

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

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<b>IN RE: ELMIRON (PENTOSAN</b>	<b>:</b>	<b>Case No. 2:20-md-02973 (BRM)(ESK)</b>
<b>POLYSULFATE SODIUM) PRODUCTS</b>	<b>:</b>	<b>MDL No. 2973</b>
<b>LIABILITY LITIGATION</b>	<b>:</b>	
	<b>:</b>	<b>JUDGE BRIAN R. MARTINOTTI</b>
	<b>:</b>	<b>JUDGE EDWARD S. KIEL</b>

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**THIS DOCUMENT RELATES TO: ALL CASES**

**CASE MANAGEMENT ORDER NO. 8**  
(Plaintiff Fact Sheets and Defendants' Fact Sheets)

**I. SCOPE OF ORDER**

This Order shall apply to the named defendants in (a) all actions transferred to *In re: Elmiron (Pentosan Polysulfate Sodium) Products Liability Litigation* (“MDL 2973”) by the Judicial Panel on Multidistrict Litigation (“JPML”) pursuant to its Order of December 15, 2020; (b) all related actions originally filed in or removed to this Court; and (c) any “tag-along” actions transferred to this Court (collectively, “the Proceedings”). This Order is binding on all Parties and their counsel in all cases currently pending or subsequently made part of the Proceedings and shall govern each case in the Proceedings.

The obligation to comply with this CMO and to provide a PFS or to take any action authorized in this Order related to deficiencies in a DFS shall be the sole obligation of the individual attorney hired by the individual Plaintiff. As with all case-specific discovery, the members of the Plaintiffs’ Leadership and/or Plaintiff Steering Committee (“PSC”) are not obligated to conduct case-specific discovery for Plaintiffs by whom they have not been individually retained, including responding to PFSs or curing deficiencies in any manner

whatsoever. Further, Plaintiffs' Leadership and/or PSC shall have no obligation to take any action with regard to the DFS deficiency process for any individual Plaintiff.

## **II. PLAINTIFF FACT SHEET**

**A.** The form of Plaintiff Fact Sheet ("PFS") that shall be used in all Proceedings is attached as **Exhibit A**.<sup>1</sup> In accordance with the schedule set forth in Section IV below, every Plaintiff in each Proceeding shall:

1. Complete and execute a PFS;
2. Produce to Defendants all documents requested in the PFS that are in the Plaintiff's possession; and
3. Provide completed (but undated), executed release authorizations for all providers and/or institutions that maintain relevant records as identified within the PFS pursuant to PFS Sections II.D.2. (if a claim for lost wages is asserted), III.B., IV.A.1., IV.A.2., IV.B. (if a claim for psychiatric and/or psychological condition is asserted), IV.D., V.A.2., V.A.3., V.B.1., V.B.2., V.C.1., V.C.2., V.C.3., VI, VII, and IX, to the extent applicable and as limited by the timeframes set forth in the specific PFS sections listed above.
  - a) Plaintiff's Counsel shall also maintain ten (1) copies of signed, undated medical authorizations from each Plaintiff for use in the event that additional medical providers are identified or updated authorizations are needed for existing providers.

**B.** Plaintiff's responses to the PFS shall be treated as answers to interrogatories under Fed. R. Civ. P. 33 and shall be signed by Plaintiff. The responses to requests for production of documents included in the PFS are made under Fed. R. Civ. P. 34 and need only be signed by counsel. The PFS shall be supplemented in accordance with Fed. R. Civ. P. 26.

**C.** The PFS shall be completed without objections as to the questions posed in the PFS.

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<sup>1</sup> The Parties have agreed on required fields that must be completed prior to a PFS being accepted via BrownGreer's MDL Centrality platform.

### **III. DEFENDANTS' FACT SHEET**

**A.** The form of Defendants' Fact Sheet ("DFS") that shall be used in all Proceedings is attached as **Exhibit B**. In accordance with the schedule set forth in Section IV below, Defendant Janssen shall:

1. Complete and execute a DFS for use in all Proceedings;
2. Produce to Plaintiffs all records required under the DFS;

**B.** Defendants' responses to the DFS shall be treated as answers to interrogatories under Fed. R. Civ. P. 33 and shall be signed by a representative of Defendant. The responses to requests for production of documents included in the DFS are made under Fed. R. Civ. P. 34 and need only be signed by counsel. The DFS shall be supplemented in accordance with Fed. R. Civ. P. 26.

**C.** The DFS shall be completed without objections as to the questions posed in the DFS.

**D.** As a matter of convenience and courtesy, the PSC has agreed to allow Defendants to respond to discovery in the DFS by providing responsive information collectively for all Plaintiffs in an Excel spreadsheet. Notwithstanding this process, prior to any case-specific deposition or trial, Defendants shall produce to Plaintiff or its designee a "long-form" DFS which shall contain the identical answers in a standard question-and-answer, PDF format, with verification, for use as an exhibit in such proceedings. Defendants shall produce a separate long-form copy, exactly corresponding in substance, for each previously produced version or amendment to a DFS.

#### IV. DEADLINE FOR SERVICE OF PFS AND DFS

##### A. Currently Filed Cases

1. For all cases filed and served as of the date of this Order, each Plaintiff shall complete and serve a PFS no later than **June 23, 2021**.
2. For all cases filed and served as of the date of this Order in which a good faith effort was made to respond to the PFS, Defendants shall complete and serve a DFS not later than **August 23, 2021**.

##### B. Cases Filed After Entry of this Order

1. For all cases filed and served after entry of this Order, each Plaintiff shall complete and serve a PFS within 45 days of the Notice of Appearance filed by the Janssen Defendants.<sup>2</sup>
2. Defendants shall complete and serve a DFS within 60 days of receipt of PFS.

C. **Service of PFS:** Each PFS shall be completed and served via the online MDL Centrality system designed, hosted, and provided by BrownGreer PLC, as set forth more fully in Exhibit C. If a PFS is being submitted by a *pro se* litigant, then a hard-copy PFS may be submitted to the following address in lieu of electronic submission: BrownGreer PLC, 250 Rocketts Way, Richmond, VA 23231.

D. **Service of DFS:** DFSs shall be completed and served via the online MDL Centrality system designed and provided by BrownGreer PLC, as set forth more fully in Exhibit C.

#### V. PROCEDURES FOR NON-COMPLIANT PFS AND DFS

The Parties shall make a good faith effort to respond to the PFS and DFS and provide reasonably available documents in their possession as required by the PFS and the DFS by the applicable deadlines set forth in this Order. The Parties recognize that, despite good faith efforts, certain alleged discovery deficiencies in the PFS or DFS responses may require Court intervention. However, before any such alleged discovery deficiencies are raised with the Court, that party

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<sup>2</sup> The Janssen Defendants are defined as follows: Janssen Pharmaceuticals, Inc., ALZA Corporation, Centocor Research & Development, Inc., Janssen Ortho LLC, Janssen Research & Development, LLC, Ortho-McNeil Pharmaceutical, LLC, Johnson & Johnson.

identifying such deficiencies shall notify the relevant opposing party in writing (the “Deficiency Letter”) of the alleged deficiency. The party receiving the Deficiency letter shall respond to the alleged discovery deficiency within two (2) weeks of the date of service of the Deficiency Letter. The parties shall conduct at least one telephonic meet and confer in an effort to resolve the issue prior to seeking the Court’s involvement. If the parties have not resolved the issue after the expiration of three weeks or the parties have not agreed to allow further time to address the alleged discovery deficiency, the party identifying the deficiency (hereinafter referred to as the “Complaining Party”) may raise the issue informally by letter brief to Special Master Honorable Robert L. Polifroni, P.J. Cv. (Ret.; Superior Court of New Jersey, Bergen County not to exceed three pages in length. Said letter-brief shall be transmitted via email to all counsel of record for the “Allegedly Deficient Party” and to Special Master Polifroni via email at [RPolifroni@hkmpp.com](mailto:RPolifroni@hkmpp.com), with a copy to the PSC at [PFS.DFS.DeficiencyLetter@DouglasAndLondon.com](mailto:PFS.DFS.DeficiencyLetter@DouglasAndLondon.com)

The Allegedly Deficient Party’s counsel shall respond to the Complaining Party Letter within fourteen (14) days of receipt of same, setting forth its position, and via email to Special Master Polifroni via email at [RPolifroni@hkmpp.com](mailto:RPolifroni@hkmpp.com), with a copy to the PSC at [PFS.DFS.DeficiencyResponse@DouglasAndLondon.com](mailto:PFS.DFS.DeficiencyResponse@DouglasAndLondon.com).

Thereafter, Special Master Polifroni will meet and confer with the parties privately and/or jointly to assist in facilitating a resolution. To the extent the Special Master Polifroni needs to issue a formal decision on the discovery dispute, he will do so. Any party may appeal the Special Master’s decision to Magistrate Judge Kiel. Any appeal must be filed within 10 days of the decision and any appeal shall follow Magistrate Judge Kiel’s local rules regarding discovery disputes.

## **VI. PROCEDURES FOR OVERDUE PFS AND DFS**

If any Plaintiff or Defendant fails to produce a PFS or DFS by the deadline set forth in Section III, counsel for the PFS/DFS Requesting Party shall notify the non-producing party in writing of the failure to produce the PFS or DFS within the deadline (“Notice of Overdue Fact Sheet Letter”). The Notice of Overdue Fact Sheet Letter will state that the failure to produce a PFS or DFS within twenty-one (21) days of the date of the letter will result in the opposing party seeking immediate dismissal of the case or striking of any and all Affirmative Defenses. If within twenty-one (21) days of the date of the Notice of Overdue Fact Sheet Letter, a Plaintiff or Defendant fails to produce a PFS or DFS and has not been granted an extension of time, counsel for the PFS/DFS Requesting Party may file with the Court a motion to dismiss without prejudice for failure to comply with this Order with a proposed order of dismissal. The non-producing party shall have fourteen (14) days to submit a response. The PFS/DFS Requesting Party will have seven (7) days from the date of non-producing party’s response to file a reply, if any. The Court should consider any and all good cause excuses in granting extensions or non-dismissals. Either party may request oral argument on the motion, or the Court may direct it. In the absence of any such request or direction, the Court will rule on the basis of the submitted papers.

The parties are encouraged to grant reasonable extensions for overdue Fact Sheets.

## **VII. MEDICAL RECORDS**

A. As referenced above in Section II.A.3., Plaintiff’s counsel shall provide authorizations for any healthcare provider, hospital, clinic, outpatient treatment center and/or any other entity, institution or agency identified in the Plaintiff Fact Sheet for the release of said records. In the event an institution, agency, or medical provider to which a signed authorization is presented refuses to provide responsive records, Defendants shall notify Plaintiff’s counsel of

the refusal and Plaintiff's counsel shall endeavor to provide a corrected or institution specific authorization as soon as practical to Defendants' counsel.

B. Records that pertain to psychiatric related care, whether by a psychiatrist or psychologist, which should only be provided if a Plaintiff places his/her psychiatric condition at issue, shall first be available to counsel for the Plaintiff who shall have 21 days to assert a recognized privilege and notify both the vendor and counsel for the Defendants with an appropriate privilege log. Absent assertion of such privilege with a privilege log within 21 days, the vendor shall automatically provide the records to Defendants.

C. **Production of Records Obtained by Authorizations.** Defendants' counsel by and through Litigation Management, Inc., shall make available medical records received pursuant to the authorizations provided in accordance with this Order to Plaintiff's counsel at Plaintiff's counsel's request subject to any arrangements Plaintiffs' counsel makes with Litigation Management, Inc. and any associated expenses.

D. Any records obtained pursuant to an authorization provided by any Plaintiff pursuant to this Order shall be deemed confidential under the terms of the Stipulated Protective Order (Doc. 5) entered in this MDL.

### **VIII. OBLIGATIONS OF PFS AND DFS**

A. Nothing herein prevents the Parties from seeking to revise and/or seek relief from the requirements of this Order if, in practice, either party reasonably determines that it does not meet the needs of the litigation or if responding to the PFS or DFS is burdensome, unduly prejudicial, or not proportional to the needs of the case.

B. Nothing herein shall preclude the Parties from serving reasonable case-specific discovery requests in connection with individual cases that have been identified for trial

work-up/bellwether process by the Court, and the Parties will meet and confer to discuss the scope of such discovery and raise any areas of dispute with the Court. No other case-specific discovery shall be permitted in any individual case beyond the PFS and DFS until a case is selected for trial work-up/bellwether process.

Dated: May 5, 2021



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Hon. Brian R. Martinotti, U.S.D.J.



# **EXHIBIT A**

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

**IN RE: ELMIRON (PENTOSAN  
POLYSULFATE SODIUM) PRODUCTS  
LIABILITY LITIGATION**

:  
: **Case No. 2:20-md-02973 (BRM)(ESK)**  
: **MDL No. 2973**  
:  
: **JUDGE BRIAN R. MARTINOTTI**  
: **JUDGE EDWARD S. KIEL**

**THIS DOCUMENT RELATES TO: ALL CASES**

**PLAINTIFF FACT SHEET**

**Instructions**

Please answer every question to the best of your knowledge. In completing this Plaintiff Fact Sheet ("PFS"), you are under oath and must provide information that is true and correct to the best of your knowledge. If you cannot recall all the details requested, please provide as much information as you can or otherwise indicate that you cannot recall. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect. For each question where the space provided does not allow for a complete answer, please attach additional sheets so that all answers are complete.

If you are asked to identify a person (such as doctors or witnesses), please provide the name and last-known address and telephone number.

**Definitions**

**PLAINTIFF, YOU, OR YOUR:** The individual who allegedly took Elmiron.

**DEFENDANT(S):** As used herein, this term means Janssen Pharmaceuticals, Inc., Ortho-McNeil Pharmaceutical, LLC, Janssen Research & Development, LLC, Janssen Ortho LLC, Johnson & Johnson, ALZA Corporation, and Centocor Research & Development, Inc. and any officers, agents, attorneys, employees, representatives, or others acting on their behalf.

**ELMIRON:** Defendant's pentosan polysulfate sodium product.

**HEALTHCARE PROVIDERS:** Any provider of healthcare, including, but not necessarily limited to, physicians, general practitioners, medical specialists, medical doctors, surgeons, plastic surgeons, nurses, nurse practitioners, physician assistants, rehabilitation specialists, physical therapists, occupational therapists, counselors, and pharmacists.

**PLAINTIFF'S FULL NAME:** \_\_\_\_\_

**I. CASE INFORMATION**

A. Please state the following for the lawsuit that you filed:

Case Caption: \_\_\_\_\_

Case Number: \_\_\_\_\_

Plaintiff's Attorney's Name: \_\_\_\_\_

Plaintiff's Attorney's Firm Name: \_\_\_\_\_

Plaintiff's Attorney's Address: \_\_\_\_\_

Plaintiff's Attorney's E-Mail Address: \_\_\_\_\_

Plaintiff's Attorney's Phone Number: \_\_\_\_\_

B. **Representative:** If you are completing this questionnaire in a representative capacity (including, but not limited to, on behalf of the estate of a deceased person, on behalf of an incapacitated individual, etc.), please complete the following:

Name and Current Address	Relationship to the Plaintiff	In What Capacity Are You Representing the Plaintiff?	Court Case Number and Approximate Date of Appointment (if applicable)

**II. PLAINTIFF'S PERSONAL INFORMATION**

A. **Background:**

Plaintiff's Full Legal Name: \_\_\_\_\_

Other Names, Nicknames, and Aliases, if Any, and the Date(s) of Such Use: \_\_\_\_\_

Social Security Number: \_\_\_\_\_

Date of Birth: \_\_\_\_\_

Place of Birth: \_\_\_\_\_

Sex: Male  Female

Plaintiff's Date, Place, and Cause of Death, if Applicable: \_\_\_\_\_

B. **Current Address:** \_\_\_\_\_

If you have lived at this address for less than 10 years, provide each of your prior addresses from 2010 to the present:

Prior Address	Approximate Dates You Lived At This Address

C. **Current Marital Status** (choose one):

- |  |   |
|--|---|
| <input type="checkbox"/> Legally married | <input type="checkbox"/> Divorced         |
| <input type="checkbox"/> Never married   | <input type="checkbox"/> Common law union |
| <input type="checkbox"/> Separated       | <input type="checkbox"/> Widowed          |

Spouse's name(s), date(s) of marriage, and date(s) of any legal separation, divorce, or annulment(s): \_\_\_\_\_

D. **Employment History:**

1. Are you making a claim for lost wages? Yes  No

2. Identify all of your employers for the past five (5) years with name, address and telephone number, your employment dates, and your position(s) there. If you are making a claim for lost wages, please also list salary, annual gross compensation, and/or other compensation received:

Name of Employer	Address	Approximate Dates of Employment	Position(s)	Reason for Leaving (Specify if for Medical Reason)	Salary/Annual Gross Income (only if making claim for lost wages)

E. **Other Lawsuits:** (a) If you have *ever* been a party to an arbitration or civil lawsuit related to your use of Elmiron and/or vision loss, or (b) if, over the last five (5) years, you have ever been a party to an arbitration or civil lawsuit related to another subject matter, please provide the following to the extent it is known:

Caption and Case Number	When and Where Filed	Nature of Claims	Attorney and/or Law Firm Representing You	Outcome (Verdict, Arbitration, Settlement or Dismissal)

F. **Criminal History:** In the last ten (10) years, have you been convicted of or pled guilty to any felony (crime punishable by imprisonment for more than one year) or any crime involving dishonesty and/or false statements? Yes  No

If yes, please list the crime or offense, the county, state, court, and outcome, including the date of any conviction or guilty plea: \_\_\_\_\_  
 \_\_\_\_\_

G. **Smoking Use/History:** Check the answer and fill in the blanks applicable to your history of smoking.

- I have never used tobacco
- I previously used tobacco, but no longer use it
- I currently use tobacco

Types of Tobacco Used: Cigarettes  Cigars  Pipe Tobacco  Smokeless Tobacco

Approximate Amount Used: On average \_\_\_\_\_ per day for \_\_\_\_\_ years

Approximate period of time: \_\_\_\_\_ to \_\_\_\_\_

H. **Alcohol Consumption:** Check the answer and fill in the blanks applicable to your use of alcohol.

I have never consumed alcohol (e.g. beer, wine, or liquor)

I previously consumed alcohol, but no longer use it

I currently consume alcohol

Approximate Amount Consumed: On average \_\_\_\_\_ per week  month   
year  \_\_\_\_\_

Approximate period of time: \_\_\_\_\_ to \_\_\_\_\_

**III. ELMIRON TREATMENT**

**A. Elmiron Use:**

1. For what condition(s) and/or symptoms were you prescribed Elmiron (e.g., pain associated with interstitial cystitis)? \_\_\_\_\_  
\_\_\_\_\_

2. If you recall, please provide your best estimate of the month and year you were first diagnosed with this condition: \_\_\_\_\_

3. Are you currently taking Elmiron? Yes  No

4. While taking Elmiron, did you believe that it provided relief from any of your interstitial cystitis symptoms?

Please check all that might apply:

Yes  In-Part  At Times  No

Cannot answer with checkbox  If you checked this, please provide your response: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

B. Please fill out the below table about your use of Elmiron:

Approximate Dates of Use	Dose and Frequency of Use	Prescribing Healthcare Provider(s) and Address(es)	Name and Address of Pharmacy Used

C. Have you ever received any samples of Elmiron? Yes  No  Do Not Recall

If yes, please complete the following:

Approximate Date Sample Was Received	Provider of Sample	Approximate Number/Amount of Samples Received

D. Has any Healthcare Provider ever provided you any written instructions, warnings or oral instructions regarding Elmiron? Yes  No  Do Not Recall

E. Has any Healthcare Provider told you to stop using Elmiron? Yes  No  Do Not Recall

F. Have you ever had any communications with any of the Defendants or their representatives, or the FDA about Elmiron? Yes  No  Do Not Recall

G. Prior to filing this lawsuit, did you ever see any advertisements for Elmiron, other than attorney advertisements? Yes  No  Do Not Recall

H. Prior to filing this lawsuit, did you ever see any attorney advertisements about Elmiron? Yes  No  Do Not Recall

**IV. ALLEGED INJURIES AND DAMAGES**

A. **Alleged Injuries:** Please identify and set forth the injuries/conditions for which you are seeking damages as a result of your use of Elmiron:

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\_\_\_\_\_

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1. If you sought or plan to seek medical treatment for these injuries/conditions, please identify the Healthcare Provider(s) who rendered or will render care and treatment for these injuries/conditions in the chart below:

<b>Name and Address of Healthcare Provider(s) Who Rendered Care and Treatment for Injury(ies)/Condition(s)</b>	<b>Injury(ies)/Condition(s) for which Treatment Was Rendered</b>	<b>Approximate Date(s) of Treatment</b>



2. If you were admitted to and/or received medical care and treatment for these injuries/conditions at a hospital, please complete the information requested in the chart below:

Name and Address of Hospital	Injury(ies)/Condition(s) for Which Treatment Was Rendered	Approximate Date(s) of Treatment

B. **Psychiatric and/or Psychological Injury:** Are you claiming a psychiatric and/or psychological condition that you have or had is or was related to your use of Elmiron? Yes  No

1. If yes, please complete the following:

Condition	Type of Treatment (if any)	Name and Address of Healthcare Providers	Approximate Date(s) of Treatment	Are You Still Experiencing This Condition?

C. **Activities:**

1. Identify any and all activities that you used to engage in that you claim you can no longer engage in or cannot engage in to the level prior to your injury as a result of using Elmiron:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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2. Have you ever been advised to stop driving due to vision issues?

Yes  No

If yes, when and by whom? \_\_\_\_\_

D. **Discussions with Healthcare Providers:** Have you had discussions with any treating healthcare provider(s) about whether your injuries are related to Elmiron?

Yes  No  Do Not Recall

1. If yes, for each Healthcare Provider, please complete the following:

Healthcare Provider	Address	Healthcare Provider's Specialty	Approximate Date of Discussion

E. **Loss of Consortium:** Has anyone filed a loss of consortium claim in connection with your lawsuit regarding Elmiron? Yes  No

If yes, please complete the following:

Name of Plaintiff(s) Claiming Loss of Consortium	Relation to Plaintiff

F. **Out-of-Pocket Expenses:** Are you seeking recovery for any out-of-pocket expenses associated with your use of Elmiron and/or the health condition(s) you allege you suffered as a result of such use? Yes  No

If yes, please identify and itemize all out-of-pocket expenses:

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G. Are you seeking future medical expenses? Yes  No  Don't Know

**V. PLAINTIFF'S MEDICAL BACKGROUND**

**A. Medical Conditions:**

1. To the best of your knowledge, have you suffered from any of the following:

Medical Condition	
Autoimmune Disorder If <b>Yes</b> , please specify type:	Yes ___ No ___ Don't know ___
Cancer Treated by Radiation or Chemotherapy If <b>Yes</b> , please specify type:	Yes ___ No ___ Don't know ___
Diabetes	Yes ___ No ___ Don't know ___
Drug Toxicity that Affected Your Eyes or Vision (other than Elmiron/PPS) including drug-induced retinal, kidney or liver toxicities.	Yes ___ No ___ Don't know ___
Fibromyalgia	Yes ___ No ___ Don't know ___
Hypertension	Yes ___ No ___ Don't know ___

Interstitial Cystitis	Yes ___ No ___ Don't know ___
Lupus	Yes ___ No ___ Don't know ___
Macular Degeneration	Yes ___ No ___ Don't know ___
Pattern Dystrophy	Yes ___ No ___ Don't know ___
Renal Disorders	Yes ___ No ___ Don't know ___
Retinal Detachment	Yes ___ No ___ Don't know ___
Retinopathy (including diabetic)	Yes ___ No ___ Don't know ___
Rheumatoid Arthritis	Yes ___ No ___ Don't know ___
Trauma-Related Condition of Head (including, but not limited to, eye)  If Yes, please specify type:	Yes ___ No ___ Don't know ___

2. For each condition for which you answered Yes in the previous chart, please provide the information requested below. Please also list *any other injuries, illnesses or disabilities* related to vision loss not listed in the previous chart for which you have been treated or diagnosed during the period beginning ten (10) years prior to when you began taking Elmiron to the present

<b>Injury or Condition</b>	<b>Approximate Date of Diagnosis</b>	<b>Diagnosing Physician</b>	<b>Treating Healthcare Provider(s)</b>	<b>Medication / Treatment</b>	<b>Are You Still Experiencing This Condition?</b>

3. Have you ever received a determination of legal blindness? Yes  No

If yes, please provide the following:

<b>Government Agency or Healthcare Provider Making Determination</b>	<b>Approximate Date of Determination</b>	<b>Basis of Determination</b>	<b>Has Determination Been Reversed? (If so, Specify When, By Whom, on What Basis)</b>

**B. Prescriptions:**

1. To the best of your knowledge, list all medications that you have taken for at least three (3) months for the period beginning five (5) years prior to when you began taking Elmiron to the present:

<b>Medication</b>	<b>Approximate Dates of Use</b>	<b>Prescribing Healthcare Provider</b>	<b>Reason for Use</b>	<b>Name and Address of Pharmacy</b>

2. Have you ever received a prescription for glasses or contacts? Yes  No

If yes, please provide the following:

Prescribing Healthcare Provider	Approximate Dates of Treatment

**C. Procedures:**

1. Did you undergo any eye imaging and/or visual testing for vision loss during the period beginning five (5) years prior to when you began taking Elmiron to the present? Yes  No

If you answered Yes, please provide the following:

Test Type	Approximate Date of Testing	Recommending/Performing Healthcare Provider(s)	Reason for Testing	Results of Testing (Including Any Diagnosis)

2. Have you undergone any genetic testing related to vision loss (e.g., Mutations in PRPH2, BEST1, ABCA4, IMPG1/IMPG2, MT-TL1; Mitochondrial disorders (MIDD/MEALAS); Stargardt disease; Myotonic dystrophy (DMPK); or McArdle’s Disease (PYGM))  
 Yes  No  Do Not Recall

If you answered Yes, please provide the following:

Test Type	Approximate Date of Testing	Recommending/Performing Healthcare Provider(s)	Reason for Testing	Results of Testing (Including Any Diagnosis)

3. Have you ever undergone any eye surgery (e.g., corrective eye surgery, surgery for retinal detachment or retinal tear, glaucoma or cataract surgery, etc.)? Yes  No

If yes, please provide the following:

Procedure	Approximate Date of Procedure	Recommending/Performing Healthcare Provider(s)

**VI. HEALTHCARE PROVIDERS**

For primary care physicians, gynecologists, urologists, urogynecologists, endocrinologists, optometrists and ophthalmologists not previously disclosed in this Plaintiff Fact Sheet, to the best of your knowledge please complete the following for your Healthcare Providers for the period beginning five (5) years prior to when you began taking Elmiron to the present:

Name	Address	Specialty

**VII. INSURANCE**

Identify each health insurance carrier/company that provided you with medical coverage and/or pharmacy benefits since you began taking Elmiron:

Carrier	Policy Number	Named Insured

Do you receive coverage under Medicare and/or Medicaid? Yes  No

If yes, please state the following:

Medicare or Medicaid Number	Approximate Date that Coverage Began

**VIII. FAMILY MEDICAL HISTORY**

Is there a history of eye disease or vision disorders, including but not limited to age-related macular degeneration (“AMD”), pattern dystrophy, Stargardt’s disease, maculopathies, or retinopathies in your family? Yes  No

If yes, provide the following for each family member:

Relationship to Plaintiff	Disease or Disorder

**IX. WORKERS’ COMP/DISABILITY/SOCIAL SECURITY**

Within the last five (5) years, have you filed for workers’ compensation, social security, and/or state or federal disability benefits? Yes  No

If yes, state the following for each:

Year Claim Was Filed	Company and/or Court Where Claim Was Filed	Nature of Claimed Injury	Period of Disability	Amount of Award



**X. DECLARATION**

My signature on this PFS (including through the use of an electronic signature) indicates that I have read this PFS, understood its contents, and provided the information set forth in response. Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that all of the information provided and in connection with this PFS is true and correct to the best of my knowledge, information, and belief at the present time.

Further, I acknowledge that I have an obligation to supplement the above responses if I become aware of additional responsive information, or if I learn that they are in some material respects incomplete or incorrect:

Date: \_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Print Name

## XI. DOCUMENTS

- A. **Authorizations:** Please sign and attach to this Plaintiff Fact Sheet the authorizations for the release of records appended hereto. The authorizations provided shall be completed (but undated), executed release authorizations for all providers and/or institutions that maintain relevant records as identified within the PFS pursuant to PFS Sections II.D.2. (if a claim for lost wages is asserted), III.B., IV.A.1., IV.A.2., IV.B. (if a claim for psychiatric and/or psychological condition is asserted), IV.D., V.A.2., V.A.3., V.B.1., V.B.2., V.C.1., V.C.2., V.C.3., VI, VII, and IX, to the extent applicable and as limited by the timeframes set forth in the specific PFS sections listed above.
- B. **Legal Documentation:** If completing this Plaintiff Fact Sheet on behalf of another person, please attach the legal documentation establishing that you are the legal representative, including, but not limited to, letters testamentary, letters of administration and death certificates.
- C. **Documents in Your Possession:** Please indicate whether you have in your possession, custody or control any of the documents listed below. If so, please attach copies of the following. This does not include privileged materials. It also does not include Plaintiff's social media at this time.
1. All non-privileged documents you reviewed that assisted you in the preparation of the answers to this form. Yes  No  N/A
  2. Any records in your possession from treating healthcare providers, hospitals, pharmacies, insurance and other Healthcare Providers identified in response to this Plaintiff Fact Sheet. Yes  No  N/A
  3. Copies of any Elmiron packaging or labeling, including, but not limited to, written instructions, product warnings, package inserts, medication guides, pharmacy handouts, or other materials distributed with or provided to you in connection with your use of Elmiron. Yes  No  N/A
  4. All documents that evidence, reflect, or relate to any advertisements or promotions for Elmiron and articles discussing Elmiron that you have seen. Yes  No  N/A
  5. All documents relating to your purchase of Elmiron. Yes  No  N/A
  6. All documents in your possession that you believe were provided to you (not to your lawyer) by any of the Defendants. Yes  No  N/A
  7. All documents you received from your Healthcare Provider(s) relating to Elmiron and/or the injuries you allege Elmiron caused. Yes  No  N/A
  8. All documents recording, demonstrating or recounting any of your injuries and/or damages alleged to result from your use of Elmiron, including, but not limited to, personal or professional letters, notes, diaries, calendars, journals, logs, date books, photographs, drawings,

- video or audio recordings, DVDs, or any other media, including any “day in the life” videos, or any other materials or things of yours. Yes   
No  N/A
9. Copies of any communications you have had with any of the Defendants or the FDA about Elmiron. Yes  No  N/A
10. All documents, in your possession, including, but not limited to, medical records, related to any genetic testing you have undergone from ten (10) years prior to your alleged retinal injury, macular degeneration, vision loss and/or other injuries alleged to result from your use of Elmiron to the present. Yes  No  N/A
11. All documents that evidence, reflect, or relate to the potential health hazards associated with the use of Elmiron that you obtained from any source prior to filing your complaint, including, but not limited to, any of the Defendants or any of Defendants’ employees, representatives, or agents, your Healthcare Providers, or the Internet. Yes  No   
N/A
12. If you claim any loss from medical expenses, copies of all bills from any treating healthcare provider, hospital, pharmacy or other Healthcare Provider. Yes  No  N/A
13. All records of any other expenses for which you seek recovery allegedly incurred as a result of the injuries alleged in the complaint. Yes   
No  N/A
14. Deceased person’s death certificate (if applicable). Yes  No   
N/A
15. Copies of letters testamentary or letters of administration relating to your status as a plaintiff (if applicable). Yes  No  N/A

**EXHIBIT A**  
**TO PLAINTIFF FACT SHEET**  
**(Authorizations)**

**LIMITED AUTHORIZATION TO DISCLOSE HEALTH INFORMATION**  
**(Pursuant to the Health Insurance Portability and Accountability Act "HIPAA" of 4/14/03)**

TO:  
Patient Name:  
DOB:  
SSN:

I, \_\_\_\_\_, hereby authorize you to release and furnish to: (1) King & Spalding LLP; (2) Skadden, Arps, Slate, Meagher & Flom LLP; (3) Litigation Management, Inc. and/or their duly assigned agents, copies of the following information:

- \* All medical records, including inpatient, outpatient, and emergency room treatment, all clinical charts, reports, documents, correspondence, test results, statements, questionnaires/histories, office and doctor's handwritten notes, and records received by other physicians. Said medical records shall include all information regarding AIDS and HIV status.
- \* All autopsy, laboratory, histology, genetic testing, cytology, pathology, radiology, CT Scan, MRI, echocardiogram and cardiac catheterization reports.
- \* All radiology films, mammograms, myelograms, CT scans, photographs, bone scans, pathology/cytology/histology/autopsy/immunohistochemistry specimens, cardiac catheterization videos/CDs/films/reels, and echocardiogram videos.
- \* All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.
- \* All billing records including all statements, itemized bills, and insurance records.
- \* The undersigned does not authorize the disclosure of "psychotherapy notes" as such term is defined by the Health Insurance Portability and Accountability Act, 45 CFR §164.501.

1. To my medical provider: **this authorization is being forwarded by, or on behalf of, attorneys for the defendants. You are not authorized to discuss any aspect of the above-named person's medical history, care, treatment, diagnosis, prognosis, information revealed by or in the medical records, or any other matter bearing on his or her medical or physical condition, unless you receive an additional authorization permitting such discussion. Subject to all applicable legal objections, this restriction does not apply to discussing my medical history, care, treatment, diagnosis, prognosis, information revealed by or in the medical records, or any other matter bearing on my medical or physical condition at a deposition or trial.**
2. I understand that the information in my health record may include information relating to sexually transmitted disease, acquired immunodeficiency syndrome (AIDS), or human immunodeficiency virus (HIV). It may also include information about behavioral or mental health services, and treatment for alcohol and drug abuse.
3. I understand that I have the right to revoke this authorization at any time. I understand that if I revoke this authorization I must do so in writing and present my written revocation to the health information management department. I understand the revocation will not apply to information that has already been released in response to this authorization. I understand the revocation will not apply to my insurance company when the law provides my insurer with the right to contest a claim under my policy. Unless otherwise revoked, this authorization will expire in one year.
4. I understand that authorizing the disclosure of this health information is voluntary. I can refuse to sign this authorization. I need not sign this form in order to assure treatment. I understand I may inspect or copy the information to be used or disclosed as provided in CFR 164.524. I understand that any disclosure of information carries with it the potential for an unauthorized re-disclosure and the information may not be protected by federal confidentiality rules. If I have questions about disclosure of my health information, I can contact the releaser indicated above.
5. A notarized signature is not required. CFR 164.508. A copy of this authorization may be used in place of an original.

Print Name: \_\_\_\_\_ (plaintiff/representative)

Signature: \_\_\_\_\_ (Dated)

**AUTHORIZATION TO DISCLOSE EMPLOYMENT RECORDS AND INFORMATION  
(HIPAA COMPLIANT AUTHORIZATION FORM PURSUANT TO 45 CFR 164.508)**

TO: \_\_\_\_\_  
Name of Employer  
\_\_\_\_\_  
Address, City, State and Zip Code

RE: Employee Name: \_\_\_\_\_ AKA: \_\_\_\_\_  
Date of Birth: \_\_\_\_\_ Social Security Number: \_\_\_\_\_  
Address: \_\_\_\_\_

I authorize the disclosure of my employment records including medical information protected by HIPAA, 45 CFR 164.508, for the purpose of review and evaluation in connection with a legal claim.

I expressly request that all entities identified above disclose full and complete records, including the following:

This will authorize you to furnish copies of all applications for employment; resumes; records of all positions held; job descriptions of positions held; wage and income statements and/or compensation records; wage increases and decreases; evaluations, reviews and job performance summaries; W-2s; employee health files, and correspondence and memoranda regarding the undersigned.

I authorize you to release the information to:

King & Spalding LLP  
Name (Records Requestor)

1185 6th Ave                      New York                      NY 10036  
Street Address                      City                      State and Zip Code

Skadden, Arps, Slate, Meagher & Flom LLP  
Name (Records Requestor)

One Manhattan West                      New York                      NY 10001  
Street Address                      City                      State and Zip Code

Litigation Management, Inc.  
Name (Records Requestor)

6000 Parkland Blvd # 100                      Cleveland                      OH 44124  
Street Address                      City                      State and Zip Code

I intend that this authorization shall be continuing in nature. If information responsive to this authorization is created, learned or discovered at any time in the future, either by you or another party, you must produce such information to the Records Requestor at that time.

I acknowledge the right to revoke this authorization by writing to you at the above referenced address. However, I understand that any actions already taken in reliance on this authorization cannot be reversed, and my revocation will not affect those actions. Any facsimile, copy or photocopy of the authorization shall authorize you to release the records herein.

\_\_\_\_\_  
Signature of Employee or Personal Representative                      Date                      Name of Employee or Personal Representative

\_\_\_\_\_  
Description of Personal Representative's Authority to Sign for Employee (attach documents that show authority)

**AUTHORIZATION FOR  
RELEASE OF WORKERS'  
COMPENSATION RECORDS**

To: \_\_\_\_\_  
Name  
\_\_\_\_\_  
Address  
\_\_\_\_\_  
City, State and Zip Code

This will authorize you to furnish copies of any and all workers' compensation records of any sort including, but not limited to, statements, applications, disclosures, correspondence, notes, settlements, agreements, contracts or other documents, concerning:

\_\_\_\_\_  
*Name of Claimant*

whose date of birth is \_\_\_\_\_ and whose social security number is \_\_\_\_\_

You are authorized to release the above records to the following representatives of defendants in the above-entitled matter, who have agreed to pay reasonable charges made by you to supply copies of such records.

King & Spalding LLP  
**Name of Representative**

Records Requestor: Attorney  
**Representative Capacity (e.g., attorney, records requestor, agent, etc.)**

1185 6th Ave  
**Street Address**

New York, NY 10036  
**City, State and Zip Code**

Skadden, Arps, Slate, Meagher & Flom LLP  
**Name of Representative**

Records Requestor: Attorney  
**Representative Capacity (e.g., attorney, records requestor, agent, etc.)**

One Manhattan West  
**Street Address**

New York, NY 10001  
**City, State and Zip Code**

Litigation Management, Inc.  
**Name of Representative**

Records Requestor: Agent  
**Representative Capacity (e.g., attorney, records requestor, agent, etc.)**

6000 Parkland Blvd # 100  
**Street Address**

Cleveland, OH 44124  
**City, State and Zip Code**

---

This authorization only authorizes release of documents and records. This authorization does not authorize you to disclose anything other than documents and records to anyone.

This authorization shall be considered as continuing in nature and is to be given full force and effect to release information of any of the foregoing learned or determined after the date hereof. It is expressly understood by the undersigned and you are authorized to accept a copy or photocopy of this authorization with the same validity as through the original had been presented to you.

Date: \_\_\_\_\_

\_\_\_\_\_  
Claimant Signature  
*[NAME]*

Date: \_\_\_\_\_

\_\_\_\_\_  
Witness Signature



**AUTHORIZATION FOR RELEASE OF  
DISABILITY CLAIMS RECORDS**

To:

\_\_\_\_\_  
Name

\_\_\_\_\_  
Address

\_\_\_\_\_  
City, State and Zip Code

This will authorize you to furnish copies of any and all records of disability claims of any sort including, but not limited to, statements, applications, disclosures, correspondence, notes, settlements, agreements, contracts or other documents, concerning:

\_\_\_\_\_  
*Name of Claimant*

whose date of birth is \_\_\_\_\_ and whose social security number is \_\_\_\_\_

You are authorized to release the above records to the following representatives of defendants in the above-entitled matter, who have agreed to pay reasonable charges made by you to supply copies of such records.

King & Spalding LLP  
**Name of Representative**

Records Requestor: Attorney  
**Representative Capacity (e.g., attorney, records requestor, agent, etc.)**

1185 6th Ave  
**Street Address**

New York, NY 10036  
**City, State and Zip Code**

Skadden, Arps, Slate, Meagher & Flom LLP  
**Name of Representative**

Records Requestor: Attorney  
**Representative Capacity (e.g., attorney, records requestor, agent, etc.)**

One Manhattan West  
**Street Address**

New York, NY 10001  
**City, State and Zip Code**

Litigation Management, Inc.  
**Name of Representative**

Records Requestor: Agent  
**Representative Capacity (e.g., attorney, records requestor, agent, etc.)**

6000 Parkland Blvd # 100  
**Street Address**

Cleveland, OH 44124

**City, State and Zip Code**

This authorization only authorizes release of documents and records. This authorization does not authorize you to disclose anything other than documents and records to anyone.

This authorization shall be considered as continuing in nature and is to be given full force and effect to release information of any of the foregoing learned or determined after the date hereof. It is expressly understood by the undersigned and you are authorized to accept a copy or photocopy of this authorization with the same validity as through the original had been presented to you.

Date: \_\_\_\_\_

\_\_\_\_\_  
Claimant/Guardian/Personal Representative Signature  
*[NAME]*

Date: \_\_\_\_\_

\_\_\_\_\_  
Witness Signature

**AUTHORIZATION FOR RELEASE OF  
HEALTH INSURANCE RECORDS**

To:

\_\_\_\_\_  
Name

\_\_\_\_\_  
Address

\_\_\_\_\_  
City, State and Zip Code

This will authorize you to furnish copies of any and all insurance claims applications and benefits, and all medical, health, hospital, physicians, nursing or allied health professional reports, records or notes, invoices and bills, in your possession that pertain to the named insured identified below.

\_\_\_\_\_  
*Name of Insured*

whose date of birth is \_\_\_\_\_ and whose social security number is \_\_\_\_\_

You are authorized to release the above records to the following representatives of defendants in the above-entitled matter, who have agreed to pay reasonable charges made by you to supply copies of such records.

King & Spalding LLP  
**Name of Representative**

Records Requestor: Attorney  
**Representative Capacity (e.g., attorney, records requestor, agent, etc.)**

1185 6th Ave  
**Street Address**

New York, NY 10036  
**City, State and Zip Code**

Skadden, Arps, Slate, Meagher & Flom LLP  
**Name of Representative**

Records Requestor: Attorney  
**Representative Capacity (e.g., attorney, records requestor, agent, etc.)**

One Manhattan West  
**Street Address**

New York, NY 10001  
**City, State and Zip Code**

Litigation Management, Inc.  
**Name of Representative**

Records Requestor: Agent  
**Representative Capacity (e.g., attorney, records requestor, agent, etc.)**

6000 Parkland Blvd # 100  
**Street Address**

Cleveland, OH 44124  
**City, State and Zip Code**

This authorization does not authorize you to disclose anything other than documents and records to anyone.

This authorization shall be considered as continuing in nature and is to be given full force and effect to release information of any of the foregoing learned or determined after the date hereof. It is expressly understood by the undersigned and you are authorized to accept a copy or photocopy of this authorization with the same validity as through the original had been presented to you.

Date: \_\_\_\_\_

\_\_\_\_\_  
Insured  
[NAME]

Date: \_\_\_\_\_

\_\_\_\_\_  
Witness Signature

**LIMITED AUTHORIZATION TO DISCLOSE PSYCHIATRIC,  
PSYCHOLOGICAL AND/OR MENTAL HEALTH TREATMENT NOTES/RECORDS**  
**(Pursuant to the Health Insurance Portability and Accountability Act "HIPAA" of 4/14/03)**

TO:  
Patient Name:  
DOB:  
SSN:

I, \_\_\_\_\_, hereby authorize you to release and furnish to: (1) King & Spalding LLP, (2) Skadden, Arps, Slate, Meagher & Flom LLP, (3) Litigation Management, Inc. and/or their duly assigned agents, copies of the following records and/or information:

- All “psychotherapy notes”, as such term is defined by the Health Insurance Portability and Accountability Act, 45 CFR §164.501. Under HIPAA, the term “psychotherapy notes” means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversations during a private counseling session or a group, joint or family counseling session and that are separated from the rest of the individual’s record. This authorization does not authorize ex parte communication concerning same.

1. To my medical and/or mental health provider: **this authorization is being forwarded by, or on behalf of, attorneys for the defendants. You are not authorized to discuss any aspect of the above-named person's medical history, mental health history, care, treatment, diagnosis, prognosis, information revealed by or in the medical or mental health records, or any other matter bearing on his or her medical, psychological, or physical condition, unless you receive an additional authorization permitting such discussion. Subject to all applicable legal objections, this restriction does not apply to discussing my medical history, mental health history, care, treatment, diagnosis, prognosis, information revealed by or in the medical or mental health records, or any other matter bearing on my medical, psychological, or physical condition at a deposition or trial.**

2. I understand that the information in my health record may include information relating to sexually transmitted disease, acquired immunodeficiency syndrome (AIDS), or human immunodeficiency virus (HIV). It may also include information about behavioral or mental health services, and treatment for alcohol and drug abuse.

3. I understand that I have the right to revoke this authorization at any time. I understand that if I revoke this authorization I must do so in writing and present my written revocation to the health information management department. I understand the revocation will not apply to information that has already been released in response to this authorization. I understand the revocation will not apply to my insurance company when the law provides my insurer with the right to contest a claim under my policy. Unless otherwise revoked, this authorization will expire in one year.

4. I understand that authorizing the disclosure of this health information is voluntary. I can refuse to sign this authorization. I need not sign his form in order to assure treatment. I understand I may inspect or copy the information to be used or disclosed as provided in CFR 164.524. I understand that any disclosure of information carries with it the potential for an unauthorized re-disclosure and the information may not be protected by federal confidentiality rules. If I have questions about disclosure of my health information, I can contact the releaser indicated above.

5. A notarized signature is not required. CFR 164.508. A copy of this authorization may be used in place of an original.

Print Name: \_\_\_\_\_ (plaintiff/representative)

Signature: \_\_\_\_\_ Date \_\_\_\_\_

## AUTHORIZATION TO DISCLOSE MEDICAID INFORMATION

To:

I, the undersigned, hereby authorize and request the above-named entity to disclose to the agents or designees of (1) King & Spalding LLP [1185 6th Ave New York, NY 10036]; (2) Skadden, Arps, Slate, Meagher & Flom LLP [One Manhattan West New York, NY 10001]; (3) Litigation Management, Inc. [6000 Parkland Blvd # 100 Cleveland, OH 44124], any and all records containing Medicaid information, including those that may contain protected health information (PHI) regarding \_\_\_\_\_, whether created before or after the date of signature. This authorization should also be construed to permit agents or designees of (1) King & Spalding LLP, (2) Skadden, Arps, Slate, Meagher & Flom LLP, (3) Litigation Management, Inc. to copy, inspect and review any and all such records. Records requested may include, but are not limited to:

all Medicaid records, including explanations of Medicaid benefit records and claims records; any statements, communications, pro reviews, denials, appeals, correspondence, reports, questionnaires or records submitted in connection with claims; all reports from physicians, hospitals, dental providers, prescriptions; correspondence, test results and any other medical records; records of claims paid to or on the behalf of \_\_\_\_\_; records of litigation and any other records of any kind. I expressly request that all covered entities under HIPAA identified above disclose full and complete protected medical information.

A photocopy of this authorization shall be considered as effective and valid as the original, and this authorization will remain in effect until the earlier of: (i) the date of settlement or final disposition of In Re: Elmiron Products Liability Litigation or (ii) five (5) years after the date of signature of the undersigned below. The purpose of this authorization is for civil litigation. By signing this authorization, I expressly do not authorize any ex parte interview or oral communication about me or my medical history by (1) King & Spalding LLP, (2) Skadden, Arps, Slate, Meagher & Flom LLP, (3) Litigation Management, Inc. without the presence of my attorney.

### NOTICE

- **The individual signing this authorization has the right to revoke this authorization at any time, provided the revocation is in writing to (1) King & Spalding LLP, (2) Skadden, Arps, Slate, Meagher & Flom LLP, (3) Litigation Management, Inc., except to the extent that the entity has already relied upon this Authorization to disclose protected health information (PHI).**
- **The individual signing this authorization understands that the covered entity to whom this authorization is directed may not condition treatment, payment, enrollment or eligibility benefits on whether or not the individual signs the authorization.**
- **The individual signing this authorization understands that protected health information (PHI) disclosed pursuant to this authorization may be subject to redisclosure by the recipients and that, in such case, the disclosed PHI no longer will be protected by federal privacy regulations.**
- **The individual signing this authorization understands information authorized for release may include records that may indicate the presence of a communicable disease.**
- **The individual signing this authorization understands that they shall be entitled to receive a copy of all documents requested via this authorization within a reasonable period of time after such records are received by (1) King & Spalding LLP, (2) Skadden, Arps, Slate, Meagher & Flom LLP, (3) Litigation Management, Inc.**

I have read this Authorization and understand that it will permit the entity identified above to disclose PHI to (1) King & Spalding LLP, (2) Skadden, Arps, Slate, Meagher & Flom LLP, (3) Litigation Management, Inc..

\_\_\_\_\_  
Name of Individual

\_\_\_\_\_  
Signature of Individual or Individual

\_\_\_\_\_  
Former/Alias/Maiden Name of Individual

\_\_\_\_\_  
Date

\_\_\_\_\_  
Individual's Date of Birth

\_\_\_\_\_  
Name of Individual Representative

\_\_\_\_\_  
Individual's Social Security Number

\_\_\_\_\_  
Description of Authority

\_\_\_\_\_  
Individual's Address



## Medicare

Beneficiary Services: 1-800-MEDICARE (1-800-633-4227)  
TTY/TDD: 1-877-486-2048

This form is used to advise Medicare of the person or persons you have chosen to have access to your personal health information.

### Where to Return Your Completed Authorization Forms:

After you complete and sign the authorization form, return it to the address below:

**Medicare CCO, Written Authorization Dept.**  
**PO Box 1270**  
**Lawrence, KS 66044**

### For New York Medicare Beneficiaries ONLY

The New York State Public Health Law protects information that reasonably could identify someone as having HIV symptoms or infection, and information regarding a person's contacts. Because of New York's laws protecting the privacy of information related to alcohol and drug abuse, mental health treatment, and HIV, there are special instructions for how you, as a New York resident, should complete this form.

- For question 2A, check the box for *Limited Information*, even if you want to authorize Medicare to release any and all of your personal health information.
- **Then proceed to question 2B.** You may also check any of the remaining boxes and include any additional limitations in the space provided. For example, you could write "payment information".

### Instructions for Completing Section 2C of the Authorization Form:

*Please select one of the following options.*

- **Option 1** To **include** all information, check the box: "All information, including information about alcohol and drug abuse, mental health treatment, and HIV". Proceed with the rest of the form.
- **Option 2** To **exclude** the information listed above, check the box "Exclude information about alcohol and drug abuse, mental health treatment, and HIV". Then proceed with the rest of the form.



If you have any questions or need additional assistance, please feel free to call us at 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Sincerely,

1-800-MEDICARE  
Customer Service Representative

Encl.

## **Information to Help You Fill Out the “1-800-MEDICARE Authorization to Disclose Personal Health Information” Form**

By law, Medicare must have your written permission (an “authorization”) to use or give out your personal medical information for any purpose that isn't set out in the privacy notice contained in the Medicare & You handbook. You may take back (“revoke”) your written permission at any time, except if Medicare has already acted based on your permission.

If you want 1-800-MEDICARE to give your personal health information to someone other than you, you need to let Medicare know in writing.

If you are requesting personal health information for a deceased beneficiary, please include a copy of the legal documentation which indicates your authority to make a request for information. (For example: Executor/Executrix papers, next of kin attested by court documents with a court stamp and a judge's signature, a Letter of Testamentary or Administration with a court stamp and judge's signature, or personal representative papers with a court stamp and judge's signature.) Also, please explain your relationship to the beneficiary.

Please use this step by step instruction sheet when completing your “1-800-MEDICARE Authorization to Disclose Personal Health Information” Form. Be sure to complete all sections of the form to ensure timely processing.

**1. Print the name of the person with Medicare.**

Print the Medicare number exactly as it is shown on the red, white, and blue Medicare card.

Print the birthday in month, day, and year (mm/dd/yyyy) of the person with Medicare.

**2. This section tells Medicare what personal health information to give out. Please check a box in 2A to indicate how much information Medicare can disclose. If you only want Medicare to give out limited information (for example, Medicare eligibility), also check the box(es) in 2B that apply to the type of information you want Medicare to give out. Box 2C must be completed by **New York Residents**.**

**3. This section tells Medicare when to start and/or when to stop giving out your personal health information. Check the box that applies and fill in dates, if necessary.**

**4. This section tells Medicare the reason for disclosure.**

**5. Medicare will give your personal health information to the person(s) or organization(s) you fill in here. You may fill in more than one person or organization.**

If you designate an organization, you must also identify one or more individuals in that organization to whom Medicare may disclose your personal health information.

6. The person with Medicare or personal representative must sign their name, fill in the date, and provide the phone number and address of the person with Medicare.

If you are a personal representative of the person with Medicare, check the box, provide your address and phone number, and attach a copy of the paperwork that shows you can act for that person (for example, Power of Attorney).

7. Send your completed, signed authorization to Medicare at the address shown here on your authorization form.
8. If you change your mind and don't want Medicare to give out your personal health information, write to the address shown under number seven on the authorization form and tell Medicare. Your letter will revoke your authorization and Medicare will no longer give out your personal health information (except for the personal health information Medicare has already given out based on your permission).

You should make a copy of your signed authorization for your records before mailing it to Medicare.

You have the right to get Medicare information in an accessible format, like large print, Braille, or audio. You also have the right to file a complaint if you feel you've been discriminated against. Visit [Medicare.gov/about-us/accessibility-nondiscrimination-notice](https://www.medicare.gov/about-us/accessibility-nondiscrimination-notice), or call 1-800-MEDICARE (1-800-633-4227) for more information. TTY users can call 1-877-486-2048.

### 1-800-MEDICARE Authorization to Disclose Personal Health Information

Use this form if you want 1-800-MEDICARE to give your personal health information to someone other than you.

1. Print Name (First and last name of the person with Medicare)      Medicare Number (Exactly as shown on the Medicare Card)      Date of Birth (mm/dd/yyyy)

2. Medicare will only disclose the personal health information you want disclosed.

**2A: Check only one box below to tell Medicare the specific personal health information you want disclosed:**

Limited Information (go to question 2b)

Any Information (go to question 3)

**2B: Complete only if you selected “limited information”. Check all that apply:**

Information about your Medicare eligibility

Information about your Medicare claims

Information about plan enrollment (e.g. drug or MA Plan)

Information about premium payments

Other Specific Information (please write below; for example, payment information)

\_\_\_\_\_  
\_\_\_\_\_

**2C: NY Residents Only**, this section must be completed.

Please select one of the following options: (Please check only one box.)

Include all information. This includes information about alcohol and drug abuse, mental health treatment, and HIV.

OR

Exclude information about alcohol and drug abuse, mental health treatment, and HIV.

**3. Check only one box below indicating how long Medicare can use this authorization to disclose your personal health information** (subject to applicable law—for example, your State may limit how long Medicare may give out your personal health information):

Disclose my personal health information indefinitely

Disclose my personal health information for a specified period only

beginning: \_\_\_\_\_ (mm/dd/yyyy) and ending: \_\_\_\_\_ (mm/dd/yyyy)

**4. Fill in the reason for the disclosure (you may write "at my request"):**  
For purposes of litigation

\_\_\_\_\_  
\_\_\_\_\_

**5. Fill in the name and address of the person or organization to whom you want Medicare to disclose your personal health information. Please provide the specific name of the person for any organization you list below. If you would like to authorize any additional individuals or organizations, please add those to the back of this form.**

Name King & Spalding LLP [Kristen Fournier]

Address 1185 6th Ave, New York, NY 10036

Name Skadden, Arps, Slate, Meagher & Flom LLP [Richard Bernardo]

Address One Manhattan West, New York, NY 10001

Name Litigation Management, Inc. \_\_\_\_\_

Address 6000 Parkland Blvd # 100, Cleveland, OH 44124 \_\_\_\_\_

**Note: You have the right to take back (“revoke”) your authorization at any time, in writing, except to the extent that Medicare has already acted based on your permission. To revoke authorization, send a written request to the address noted below.** Your authorization or refusal to authorize disclosure of your personal health information will have no effect on your enrollment, eligibility for benefits, or the amount Medicare pays for the health services you receive.

6. **I authorize 1-800-MEDICARE to disclose my personal health information listed above to the person(s) or organization(s) I have named on this form. I understand that my personal health information may be re-disclosed by the person(s) or organization(s) and may no longer be protected by law.**

\_\_\_\_\_  
Signature Telephone Number Date (mm/dd/yyyy)

**Print the address of the person with Medicare (Street Address, City, State, and ZIP)**

Check here if you are signing as a personal representative and complete below. Please attach the appropriate documentation (for example, Power of Attorney). This only applies if someone other than the person with Medicare signed above.

**Print the Personal Representative's Address (Street Address, City, State, and ZIP)**

Telephone Number of Personal Representative: \_\_\_\_\_

Personal Representative's Relationship to the Beneficiary: \_\_\_\_\_

**7. Send the completed, signed authorization to:**

Medicare CCO, Written Authorization Dept.  
PO Box 1270  
Lawrence, KS 66044

**Print Form**

**Note:** You have the right to take back (“revoke”) your authorization at any time, in writing, except to the extent that Medicare has already acted based on your permission. If you would like to revoke authorization, send a written request to the address noted above.

Your authorization or refusal to authorize disclosure of your personal health information will have no effect on your enrollment, eligibility for benefits, or the amount Medicare pays for the health services you receive.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0930. The time required to complete this information collection is estimated to average 15 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

You have the right to get Medicare information in an accessible format, like large print, Braille, or audio. You also have the right to file a complaint if you feel you’ve been discriminated against. Visit [Medicare.gov/about-us/accessibility-nondiscrimination-notice](https://www.medicare.gov/about-us/accessibility-nondiscrimination-notice), or call 1-800-MEDICARE (1-800-633-4227) for more information. TTY users can call 1-877-486-2048.

Social Security Administration

**Consent for Release of Information**

Form Approved

OMB No. 0960-0566

**Instructions for Using this Form**

Complete this form only if you want us to give information or records about you, a minor, or a legally incompetent adult, to an individual or group (for example, a doctor or an insurance company). If you are the natural or adoptive parent or legal guardian, acting on behalf of a minor child, you may complete this form to release only the minor's non-medical records. We may charge a fee for providing information unrelated to the administration of a program under the Social Security Act.

**NOTE:** Do not use this form to:

- Request the release of medical records on behalf of a minor child. Instead, visit your local Social Security office or call our toll-free number, 1-800-772-1213 (TTY-1-800-325-0778), or
- Request detailed information about your earnings or employment history. Instead, complete and mail form SSA-7050-F4. You can obtain form SSA-7050-F4 from your local Social Security office or online at [www.ssa.gov/online/ssa-7050.pdf](http://www.ssa.gov/online/ssa-7050.pdf).

**How to Complete this Form**

We will not honor this form unless all required fields are completed. An asterisk (\*) indicates a required field. Also, we will not honor blanket requests for "any and all records" or the "entire file." You must specify the information you are requesting and you must sign and date this form. We may charge a fee to release information for non-program purposes.

- Fill in your name, date of birth, and social security number or the name, date of birth, and social security number of the person to whom the requested information pertains.
- Fill in the name and address of the person or organization where you want us to send the requested information.
- Specify the reason you want us to release the information.
- Check the box next to the type(s) of information you want us to release including the date ranges, where applicable.
- For non-medical information, you, the parent or the legal guardian acting on behalf of a minor child or legally incompetent adult, must sign and date this form and provide a daytime phone number.
- If you are not the individual to whom the requested information pertains, state your relationship to that person. We may require proof of relationship.

**PRIVACY ACT STATEMENT**

Section 205(a) of the Social Security Act, as amended, authorizes us to collect the information requested on this form. We will use the information you provide to respond to your request for access to the records we maintain about you or to process your request to release your records to a third party. You do not have to provide the requested information. Your response is voluntary; however, we cannot honor your request to release information or records about you to another person or organization without your consent. We rarely use the information provided on this form for any purpose other than to respond to requests for SSA records information. However, the Privacy Act (5 U.S.C. § 552a(b)) permits us to disclose the information you provide on this form in accordance with approved routine uses, which include but are not limited to the following:

1. To enable an agency or third party to assist Social Security in establishing rights to Social Security benefits and or coverage;
2. To make determinations for eligibility in similar health and income maintenance programs at the Federal, State, and local level;
3. To comply with Federal laws requiring the disclosure of the information from our records; and,
4. To facilitate statistical research, audit, or investigative activities necessary to assure the integrity of SSA programs.

We may also use the information you provide when we match records by computer. Computer matching programs compare our records with those of other Federal, State, or local government agencies. We use information from these matching programs to establish or verify a person's eligibility for Federally-funded or administered benefit programs and for repayment of incorrect payments or overpayments under these programs. Additional information regarding this form, routine uses of information, and other Social Security programs is available on our Internet website, [www.socialsecurity.gov](http://www.socialsecurity.gov), or at your local Social Security office.

**PAPERWORK REDUCTION ACT STATEMENT**

This information collection meets the requirements of 44 U.S.C. § 3507, as amended by section 2 of the Paperwork Reduction Act of 1995. You do not need to answer these questions unless we display a valid Office of Management and Budget control number. We estimate that it will take about 3 minutes to read the instructions, gather the facts, and answer the questions. **SEND OR BRING THE COMPLETED FORM TO YOUR LOCAL SOCIAL SECURITY OFFICE. You can find your local Social Security office through SSA's website at [www.socialsecurity.gov](http://www.socialsecurity.gov). Offices are also listed under U.S. Government agencies in your telephone directory or you may call 1-800-772-1213 (TTY 1-800-325-0778).** You may send comments on our time estimate above to: SSA, 6401 Security Blvd., Baltimore, MD 21235-6401. **Send only comments relating to our time estimate to this address, not the completed form.**



Social Security Administration

**Consent for Release of Information**

Form Approved  
OMB No. 0960-0566

You must complete all required fields. We will not honor your request unless all required fields are completed. (\*Signifies a required field. \*\*Please complete these fields in case we need to contact you about the consent form).

TO: Social Security Administration

**\*My Full Name**

**\*My Date of Birth  
(MM/DD/YYYY)**

**\*My Social Security Number**

I authorize the Social Security Administration to release information or records about me to:

**\*NAME OF PERSON OR ORGANIZATION:**

King & Spalding LLP  
Skadden, Arps, Slate, Meagher & Flom LLP  
Litigation Management, Inc.

**\*ADDRESS OF PERSON OR ORGANIZATION:**

1185 6th Ave, New York, NY 10036  
One Manhattan West, New York, NY 10001  
6000 Parkland Blvd # 100, Cleveland, OH 44124

**\*I want this information released because:** For litigation purposes  
We may charge a fee to release information for non-program purposes.

**\*Please release the following information selected from the list below:**

**Check at least one box. We will not disclose records unless you include date ranges where applicable.**

1.  Verification of Social Security Number
2.  Current monthly Social Security benefit amount
3.  Current monthly Supplemental Security Income payment amount
4.  My benefit or payment amounts from date \_\_\_\_\_ to date \_\_\_\_\_
5.  My Medicare entitlement from date \_\_\_\_\_ to date \_\_\_\_\_
6.  Medical records from my claims folder(s) from date \_\_\_\_\_ to date \_\_\_\_\_  
If you want us to release a minor child's medical records, do not use this form. Instead, contact your local Social Security office.
7.  Complete medical records from my claims folder(s)
8.  Other record(s) from my file (We will not honor a request for "any and all records" or "the entire file." You must specify other records; e.g., consultative exams, award/denial notices, benefit applications, appeals, questionnaires, doctor reports, determinations.)

I am the individual, to whom the requested information or record applies, or the parent or legal guardian of a minor, or the legal guardian of a legally incompetent adult. I declare under penalty of perjury (28 CFR § 16.41(d)(2004) that I have examined all the information on this form and it is true and correct to the best of my knowledge. I understand that anyone who knowingly or willfully seeking or obtaining access to records about another person under false pretenses is punishable by a fine of up to \$5,000. I also understand that I must pay all applicable fees for requesting information for a non-program-related purpose.

**\*Signature:** \_\_\_\_\_ **\*Date:** \_\_\_\_\_

**\*\*Address:** \_\_\_\_\_ **\*\*Daytime Phone:** \_\_\_\_\_

**Relationship (if not the subject of the record):** \_\_\_\_\_ **\*\*Daytime Phone:** \_\_\_\_\_

Witnesses must sign this form ONLY if the above signature is by mark (X). If signed by mark (X), two witnesses to the signing who know the signee must sign below and provide their full addresses. Please print the signee's name next to the mark (X) on the signature line above.

1. Signature of witness \_\_\_\_\_ 2. Signature of witness \_\_\_\_\_

Address(Number and street, City, State, and Zip Code) \_\_\_\_\_ Address(Number and street, City, State, and Zip Code) \_\_\_\_\_

# **EXHIBIT B**

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

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<b>IN RE: ELMIRON (PENTOSAN</b>	:	<b>Case No. 2:20-md-02973 (BRM)(ESK)</b>
<b>POLYSULFATE SODIUM) PRODUCTS</b>	:	<b>MDL No. 2973</b>
<b>LIABILITY LITIGATION</b>	:	
	:	<b>JUDGE BRIAN R. MARTINOTTI</b>
	:	<b>JUDGE EDWARD S. KIEL</b>

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**THIS DOCUMENT RELATES TO: ALL CASES**

**DEFENDANT FACT SHEET**

**Instructions**

Defendant must complete this Defendant Fact Sheet ("DFS") and identify or provide documents and/or data relating to each Plaintiff responsive to the questions set forth below to the best of Defendant's knowledge. In completing this DFS, you are under oath and must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details requested, provide as much information as you can. The DFS shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order.

In the event the DFS does not provide you with enough space for you to complete your responses or answers, attach additional sheets if necessary. In addition, "produce" shall include, at Defendant's option, the physical production of documents to Plaintiff's counsel, the identification of how documents can be located in Defendant's document production, or making documents available to Plaintiff's counsel on a dedicated DFS website.

This DFS must be completed and served on all counsel representing a Plaintiff in the action identified in Section I below. This must be answered and served by the date established by the Court in the Case Management Order implementing this DFS.

All DFS responses are made subject to the Protective Order entered in this litigation and shall be deemed confidential and treated as "Confidential Information" as defined in the Protective Order.

## Definitions

**YOU, YOUR or YOURS:** As used herein, the terms You, Your or Yours mean the responding Defendant(s) and any officers, agents, attorneys, employees, representatives or others acting on Defendant's behalf.

**DEFENDANT(S):** As used herein, this term means Janssen Pharmaceuticals, Inc., Ortho-McNeil Pharmaceutical, LLC, Janssen Research & Development, LLC, Janssen Ortho LLC, Johnson & Johnson, ALZA Corporation, and Centocor Research & Development, Inc., and any officers, agents, attorneys, employees, representatives, or others acting on their behalf.

**DOCUMENT(S):** As used herein, the term "Document" shall be construed in the broadest sense, consistent with Federal Rules of Civil Procedure 34(a)(1)(A), refer to any designated documents or electronically stored information – including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations – stored in any medium from which information can be obtained directly

**CALL NOTES:** Entries in Defendant's call notes database(s) reflecting contacts with Prescribing Healthcare Providers related to Elmiron.

**COMMUNICATION AND/OR CORRESPONDENCE:** As used herein, the term "communication" and/or "correspondence" shall mean and refer to any oral, written or electronic transmission of information, including, without limitation, meetings, discussions, conversations, telephone calls, memoranda, letters, e-mails, text messages, conferences, or seminars or any other exchange of information between you and any other person or entity.

**ELMIRON:** Defendant's pentosyn polysulfate sodium product.

**KEY OPINION LEADER** or **THOUGHT LEADER:** This term shall mean and refer to any doctors or medical professionals hired by, consulted with, or retained by Defendant(s) to, amongst other things, consult, give lectures, respond to media inquiries, conduct clinical trials, author or contribute to articles or abstracts, sit on advisory boards and make presentations on their behalf at regulatory meetings or hearings.

**PERSON:** As used herein, the term "person" means natural person, as well as corporate and/or governmental entity.

**REMUNERATION:** Any direct payments made to the recipient of monetary value greater than \$100 in cash or in kind, but specifically excludes samples, discounts and rebates, in-kind items for charity care, educational materials intended for patients, medical devices loaned for clinical trials, and warranty services.

**SALES REPRESENTATIVE:** Any person presently or formerly engaged or employed by Defendant(s) whose job duties include calling on physicians or other healthcare professionals,

healthcare facilities, hospitals, and/or physician practice groups for the purpose of promoting Elmiron to physicians or other healthcare providers.

**SAMPLES:** As used herein, the term “Samples” refers to any medication or unit of a prescription drug not intended to be sold, which is given to promote the drug's sales. This includes any vouchers or coupons that provide for the Healthcare Providers or patients access to the medication for a specified period of time.

**MARKETING INFORMATION:** As used herein, the term “Marketing Information” includes documentation, including electronically stored information, designating particular campaigns, Promotional Material and/or other promotional efforts directed toward particular types or specialties of healthcare providers (e.g., urologists) and/or specifically identified healthcare providers.

**RELEVANT TIME PERIOD:** From five (5) years prior to the date on which Plaintiff was first prescribed Elmiron as set forth in PFS Section III.B through the later of (1) the date of the last prescription of Elmiron to Plaintiff, as set forth in PFS Section III.B, or (2) the date of the earliest treatment for the condition for which Plaintiff is seeking damages as set forth in PFS Section IV.A.1. To the extent the Relevant Time Period includes dates prior to April 2002, produce all information and documents in your possession, custody or control.

**PRESCRIBING HEALTHCARE PROVIDER:** Providers of healthcare, including but not necessarily limited to physicians, general practitioners, medical specialists, medical doctors or surgeons identified in PFS Section III.B. as a Prescribing Healthcare Provider who prescribed Elmiron to the Plaintiff.

**TREATING HEALTHCARE PROVIDER:** Any provider of healthcare, including but not necessarily limited to physicians, general practitioners, medical specialists, medical doctors, surgeons, plastic surgeons, nurses, nurse practitioners, physician assistants, rehabilitation specialists, physical therapists, occupational therapists, counselors and pharmacists, identified in the PFS Section IV.A.1 who treated the Plaintiff for his or her alleged injuries.

**I. CONTACTS WITH HEALTHCARE PROVIDERS**

**A. Healthcare Provider Information Request Letters.** For each Prescribing Healthcare Provider, please produce Medical Information Requests ("MIRs") made by the Prescribing Healthcare Provider regarding Elmiron and the corresponding company response(s), to the extent they exist, within the Relevant Time Period.

**B. Other Contacts.**

**1. Call Notes.**

(a) Identify by name any of the Defendant's Sales Representatives who called on the Prescribing Healthcare Provider(s) in any way related to Elmiron and please provide dates of each contact (or produce report listing the same).

(b) For each Sales Representative who contacted the Prescribing Healthcare Provider, please produce Call Notes, if any, for each contact between the Prescribing Healthcare Provider and the Sales Representative related to and/or regarding Elmiron.

**2. Dear Healthcare Provider Letters.**

Produce all Dear Doctor, Dear Healthcare Provider, Dear Colleague or similar type of letters or documents regarding Elmiron sent by You to the Prescribing Healthcare Providers and/or Treating Healthcare Providers identified in the PFS as well as the distribution list(s).

**3. Marketing Information.**

Produce Marketing Information related to Elmiron that has been made available to the Prescribing Healthcare Provider(s) identified in the PFS.

**4. Samples.**

To the extent the Prescribing Healthcare Provider has received samples of Elmiron, produce sampling information including (a) the date on which such samples were provided; (b) the number of sample packets and the dosages provided; and (c) who provided the sample(s).

**II. OTHER CONTACT AND CONSULTING WITH PLAINTIFF'S PRESCRIBING HEALTHCARE PROVIDER(S)**

**Consulting and Professional Relationships:** Produce documents and/or information sufficient to identify all remuneration provided to the Prescribing Healthcare Provider and Treating Healthcare Provider related to Elmiron, including amounts, date and purpose.

**III. PLAINTIFF’S PRESCRIBING HEALTHCARE PROVIDERS**

For each Prescribing Healthcare Provider, please produce documents or information that purport to track the prescribing practices of Plaintiff’s Prescribing Healthcare Provider(s) with respect to Elmiron during the Relevant Time Period. Plaintiffs shall agree to any terms of use required by any third party vendors that maintain this data, and the data will only be provided to Plaintiffs upon receipt of such agreement.

**IV. PLAINTIFF’S MEDICAL CONDITION**

- A.** Produce documents which reflect communications between Plaintiff or anyone acting on Plaintiff’s behalf (other than Plaintiff’s counsel) and Defendant concerning Plaintiff and Elmiron, prior to the filing of Plaintiff’s lawsuit.
- B.** Produce a spreadsheet with adverse event report information dated prior to the filing of Plaintiff’s lawsuit, which pertains to Plaintiff and the use of Elmiron along with underlying documentation from the adverse event report, if any. Such information shall be redacted as necessary per federal law.

**VERIFICATION**

I, Laura Donnelly, am an Assistant Secretary of Janssen Pharmaceuticals, Inc. (“Janssen”) and Janssen Research & Development, LLC (“JRD”), defendants in this action. The foregoing answers to Defendant Fact Sheet were prepared with the assistance and advice of counsel for Janssen, Johnson & Johnson (“J&J”), and JRD, upon whose advice Janssen, J&J, JRD, and I relied. Further, it was necessary to obtain information to prepare the responses from various sources, including Janssen’s, J&J’s, and JRD’s personnel and records. Many of the requests are vague and ambiguous and, thus, reasonably susceptible to numerous interpretations. Accordingly, Janssen, J&J, and JRD reserve the right to make changes in their answers. Subject to these qualifications, the foregoing responses are true and correct to the best of my knowledge, information, and belief.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

















# **EXHIBIT C**

## BROWNGREER PLC'S MDL CENTRALITY

**1. Manner of Completion and Service of Fact Sheets and Authorization Forms.** Plaintiffs and Defendants shall use the online MDL Centrality System designed and provided by BrownGreer PLC and accessible at [www.mdlcentrality.com/](http://www.mdlcentrality.com/) to complete and serve Plaintiff and Defendant Fact Sheets, as follows:

- (a) Each Plaintiff required to submit a Plaintiff Fact Sheet, shall, by counsel or as *pro se*, establish a secure online portal in the MDL Centrality online system and obtain authorized user names and secure login passwords to permit use of MDL Centrality by such counsel or Plaintiff. Except as set forth herein, Counsel for a Plaintiff or each *pro se* Plaintiff shall be permitted to view, search and download on MDL Centrality only those materials submitted by that Plaintiff and by Defendants relating to that Plaintiff, and not materials submitted by or relating to other Plaintiffs.
- (b) The Defendant shall establish a secure online portal with the MDL Centrality online system and obtain authorized user names and secure login passwords to permit use of MDL Centrality by defendants' counsel.
- (c) The Plaintiffs' Steering Committee and Attorney Designees Appointed by the Plaintiffs' Steering Committee, shall have access to and be able to view, search and download all materials submitted by all Plaintiffs and by all Defendants.
- (d) Each Plaintiff and Defendants shall use the MDL Centrality System to obtain, complete or upload data, and serve the appropriate Fact Sheet online (including the upload of PDFs or other electronic images, photographs and videos of any records required in the Fact Sheets). Each Plaintiff and Defendants shall provide a signed verification with their Fact Sheets, which will be signed in hard copy, uploaded and served through MDL Centrality.
- (e) Each Plaintiff shall use the MDL Centrality System to obtain, complete and serve online the Plaintiff's Records Authorizations. Each Plaintiff shall sign each of the required Records Authorizations, which will then be uploaded and served through MDL Centrality.
- (f) Service of a completed Fact Sheet and Records Authorizations shall be deemed to occur when the submitting party has performed each of the steps required by the MDL Centrality System to execute the online submission of the materials, and the submitting party has received confirmation on screen that the materials have been successfully submitted.
- (g) If a party must amend a previously served Fact Sheet, all subsequent versions must be named accordingly ("First Amended Fact Sheet", "Second Amended Fact Sheet", etc.), and all iterations of a Party's Fact Sheet must remain available and accessible to all Parties to a case through trial, appeal (if any), or other resolution of the litigation.



(h) The Court may establish a secure online portal with the MDL Centrality online system and obtain an authorized user name and secure login password to permit use of MDL Centrality by the Court.

**2. *HIPAA Authorization.*** By using MDL Centrality, each Plaintiff authorizes the disclosure of his or her medical records and other health information submitted as part of the PFS or DFS to BrownGreer PLC as the administrator of the MDL Centrality System, the Court, Plaintiff Leadership and Defendants, and to the authorized agents, representatives and experts of the foregoing, for purposes of this litigation.

**3. *No Impact on Privileges or Work Product Protection.*** The use of MDL Centrality by any party shall not alter or otherwise waive or affect any attorney-client privilege or work product doctrine protection otherwise available that would otherwise apply to a document in the absence of the use of MDL Centrality. Any notations placed on materials, comments entered, or documents stored or uploaded to MDL Centrality by a user shall be considered to be the work product of such user unless and until the material is served on or purposefully disclosed to the opposing party through the use of MDL Centrality or otherwise.

**4. *ECF Notifications.*** The Clerk of Court shall execute the steps necessary to include BrownGreer as the MDL Centrality Administrator as an interested party for purposes of receiving emailed ECF notifications related to this matter.