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

SHARI LEWIS AND LARRY LEWIS

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

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

Sol H. Weiss, Anapol Weiss, One Logan Square, 130 N. 18th Street, Suite 1600, Philadelphia, PA 19103, (215) 735-2098

DEFENDANTS

JANSSEN PHARMCEUTICALS, INC.

County of Residence of First Listed Defendant Montgomery
(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
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U S Government Defendant
- ☒ 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
- ☐ 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

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

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

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer w/Disabilities - Employment
- ☐ 446 Amer w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

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

FORFEITURE/PENALTY
- ☐ 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

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 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))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U S Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
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- ☐ 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

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 U.S.C. Sec. 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 Wendy Beetlestone DOCKET NUMBER 2:20-cv-02147

DATE 11/24/2020

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: Shari Lewis and Larry Lewis, 3804 Perkins Road, Arlington, TX 76016

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:

		Yes	No
1.	Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?	☐	☑
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?	☑	☐
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?	☐	☑
4.	Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?	☐	☑

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: 11/24/2020 /s/ Sol H. Weiss, Esq. 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, [redacted], 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: 11/24/2020 [redacted] [redacted]

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

Shari Lewis and Larry Lewis	:	CIVIL ACTION
v.	:	
Janssen Pharmaceuticals, Inc.	:	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)

11/24/2020	[redacted]	Shari Lewis and Larry Lewis
Date	**Attorney-at-law**	**Attorney for**
[redacted]	[redacted]	[redacted]
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SHARI LEWIS AND	)	
LARRY LEWIS	)	**CIVIL ACTION NO.**
v.	)	
JANSSEN PHARMACEUTICALS, INC.	)	**COMPLAINT**

COMES NOW THE PLAINTIFFS, Shari Lewis and Larry Lewis ("Plaintiffs"), by and for their Complaint against Defendant, state and allege upon information and belief and based upon the investigation of counsel, as follows:

INTRODUCTION

This is a personal injury action for damages arising from Plaintiff, Shari Lewis' use of Defendant's dangerously defective prescription drug, Elmiron (pentosyn polysulfate sodium), prescribed for the treatment of interstitial cystitis and bladder pain. Defendant designed, marketed, and distributed Elmiron in the United States, all the while knowing significant risks that were never disclosed to the medical and healthcare community, including Plaintiff's prescribing doctor, Food and Drug Administration (hereinafter referred to as "FDA"), to Plaintiff, and/or the public in general. Further, Defendant failed to provide adequate warnings to patients and the medical community, including Plaintiff's prescribing physician, of the risks associated with using the drug.

Throughout the time Defendant marketed Elmiron, Defendant withheld material adverse events from the public, medical community and FDA. Defendant failed to disclose the serious link between Elmiron use and significant visual damage, including pigmentary maculopathy. Ultimately, tens of thousands of patients, including Plaintiff, were placed at risk and harmed as a result of this misleading conduct.

PARTIES

1. At all times relevant hereto, Plaintiff Shari Lewis was a citizen and resident of Texas residing in Tarrant County.

2. At all times relevant hereto, Plaintiff Larry Lewis, husband of Shari Lewis, was a citizen and resident of Texas residing in Tarrant County.[1]

3. Plaintiff Shari Lewis consumed and regularly used Defendant's Elmiron (pentosyn polysulfate sodium) product. As a result of her use of Defendant's Elmiron product, Plaintiff suffered from severe physical and emotional injuries, including but not limited to loss of vision and a diagnosis of chorioretinal degeneration and pigmentary retina dystrophy caused by pentosyn polysulfate sodium toxicity. Plaintiff's treating physician directly attributes her severe visual injuries to Elmiron.

4. Defendant Janssen Pharmaceuticals, Inc, is a Pennsylvania corporation with a principal place of business located at 800 Ridgeview Drive, Horsham, Pennsylvania 19044.

5. Defendant directly or through their agents or employees designed, manufactured, marketed, and sold Elmiron in the United States which is used to manage symptoms of interstitial cystitis and painful bladder syndrome.

[1] Plaintiff Larry Lewis was a resident of California from 1997-1999.

JURISDICTION AND VENUE

6. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. §1332, because the amount in controversy exceeds $75,000.00 and the Parties are citizens of different states.

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

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

9. Defendant routinely and systematically transacts business in within this District by selling its products within this District and throughout the United States.

GENERAL ALLEGATIONS

A. Interstitial Cystitis

10. Interstitial cystitis is a medical condition in the bladder that causes bladder pressure, bladder pain, and sometimes pelvic pain. There is no known cause of interstitial cystitis. The symptoms can range from mild to debilitating. The disease is known to affect women more often than men. There is no known cure for interstitial cystitis or painful bladder syndrome.

11. The American Urological Association has established guidelines to provide a clinical framework for the diagnosis and treatment of interstitial cystitis. These guidelines were created by a comprehensive review of the literature. The guidelines include principles for the diagnosis of interstitial cystitis. The AUA guidelines further state that initial treatment type and level should depend on symptom severity, clinician judgment, and patient preferences. Treatments that may be offered are divided into first-, second-, third-, fourth-, fifth-, and sixth-line groups

based on the balance between potential benefits to the patient, potential severity of adverse events (AEs) and the reversibility of the treatment. Second-line treatment of interstitial cystitis includes multi-modal pain management approaches including manual therapy and pharmacological options including amitriptyline, cimetidine, hydroxyzine, or pentosyn polysulfate.

B. Elmiron

12. Elmiron (pentosyn polysulfate sodium) was approved in 1996 to be used as a treatment for interstitial cystitis and painful bladder symptoms.

13. Upon information and belief, Elmiron was granted an Orphan Drug designation in 1995. The original NDA was submitted in 1991 which was deemed non-approvable in 1993. A second non-approvable letter was sent in 1994 over concerns about the lack of data on efficacy of the drug.

14. Elmiron (Pentosan polysulfate sodium) 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.

15. Upon information and belief, Elmiron was first approved by the FDA in September 1996 for painful bladder symptoms at which time Baker Norton Pharmaceuticals was the sponsor of the New Drug Application.

16. Upon information and belief, in 1997 Elmiron was purchased from Baker Norton Pharmaceuticals and Ivax by Alza Pharmaceuticals.

17. Upon information and belief, in 2002, Alza Corporation was acquired by Ortho-McNeil Pharmaceuticals, Inc, a subsidiary of Janssen Pharmaceuticals. Janssen Pharmaceuticals has been the sponsor of the NDA since that time.

18. Prior to June 2020, the label and prescribing information that accompanied Elmiron when prescribed to patients contained the following: "Warnings: None."

19. According to the Drugs@FDA website, the label for Elmiron has been updated on approximately six occasions. Prior to June 2020, Elmiron's label contained no information about vision loss, including pigmentary maculopathy. Prior to June 2020, the label's sole reference to visual adverse events was a disclosure in the Adverse Reactions section that clinical trial patients reported conjunctivitis, optic neuritis, amblyopia, and retinal hemorrhage. However, none of these adverse events were related to pigmentary maculopathy.

20. Elmiron is known to take long time to exert an effect and 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. 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. Drug-Induced Retinal Toxicity

21. The administration of drugs that are physiologically foreign to the body can lead to adverse side effects or toxicity with significant consequences. The retina is especially susceptible to the effects of systemic drugs. It has an extensive dual blood supply from the retina and is one of the most metabolically active tissues in the body. The retina has minimal ability to regenerate and is therefore at high risk of drug toxicity. Thus, it is critical that eye care professionals are aware and monitor for adverse drug effects, especially those affecting the retina.

22. For example, the anti-malarial drug Plaquenil (hydroxychloroquine) is known to be associated with retinal toxicity. The label that accompanies that drug contains explicit instructions of the risk of injury and monitoring for signs of toxicity.

> Irreversible retinal damage has been observed in some patients who had received hydroxychloroquine sulfate. Significant risk factors for retinal damage include

> daily doses of hydroxychloroquine sulfate greater than 6.5 mg/kg (5 mg/kg base) of actual body weight, durations of use greater than five years, subnormal glomerular filtration, use of some concomitant drug products such as tamoxifen citrate and concurrent macular disease.
>
> A baseline ocular examination is recommended within the first year of starting PLAQUENIL. The baseline exam should include: best corrected distance visual acuity (BCVA), an automated threshold visual field (VF) of the central 10 degrees (with retesting if an abnormality is noted), and spectral domain ocular coherence tomography (SD-OCT).
>
> For individuals with significant risk factors (daily dose of hydroxychloroquine sulfate greater than 5.0 mg/kg base of actual body weight, subnormal glomerular filtration, use of tamoxifen citrate or concurrent macular disease) monitoring should include annual examinations which include BCVA, VF and SD-OCT. For individuals without significant risk factors, annual exams can usually be deferred until five years of treatment.
>
> In individuals of Asian descent, retinal toxicity may first be noticed outside the macula. In patients of Asian descent, it is recommended that visual field testing be performed in the central 24 degrees instead of the central 10 degrees.
>
> It is recommended that hydroxychloroquine be discontinued if ocular toxicity is suspected and the patient should be closely observed given that retinal changes (and visual disturbances) may progress even after cessation of therapy.

D. Elmiron-Induced Macular Toxicity

23. In November 2018, *Pearce, et al.* reported a case series of patients known to be long term users of Elmiron that presented with an atypical maculopathy that resulted in significant vision loss.

24. A follow-up study by the same authors (*Hanif, et al*.) included a retrospective review of 219 patients seen at Emory and evaluated vision loss as additional support for the association between Elmiron use and vision loss.

25. In *Jain et al.*, the authors reported a large, administrative, U.S. database was used to examine the association of PPS use and a diagnosis of a macular disorder. Their exposure cohort (PPS users) was matched 1:5 with an unexposed cohort of patients (not necessarily IC/BPS

patients). The primary outcome was any new diagnosis of a hereditary or secondary pigmentary retinopathy or any new diagnosis of dry age-related macular degeneration (AMD) or drusen in addition to the previously described retinopathy. At seven years, there was a statistically significant increase in the exposed group in multivariate analysis (odds ratio [OR] 1.41; 95% confidence interval [CI] 1.09–1.83; p=0.009].

26. At a recent meeting of the American Academy of Ophthalmologists in San Francisco, *Vora et al*. presented their findings using data from Kaiser Permanente and identified 140 patients (from the database of 4.3 million) who had taken an average of 5000 pills over a 15-year period. Of the 140 exposed patients, 91 agreed to an examination and of those, 22 patients showed clear evidence of this specific maculopathy, which authors believe was associated with PPS exposure. This work has since been published in the journal, *Opthamology* in January 2020. According to Dr. Vora:

> You have a patient with a chronic condition like interstitial cystitis, for which there is no cure and no effective treatment. They get put on these medications because it's thought to have few side effects and few risks, and no one thinks about it again. And year after year, the number of pills they're taking goes up and up.

Because it's unclear how much medication is too much, Dr. Vora is reported to recommend patients who show no signs of toxicity be screened for retina damage at least once a year. For those who do show some signs of damage, he recommends they speak with their urologist or OB/GYN about discontinuing the medication.

27. *Greenlee et al.* postulated that the mechanism of toxicity of pentosyn polysulfate may relate to the antagonist properties of pentosyn polysulfate towards the fibroblast growth factors 1, 2, and 4. The authors of that publication reported that several known FGF antagonists are associated with significant ocular side effects.

28. In *Lyons, et al.*, published in *Obstetrics and Gynecology* in 2020, the authors made the following screening and follow-up recommendations:

a. Providers discuss the risks associated with pentosan polysulfate with their patients and prescribe the lowest necessary dose and duration of pentosan polysulfate for patients who require long-term treatment. Providers may discuss alternative treatments for interstitial cystitis at their discretion.

b. A baseline examination with fundus photography, optical coherence tomography, and fundus autofluorescence imaging.

c. Testing is repeated within 5 years after pentosan polysulfate initiation and annually, thereafter. Some patients may be at higher risk for developing pentosan polysulfate maculopathy and may benefit from either more frequent screening examinations or drug avoidance.

d. We recommend that patients diagnosed with pentosan polysulfate maculopathy stop taking the drug and discuss alternative interstitial cystitis management options with their treating physician

29. Since the original report, there have been more than a dozen papers published in the medical literature regarding atypical maculopathy associated with Elmiron use.

E. Defendant's Belated Disclosure of Elmiron's Health Risks

30. Despite these publications, knowledge of countless adverse event reports and other data to be ascertained through discovery, prior to June 2020 Defendant made no change to the U.S. Elmiron label or took any steps to otherwise warn the medical community and Elmiron users of these significant health risks.

31. On June 16, 2020, the FDA advised of significant changes to Elmiron's label to disclose the risk of retinal pigmentary changes. Among other things, the "Warnings" section of the label, which was previously blank, now warns of irreversible vision changes that can progress even after patients stop taking Elmiron:

WARNINGS
Retinal Pigmentary Changes

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

32. Defendant's U.S. label change came too late to benefit Plaintiff and thousands of other Elmiron users.

33. Prior to June 2020, Defendant was aware of the risks of visual injury with Elmiron. Indeed, prior to June 2020 Defendant made label changes in other countries to warn users of serious vision injury. For example, in September 2019, Defendant changed the label of Elmiron in Canada to reflect the following warning:

Ophthalmologic

> Post-market cases of pigmentary maculopathy have been reported with chronic use of pentosan polysulfate sodium (PPS). Visual symptoms in these cases included difficulty reading and prolonged dark adaptation. All patients should have regular ophthalmic examinations for early detection of pigmentary maculopathy, particularly those with long-

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

PLAINTIFF SPECIFIC FACTS

34. In or about August 1997, Plaintiff's treating physician prescribed Elmiron to Plaintiff to manage the symptoms of her medically diagnosed interstitial cystitis. Defendant represented Elmiron to be an appropriate and suitable product for such purposes.

35. Plaintiff regularly took Elmiron from 1997 to 2020.

36. In or about 1999, Plaintiff began to experience progressive visual issues, including blurred vision and difficulty with dark adaptation. In 2002, Plaintiff's exams revealed maculopathy with pigment changes in the macular region of both eyes. In 2010, Plaintiff's exams revealed macular degeneration of the retina and she was determined to be legally blind. In June 2013, Plaintiff was diagnosed with pigmentary retina dystrophy. During an additional OCT exam in October 2020, Plaintiff's retina specialist noted significant retinal pigment epithelium changes as well as bilateral "diffuse outer retina atrophy" and diagnosed Plaintiff with chorioretinal degeneration caused by Elmiron toxicity. As a result of Defendant's actions and inactions, Plaintiff was significantly and permanently injured due to Elmiron which caused Plaintiff various injuries and damages due to her vision loss. Plaintiff accordingly seeks damages associated with these injuries.

37. Defendant ignored reports from patients and health care providers throughout the United States of Elmiron's failure to perform as intended, and injuries associated with long term use which led to the severe and debilitating injuries suffered by Plaintiff, and numerous other patients. Rather than doing adequate testing to determine the cause of these injuries or rule out Elmiron's design as the cause of the injuries, Defendant continued to market Elmiron as a safe and effective prescription drug for interstitial cystitis.

38. Defendant did not timely or adequately apprise the public and physicians, including Plaintiff's physicians, of the adverse effect or defects in Elmiron despite Defendant's knowledge that it was associated with visual effects following use. Defendant did not timely or adequately apprise the public and physicians, including Plaintiff's physicians, to monitor Elmiron users' vision and eyes with regular examination.

39. Defendant's' Elmiron was at all times utilized and prescribed in a manner foreseeable to Defendant, as Defendant generated the instructions for use for Plaintiff to take Elmiron.

40. Plaintiff and Plaintiff's physicians foreseeably used the Defendant's Elmiron, and did not misuse, or alter the Elmiron in an unforeseeable manner.

41. Through their affirmative misrepresentations and omissions, Defendant actively concealed from Plaintiff and his/her physicians the true and significant risks associated with Elmiron consumption.

42. As a result of Defendant's actions, Plaintiff and her physicians were unaware, and could not have reasonably known or have learned through reasonable diligence that Plaintiff would be exposed to the risks identified in this Complaint and that those risks were the direct and proximate result of Defendant's conduct.

43. As a direct result of being prescribed and consuming Elmiron, Plaintiff has been permanently and severely injured, having suffered serious consequences.

44. Plaintiff, as a direct and proximate result of Elmiron, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress, along with economic loss due to medical expenses and living-related expenses due to her new lifestyle.

45. As a direct result of Plaintiff, Shari Lewis' Elmiron use, Plaintiff's spouse, Larry Lewis has suffered a loss of services, society and companionship which will continue indefinitely into the future.

46. Plaintiff's physicians would not have prescribed Elmiron had Defendant properly disclosed the risks associated with its use or in the alternative, would have actively monitored her vision with regular eye exams.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

47. 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.

48. 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.

49. 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.

50. 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.

COUNT I
STRICT LIABILITY

51. Plaintiffs incorporate by referenced each and every preceding paragraph as though fully set forth herein.

52. At all times relevant hereto, Defendant manufactured, designed, distributed, and/or sold Elmiron.

53. At all times relevant hereto, the dangerous propensities of Elmiron were known to Defendant, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective products, and not known to ordinary physicians who would be expected to prescribe the drug to their patients.

54. The Elmiron product as distributed by Defendant was a defective and unreasonably dangerous product, as Defendant failed to provide appropriate and adequate warnings and instructions to render the products reasonably safe for its ordinary, intended, and reasonably foreseeable uses; in particular the common, foreseeable and intended use of Elmiron to treat painful bladder syndrome and interstitial cystitis.

55. Defendant failed to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physician that Defendant's Elmiron product was designed and/or manufactured in a way that could cause injuries and damages, including lasting and permanent visual injuries.

56. Defendant failed to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physician as to the risks of the Defendant's Elmiron product. To the contrary, Defendant withheld information from Plaintiff and Plaintiff's physician regarding the true risks related to prescribing the Elmiron product.

57. The Elmiron product, as distributed by Defendant, was dangerous in design at

the time it left the Defendant's control.

58. Plaintiff did not misuse or materially alter the Elmiron as prescribed and dispensed to Plaintiff and used by Plaintiff.

59. At the time the Elmiron product left Defendant's control, there existed feasible and suitable alternative design for the treatment of interstitial cystitis that was capable of preventing Plaintiff's damages or alternatively a plan for monitoring ocular health in association with use of Elmiron.

60. When compared to other feasible alternatives, the Elmiron product greatly results in a much higher risk of visual injuries and side effects. Other feasible alternative treatments exist which do not present the same frequency and severity of risks.

61. At all times relevant to this action, Defendant manufactured, supplied, distributed, and/or sold Elmiron in a defective and dangerous condition, as described above, to Plaintiff.

62. The Elmiron received by Plaintiff did not perform safely as an ordinary consumer would have expected it to perform when used in a reasonably foreseeable way.

63. Furthermore, a reasonable patient would conclude the possibility and seriousness of harm outweighs the benefit from it's normal, intended use.

64. As a direct, foreseeable and proximate result of Defendant's defective Elmiron product, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, as referenced above, when his physicians, lacking adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) Defendant provided to physicians for their respective products. Plaintiff has suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income and disability.

COUNT II
NEGLIGENCE

65. Plaintiffs incorporate by referenced each and every preceding paragraph as though fully set forth herein.

66. At all times relevant hereto, it was the duty of Defendant to use reasonable care in the manufacturing, design, distribution, and/or sale of Elmiron.

67. Defendant failed to exercise ordinary care in the manufacture, sale, labeling, and marketing Elmiron in that Defendant know or should have known that Elmiron created a high risk of unreasonable harm to Plaintiffs and other users.

68. In disregard of its duty, Defendant committed one or more of the following negligent acts or omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Elmiron without thorough and adequate pre- and post-market testing of the product;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Elmiron while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Elmiron;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Elmiron was safe for its intended use;

d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendant knew and had reason to know that Elmiron was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users;

e. Failing to warn Plaintiff, the medical and h e althcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative products available to Plaintiff and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would use

Elmiron;

g. Advertising, marketing, and recommending the use of Elmiron, while concealing and failing to disclose or warn of the dangers known by Defendant to be connected with, and inherent in, the use of Elmiron;

h. Representing that Elmiron was safe for its intended use when in fact Defendant knew and should have known the product was not safe for its intended purpose;

i. Failing to disclose to and inform the medical community and consumers that other forms of safer and effective alternative products were available for use for the purpose for which Elmiron was manufactured;

j. Continuing to manufacture and sell Elmiron with the knowledge that Elmiron was unreasonably unsafe and dangerous;

k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Elmiron so as to avoid the risk of serious harm associated with the use of Elmiron. Failing to design and manufacture Elmiron so as to ensure the drug was at least as safe and effective as other similar products;

l. Failing to ensure the product was accompanied by proper and accurate warnings about requiring baseline visual examinations and regular eye examinations while using the drug to monitor for retinal or macular toxicity associated with the use of Elmiron;

m. Failing to ensure the product was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Elmiron and that use of Elmiron created a high risk of severe injuries; and

n. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Elmiron.

69. As a direct and proximate result of one or more of the above-stated negligent acts by Defendant, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability.

COUNT III
LOSS OF CONSORTIUM

70. Plaintiffs incorporate by reference each and every preceding paragraph as though fully set forth herein.

71. Plaintiff, Larry Lewis, was at all times relevant the husband of Plaintiff, Shari Lewis.

72. Plaintiff, Larry Lewis, was and is entitled to the companionship, services and society of his wife, Shari Lewis.

73. Due to the injuries described above, Plaintiff, Larry Lewis, has been cause, presently and into the future, the loss of Plaintiff, Shari Lewis' companionship, services, and society and seeks damages for such losses.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at lengthy herein, and prays judgment in her favor and against the Defendant awarding the following:

1. A monetary award sufficient to compensate Plaintiffs for the following categories of damages:

   a. General damages for severe physical pain, mental suffering, inconvenience, and loss of the enjoyment of life;

   b. Past, present, and future damages for costs of medical and rehabilitative treatment and care for Plaintiff; and

   c. Loss of spousal consortium.

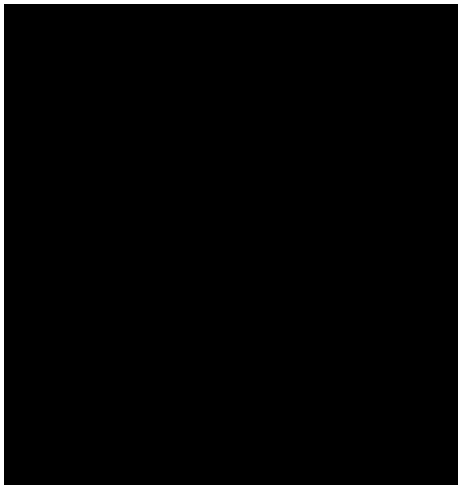
2. Plaintiffs' cost of this action, together with interest on past and future special and general damage amounts from the date of injury at the legal rate until paid, interest on any

judgment awarded herein at the legal rate until paid, and such other and further relief as the Court deems equitable and just.

3. Any other award this Court deems equitable and just.

4. Plaintiffs demand a jury trial.

Date: November 24, 2020



Attorneys for Plaintiffs, Shari Lewis and Larry Lewis