

89. Defendant owed Plaintiff and all consumers a duty of reasonable care in how it manufactured, designed, sold, distributed, supplied, promoted, placed in the stream of commerce, and/or warned of the dangers of Elmiron.

90. Defendant breached its duty of care and was negligent as described herein in the design, manufacture, labeling, warning, instruction, training, selling, marketing, and distribution of Elmiron in one or more of the following respects:

    a. Failing to manufacture the product so as to avoid an unreasonable risk of harm to patients whom consumed the product, including Plaintiff;

    b. Failing to use reasonable care in the testing of the product so as to avoid an unreasonable risk of harm to patients in whom the product was consumed, including Plaintiff;

    c. Failing to use reasonable care in the inspection of the product so as to avoid an unreasonable risk of harm to patients whom consumed the product, including Plaintiff;

    d. Failing to design the product so as to avoid an unreasonable risk of harm to users whom consumed the product, including Plaintiff;

    e. Failing to use reasonable care in instructing and/or warning health care providers, the FDA and the public of the risks associated with the product, including the risk

of retina changes and vision-related symptoms, so as to avoid an unreasonable risk of harm to patients whom consumed the product, including Plaintiff;

f. Failing to conform with Defendant's own representations so as to avoid an unreasonable risk of harm to patients whom consumed the product, including Plaintiff;

g. Failing to use reasonable care in marketing and promoting the product, so as to avoid an unreasonable risk of harm to patients whom consumed the product, including Plaintiff;

h. Failing to conduct post-market vigilance or surveillance;

i. Falsely representing and promoting Elmiron as a safe and effective option;

j. Concealing from Plaintiff and her health care providers information about the propensity of Elmiron to cause great harm, and/or;

k. Otherwise negligently or carelessly designing, manufacturing, marketing, distributing, warning, labeling, testing, or selling the product.

91. Prior to the fall of 2018, Plaintiff could not, using ordinary care, have discovered these Elmiron defects.

92. Upon learning of the potential link between her injuries and her Elmiron use, Plaintiff promptly discontinued her use of Elmiron.

93. Prior to discontinuation, Plaintiff used Elmiron in a way that was reasonably predicted by Defendant.

94. As a direct and proximate result of Defendant's negligence, Plaintiff has been injured, sustained pain, suffering, loss of enjoyment of life, loss of care, comfort and consortium, economic loss and damages including, but not limited to, medical expenses.

JURY DEMAND

Plaintiff demands a Jury Trial on all issues of fact.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendant, jointly and severally, as follows:

A. For an award of compensatory damages, including damages against Defendant for pain and suffering, medical and hospital expenses, loss of income, and other damages according to proof at trial in excess of $75,000;

B. For an award of punitive or exemplary damages against Defendant in excess of $75,000;

C. For reasonable attorneys' fees and costs;

D. For pre-judgment interest; and

E. For such further and other relief the court deems just, equitable, and proper.

Dated: September 30, 2020

Respectfully Submitted,

ANAPOL WEISS

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