BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: ELMIRON (PENTOSAN POLYSULFATE SODIUM) PRODUCTS LIABILITY LITIGATION	MDL Docket No.: 2973

DEFENDANT JANSSEN PHARMACEUTICALS, INC.'S RESPONSE TO MOTION TO TRANSFER ACTIONS TO THE DISTRICT OF NEW JERSEY PURSUANT TO 28 U.S.C. § 1407 FOR CONSOLIDATED PRETRIAL PROCEEDINGS

Defendant Janssen Pharmaceuticals, Inc. ("Janssen") does not oppose movants' request that the cases pending in federal courts across the country involving ELMIRON® be centralized and transferred pursuant to 28 U.S.C. § 1407 to a single district court for coordinated pretrial proceedings. However, given the growing trend in recent years that the mere formation of multidistrict litigation can result in the filing of meritless claims in an effort to increase plaintiff inventories and encourage settlement, these cases need to be centralized and transferred to a judge with not only the skill and knowledge to efficiently and effectively manage the coordinated proceedings, but also the willingness and motivation to rein in any abuses that may result from the fact of coordination. With this concern in mind, Janssen does not oppose movants' proposal that Judge Brian Martinotti of the District of New Jersey be the transferee judge.

BACKGROUND

There are currently at least 93 actions pending in 11 different federal judicial districts asserting claims involving ELMIRON®.[1]

[1] At least 30 additional cases have been filed since Plaintiffs filed the Motion to Transfer.

Plaintiffs And Their Basic Allegations

ELMIRON® is the only oral prescription medication approved by the FDA for the relief of bladder pain or discomfort associated with a condition known as interstitial cystitis. It was approved by the FDA over 20 years ago in 1996. Interstitial cystitis is a chronic bladder condition where individuals experience a range of symptoms from discomfort to debilitating pain. There is no known cause of interstitial cystitis and no known cure. When the FDA approved ELMIRON® in 1996, it concluded that the "drug product is safe and effective." Ex. A, FDA Approval Letter at 1.

Plaintiffs claim that ELMIRON® causes a wide range of ophthalmological issues, including but not limited to blurred vision, vision loss, difficulty adjusting to the dark, difficulty reading, and a condition sometimes referred to in the literature as "pigmentary maculopathy." On June 24, 2019, once Janssen had identified and evaluated the safety signal regarding pigmentary changes to the retina, it submitted a proposed update to the ELMIRON® United States Prescribing Information (USPI) to the FDA. In this Prior Approval Supplement, Janssen proposed to add a new warning regarding pigmentary changes in the retina and to include it as a post-marketing adverse reaction. The FDA approved an amendment to the USPI on June 16, 2020, which resulted in revisions to ELMIRON®'s USPI to include warnings related to retinal pigmentary changes. The label now states "Warnings: Retinal Pigmentary Changes" and notes that "Pigmentary changes in the retina, reported in the literature as pigmentary maculopathy, have been identified with long-term use of ELMIRON®." Ex. B, June 16, 2020 Label at 4.

Janssen Is The Only Common Defendant Across All Cases

While there are a number of co-defendants named in the pending actions, Janssen is the only defendant named in all of these cases, as it holds the New Drug Application (NDA) for ELMIRON®.[2]

While Janssen is a Pennsylvania corporation, its principal place of business is in Titusville, New Jersey. The majority of the Janssen teams responsible for clinical research, medical affairs, regulatory approvals and compliance, labeling, marketing, and sales of ELMIRON® are based in New Jersey. And individuals with substantive knowledge and decision-making authority regarding the labeling, regulatory compliance, marketing, and sale of ELMIRON® in the United States who may be potential trial witnesses are located in New Jersey.

The Location And Status Of The Pending Actions

Of the at least 93 cases relating to ELMIRON® that are currently pending, none has advanced significantly through discovery, nor toward trial, such that transfer would be unduly prejudicial or inefficient. Janssen has been served in 82 of the 93 cases. As of the time of these papers, answers have been filed in only 18 cases. In the remaining 74 cases, a response to the complaint has yet to be filed, motions to dismiss are awaiting disposition, dispositive motion briefing is in progress, or the case has been stayed pending the Panel's decision on the Motion to Transfer. There has not yet been a significant legal ruling. No dispositive motions have been ruled on.

[2] The following defendants have been variously named in the 82 cases in which Janssen has been served: Alza Corporation; Baker Norton Pharmaceuticals, Inc.; Bayer Corporation; Bayer Healthcare LLC; Bayer Healthcare Pharmaceuticals, Inc.; Bayer US L.L.C.; Centocor Research & Development, Inc.; Ivax Corporation; Ivax LLC; Janssen Ortho LLC; Janssen Pharmaceuticals, Inc.; Janssen Research & Development L.L.C.; Johnson & Johnson; Ortho-McNeil Pharmaceuticals, Inc.; Teva Branded Pharmaceutical Products R&D, Inc.; Teva Pharmaceutical Industries Ltd.; and Teva Pharmaceuticals USA, Inc.

ARGUMENT

I. Janssen Does Not Oppose Transfer And Centralization Of ELMIRON® Actions.

While Janssen disagrees with Plaintiffs' characterization of the facts, it does not oppose pretrial centralization of this litigation. Of course, these cases all involve very individualized and plaintiff-specific issues, including different usage histories, different prescribing physicians, and different alleged symptoms. But the cases will also likely present common discovery and other pretrial matters regarding ELMIRON® which would benefit from coordinated pretrial proceedings.

Although Janssen acknowledges that there are benefits to be achieved through centralization, Janssen also recognizes the potential pitfalls of multidistrict litigation. Creating a multidistrict proceeding can encourage the filing of claims of questionable merit and allow those claims to avoid the judicial scrutiny that they otherwise would receive if filed individually. As Judge Clay Land, transferee judge overseeing *In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation* observed, "the evolution of the [multidistrict litigation] process toward providing an alternative dispute resolution forum for global settlements has produced incentives for the filing of cases that otherwise would not be filed if they had to stand on their own merit as a stand-alone action." *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, MDL Doc. No. 2004, 4:08-md-2004, 2016 WL 4705827, at *1 (M.D. Ga. Sept. 7, 2016). This results in a multidistrict proceeding—established for the purpose of managing cases efficiently so as to achieve judicial economy—"becom[ing] populated with many non-meritorious cases that must nevertheless be managed by the transferee judge." *Id.*

To avoid these pitfalls, when choosing an appropriate transferee judge, it is critical to identify a judge with the knowledge, skill, and experience in the efficient management of complex cases. A potential transferee judge should demonstrate the willingness and motivation to actively manage the cases and swiftly address issues to ensure that the benefits of centralization are

achieved. A transferee judge also should be willing "to consider approaches that weed out non-meritorious cases early, efficiently, and justly." *Id.* at *2.

II. Janssen Does Not Oppose The District Of New Jersey As the Forum For The Multidistrict Litigation.

Janssen does not oppose movants' request that the District of New Jersey be the forum for transfer and centralization of the ELMIRON® cases for pretrial proceedings[3] before Judge Brian Martinotti. As the movants explain, the District of New Jersey generally and Judge Martinotti specifically have significant experience handling multidistrict litigation involving pharmaceutical and medical device products liability actions.

A. The District of New Jersey is an appropriate and convenient forum.

There presently are two courts with a significant number of ELMIRON® cases pending, and the District of New Jersey is one of them. There are 32 cases now pending in the District of New Jersey, all before Judge Martinotti. *See, e.g.*, *In re 100% Grated Parmesan Cheese Mktg. & Sales Practices Litig.*, 201 F. Supp. 3d 1375, 1378–79 (J.P.M.L 2016) (selecting district where "a significant number of actions are pending"); *In re: Walgreens Herbal Supplements Mktg. & Sales Practices Litig.*, 109 F. Supp. 3d 1373, 1376 (J.P.M.L. 2015) (selecting Northern District of Illinois because "[a] significant number of actions are pending in this district, which is also where the Walgreens defendants are based") *In re: Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 787 F. Supp. 2d 1355, 1357 (J.P.M.L 2011) ("We are persuaded that the District of New Jersey is an appropriate transferee forum for this litigation given the number of cases pending there.").

The District of New Jersey is a convenient forum given that Janssen maintains its

[3] While Janssen does not oppose the transfer and centralization of these cases for pretrial purposes, it believes the transferor courts are likely the better fora for trial.

headquarters there. The majority of the Janssen teams responsible for medical affairs, regulatory approvals and compliance, labeling, marketing, and sales of ELMIRON® are based in New Jersey. And individuals with substantive knowledge and decision-making authority regarding the labeling, regulatory compliance, marketing, and sale of ELMIRON® in the United States who could be potential witnesses at trial are located in New Jersey. *See, e.g.*, *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Prods. Liab. Litig.*, 220 F. Supp. 3d 1356, 1359 (J.P.M.L. 2016) ("As Johnson & Johnson is headquartered in New Jersey, relevant evidence and witnesses likely are located in the District of New Jersey"); *In re Benicar (Olmesartan) Prods. Liab. Litig.*, 96 F. Supp. 3d 1381, 1383 (J.P.M.L. 2015) (selecting District of New Jersey for multidistrict proceedings because "defendants, are headquartered in that district, and thus many witnesses and relevant documents are likely to be found there"); *In re Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prods. Liab. Litig.*, 53 F. Supp. 3d 1379, 1381 (J.P.M.L. 2014) (establishing MDL in the Southern District of Indiana in part because "[defendant] Cook is headquartered in Indiana, where relevant documents and witnesses are likely to be found").

Moreover, the District of New Jersey is geographically accessible to all counsel and parties involved in this litigation, making it a good choice for transferee forum. *See In re Comp. of Managerial, Prof'l & Technical Emp. Antitrust Litig.*, 206 F.Supp. 2d 1374, 1375-76 (J.P.M.L. 2002) (holding District of New Jersey is an "accessible, urban district[] equipped with the resources that [a] complex docket is likely to require"); *In re: Nickelodeon Consumer Privacy Litig.*, 949 F. Supp. 2d 1377, 1378 (J.P.M.L. 2013) (same).

B. Judge Martinotti is uniquely qualified to oversee these cases.

The Panel frequently looks to assign MDLs to an "able jurist who has experience presiding over complex, multidistrict litigation." *In re Secondary Ticket Mkt. Refund Litig.*, No.

MDL 2951, 2020 WL 4670728, at *2 (J.P.M.L. Aug. 6, 2020); *see also, e.g.*, *In re Delta Dental Antitrust Litig.*, 433 F. Supp. 3d 1358, 1359-60 (J.P.M.L. 2020) (assigning MDL to "an able jurist with significant MDL experience"); *In re Fairlife Milk Prods. Mktg. & Sales Practices Litig.*, 396 F. Supp. 3d 1370, 1371 (J.P.M.L. 2019) (assigning MDL to "a jurist with significant multidistrict litigation experience").

Judge Martinotti has precisely that experience, as well as extensive experience with state coordinated proceedings as a state court judge. *See In re: Invokana (Canagliflozin) Prods. Liab. Litig.*, No. MDL-2750 (D.N.J.); *In re: Allergan Biocell Textured Breast Implant Prods. Liab. Litig.*, No. MDL-2921 (D.N.J.); Case Mgmt. Order, *In re: Nuvaring Litig.*, No. BER-L-3081-09 (N.J. Super. Ct. Sept. 18, 2009); Case Mgmt. Order, *In re: Zelnorm Litig.*, No. BER-L-280-09 (N.J. Super. Ct. Sept. 14, 2009); Case Mgmt. Order, *In re Yaz, Yasmin, Ocella Litig.*, No. BER-L-3572-10 (Apr. 26, 2010); Case Mgmt. Order, *In re DePuy ASR Hip Implants Litig.*, No. BER-L-3971-11 (May 10, 2011); Case Mgmt. Order, *In re Stryker Rejuvenate & ABG II Hip Implant Litig.*, No. BER-L-936-13 (Feb. 20, 2013); Case Mgmt. Order, *In re Mirena Litig*., No. BER-L-4098-13 (July 1, 2013); Notice to the Bar: Multicounty Litigation Reassignment—Pelvic Mesh (N.J. Oct. 31, 2014), http://judiciary.state.nj.us/notices/2014/n141105b.pdf.

As someone with experience in both federal and state coordinated proceedings, Judge Martinotti has a demonstrated track record of achieving cooperation and synchronization between federal and state courts in related cases. That is important here as there are currently at least 14 ELMIRON® cases pending in state courts. Judge Martinotti is part of Emory Law's Institute for Complex Litigation and Mass Claims' working group devoted to "the strategic role of the

interplay between state and federal courts."[4] He has spoken at conferences "regarding state-federal coordination strategy."[5] He has also published on the issue. In his article on complex litigation, he wrote:

> Lastly, although not a case management technique per se, state and federal court judges must seek to cooperate with one another where there are related cases pending in federal MDLs and state courts. As mass torts in New Jersey often have related matters pending in federal courts (in the form of MDLs or individual plaintiffs who have removed their case to federal court), one of the most important functions for a mass tort judge in state court is coordinating with federal courts. It is imperative for judges in state and federal courts to keep in close contact and stay abreast of developments in their respective cases. This mutual relationship can be accomplished through formal procedures (e.g., CMCs), informal status updates from liaison counsel, or from federal judges themselves. Doing so helps ensure consistent results across the inventory of cases, avoids duplicative litigation, and allows for more efficient handling of matters in all court systems.

Hon. Brian R. Martinotti, *Complex Litigation in New Jersey and Federal Courts: An Overview of the Current State of Affairs and A Glimpse of What Lies Ahead*, 44 Loy. U. Chi. L.J. 561, 575 (2012) (footnotes omitted).

Significantly, Judge Martinotti already has utilized MDL coordination techniques to organize and move forward the cases before him. He has issued multiple case management orders which have helped steer the litigation in an efficient manner. *See, e.g.*, Ex. C, Case Management Order No. 1; Ex. D, Case Management Order 2; Ex. E, Case Management Order to Govern Privileged Materials and Privilege Logs; Ex. F, Case Management Order No. 3; Ex. G, Case Management Order No. 4; Ex. H, Case Management Order No. 5.

By way of example, upon learning that motions to dismiss were filed, Judge Martinotti

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[4] https://law.emory.edu/centers-and-programs/the-institute-for-complex-litigation-and-mass-claims-judges.html

[5] https://law.emory.edu/_includes/documents/sections/faculty-and-scholarship/centers/FirstJointCoordinationConference-june2018.pdf

effectively issued a stay of motion practice by terminating all pending motions and tolling the deadline for responding to complaints. Ex. C, CMO No. 1 at ¶¶ II.B-C. The purpose of this procedure was to allow the parties to negotiate in order to reduce or otherwise streamline the number of defendants and claims in the matters to a more uniform set of parties and issues. *Id.* at ¶ II.A. The effort already has been successful. As a result of this process, Teva Pharmaceuticals USA, Inc. as well as all Bayer-related entities have been dismissed from the District of New Jersey actions. *See* Ex. H, CMO No. 5 at ¶ III.1-2. And work is still continuing in this regard.

In another case management order, Judge Martinotti set up a procedure for the filing of a Master Initial Disclosure. Ex. D, CMO No. 2 at § 1.A. This procedure was "intended to conserve judicial and party resources, eliminate duplicative discovery, serve the convenience of the parties and witnesses, and promote the just and efficient conduct of this litigation." *Id.* at § 1. Additionally, he has set up a privilege log protocol for exchanging privilege logs and challenging entries, Ex. E, Privilege CMO, and approved a Protective Order for use in all cases. Ex. I, Protective Order.

Finally, Judge Martinotti has demonstrated that he fully understands the goals of an MDL and how best to posture the cases to achieve those goals if this panel so orders, regardless of the ultimate venue. When Judge Martinotti learned that certain plaintiffs had filed for coordination in the District of New Jersey, but some plaintiffs with cases pending in other jurisdictions opposed the motion, he immediately called for coordination where practicable. Ex. G, CMO No. 4. The relevant case management order states in pertinent part:

> Having heard from counsel regarding the status of the cases pending before this Court and the litigation more broadly, the Court encourages counsel in the District of New Jersey cases, and counsel agrees, that the parties should endeavor to work collaboratively and cooperatively with attorneys in other jurisdictions who have filed Elmiron lawsuits to coordinate content and entry of orders, avoid duplicative efforts and inconsistent processes, and conserve judicial resources to the extent

> practicable. . . .
>
> To the extent any other jurisdictions have not issued stays or are proceeding forward, the parties will update the Court on their efforts to coordinate with those other jurisdictions at the next case management conference.

Id. at ¶¶ IV.A, IV.C.

CONCLUSION

Janssen does not oppose transfer of the ELMIRON® actions to the District of New Jersey before Judge Martinotti.

Dated: October 15, 2020

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Exhibit A

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-193

Baker Norton Pharmaceuticals, Inc.
4400 Biscayne Boulevard
Miami, Florida 33137

SEP 2 6 1996

Attention: Ed Mitchell, Ph.D.
Vice President, Regulatory Affairs

Dear Dr. Mitchell:

Please refer to your June 11, 1991, new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Elmiron (pentosan polysulfate sodium) Capsules.

We acknowledge receipt of your correspondence and amendments dated August 28 and 30, September 9, 10, and 11, and October 3 and 28, 1991; January 22 and 27, June 2 and 22, November 9, and December 10, 1992; February 4, March 2, April 6 and 20, May 26, June 2, and July 7 and 20, 1993, February 11, November 8, and December 28, 1994; January 25, March 2, May 22, June 19, August 31, October 26 and 30, and December 1 (2) and 11, 1995; and January 31, February 15, March 4, April 10, May 6, August 12, and September 3, 13 and 20 1996. We also acknowledge receipt of a correspondence (undated) on February 17, 1994.

This new drug application provides for a semi-synthetically produced heparin-like macromolecular carbohydrate derivative indicated for the relief of pain or discomfort associated with interstitial cystitis.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling. The labeling includes a Medication Guide for patients. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit sixteen copies of the FPL, including patient package insert, as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-193. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you of your Phase 4 commitments specified in your submissions dated April 10 and September 20, 1996. These commitments, along with any completion dates agreed upon, are listed below.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. Should an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to this NDA as correspondences. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

In addition, please submit three copies of the introductory promotional material, revised in accordance with approved labeling, that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Medical Imaging and Radiopharmaceutical Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications,
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Susan L. Cusack
Consumer Safety Officer
(301) 443-3500

Sincerely yours,

Paula Botstein 9/26/96

Paula Botstein, M.D.
Acting Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:
Labeling dated September 25, 1996.

cc:
Original NDA 20-193
HFD-160/Div. files
HFD-160/CSO/Cusack
HFD-160/Paserchia/Love/Hunt/Lee/Davi/Welch
HFD-2/M.Lumpkin
HFD-103/P.Botstein
HFD-101/L.Carter (with labeling)
HFD-820/Yuan Yuan Chiu
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HF-35/Orphan Drugs (with labeling)
HFD-80 (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613 (with labeling)
HFD-735/(with labeling) - for all NDAs and supplements for adverse reaction changes.

drafted: slc/September 19, 1996/20193ap.001
revised: JC/9.25.96/20193ap.002
final:JC/9.25.96

APPROVAL [with Phase 4 Commitments]

9/25/96

9/25/96

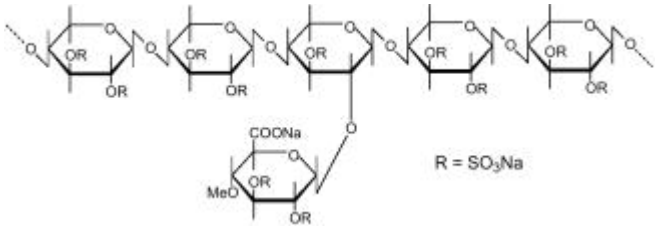
Exhibit B

ELMIRON®-100 MG
(PENTOSAN POLYSULFATE SODIUM)
CAPSULES

PRESCRIBING INFORMATION

DESCRIPTION

Pentosan polysulfate sodium is a semi-synthetically produced heparin-like macromolecular carbohydrate derivative, which chemically and structurally resembles glycosaminoglycans. It is a white odorless powder, slightly hygroscopic and soluble in water to 50% at pH 6. It has a molecular weight of 4000 to 6000 Dalton with the following structural formula:



ELMIRON® is supplied in white opaque hard gelatin capsules containing 100 mg pentosan polysulfate sodium, microcrystalline cellulose, and magnesium stearate. It also contains pharmaceutical glaze (modified) in SD-45, synthetic black iron oxide, FD&C Blue No. 2 aluminum lake, FD&C Red No. 40 aluminum lake, FD&C Blue No. 1 aluminum lake, D&C Yellow No. 10 aluminum lake, n-butyl alcohol, propylene glycol, SDA-3A alcohol, and titanium dioxide. It is formulated for oral use.

CLINICAL PHARMACOLOGY

General

Pentosan polysulfate sodium is a low molecular weight heparin-like compound. It has anticoagulant and fibrinolytic effects. The mechanism of action of pentosan polysulfate sodium in interstitial cystitis is not known.

Pharmacokinetics

Absorption

In a clinical pharmacology study in which healthy female volunteers received a single oral 300 or 450 mg dose of pentosan polysulfate sodium containing radiolabeled drug as a solution under fasted conditions, maximal levels of plasma radioactivity were seen approximately at a median of 2 hours (range 0.6-120 hours) after dosing. Based on urinary excretion of radioactivity, a mean of approximately 6% of a radiolabeled oral dose of pentosan polysulfate sodium is absorbed and reaches the systemic circulation.

Food Effects: In clinical trials, ELMIRON® was administered with water 1 hour before or 2 hours after meals; the effect of food on absorption of pentosan polysulfate sodium is not known.

Distribution

Preclinical studies with parenterally administered radiolabeled pentosan polysulfate sodium showed distribution to the uroepithelium of the genitourinary tract with lesser amounts found in the liver, spleen, lung, skin, periosteum, and bone marrow. Erythrocyte penetration is low in animals.

Metabolism

The fraction of pentosan polysulfate sodium that is absorbed is metabolized by partial desulfation in the liver and spleen, and by partial depolymerization in the kidney to a large number of metabolites. Both the desulfation and depolymerization can be saturated with continued dosing.

Excretion

Following administration of an oral solution of a 300 or 450 mg dose of pentosan polysulfate sodium containing radiolabeled drug to groups of healthy subjects, plasma radioactivity declined with mean half-lives of 27 and 20 hours, respectively. A large proportion of the orally administered dose of pentosan polysulfate sodium (mean 84% in the 300 mg group and 58% in the 450 mg group) is excreted in feces as unchanged drug. A mean of 6% of an oral dose is excreted in the urine, mostly as desulfated and depolymerized metabolites. Only a small fraction of the administered dose (mean 0.14%) is recovered as intact drug in urine.

Special Populations

The pharmacokinetics of pentosan polysulfate sodium has not been studied in geriatric patients or in patients with hepatic or renal impairment. See also PRECAUTIONS-Hepatic Insufficiency.

Drug-Drug Interactions

In a study in which healthy subjects received pentosan polysulfate sodium 100 mg capsule or placebo every 8 hours for 7 days, and were titrated with warfarin to an INR of 1.4 to 1.8, the pharmacokinetic parameters of R-warfarin and S-warfarin were similar in the absence and presence of pentosan polysulfate sodium. INR for warfarin + placebo and warfarin + pentosan polysulfate sodium were comparable. See also PRECAUTIONS on the use of ELMIRON® in patients receiving other therapies with anticoagulant effects.

Pharmacodynamics

The mechanism by which pentosan polysulfate sodium achieves its effects in patients is unknown. In preliminary clinical models, pentosan polysulfate sodium adhered to the bladder wall mucosal membrane. The drug may act as a buffer to control cell permeability preventing irritating solutes in the urine from reaching the cells.

CLINICAL TRIALS

ELMIRON® was evaluated in two clinical trials for the relief of pain in patients with chronic interstitial cystitis (IC). All patients met the NIH definition of IC based upon the results of cystoscopy, cytology, and biopsy. One blinded, randomized, placebo-controlled study evaluated 151 patients (145 women, 5 men, 1 unknown) with a mean age of 44 years (range 18 to 81). Approximately equal numbers of patients received either placebo or ELMIRON® 100 mg three times a day for 3 months. Clinical improvement in bladder pain was based upon the patient's own assessment. In this study, 28/74 (38%) of patients who received ELMIRON® and 13/74 (18%) of patients who received placebo showed greater than 50% improvement in bladder pain ($p = 0.005$).

A second clinical trial, the physician's usage study, was a prospectively designed retrospective analysis of 2499 patients who received ELMIRON® 300 mg a day without blinding. Of the 2499 patients, 2220 were women, 254 were men, and 25 were of unknown sex. The patients had a mean age of 47 years and 23% were over 60 years of age. By 3 months, 1307 (52%) of the patients had dropped out or were ineligible for analysis, overall, 1192 (48%) received ELMIRON® for 3 months; 892 (36%) received ELMIRON® for 6 months; and 598 (24%) received ELMIRON® for one year.

Patients had unblinded evaluations every 3 months for the patient's rating of overall change in pain in comparison to baseline and for the difference calculated in "pain/discomfort" scores. At baseline, pain/discomfort scores for the original 2499 patients were severe or unbearable in 60%, moderate in 33% and mild or none in 7% of patients. The extent of the patients' pain improvement is shown in Table 1.

At 3 months, 722/2499 (29%) of the patients originally in the study had pain scores that improved by one or two categories. By 6 months, in the 892 patients who continued taking ELMIRON®, an additional 116/2499 (5%) of patients had improved pain scores. After 6 months, the percent of patients who reported the first onset of pain relief was less than 1.5% of patients who originally entered in the study (see Table 2).

Table 1: Pain Scores in Reference to Baseline in Open Label Physician's Usage Study (N=2499)*

Efficacy Parameter	3 months†	6 months†
Patient Rating of Overall Change in Pain (Recollection of difference between current pain and baseline pain)‡	N=1161 Median = 3 Mean = 3.44 CI: (3.37, 3.51)	N=724 Median = 4 Mean = 3.91 CI: (3.83, 3.99)
Change in Pain/Discomfort Score (Calculated difference in scores at the time point and baseline)§	N=1440 Median = 1 Mean = 0.51 CI: (0.45, 0.57)	N=904 Median = 1 Mean = 0.66 CI: (0.61, 0.71)

* Trial not designed to detect onset of pain relief

† CI = 95% confidence interval

‡ 6-point scale: 1 = worse, 2 = no better, 3 = slightly improved, 4 = moderately improved, 5 = greatly improved, 6 = symptom gone

§ 3-point scale: 1 = none or mild, 2 = moderate, 3 = severe or unbearable

Table 2: Number (%) of Patients with New Relief of Pain/Discomfort* in the Open-Label Physician's Usage Study (N=2499)

	at 3 months† (n=1192)	at 6 months‡ (n=892)
Considering only the patients who continued treatment	722/1192 (61%)	116/892 (13%)
Considering all the patients originally enrolled in the study	722/2499 (29%)	116/2499 (5%)

* First-time Improvement in pain/discomfort score by 1 or 2 categories

† Number (%) of patients with improvement of pain/discomfort score at 3 months when compared to baseline

‡ Number (%) of patients without pain/discomfort improvement at 3 months who had improvement at 6 months

INDICATIONS AND USAGE

ELMIRON® (pentosan polysulfate sodium) is indicated for the relief of bladder pain or discomfort associated with interstitial cystitis.

CONTRAINDICATIONS

ELMIRON® is contraindicated in patients with known hypersensitivity to the drug, structurally related compounds, or excipients.

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.

PRECAUTIONS

General

ELMIRON® is a weak anticoagulant (1/15 the activity of heparin). At a daily dose of 300 mg (n=128), rectal hemorrhage was reported as an adverse event in 6.3% of patients. Bleeding complications of ecchymosis, epistaxis, and gum hemorrhage have been reported (see ADVERSE REACTIONS). Patients undergoing invasive procedures or having signs/symptoms of underlying coagulopathy or other increased risk of bleeding (due to other therapies such as coumarin anticoagulants, heparin, t-PA, streptokinase, high dose aspirin, or nonsteroidal anti-inflammatory drugs) should be evaluated for hemorrhage. Patients with diseases such as aneurysms, thrombocytopenia, hemophilia, gastrointestinal ulcerations, polyps, or diverticula should be carefully evaluated before starting ELMIRON®.

A similar product that was given subcutaneously, sublingually, or intramuscularly (and not initially metabolized by the liver) is associated with delayed immunoallergic thrombocytopenia with symptoms of thrombosis and hemorrhage. Caution should be exercised when using ELMIRON® in patients who have a history of heparin induced thrombocytopenia.

Alopecia is associated with pentosan polysulfate and with heparin products. In clinical trials of ELMIRON®, alopecia began within the first 4 weeks of treatment. Ninety-seven percent (97%) of the cases of alopecia reported were alopecia areata, limited to a single area on the scalp.

Hepatic Insufficiency

ELMIRON® has not been studied in patients with hepatic insufficiency. Because there is evidence of hepatic contribution to the elimination of ELMIRON®, hepatic impairment may have an impact on the pharmacokinetics of ELMIRON®. Caution should be exercised when using ELMIRON® in this patient population.

Mildly (< 2.5 x normal) elevated transaminase, alkaline phosphatase, γ-glutamyl transpeptidase, and lactic dehydrogenase occurred in 1.2% of patients. The increases usually appeared 3 to 12 months after the start of ELMIRON® therapy, and were not associated with jaundice or other clinical signs or symptoms. These abnormalities are usually transient, may remain essentially unchanged, or may rarely progress with continued use. Increases in PTT and PT (< 1% for both) or thrombocytopenia (0.2%) were noted.

Information for Patients

Patients should take the drug as prescribed, in the dosage prescribed, and no more frequently than prescribed.

Patients should be informed that changes in vision should be reported and evaluated. Retinal examinations including optical coherence tomography (OCT) and auto-fluorescence imaging are suggested for all patients within six months of starting ELMIRON® and periodically during long-term treatment (see WARNINGS).

Patients should be reminded that ELMIRON® has a weak anticoagulant effect. This effect may increase bleeding times.

Laboratory Test Findings

Pentosan polysulfate sodium did not affect prothrombin time (PT) or partial thromboplastin time (PTT) up to 1200 mg per day in 24 healthy male subjects treated for 8 days. Pentosan polysulfate sodium also inhibits the generation of factor Xa in plasma and inhibits thrombin-induced platelet aggregation in human platelet rich plasma *ex vivo*. (See PRECAUTIONS-Hepatic Insufficiency Section for additional information.)

Carcinogenicity, Mutagenesis, Impairment of Fertility

Long-term carcinogenicity studies of ELMIRON® in F344/N rats and B6C3F1 mice have been conducted. In these studies, ELMIRON® was orally administered once daily via gavage, 5 days per week, for up to 2 years. The dosages administered to mice were 56, 168 or 504 mg/kg. The dosages administered to rats were 14, 42, or 126 mg/kg for males, and 28, 84, or 252 mg/kg for females. The dosages tested were up to 60 times the maximum recommended human dose (MRHD) in rats, and up to 117 times the MRHD in mice, on a mg/kg basis. The results of these studies in rodents showed no clear evidence of drug-related tumorigenesis or carcinogenic risk.

Pentosan polysulfate sodium was not clastogenic or mutagenic when tested in the mouse micronucleus test or the Ames test (*S. typhimurium*). The effect of pentosan polysulfate sodium on spermatogenesis has not been investigated.

Pregnancy

Reproduction studies have been performed in mice and rats with intravenous daily doses of 15 mg/kg, and in rabbits with 7.5 mg/kg. These doses are 0.42 and 0.14 times the daily oral human doses of ELMIRON® when normalized to body surface area. These studies did not reveal evidence of impaired fertility or harm to the fetus from ELMIRON®. Direct *in vitro* bathing of cultured mouse embryos with pentosan polysulfate sodium (PPS) at a concentration of 1 mg/mL may cause reversible limb bud abnormalities. Adequate and well-controlled studies have not been performed in pregnant women. Because animal studies are not always predictive of human response, this drug should be used in pregnancy only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ELMIRON® is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients below the age of 16 years have not been established.

ADVERSE REACTIONS

ELMIRON® was evaluated in clinical trials in a total of 2627 patients (2343 women, 262 men, 22 unknown) with a mean age of 47 [range 18 to 88 with 581 (22%) over 60 years of age]. Of the 2627 patients, 128 patients were in a 3-month trial and the remaining 2499 patients were in a long-term, unblinded trial.

Deaths occurred in 6/2627 (0.2%) patients who received the drug over a period of 3 to 75 months. The deaths appear to be related to other concurrent illnesses or procedures, except in one patient for whom the cause was not known.

Serious adverse events occurred in 33/2627 (1.3%) patients. Two patients had severe abdominal pain or diarrhea and dehydration that required hospitalization. Because there was not a control group of patients with interstitial cystitis who were concurrently evaluated, it is difficult to determine which events are associated with ELMIRON® and which events are associated with concurrent illness, medicine, or other factors.

Adverse Experience in Placebo-Controlled Clinical Trials of ELMIRON® 100 mg Three Times a Day for 3 Months

Body System/Adverse Experience	ELMIRON® n=128	Placebo n=130
CNS Overall Number of Patients*	3	5
Insomnia	1	0
Headache	1	3
Severe Emotional Lability/Depression	2	1
Nystagmus/Dizziness	1	1
Hyperkinesia	1	1
GI Overall Number of Patients*	7	7
Nausea	3	3
Diarrhea	3	6
Dyspepsia	1	0
Jaundice	0	1
Vomiting	0	2
Skin/Allergic Overall Number of Patients*	2	4
Rash	0	2
Pruritus	0	2
Lacrimation	1	1
Rhinitis	1	1
Increased Sweating	1	0
Other Overall Number of Patients*	1	3
Amenorrhea	0	1
Arthralgia	0	1
Vaginitis	1	1
Total Events	17	27
Total Number of Patients Reporting Adverse Events	13	19

* Within a body system, the individual events do not sum to equal overall number of patients because a patient may have more than one event.

The adverse events described below were reported in an unblinded clinical trial of 2499 interstitial cystitis patients treated with ELMIRON®. Of the original 2499 patients, 1192 (48%) received ELMIRON® for 3 months; 892 (36%) received ELMIRON® for 6 months; and 598 (24%) received ELMIRON® for one year, 355 (14%) received ELMIRON® for 2 years, and 145 (6%) for 4 years.

Frequency (1 to 4%): Alopecia (4%), diarrhea (4%), nausea (4%), headache (3%), rash (3%), dyspepsia (2%), abdominal pain (2%), liver function abnormalities (1%), dizziness (1%).

Frequency (≤ 1%):

Digestive: Vomiting, mouth ulcer, colitis, esophagitis, gastritis, flatulence, constipation, anorexia, gum hemorrhage.

Hematologic: Anemia, ecchymosis, increased prothrombin time, increased partial thromboplastin time, leukopenia, thrombocytopenia.

Hypersensitive Reactions: Allergic reaction, photosensitivity.

Respiratory System: Pharyngitis, rhinitis, epistaxis, dyspnea.

Skin and Appendages: Pruritus, urticaria.

Special Senses: Conjunctivitis, tinnitus, optic neuritis, amblyopia, retinal hemorrhage.

Post-Marketing Experience

The following adverse reactions have been identified during post approval use of pentosan polysulfate sodium; because these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:

- pigmentary changes in the retina (see WARNINGS).

Rectal Hemorrhage

ELMIRON® was evaluated in a randomized, double-blind, parallel group, Phase 4 study conducted in 380 patients with interstitial cystitis dosed for 32 weeks. At a daily dose of 300 mg (n=128), rectal hemorrhage was reported as an adverse event in 6.3% of patients. The severity of the events was described as “mild” in most patients. Patients in that study who were administered ELMIRON® 900 mg daily, a dose higher than the approved dose, experienced a higher incidence of rectal hemorrhage, 15%.

Liver Function Abnormality

A randomized, double-blind, parallel group, Phase 2 study was conducted in 100 men (51 ELMIRON® and 49 placebo) dosed for 16 weeks. At a daily dose of 900 mg, a dose higher than the approved dose, elevated liver function tests were reported as an adverse event in 11.8% (n=6) of ELMIRON®-treated patients and 2% (n=1) of placebo-treated patients.

OVERDOSAGE

Overdose has not been reported. Based upon the pharmacodynamics of the drug, toxicity is likely to be reflected as anticoagulation, bleeding, thrombocytopenia, liver function abnormalities, and gastric distress. (See CLINICAL PHARMACOLOGY and PRECAUTIONS sections.) At a daily dose of 900 mg for 32 weeks (n=127) in a clinical trial, rectal hemorrhage was reported as an adverse event in 15% of patients. At a daily dose of ELMIRON® 900 mg for 16 weeks in a clinical trial that enrolled 51 patients in the ELMIRON® group and 49 in the placebo group, elevated liver function tests were reported as an adverse event in 11.8% of

patients in the ELMIRON® group and 2% of patients in the placebo group. In the event of acute overdosage, the patient should be given gastric lavage if possible, carefully observed and given symptomatic and supportive treatment.

DOSAGE AND ADMINISTRATION

The recommended dose of ELMIRON® is 300 mg/day taken as one 100 mg capsule orally three times daily. The capsules should be taken with water at least 1 hour before meals or 2 hours after meals.

Patients receiving ELMIRON® should be reassessed after 3 months. If improvement has not occurred and if limiting adverse events are not present, ELMIRON® may be continued for another 3 months.

The clinical value and risks of continued treatment in patients whose pain has not improved by 6 months is not known.

HOW SUPPLIED

ELMIRON® is supplied in white opaque hard gelatin capsules imprinted "BNP7600" containing 100 mg pentosan polysulfate sodium. Supplied in bottles of 100 capsules.

NDC NUMBER 50458-098-01

Storage

Store at controlled room temperature 15°-30°C (59°-86°F).

Keep out of reach of children.

ELMIRON® is a Registered Trademark of Teva Branded Pharmaceutical Products R&D, Inc. under license to Janssen Pharmaceuticals, Inc.

Product of Germany

Manufactured by:

Janssen Ortho LLC

Gurabo, Puerto Rico 00778

Manufactured for:

Janssen Pharmaceuticals, Inc.

Titusville, New Jersey 08560

Revised: June 2020

PHARMACIST: PLEASE DISPENSE ONE PATIENT LEAFLET PER PRESCRIPTION

Patient Leaflet

Questions and Answers About

ELMIRON®

(Generic name = pentosan polysulfate sodium)

Capsules

What is the most important information I should know about ELMIRON®?
ELMIRON® (pronounced EL ma ron) is used to treat the pain or discomfort of interstitial cystitis (IC). You must take ELMIRON® as prescribed by your doctor in the dosage prescribed but no more frequently than prescribed. Pigment changes in the retina of the eye (also referred to as pigmentary maculopathy in medical journal articles) have been reported with long-term use of ELMIRON®. While the cause of the pigmentary changes is unclear, continued long term dosing with ELMIRON® may be a risk factor. The consequences of these pigmentary changes in the retina are not fully understood. Visual symptoms that have been reported include: difficulty reading, slow adjustment to low or reduced light environments, and blurred vision. If you already have retinal pigment changes from other causes, it may be difficult to distinguish future retinal pigment changes if they occur. Call your doctor (including your eye doctor) if you notice any changes in your vision. Throughout your treatment, regular eye examinations that include retinal examinations are suggested for early detection of retinal/macular changes. Your doctor will discuss with you when to get your first eye examination and follow up exams, and whether the treatment should be continued since these changes may be irreversible and may progress even after stopping treatment. ELMIRON® is a weak anticoagulant (blood thinner) which may increase bleeding. Call your doctor if you will be undergoing surgery or will begin taking anticoagulant therapy such as warfarin sodium, heparin, high doses of aspirin, or anti-inflammatory drugs such as ibuprofen.

What is ELMIRON®?

ELMIRON® is used to treat the pain or discomfort of interstitial cystitis (IC). It is not known exactly how ELMIRON® works, but it is not a pain medication like aspirin or acetaminophen and therefore must be taken continuously for relief as prescribed.

Who should not take ELMIRON®?

- Patients undergoing surgery should speak with their doctor about when to discontinue ELMIRON® prior to surgery.
- ELMIRON® should be used during pregnancy only if clearly needed.

What does your doctor need to know?

- Tell your doctor if you have a personal or family history of eye problems of the retina.
- Tell your doctors (including your eye doctor) if you experience visual changes such as reading difficulty, slower adjustment to low or reduced light, or blurred vision. (See "**WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT ELMIRON®?**")
- If you are taking anticoagulant therapy such as warfarin sodium, heparin, high doses of aspirin, or anti-inflammatory drugs such as ibuprofen.
- If you are pregnant.
- If you have any liver problems.

How should I take ELMIRON®?

You should take 1 capsule of ELMIRON® by mouth three times a day, with water at least 1 hour before meals or 2 hours after meals. Each capsule contains 100 mg of ELMIRON®.

What should I avoid while taking ELMIRON®?

Anticoagulant therapy such as warfarin sodium, heparin, high doses of aspirin or anti-inflammatory drugs such as ibuprofen until you speak with your doctor.

What are the most common side effects of ELMIRON®?

The most common side effects are hair loss, diarrhea, nausea, blood in the stool, headache, rash, upset stomach, abnormal liver function tests, dizziness and bruising.

Call your doctor if any of these side effects persist or are bothersome or if there is blood in your stool.

If you suspect that someone may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

This leaflet provides a summary of information about ELMIRON®. Medicines are sometimes prescribed for uses other than those listed in a Patient Leaflet. If you have any questions or concerns, or want more information about ELMIRON®, contact your doctor or pharmacist. Your pharmacist also has a longer leaflet about ELMIRON® that is written for health professionals that you can ask to read.

Keep out of reach of children.

Product of Germany

Manufactured by:

Janssen Ortho LLC

Gurabo, Puerto Rico 00778

Manufactured for:

Janssen Pharmaceuticals, Inc.

Titusville, New Jersey 08560

Revised: June 2020

Exhibit C

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

VALERIE HULL AND EDWARD HULL,[1]	:	
Plaintiffs,	:	**Case No. 3:20-cv-07079**
v.	:	**JUDGE BRIAN R. MARTINOTTI** **JUDGE ZAHID N. QURAISHI**
JANSSEN PHARMACEUTICALS, INC., *et al.,*	:	
Defendants.	:	
This Document Relates to All Cases	:	

CASE MANAGEMENT ORDER NO. 1

The Court having held an initial case management conference on August 26, 2020, in this case and the cases identified in footnote and for good cause shown, enters the following Order:

I. STATUS OF THE LITIGATION

[1] This order applies to and shall be filed in the following pending and related actions: (1) *Lynn Brewer and William Brewer v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07758-BRM-ZNQ; (2) *Harriet Comstock v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07756-BRM-ZNQ; (3) *Sherry Dobbins and James Dobbins v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-09530; (4) *Carol Dubois v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-10080-BRM-ZNQ; (5) Deborah Edwards v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07753-BRM-ZNQ; (6) *Linda Holmberg and Roy Daniel Holmberg v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11440-BMR-ZNQ (7) *Valerie Hull and Edward Hull v. Janssen Pharmaceuticals, Inc., et al.*, 2:20-v-07079; (8) *Clara Johns v. Alza Corp., et al*, 3:20-cv-10341-BRM-ZNQ; (9) *Shirley Ruth Levy v. Alza Corp., et al.*, 3:20-cv-10342-BRM-ZNQ; (10) *Sheryl McCall and David McCall v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-08074-BRM-ZNQ; (11) *Barbara Mayou and Keith Mayou v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07750-BRM-ZNQ; (12) *Maria Rogers v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10966; (13) *Heather Shaffer v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10968; (14) *Becky Worden v. Janssen Pharmaceuticals, Inc., et al.* 3:20-cv-06070-FLW-TJB; (15) *Ronna York v. Janssen Pharmaceuticals, Inc., et al*, 3:20-cv-10960

A. As of August 26, 2020, 15 cases alleging products liability claims relating to use of Elmiron have been filed in the District of New Jersey with 9 complaints having being served. Fourteen out of the 15 cases are assigned to Judge Martinotti, and one to Judge Wolfson (*Worden*).

II. PENDING MOTIONS

A. The parties are meeting and conferring as to the appropriate defendants named in certain cases and shall either submit an agreed to Case Management Order or stipulation addressing these defendants and/or report at the next case management conference the status of these defendants remaining in these cases.

B. All pending motions, except for requests for *pro hac vice* admission, shall be administratively terminated without prejudice by the Clerk so that the parties can meet and confer and discuss dismissal of claims and certain defendants as set forth in Section II.A., above

C. With respect to all case, the deadline for one or more defendants' initial entry of appearance or deadlines to answer or otherwise respond is tolled until further order of this Court.

III. PROPOSED CASE MANAGEMENT ORDERS

A. The meet and confer process regarding a preservation order, ESI protocol, an Order to address Automatic Disclosures requirements, and an Order addressing medical records and authorizations for the collection of medical records as part of the fact sheet process shall continue.

IV. SCHEDULING

A. The next case management conference is scheduled for **September 15, 2020, at 10**

a.m. Counsel for plaintiffs and defendants shall endeavor to provide a reasonable list of attendees in advance of the conference, so that the conference can be conducted by WebEx or Zoom.

B. Counsel for plaintiffs and defendants is required to submit via email a joint agenda five days prior to the next scheduled conference. If there are any disagreements as to the agenda, counsel shall set forth each party's position.

C. The parties shall meet and confer on a weekly basis regarding newly filed cases, and counsel for the Janssen Defendants shall provide a weekly update of cases filed in the District of New Jersey to Dana_Sledge-Courtney@njd.uscourts.gov.

D. Counsel shall abide by Judge Martinotti's and Judge Quraishi's submission and communication procedures, respectively, unless and until the Court so orders superseding rules for this litigation.

Dated: August 31, 2020

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

Exhibit D

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

SHERYL MCCALL and DAVID MCCALL, [1]	:	
Plaintiffs,	:	**Case Nos. 3:20-cv-08074; 3:20-cv-07758; 3:20-cv-07756; 3:20-cv-09530; 3:20-cv-10080; 3:20-cv-07753; 3:20-cv-11912; 2:20-cv-07079; 3:20-cv-12421; 3:20-cv-07750; 3:20-cv-10966; 3:20-cv-10960**
v.	:	
JANSSEN PHARMACEUTICALS, INC., *et al.,*	:	
Defendants.	:	
This Document Relates to All Cases	:	**JUDGE BRIAN R. MARTINOTTI** **JUDGE ZAHID N. QURAISHI**

CASE MANAGEMENT ORDER NO. 2

1. SCOPE AND APPLICABILITY OF ORDER. This Case Management Order is intended to conserve judicial and party resources, eliminate duplicative discovery, serve the convenience of the parties and witnesses, and promote the just and efficient conduct of this litigation. The following protocols and limitations in this Case Management Order ("CMO")

[1] This order applies to and shall be filed in the following pending and related actions: (1) *Lynn Brewer and William Brewer v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07758-BRM-ZNQ; (2) *Harriet Comstock v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07756-BRM-ZNQ; (3) *Sherry Dobbins and James Dobbins v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-09530-BRM-ZNQ; (4) *Carol Dubois v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10080-BRM-ZNQ; *(5) Deborah Edwards v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07753-BRM-ZNQ; (6) *Iris Groudan v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11912 – BRM-ZNQ (7) *Valerie Hull and Edward Hull v. Teva Pharmaceuticals, Inc., et al.*, 2:20-cv-07079-BRM-JAD; (8) *Elizabeth Lafave v. Teva Branded Pharmaceutical Products R&D, Inc., et al.*, 3:20-cv-12421-BRM-ZNQ; (9) *Barbara Mayou and Keith Mayou v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07750-BRM-ZNQ; (10) *Maria A. Rodgers v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10966-BRM-ZNQ; (11) *Ronna D. York v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10960-BRM-ZNQ

shall apply in all Elmiron products liability and/or personal injury cases pending before this Court now, or that might be filed or transferred to this Court.

A. RULE 26 INITIAL DISCLOSURES

The parties agree that the requirements of Fed.R.Civ.P. 26(a)(1)(A) shall hereby be suspended and waived for all parties going forward. However, in an effort to advance the litigation, each defendant currently served with a case agrees to provide a Master Initial Disclosure on or before October 30, 2020. Service of these disclosures shall be made by email on each Plaintiff Counsel of record with an Elmiron case pending before this Court. In lieu of Initial Disclosures, Plaintiffs are participating in a fact sheet meet and confer process, *see* section C, below.

B. SERVICE OF DOCUMENTS & NOTICE OF PARTIES

On behalf of Defendants, the parties agree that, with the exception of summons, Complaints, and materials served via the Court's e-filing (ECF) system, legal documents related to one or more Elmiron cases pending before this Court should be served on the following:

Michael C. Zogby, Esq.
Faegre Drinker Biddle & Reath LLP
600 Campus Dr.
Florham Park, NJ 07932
michael.zogby@faegredrinker.com

Kristen Renee Fournier, Esq.
King & Spalding LLP
1185 Avenue of the Americas
New York, NY 10036
kfournier@kslaw.com

Defendants shall notify the Plaintiffs of any new Elmiron products liability and/or personal injury cases filed before this Court, or cases that might be transferred to this Court. This notice shall be via email to Michael London, Esq. at MLondon@DouglasandLondon.com.

C. PLAINTIFF MEDICAL RECORDS AND AUTHORIZATIONS

During various meet and confers, Defendants have expressed a desire to begin the process of medical record and authorization collections for each Plaintiff as soon as practicable, and the parties are continuing to work on this issue as part of the fact sheet meet and confer process.

Dated: September 14, 2020

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

Exhibit E

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

		Case Nos.
SHERYL MCCALL and DAVID MCCALL,	:	**3:20-cv-08074; 3:20-cv-12605;**
	:	**3:20-cv-07758; 3:20-cv-07756;**
	:	**3:20-cv-09530; 3:20-cv-10080;**
Plaintiffs,	:	**3:20-cv-07753; 3:20-cv-12328;**
	:	**3:20-cv-11913; 3:20-cv-11912;**
v.	:	**3:20-cv-12608; 2:20-cv-07079;**
	:	**3:20-cv-10341; 3:20-cv-11921;**
JANSSEN PHARMACEUTICALS, INC., *et al.,*	:	**3:20-cv-12421; 3:20-cv-10342;**
	:	**3:20-cv-07750; 3:20-cv-12547;**
	:	**3:20-cv-10966; 3:20-cv-11919;**
Defendants.	:	**3:20-cv-10968; 3:20-cv-12264;**
	:	**3:20-cv-06070; 3:20-cv-10960**
This Document Relates to All Cases[1]	:	**JUDGE BRIAN R. MARTINOTTI**
		JUDGE ZAHID N. QURAISHI

[1] (1) *Rebecca Anthony and Carlie Anthony v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12605-BRM-ZNQ (2) *Lynn Brewer and William Brewer v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07758-BRM-ZNQ; (3) *Harriet Comstock v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07756-BRM-ZNQ; (4) *Sherry Dobbins and James Dobbins v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-09530-BRM-ZNQ; (5) *Carol Dubois v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-10080*-BRM-ZNQ; (6) *Deborah Edwards v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07753-BRM-ZNQ; (7) *Margaret Emmons v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12328-BRM-ZNQ; (8) *Marilyn J. Evans v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11913-BRM-ZNQ; (9) *Iris Groudan v. Janssen Pharmaceuticals Inc., et al.*, 3:20-cv-11912-BRM-ZNQ; (10) *Carol Hardy and Roger Hardy v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12608-BRM-ZNQ (11) *Valerie Hull and Edward Hull v. Teva Pharmaceuticals, Inc., et al.*, 2:20-cv-07079-BRM-ZNQ; (12) *Clara Johns v. ALZA Corp., et al*, 3:20-cv-10341-BRM-ZNQ; (13) *Tiffany Kotz v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11921-BRM-ZNQ (14) *Elizabeth Lafave v. Teva Branded Pharmaceutical Products R&D, Inc., et al.*, 3:20-cv-12421-BRM-ZNQ; (15) *Shirley Ruth Levy v. ALZA Corp., et al.*, 3:20-cv-10342-BRM-ZNQ; (16) *Barbara Mayou and Keith Mayou v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07750-BRM-ZNQ; (17) *Sheryl McCall and David McCall v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-08074-BRM-ZNQ; (18) *Loretta Reid v. Janssen Pharmaceutical, Inc., et al.*, 3:20-cv-12547-BRM-ZNQ; (19) *Maria A. Rodgers v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10966-BRM-ZNQ; (20) *Michelle Scott v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11919-BRM-ZNQ (21) *Heather Shaffer v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10968-BRM-ZNQ; (22) *Cynthia Vescio v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12264-BRM-ZNQ; (23) *Becky Worden v. Janssen Pharmaceuticals, Inc., et al.* 3:20-cv-06070-BRM-ZNQ; (24) *Ronna York v. Janssen Pharmaceuticals, Inc., et al*, 3:20-cv-10960-BRM-ZNQ.

CASE MANAGEMENT ORDER TO GOVERN PRIVILEGED MATERIALS AND PRIVILEGE LOGS

The undersigned counsel for Defendants and Plaintiffs (collectively, the "Parties" and each, a "Party") in the above captioned action agree that the Parties and non-parties will be required to produce or disclose in this proceeding certain information and documents that are subject to claimed privileges under applicable law. Such documents, described in more detail below, include information that is protected by attorney work-product, attorney-client or other applicable privilege that might exist.

I. PRIVILEGE LOGGING PROTOCOL

A. **General Principles. Privilege logs shall comply with Fed. R. Civ. P. 26(b)(5), which requires a party to:**

1. Expressly identify the privilege asserted; and

2. Describe the nature of the documents, communications, or tangible things not produced or disclosed . . . in a manner that, without revealing information itself privileged or protected, will enable other parties to assess this claim. Fed. R. Civ. P. 26(b)(5).

B. **Specific Principles.**

1. **Asserting Privilege or Protection.** A party who withholds or redacts documents on the grounds of attorney-client privilege and/or work product protection shall provide:

a. a listing of such documents in electronic spreadsheet format providing the following objective metadata fields ("objective metadata" does not include substantive content from, or a subjective description of, the document being withheld or redacted):

i. the Bates number of the document (if redacted);

ii. the nature of the privilege asserted (e.g., "attorney-client privilege" or "attorney work product");

iii. the name(s) and email addresses of the author(s) of the document, (if known) (to the extent a document is comprised of an email chain, the name of the author on the most recent email in the chain will be identified);

iv. the name(s) and email addresses of the recipient(s) of the document, including anyone who was sent the document as a "CC" or a "BCC," (if known) (to the extent a document is comprised of an email chain, the name(s) of the recipient(s) on the most recent email in the chain will be identified);

v. the name(s) and email addresses of the email thread participant(s), including anyone who was sent the document as a "CC" or a "BCC," (if known) (to the extent a document is comprised of an email chain, the name(s) of all recipients throughout the entirety of the chain will be identified);

vi. the custodian(s) of the document;

vii. the document type, including, for example, whether the document is an email, paper file, a meeting presentation, a spreadsheet, or other descriptive identifier of the document type;

viii. the date the document was created (if known), sent (if applicable); and last modified (if applicable).

b. The withholding/redacting party need not provide an individualized or subjective description of the privilege or protection claimed for documents corresponding to the following categories:

i. Communications including outside counsel;

ii. Emails from an attorney and attachments;

iii. Emails sent to an attorney (attorney in the TO field) and attachments;

iv. Emails copied to an attorney (attorney in the CC field) and attachments;

v. Documents prepared or edited by an attorney (not attached to emails);

vi. Documents prepared or edited for review by an attorney (not attached to emails);

vii. Emails between non-lawyers conveying legal advice;

viii. Documents with reference to legal advice; and

ix. Status of legal matters, legal settlements.

c. The withholding/redacting party shall specify the category to which a privileged or protected document corresponds.

d. The withholding/redacting party shall provide individualized descriptions for documents that it asserts are privileged or protected but that do not correspond to a category listed above.

2. **Documents presumptively not to be logged on Privilege Log**. The following documents presumptively need not be included on a privilege log:

a. Written or electronic communications regarding this action exclusively between a party and its trial counsel after commencement of this action; and

b. work product solely related to this action created by trial counsel after commencement of the action.

3. **Privilege Log descriptions of email threads**. A party may use electronic email threading to identify emails that are part of the same thread and need include only an entry for the most inclusive email thread on the log to identify withheld or redacted emails that constitute an email thread; provided, however, that no emails within the thread are sent or received by, or forwarded to, third parties Disclosure must be made that the e-mails are part of an email thread.

4. **Privilege Log descriptions of exact duplicates**. A party need include only one entry on the log to identify withheld documents that are exact duplicates.

5. The privilege log should indicate which individuals listed on the log are attorneys.

II. PRIVILEGE LOGGING PROTOCOL

A. **Challenging Asserted Privilege and Protection.** If a party challenges in writing an assertion of privilege or protection from discovery then the parties shall meet and confer and make a good faith effort to cooperatively classify the challenged documents into categories that are subject to common factual and legal issues in so far as practicable and shall attempt to resolve the privilege challenges. If thereafter, the parties are unable to resolve any of the privilege challenges, either party may request a conference with the Court to set processes for resolving the challenges, which normally will include:

1. a schedule for briefing the legal issues relevant to each category or setting argument;

2. a ruling date for issues that can be resolved on the briefs alone; and/or

3. a schedule for providing representative, rationale-based and/or random samples for the Court's review in camera with respect to any categories that cannot be resolved by the parties or by the Court before briefing; and/or

4. a schedule for the parties to meet and confer to attempt in good faith to apply the Court's rulings on the samples to whole categories or within categories insofar as possible; and/or

5. a schedule for repeating this process as needed.

Plaintiffs may challenge privilege designations either document-by-document or in clusters of documents

Nothing herein shall shift or in any way alter the burden on establishing privilege protections by the party asserting privilege protections.

Although the Parties are encouraged to meet-and-confer over any challenge being asserted to a privilege designation before bringing the privilege challenge to the Court's attention for resolution and adjudication, nothing herein shall be construed to serve as a delay or obstacle for any party who might seek to challenge a claim of privilege per this section.

Dated: October 7th, 2020

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

Exhibit F

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

SHERYL MCCALL and DAVID MCCALL,	:	
Plaintiffs,	:	**Case Nos.**
v.	:	**3:20-cv-08074; 3:20-cv-12605; 3:20-cv-07758; 3:20-cv-07756; 3:20-cv-09530; 3:20-cv-10080;**
JANSSEN PHARMACEUTICALS, INC., *et al.,*	:	**3:20-cv-07753; 3:20-cv-12328; 3:20-cv-11913; 3:20-cv-11912; 3:20-cv-12608; 2:20-cv-07079;**
Defendants.	:	**3:20-cv-11921; 3:20-cv-12421; 3:20-cv-07750; 3:20-cv-10966;**
This Document Relates to All Cases	:	**3:20-cv-11919; 3:20-cv-10968; 3:20-cv-12264; 3:20-cv-06070; 3:20-cv-10960**
		JUDGE BRIAN R. MARTINOTTI **JUDGE ZAHID N. QURAISHI**

CASE MANAGEMENT ORDER NO. 3

The Court having held a case management conference on September 15, 2020, and for good cause shown, enters the following Order:

I. STATUS OF THE LITIGATION

A. As of September 18, 2020, all 25 cases alleging products liability claims relating to use of Elmiron filed in the District of New Jersey are assigned to Judge Martinotti with 21 complaints having been served.[1]

[1] This order applies to and shall be filed in the following served actions: (1) *Rebecca Anthony and Carlie Anthony v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12605-BRM-ZNQ; (2) *Lynn Brewer and William Brewer v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07758-BRM-ZNQ; (3) *Harriet Comstock v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07756-BRM-ZNQ; (4) *Sherry Dobbins and James Dobbins v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-09530-BRM-

II. PENDING MOTIONS

A. All pending motions have been administratively terminated without prejudice for leave to file at a later date. The parties may continue to meet and confer on possible motions to dismiss and shall report, if necessary, at the next case management conference. Defendants' initial entries of appearance and deadlines to answer or otherwise plead remain tolled until further order of this Court.

III. PROPOSED CASE MANAGEMENT ORDERS

A. On September 17, 2020, the Court entered the parties' proposed Protective Order in all served cases.

B. The parties are actively meeting and conferring regarding the following additional orders: preservation order, privilege log protocol/order, and an ESI protocol. The parties indicated that they are close to agreements on each proposed order, and shall either submit agreed-upon forms or report on the status at the next case management conference.

ZNQ; (5) *Carol Dubois v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10080-BRM-ZNQ; (6) *Deborah Edwards v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07753-BRM-ZNQ; (7) *Margaret Emmons v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12328-BRM-ZNQ; (8) *Marilyn J. Evans v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11913-BRM-ZNQ; (9) *Iris Groudan v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11912-BRM-ZNQ; (10) *Carol Hardy and Roger Hardy v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12608-BRM-ZNQ; (11) *Valerie Hull and Edward Hull v. Teva Branded Pharmaceuticals USA, Inc., et al.*, 2:20-cv-07079-BRM-JAD; (12) *Tiffany Kotz v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11921-BRM-ZNQ; (13) *Elizabeth Lafave v. Teva Branded Pharmaceutical Products R&D, Inc., et al.*, 3:20-cv-12421-BRM-ZNQ; (14) *Barbara Mayou and Keith Mayou v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07750-BRM-ZNQ; (15) *Sheryl McCall and David McCall v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-08074-BRM-ZNQ; (16) *Maria A. Rodgers v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10966-BRM-ZNQ; (17) *Michelle Scott v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11919-BRM-ZNQ; (18) *Heather E. Shaffer v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10968-BRM-ZNQ; (19) *Cynthia Vescio v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12264-BRM-ZNQ; (20) *Becky Worden v. Janssen Pharmaceuticals, Inc., et al.* 3:20-cv-06070-FLW-TJB; (21) *Ronna D. York v. Janssen Pharmaceuticals, Inc., et al*, 3:20-cv-10960-BRM-ZNQ

C. The parties continue to meet and confer on the dismissal of Teva and Bayer Defendants, and shall either submit agreed-upon stipulations or report on status during the next case management conference.

D. The parties are meeting and conferring regarding a plaintiff fact sheet process and collection of medical records.

E. The Plaintiffs indicated they intend to propound a master set of discovery requests including interrogatories and document demands on the Janssen Defendants only.

F. Plaintiffs have requested prioritizing of the production of the New Drug Application ("NDA") by the Janssen Defendants. The Janssen Defendants have begun the gathering of this hard-copy and electronic production, and with the Court's guidance on making this production forthwith, the Janssen Defendants hope to begin production of it soon. Plaintiffs and the Janssen Defendants shall provide an update related to the NDA production at the next case management conference.

IV. SCHEDULING

A. The next case management conference is scheduled for **October 7, 2020, at 10:30 a.m.** Counsel for plaintiffs shall provide a reasonable list of attendees in advance of the conference, so that the conference can be conducted by WebEx or Zoom.

B. Counsel is required to submit via email a joint agenda five days prior to the next scheduled conference. If there are any disagreements as to the agenda, counsel shall set forth each party's position.

C. The parties shall meet and confer on a weekly basis regarding newly filed cases, and counsel for the Janssen Defendants shall provide a weekly update of cases filed

in the District of New Jersey to Dana_Sledge-Courtney@njd.uscourts.gov.

D. Counsel shall abide by Judge Martinotti's and Judge Quraishi's submission and communication procedures, respectively, unless and until the Court so orders superseding rules for this litigation.

Dated: September 21, 2020

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

Exhibit G

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

SHERYL MCCALL and DAVID MCCALL,	:	**Case Nos. 3:20-cv-08074; 3:20-cv-12605; 3:20-cv-07758; 3:20-cv-07756; 3:20-cv-09530; 3:20-cv-10080; 3:20-cv-07753; 3:20-cv-12328; 3:20-cv-11913; 3:20-cv-11912; 3:20-cv-12608; 3:20-cv-07079; 3:20-cv-10341; 3:20-cv-11921; 3:20-cv-12421; 3:20-cv-10342; 3:20-cv-07750; 3:20-cv-12547; 3:20-cv-10966; 3:20-cv-11919; 3:20-cv-10968; 3:20-cv-12264; 3:20-cv-06070; 3:20-cv-10960**
Plaintiffs,	:	
v.	:	
JANSSEN PHARMACEUTICALS, INC., *et al.,*	:	
Defendants.	:	
This Document Relates to All Cases[1]	:	**JUDGE BRIAN R. MARTINOTTI JUDGE ZAHID N. QURAISHI**

[1] This order applies to and shall be served in the following cases: (1) *Rebecca Anthony and Carlie Anthony v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12605-BRM-ZNQ (2) *Lynn Brewer and William Brewer v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07758-BRM-ZNQ; (3) *Harriet Comstock v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07756-BRM-ZNQ; (4) *Sherry Dobbins and James Dobbins v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-09530-BRM-ZNQ; (5) *Carol Dubois v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-10080*-BRM-ZNQ*;* (6) *Deborah Edwards v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07753-BRM-ZNQ; (7) *Margaret Emmons v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12328-BRM-ZNQ; (8) *Marilyn J. Evans v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11913-BRM-ZNQ; (9) *Iris Groudan v. Janssen Pharmaceuticals Inc., et al.*, 3:20-cv-11912-BRM-ZNQ; (10) *Carol Hardy and Roger Hardy v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12608-BRM-ZNQ (11) *Valerie Hull and Edward Hull v. Teva Pharmaceuticals, Inc., et al.*, 3:20-cv-07079-BRM-ZNQ; (12) *Clara Johns v. ALZA Corp., et al*, 3:20-cv-10341-BRM-ZNQ; (13) *Tiffany Kotz v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11921-BRM-ZNQ (14) *Elizabeth Lafave v. Teva Branded Pharmaceutical Products R&D, Inc., et al.*, 3:20-cv-12421-BRM-ZNQ; (15) *Shirley Ruth Levy v. ALZA Corp., et al.*, 3:20-cv-10342-BRM-ZNQ; (16) *Barbara Mayou and Keith Mayou v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07750-BRM-ZNQ; (17) *Sheryl McCall and David McCall v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-08074-BRM-ZNQ; (18) *Loretta Reid v. Janssen Pharmaceutical, Inc., et al.*, 3:20-cv-12547-BRM-ZNQ; (19) *Maria A. Rodgers v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10966-BRM-ZNQ; (20) *Michelle Scott v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11919-BRM-ZNQ (21) *Heather Shaffer v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10968-BRM-ZNQ; (22) *Cynthia Vescio v. Janssen*

CASE MANAGEMENT ORDER NO. 4

The Court having held a case management conference on October 7, 2020, and for good cause shown, enters the following Order:

I. STATUS OF LITIGATION AND COORDINATION

A. As of October 7, 2020, 27 cases alleging products liability claims relating to use of Elmiron have been filed in the District of New Jersey with 24 complaints being served. All cases are assigned to Judge Martinotti.

II. PENDING MOTIONS

A. All pending motions have been administratively terminated without prejudice for leave to file at a later date. The parties may continue to meet and confer on possible motions to dismiss and shall report on their progress, if necessary, at the next case management conference. Defendants' initial entries of appearance and deadlines to answer or otherwise plead remain tolled until further order of this Court.

III. PROPOSED CASE MANAGEMENT ORDERS

A. The parties are actively meeting and conferring to finalize an ESI protocol. The parties indicated that they are close to an agreement and shall either submit an agreed-upon form before the next case management conference or report on the status of these negotiations at the next case management conference.

B. The parties continue to meet and confer on the dismissal of the Bayer Defendants, as well as noticing a one-time, Rule 30(B)(6) most knowledgeable deposition on

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Pharmaceuticals, Inc., et al., 3:20-cv-12264-BRM-ZNQ; (23) *Becky Worden v. Janssen Pharmaceuticals, Inc., et al.* 3:20-cv-06070-BRM-ZNQ; (24) *Ronna York v. Janssen Pharmaceuticals, Inc., et al*, 3:20-cv-10960-BRM-ZNQ.

this issue. The parties shall either submit an agreed-upon order or report on status during the next case management conference.

C. The parties also continue to meet and confer on the dismissal of additional Teva entities, and will report on the status of their discussions at the next case management conference.

D. The parties are meeting and conferring regarding a plaintiff fact sheet/defense fact sheet process, and the related collection of signed authorizations and medical records, and shall either submit agreed-upon proposals or report on status during the next case management conference.

E. Plaintiffs indicated that they intend to propound a master set of discovery requests, including interrogatories and document demands, within the next week on the Janssen Defendants.

F. Plaintiffs have requested prioritizing production of the New Drug Application ("NDA") by the Janssen Defendants. The Janssen Defendants are in the process of collecting and preparing the NDA for production, which is expected to begin within the next fourteen days. The parties shall provide an update related to the NDA production at the next case management conference.

IV. COORDINATION/COOPERATION

A. Having heard from counsel regarding the status of the cases pending before this Court and the litigation more broadly, the Court encourages counsel in the District of New Jersey cases, and counsel agrees, that the parties should endeavor to work collaboratively and cooperatively with attorneys in other jurisdictions who have filed Elmiron lawsuits to coordinate content and entry of orders, avoid duplicative

efforts and inconsistent processes, and conserve judicial resources to the extent practicable.

B. Based on the above-stated goals, the Court hereby appoints Paola Pearson, Esq., of Anapol Weiss, as liaison counsel for purposes of coordinating with counsel representing plaintiffs in Elmiron-related cases filed in the Eastern District of Pennsylvania. Ms. Pearson and designated counsel from the consolidated New Jersey litigation shall work together—towards the above-stated goals – as reasonably as possible recognizing that the Eastern District of Pennsylvania plaintiffs may have different views and obligations than the coordinated New Jersey plaintiffs have.

C. To the extent any other jurisdictions have not issued stays or are proceeding forward, the parties will update the Court on their efforts to coordinate with those other jurisdictions at the next case management conference. Defendants' counsel Michael C. Zogby shall provide updated case and new counsel lists of other jurisdictions' Elmiron new case filings, not simply for new New Jersey filings, as required under CMO 1.

V. SCHEDULING

A. The next case management conference is scheduled for **October 26, 2020, at 9:00 a.m.** Counsel for plaintiffs shall provide a reasonable list of attendees in advance of the conference, so that the conference can be conducted by WebEx or Zoom.

B. Counsel is required to submit via email a joint agenda **three** days prior to the next scheduled conference. If there are any disagreements as to the agenda, counsel shall set forth each party's position.

C. The parties shall meet and confer on a weekly basis regarding newly filed cases, and counsel for the Janssen Defendants shall provide a weekly update of cases filed in the District of New Jersey to Dana_Sledge-Courtney@njd.uscourts.gov.

D. Counsel shall abide by Judge Martinotti and Judge Quraishi's submission and communication procedures, respectively, unless and until the Court so orders superseding rules for this litigation.

Dated: October 13th, 2020

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

Exhibit H

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

		Case Nos.
SHERYL MCCALL and DAVID MCCALL,	:	**3:20-cv-08074; 3:20-cv-12605;**
	:	**3:20-cv-07758; 3:20-cv-07756;**
	:	**3:20-cv-09530; 3:20-cv-10080;**
Plaintiffs,	:	**3:20-cv-07753; 3:20-cv-12328;**
	:	**3:20-cv-11913; 3:20-cv-11912;**
v.	:	**3:20-cv-12608; 3:20-cv-07079;**
	:	**3:20-cv-10341; 3:20-cv-11921;**
JANSSEN PHARMACEUTICALS, INC., *et al.,*	:	**3:20-cv-12421; 3:20-cv-10342;**
	:	**3:20-cv-07750; 3:20-cv-12547;**
	:	**3:20-cv-10966; 3:20-cv-11919;**
Defendants.	:	**3:20-cv-10968; 3:20-cv-12264;**
	:	**3:20-cv-13596; 3:20-cv-06070;**
***This Document Relates to All Cases*[1]**	:	**3:20-cv-10960**

JUDGE BRIAN R. MARTINOTTI
JUDGE ZAHID N. QURAISHI

[1] The served cases are: (1) *Rebecca Anthony and Carlie Anthony v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12605-BRM-ZNQ; (2) *Lynn Brewer and William Brewer v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07758-BRM-ZNQ; (3) *Harriet Comstock v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07756-BRM-ZNQ; (4) *Sherry Dobbins and James Dobbins v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-09530-BRM-ZNQ; (5) *Carol Dubois v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10080-BRM-ZNQ; (6) *Deborah Edwards v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07753-BRM-ZNQ; (7) *Margaret Emmons v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12328-BRM-ZNQ; (8) *Marilyn J. Evans v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11913-BRM-ZNQ; (9) *Iris Groudan v. Janssen Pharmaceuticals Inc., et al.*, 3:20-cv-11912-BRM-ZNQ; (10) *Carol Hardy and Roger Hardy v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12608-BRM-ZNQ; (11) *Valerie Hull and Edward Hull v. Teva Pharmaceuticals, Inc., et al.*, 3:20-cv-07079-BRM-ZNQ; (12) *Clara Johns v. ALZA Corp., et al*, 3:20-cv-10341-BRM-ZNQ; (13) *Tiffany Kotz v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11921-BRM-ZNQ; (14) *Elizabeth Lafave v. Teva Branded Pharmaceutical Products R&D, Inc., et al.*, 3:20-cv-12421-BRM-ZNQ; (15) *Shirley Ruth Levy v. ALZA Corp., et al.*, 3:20-cv-10342-BRM-ZNQ; (16) *Barbara Mayou and Keith Mayou v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07750-BRM-ZNQ; (17) *Sheryl McCall and David McCall v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-08074-BRM-ZNQ; (18) *Loretta Reid v. Janssen Pharmaceutical, Inc., et al.*, 3:20-cv-12547-BRM-ZNQ; (19) *Maria A. Rodgers v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10966-BRM-ZNQ; (20) *Michelle Scott v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11919-BRM-ZNQ; (21) *Heather Shaffer v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10968-BRM-ZNQ; (22) *Cynthia Vescio v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12264-BRM-ZNQ; (23) *Deborah F. Weiner v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-13596-BRM-ZNQ; (24) *Becky Worden v. Janssen*

Case Management Order No. 5 Regarding Dismissal of Bayer Defendants

Plaintiffs in the above captioned case as well as those with cases pending in the District of New Jersey before Judge Brian Martinotti[2] and Defendants Janssen Pharmaceuticals, Inc., Ortho-McNeil Pharmaceuticals, Janssen Pharmaceutica, Inc., Janssen Research and Development, LLC (f/k/a Johnson & Johnson Pharmaceutical Research and Development), Janssen Ortho LLC, and Johnson & Johnson (collectively "**Named Janssen Defendants**") and Bayer Corporation, Bayer HealthCare LLC, Bayer HealthCare Pharmaceuticals Inc. (f/k/a Bayer Pharmaceuticals Corporation), and Bayer U.S. LLC (collectively "**Named Bayer Defendants**"), having met and conferred, jointly respectfully request that the Court dismiss the Named Bayer Defendants from those cases where they are named[3] as follows:

I. INVOLVEMENT OF NAMED BAYER DEFENDANTS IN ELMIRON® LITIGATION

1. The cases brought by Plaintiffs concern the prescription medication ELMIRON® (the "ELMIRON® Litigation"), which was approved by the FDA in September 1996 to treat the pain and discomfort associated with interstitial cystitis.

2. The Named Janssen Defendants and the Named Bayer Defendants represent and warrant to the Court and to the undersigned Plaintiffs that none of the Named Bayer Defendants (including, but not limited to, any corporate parent, subsidiary or affiliate), were involved in developing, designing, or testing ELMIRON®, and none of the Named Bayer Defendants (including, but not limited to, any corporate parent, subsidiary or affiliate), has ever held the ELMIRON New Drug Application ("NDA") since the product was approved by the FDA in 1996.

Pharmaceuticals, Inc., et al., 3:20-cv-06070-BRM-ZNQ; (25) *Ronna York v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10960-BRM-ZNQ.

[2] All cases served and currently pending before Judge Brian Martinotti are identified in footnote 1.

[3] The Clerk of the Court is hereby directed to dismiss the Named Bayer Defendants from the following served cases: (1) *Clara Johns v. ALZA Corporation, et al.*, 3:20-cv-10341-BRM-ZNQ; (2) *Elizabeth Lafave v. Teva Branded Pharmaceutical Products R&D, Inc., et al.*, 3:20-cv-12421-BRM-ZNQ; (3) *Shirley Ruth Levy v. ALZA Corporation, et al.*, 3:20-cv-10342-BRM-ZNQ.

3. In October 2005, Bayer Pharmaceuticals Corporation and Ortho-McNeil Pharmaceutical, Inc. entered into a limited co-promotion agreement related to ELMIRON® (the "Agreement"). Under the Agreement, which terminated in 2011, certain of the Named Bayer Defendants were given the right to market and promote ELMIRON® to certain prescribers in the United States.

II. AGREEMENT BETWEEN PLAINTIFFS AND THE JANSSEN DEFENDANTS

1. The Named Janssen Defendants agree that, pursuant to the terms of the Agreement, they have agreed to defend, indemnify and hold harmless the Named Bayer Defendants (including, but not limited to, any corporate parent, subsidiary or affiliate), for any claims related to the Named Bayer Defendants' promotion, marketing, or sale of ELMIRON® during the time the Agreement was in effect.

2. The Named Janssen Defendants agree that they will not assert any position *in judicio*, affirmative defense, cross claim, or counter claim, against any party alleging that they are not liable for claims arising from the sales, marketing, or promotional activity undertaken by the Named Bayer Defendants during the time the Agreement was in effect. The Named Janssen Defendants agree that, for purposes of the ELMIRON® Litigation and as between the Named Janssen Defendants and Plaintiffs, they shall not argue that the Named Bayer Defendants are at fault or that the Named Janssen Defendants are not responsible for claims arising from the sales, marketing, or promotional activity undertaken by the Named Bayer Defendants during the time the Agreement was in effect.

3. In support of the representations made herein, the Named Janssen Defendants further agree to a one-time deposition of a person most knowledgeable on the sole subject of the limited co-promotion agreement set forth in Paragraph I.3 and their related representations regarding defense of these matters as set forth in Paragraphs II.1 and II.2.

4. Nothing contained herein will be relied upon by any party or used by any party to establish the propriety of Johnson & Johnson as a defendant in the ELMIRON® Litigation, and Johnson & Johnson reserves all rights to make future arguments relative to its inclusion in this Litigation.

III. AGREEMENT BETWEEN PLAINTIFFS AND THE BAYER DEFENDANTS

1. Plaintiffs hereby dismiss without prejudice (subject to the limitations identified in Section III.3 below) the named Bayer Defendants (including, but not limited to, any corporate parent, subsidiary, or affiliate), from any cases pending in the District of New Jersey in which they have been named to date.

2. Plaintiffs hereby agree that they will not name or bring suit against any of the Named Bayer Defendants, or other defendants within the Bayer corporate family (including, but not limited to, any corporate parent, subsidiary, or affiliate), in future cases filed in the ELMIRON® Litigation absent the limited circumstances discussed in Paragraph III.3 below.

3. Plaintiffs maintain the right to re-file dismissed claims against the Named Bayer Defendants or bring new claims against the Named Bayer Defendants only if evidence arises during the ELMIRON® Litigation that is sufficient to support a claim against any one or all of the Named Bayer Defendants that is not covered by the Named Janssen Defendants' indemnification obligations. The Named Janssen Defendants and the Named Bayer Defendants represent and warrant to the Court and to Plaintiffs that, as of the date of this Order and to the best of their knowledge, no such evidence exists.

4. Any claims that Plaintiffs may have against the Named Bayer Defendants, to the extent timely as of the date the respective plaintiff's action was filed in this Court, are tolled for statute of limitation purposes as of the date of this Order. This tolling provision applies not only to currently filed Plaintiffs but also those Plaintiffs who in the future file a claim in the ELMIRON® Litigation and do not name as party-defendants any of the Named Bayer Defendants.

5. Plaintiffs' potential claims against the Named Bayer Defendants in any given case shall remain tolled until thirty (30) days following the date that all of Plaintiffs' claims against the Named Janssen Defendants are dismissed or are otherwise resolved provided that any new action, asserting the same or fewer claims naming the Named Bayer Defendants (subject to the limitations set forth in Section III.3 above), is filed in this Court.

6. The Named Bayer Defendants agree that they are and will continue to preserve ESI and other materials consistent with their obligations under the law, including the Federal Rules of Civil Procedure and applicable case law. The Named Bayer Defendants further agree that they will cooperate with the Named Janssen Defendants in providing all information responsive to Plaintiffs' Discovery Requests to Defendants in the possession of the Named Bayer Defendants through Rule 34 document requests without the necessity of a Rule 45

subpoena to a non-party and for such purposes remain subject to the jurisdiction of this Court with respect to such obligations notwithstanding the dismissals discussed herein.

The Clerk of the Court is hereby directed to dismiss the Named Bayer Defendants from the following served cases: (1) *Clara Johns v. ALZA Corporation, et al.*, 3:20-cv-10341-BRM-ZNQ; (2) *Elizabeth Lafave v. Teva Branded Pharmaceutical Products R&D, Inc., et al.*, 3:20-cv-12421-BRM-ZNQ; (3) *Shirley Ruth Levy v. ALZA Corporation, et al.*, 3:20-cv-10342-BRM-ZNQ.

SO ORDERED, this 15th day of October, 2020

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

Exhibit I

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

SHERYL MCCALL and DAVID MCCALL,	:	
	:	**Case Nos.**
	:	**3:20-cv-08074; 3:20-cv-12605;**
Plaintiffs,	:	**3:20-cv-07758; 3:20-cv-07756;**
	:	**3:20-cv-09530; 3:20-cv-10080;**
v.	:	**3:20-cv-07753; 3:20-cv-12328;**
	:	**3:20-cv-11913; 3:20-cv-11912;**
JANSSEN PHARMACEUTICALS, INC., *et al.,*	:	**3:20-cv-12608; 2:20-cv-07079;**
	:	**3:20-cv-11921; 3:20-cv-12421;**
	:	**3:20-cv-07750; 3:20-cv-10966;**
Defendants.	:	**3:20-cv-11919; 3:20-cv-10968;**
	:	**3:20-cv-12264; 3:20-cv-06070;**
This Document Relates to All Cases[1]	:	**3:20-cv-10960**
		JUDGE BRIAN R. MARTINOTTI
		JUDGE ZAHID N. QURAISHI

[1] The served cases are: (1) *Rebecca Anthony and Carlie Anthony v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12605-BRM-ZNQ; (2) *Lynn Brewer and William Brewer v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07758-BRM-ZNQ; (3) *Harriet Comstock v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07756-BRM-ZNQ; (4) *Sherry Dobbins and James Dobbins v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-09530-BRM-ZNQ; (5) *Carol Dubois v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10080-BRM-ZNQ; (6) *Deborah Edwards v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07753-BRM-ZNQ; (7) *Margaret Emmons v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12328-BRM-ZNQ; (8) *Marilyn J. Evans v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11913-BRM-ZNQ; (9) *Iris Groudan v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11912-BRM-ZNQ; (10) *Carol Hardy and Roger Hardy v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12608-BRM-ZNQ; (11) *Valerie Hull and Edward Hull v. Teva Branded Pharmaceuticals USA, Inc., et al.*, 2:20-cv-07079-BRM-JAD; (12) *Tiffany Kotz v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11921-BRM-ZNQ; (13) *Elizabeth Lafave v. Teva Branded Pharmaceutical Products R&D, Inc., et al.*, 3:20-cv-12421-BRM-ZNQ; (14) *Barbara Mayou and Keith Mayou v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07750-BRM-ZNQ; (15) *Sheryl McCall and David McCall v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-08074-BRM-ZNQ; (16) *Maria A. Rodgers v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10966-BRM-ZNQ; (17) *Michelle Scott v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11919-BRM-ZNQ; (18) *Heather E. Shaffer v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10968-BRM-ZNQ; (19) *Cynthia Vescio v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12264-BRM-ZNQ; (20) *Becky Worden v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-06070-BRM-ZNQ; (21) *Ronna York v. Janssen Pharmaceuticals, Inc., et al*, 3:20-cv-10960-BRM-ZNQ.

PROTECTIVE ORDER

The undersigned counsel for Defendants and Plaintiffs (collectively, the "Parties" and each, a "Party") in the above captioned action agree that the Parties and non-parties will be required to produce or disclose in this proceeding certain information and documents that are subject to confidentiality limitations on disclosure under applicable law. Such documents, described in more detail below, include information that is a trade secret or other confidential research, development, or commercial information that is proprietary in nature.

Accordingly, the defendants desire entry of an order, and the plaintiffs consent to the terms herein, pursuant to Federal Rule of Civil Procedure 26(c) to ensure that protection is afforded only to material so entitled and that will address any inadvertent production of documents or information protected from disclosure by the attorney-client privilege, work-product immunity, or other applicable privilege.

Therefore, the Parties hereby stipulate to the following negotiated terms, subject to the Court's approval, and the Court, for good cause shown and after having an opportunity to discuss this Protective Order with the Parties, hereby ORDERS that the following procedures shall be followed in this proceeding to facilitate the orderly and efficient discovery while minimizing the potential for unauthorized disclosure or use of confidential or proprietary information and documents.

1. **Scope.**

   a. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, including all copies, excerpts, or compilations

thereof, whether revealed in a document, deposition, other testimony, or discovery response, that any party to this proceeding (the "Producing Party" or "Designating Party) produces to any other party (the "Receiving Party") and that the Producing Party designates as confidential under this Protective Order.

b. This Protective Order is binding upon all Parties and their counsel in this proceeding, upon all signatories to Exhibit "A", and upon (as applicable) their respective corporate parents, subsidiaries, and affiliates, including their successors, and their respective attorneys, principals, experts, consultants, representatives, directors, officers, employees, and others as set forth in this Protective Order— and upon all signatories to Exhibit "A".

c. If additional parties are added other than parents, subsidiaries or affiliates of current parties to this litigation, their ability to receive a document protected by this Protective Order will be subject to their being bound, by agreement or Court Order, to this Protective Order.

d. Third Parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Producing Party for purposes of this Protective Order.

e. Nothing herein shall be construed as an admission or concession by any Party that designated Confidential Material, or any Document or Information derived from Confidential Material, constitutes material, relevant, or admissible evidence in this matter.

2. **Definitions.** In this Order, the terms set forth below shall have the following meanings:

a. "Proceeding" or "Action" means the above-entitled proceeding.

b. "Court" means the Honorable Judge currently assigned to this proceeding or any other judge to which this proceeding may be assigned, including Court staff participating in such proceedings.

c. "Document" or "Documents" shall have the meaning set out in the Federal Rules of Civil Procedure 34(a) and, for purposes of this order, shall include electronically stored information.

d. "Testimony" means all depositions, declarations or other pre-trial testimony taken or used in this Proceeding.

e. "Information" means the content of Documents or Testimony, as well as any matter derived therefrom or based thereon.

3. **Confidential Discovery Material.** "Confidential Discovery Material," as used herein, means information of any type, kind or character that the Producing Party believes in good faith constitutes, reflects, discloses, or contains information regarding trade secrets (as defined in the Uniform Trade Secrets Act) or other proprietary research, development, manufacturing, commercial or business information. Without prejudice to the right of a Producing Party to object to the production of the following information or of a party to seek production and/or de-designation, examples of the information that may be alleged to be subject to such designation include but are not limited to the Producing Party's:

a. Customer names.

b. Proprietary licensing, distribution, marketing, design, development, research and manufacturing information regarding products and medicines, whether previously or currently marketed or under development (not to include disseminated marketing materials or materials that, on its face, was published to the general public).

c. Personnel records.

d. Financial information not publicly filed with any federal or state regulatory authorities or not contained within any publicly available quarterly or annual reports.

e. Private medical information that identifies a person unless such identifying information is redacted.

f. Information submitted to any governmental or regulatory agency, which information is exempt from public disclosure.

g. All material, data, and information excerpted from "Confidential Material," to the extent the same are not publicly available or otherwise subject to the exclusions herein.

h. Specifically excluded from the definition of "Confidential Material" are:

Any Documents, Testimony, or Information that have been, or in the future will be, designated as "not confidential" by order of any court.

"Designating Party" means the Party or non-party that designates Documents, Testimony, or Information as Confidential Material.

"Disclose," "Disclosed" or "Disclosure" means to reveal, divulge, give, or make available Documents, Testimony, or any part thereof, or any Information contained therein.

4. **Designations of Confidential Material.**

a. Designation of Documents. A Designating Party may designate Documents as Confidential Material by placing a stamp or marking on the Documents stating the following: **CONFIDENTIAL, SUBJECT TO PROTECTIVE ORDER, PRODUCED BY [PARTY NAME] IN [NAME OF LITIGATION].** Such markings shall not obscure, alter, or interfere with the legibility of the original document. Documents designated as Confidential Material – Attorney Eyes Only prior to the entry of this Order shall be accorded the same protections, and treated identically as Confidential Material as defined in this Order.

i. All copies, duplicates, extracts, excerpts (hereinafter referred to collectively as "copies") of Confidential Material shall be marked with the same confidential stamp or marking as contained on the original, unless the original confidential stamp or marking already appears on the copies.

b. Designation of Deposition Transcripts.

i. During depositions, Confidential Material may be used or marked as exhibits, but shall remain subject to this Order and may not be shown to the witness unless such witness is a Qualified Person as describe below.

ii. If deposition Testimony or exhibits contain or refer to Confidential Material, or if they contain or refer to Documents, Testimony, or Information to be designated as Confidential Material, the Designating Party, by and through counsel, shall either:

a. On the record at the deposition, designate the Testimony or exhibit(s) as Confidential Material or, as applicable, identify already-designated Confidential Material, or

b. No later than thirty (30) days after receiving a copy of the deposition transcript, inform the deposing counsel and counsel for other Parties that the Testimony or exhibit(s) constitute Confidential Material; during the thirty-day period, the entire deposition testimony, transcript, and exhibits shall be treated as Confidential Material under this Order.

iii. When a Party designates testimony as Confidential Material during the deposition, counsel for that Party may exclude from the deposition all persons who are not Qualified Persons under this Order.

iv. When portions of a deposition transcript or its exhibits are designated for protection, each page of the transcript or exhibit pages shall be marked by the Court Reporter with the legend "**CONFIDENTIAL**."

c. Written Pleadings, Motion Papers, and Discovery Materials. A party may designate as Confidential Material portions of interrogatories and

interrogatory answers, responses to requests for admissions and the requests themselves, requests for production of documents and things and responses to such requests, pleadings, motions, affidavits, and briefs that quote, summarize, or contain Confidential Material. To the extent feasible, such Confidential Material shall be prepared in such a manner that it is bound separately from material not entitled to protection.

d. Designation of Other Confidential Material. With respect to Confidential Material produced in some form other than as described above, including, without limitation, compact discs or DVDs or other tangible items, the Designating Party must affix in a prominent place on the exterior of the container or containers in which the Information or item is stored the legend "**CONFIDENTIAL, SUBJECT TO PROTECTIVE ORDER, PRODUCED BY [PARTY NAME] IN [NAME OF LITIGATION]**". If only portions of the Information or item warrant protection, the Designating Party, to the extent practicable, shall identify the portions that constitute "Confidential Materials."

e. With respect to Documents or Information produced or disclosed by a non-party, the non-party may designate the Documents or Information as Confidential Material pursuant to this Order. A Party so designating material produced by a non-Party shall notify all other Parties within fourteen (14) days of receipt of such Document or Information that the same or portions thereof constitute or contain Confidential Material. In order to avoid disruption, this Court's management of this litigation, transfer to this Court of

any motions related to compliance with a FRCP 45 subpoena issued by this Court are encouraged pursuant to FRCP 45(f).

5. **Required Treatment of Confidential Material.**

a. Except as specifically provided in this Order, counsel shall keep all Confidential Material disclosed or produced to them within their exclusive possession and control, shall take all necessary and prudent measures to maintain the confidentiality of such materials and information, and shall not permit unauthorized dissemination of such materials to anyone.

b. Confidential Material shall not be disclosed in any way to anyone for any purpose other than as required for the preparation of trial in this action or other related actions as defined in Paragraph 10, below.

i. Nothing in this Order shall preclude a Party from introducing into evidence at an evidentiary hearing any Confidential Material that is admissible under applicable law. The Parties shall meet and confer regarding the procedures for use of Confidential Material at any evidentiary hearing and shall move the Court for entry of an appropriate order.

c. Access to and disclosure of Confidential Material shall be limited to those persons designated as Qualified Persons, below. Any Qualified Person who examines any Confidential Material shall not disseminate orally, or by any

other means, any protected information other than as permitted by this Order.

d. Confidential Material shall not be used for any business, competitive or other non-litigation purpose without the express written consent of counsel for the Designating Party or by order of the Court.

i. Nothing in this Protective Order shall limit any Designating Party's use of its own documents or shall prevent any Designating Party from disclosing its own Confidential Material to any person for any purpose. The other party may move to de-designate other confidential documents that are responsive, or contextual to documents marked confidential that have been made public by the Designating Party.

ii. Nothing herein shall prevent Plaintiffs from viewing or receiving and retaining copies of their own medical records and from disclosing such medical records to, and sharing them with, their physicians.

iii. Nothing herein shall prevent Defendants from viewing or retaining copies of medical records of Plaintiffs that are in their possession or control or from disclosing such records to other Qualified Persons, regardless of whether or not the documents have been designated as Confidential Material.

iv. Disclosures described in the above sub-paragraphs shall not affect any confidential designation made pursuant to the terms of this Protective

Order so long as the disclosure is made in a manner that is reasonably calculated to maintain the confidentiality of the designated Information, Testimony, and/or Document.

e. To avoid security risks inherent in certain current technologies and to facilitate compliance with the terms of this Order, and unless otherwise ordered or agreed upon in writing by the Designating Party whose Confidential Material is at issue, all Qualified Persons with access to Confidential Material shall comply with the following:

i. They shall use secure means to store and transmit Confidential Material.

ii. Qualified Persons may only store Confidential Material with a reputable service provider who takes reasonable and necessary steps to ensure that the service document storage method they use is secure, including use of a secure domestic document hosting facility that uses encrypted web-enabled software that allows for secure and protected sharing and collaboration and may not be accessed by individuals who are not authorized to review Confidential Material.

iii. Notwithstanding the foregoing provision, Qualified Persons, as defined in the following paragraph, shall not be prohibited from transmitting Confidential Material to any other Qualified Person through electronic mail, as attachments to an electronic mail in the form of separate PDF files or zip files, through secure tools provided by a reputable service provider as described herein, or via FTP file transfer.

6. **Qualified Persons With Respect to Confidential Material.** Confidential Material may be disclosed only to the following persons (referred to as "Qualified Persons" throughout this Order):

a. When produced by any defendant in the action: all other defendants, their inside and outside counsel and insurers (any materials provided to an insurer or its counsel shall not be used for any purpose other than evaluation of the claims asserted in this litigation and shall not be used outside the claims asserted in this litigation), as applicable, the defendants' employees, partners, members, directors, and officers, and the Plaintiffs, and their attorneys in the action.

b. When produced by Plaintiffs: all defendants (including partners, members, directors, officers, and employees of defendants) and their inside and outside counsel and insurers. Any materials provided to an insurer or its counsel shall not be used for any purpose other than evaluation of the claims asserted in this litigation and shall not be used outside the claims asserted in this litigation.

c. With respect to Qualified Persons encompassed by the preceding two paragraphs (a) and (b), such persons include the attorneys' employees and agents (*e.g.*, outside copy services, organizations involved in organizing, filing, coding, converting, storing, or retrieving data or designing programs for handling data connected with this action, including the performance of such duties in relation to a computerized litigation support system, and stenographers). Disclosure shall be limited only to those attorneys' employees

and agents who need access to Confidential Material for the purpose of litigation of this action.

d. Experts, consultants and case-specific medical professionals ("Consultants") whose assistance is necessary to assist counsel in the preparation of this Proceeding, whether or not the Consultant is designated as an expert and retained to testify, with the following qualifications:

i. Disclosure shall not be made to any consultant who, as described in Paragraph 8, is currently employed by or a paid consultant to a competitor of the Designating party and receiving payments during the course of the litigation from a competitor, and

ii. Disclosure shall not be made to any consultant if counsel for the Party retaining that consultant has actual knowledge that the consultant has been found to have violated the terms of a protective order in any litigation or legal proceeding.

e. Any expert to whom disclosure of Confidential Material is authorized must be informed of this Protective Order and must sign a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A."

f. A deponent or a witness at a deposition or pre-trial hearing:

i. If a Party wishes to disclose Confidential Material to a deponent or witness before or during a deposition or pre-trial hearing, the deponent or witness must be informed of this Protective Order and either sign a copy

of the Non-Disclosure Agreement attached hereto as Exhibit "A," or consent under oath on the record to abide by its provisions, and

ii. The Parties agree that this provision does not preclude the Designating Party from objecting to or moving to preclude disclosure to any deponent or witness.

g. A person identified in the Confidential Material as an author, source, addressee, or recipient of the communication, or who already has a copy of the Confidential Material.

h. Any mediators or arbitrators selected to assist in resolution of this matter, and their personnel who are actively engaged in assisting them.

i. The Court or any Court personnel, including any court reporters.

j. Any person mutually agreed upon among the Parties, provided that such person has been informed of this Protective Order and has signed a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A."

7. **Further Requirements With Respect to Qualified Persons.**

a. Before being given access to any Confidential Material, each Qualified Person, other than the Court, the employees and staff of the Court, counsel of record, and the direct employees of counsel of record, and other than as set forth above with respect to those witnesses to whom Confidential Material is disclosed or shown at a deposition or pre-trial hearing as set forth in

Paragraph 6(e), shall be advised of the terms of this Order, shall be given a copy of this Order, shall agree in writing to be bound by the terms of this Order by signing a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A" and shall consent to the exercise of personal jurisdiction by this Court in any proceeding(s) to determine if the signatory violated this Order. Counsel for each Party shall maintain a list of all Qualified Persons to whom they or their client(s) have provided any Confidential Material.

b. The witness who is a Qualified Person pursuant to Paragraph 6(e) but who has not signed a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A" may be shown Confidential Material during his or her testimony, but shall not be given a copy of the Confidential Material to keep. Any Confidential Material distributed or disclosed to a Qualified Person who is a signatory of Exhibit "A" shall be returned to the Party's counsel who provided it to the Qualified Person or shall be destroyed at the completion of the Qualified Person's consultation or representation in this case.

8. **Non-Disclosure to Competitors.** Notwithstanding the foregoing, without express written consent or court order, in no event shall any disclosure of a defendant's Confidential Material be made to any person who, upon reasonable and good faith inquiry, could be determined to be a current employee of a "Competitor" or a paid consultant receiving payments during the course of the litigation from a competitor. In the context of this Proceeding, a "Competitor" shall mean any manufacturer or seller of any product intended to treat interstitial cystitis or painful bladder syndrome.

9. **Challenges to Designations.**

a. The Designating Party bears the burden of establishing confidentiality.

b. Nothing in this Order shall constitute a waiver of any Party's right to object to the designation or non-designation of Documents, Testimony, or Information as Confidential Material.

c. If a Party contends that any Document, Testimony, or Information has been erroneously or improperly designated as Confidential Material, or has been improperly redacted, the material at issue shall be treated as confidential under the terms of this Order until:

i. the Parties reach a written agreement, or

ii. this Court issues an order determining that the material is not confidential and shall not be given confidential treatment.

d. In the event that counsel for a Party receiving Confidential Material in discovery objects to such designation, said counsel shall advise counsel for the Designating Party, in writing, of such objections, the specific Confidential Material (identified by Bates number, if possible) to which each objection pertains, and the reasons and support for such objections (the "Designation Objections").

e. Counsel for the Designating Party shall have 15 days from receipt of written Designation Objections pertaining up to 100 documents to meet and confer in

good faith and respond in writing as to whether the designations will be maintained or withdrawn.

f. If the Parties are unable to resolve the dispute regarding the Designation Objections, the Party challenging the designations may file a motion with the Court seeking an order to de-designate (*i.e.*, to rule to be not confidential) the Confidential Material subject to the Designation Objections (the "Designation Motion").

i. The Designating Party shall have the burden of establishing the applicability of its "confidential" designation.

10. **Use of Confidential Material in Court in Pretrial Proceedings.** The Parties will seek guidance from the Court with mutual intent to honor the protections afforded to Confidential Materials by this Order regarding a procedure for disclosing Confidential Material to the Court in pretrial proceedings.

11. **Redactions.**

a. To protect against unauthorized disclosure of Confidential Discovery Material, and to comply with all applicable state and federal laws and regulations, the Producing Party may redact from produced documents, materials and other things, the following items:

i. The names, street addresses, Social Security numbers, tax identification numbers, and other personal identifying information of patients, health care providers, and individuals in clinical studies or adverse event reports.

Other general identifying information, however, such as patient or health provider numbers, shall not be redacted unless required by state or federal law, and

ii. The Social Security numbers, tax identification numbers and other personal identifying information of employees in any records.

b. Defendants reserve the right to redact information (including but not limited to proprietary financial material and products unrelated to this litigation) that is not relevant to plaintiffs' claims.

c. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients that are not redacted shall be treated as Confidential, regardless of whether the document containing such names is designated as Confidential Material.

d. Notwithstanding any of the foregoing provisions, nothing contained herein shall be construed as a waiver of a party's ability to challenge such redactions pursuant to the procedures set forth in Section 11 herein. The burden as to the propriety of any redaction remains on the Designating Party at all times.

12. **Subpoena by Other Courts or by Agencies.**

a. If another court or an administrative agency requests, subpoenas, or orders the disclosure of Confidential Material from a Party that has obtained such material under the terms of this Order, the Party so requested, subpoenaed, or

ordered shall notify the Designating Party by electronic mail transmission, express mail, or overnight delivery to counsel of record for the Designating Party not later than ten (10) days prior to producing or disclosing any Confidential Material, and shall furnish such counsel with a copy of the requests, subpoena, or order. The recipient of the Subpoena shall not disclose any Confidential Material pursuant to the Subpoena prior to the date specified for production on the Subpoena.

b. Upon receipt of this notice, the Designating Party may, in its sole discretion and at its own cost, move to quash or limit the request, subpoena, or order, otherwise oppose the disclosure of the Confidential Material, or seek to obtain confidential treatment of such Confidential Material, to the fullest extent available under law, by the person or entity issuing the request, subpoena, or order.

13. **Disposition of Confidential Material.**

a. Upon the request of any Party after the final conclusion of this action (including without limitation any appeals and after the time for filing all appellate proceedings has passed), each Party shall destroy all Confidential Material or otherwise shall comply with an applicable order of the Court, subject to the exception described herein.

b. The destruction of Confidential Material under this paragraph shall include, without limitation, all copies, and duplicates thereof.

c. The Parties shall certify, within 60 days of receipt of a written request for certification, that all Confidential Material required to be destroyed has been so destroyed.

d. As an exception to the above requirements, and unless otherwise ordered by the Court, counsel may retain: (a) copies of pleadings or other papers that have been filed with the Court and that are Confidential Material or that reflect, reference, or contain Confidential Material; (b) their work product; and (c) transcripts and exhibits thereto. The terms and provisions of this Order shall continue to apply to any such materials retained by counsel.

14. **Order Survives Termination of Action.** After the termination of this action by entry of a final judgment or order of dismissal, the provisions of this Order shall continue to be binding. This Order is, and shall be deemed to be, an enforceable agreement between the Parties, their agents, and their attorneys. The Parties agree that the terms of this Order shall be interpreted and enforced by this Court.

15. **No Waiver of Any Privilege Upon Inadvertent Production.**

a. The Parties have agreed that, in discovery in this lawsuit, they do not intend to disclose information subject to a claim of attorney-client privilege or attorney work product protection.

i. This Order does not affect or constitute a waiver of any Party's right to withhold or redact information protected from disclosure by the attorney-

client privilege, physician-patient privilege, work product doctrine, or any other applicable privilege, protection, law, or regulation.

ii. Pursuant to Federal Rule of Evidence 502(d) and Federal Rule of Civil Procedure 26(b)(5)(B), the production or disclosure of any discovery material that a Party (the "Disclosing Party") thereafter claims should not have been produced or disclosed based on privilege or work product protections ("Inadvertently Disclosed Information"), shall not constitute or be deemed a waiver or forfeiture in whole or in part—in this or any other action— of any claim of attorney-client privilege or work product immunity that the Disclosing Party would otherwise be entitled to assert with respect to the Inadvertently Disclosed Information and its subject matter. As set forth below, such Inadvertently Disclosed material shall be returned to the Producing Party or destroyed upon request.

iii. In accordance with the requirements of applicable law or rules of procedure, and unless otherwise agreed by the Parties, with each production of documents the Producing Party shall provide a privilege log as set forth below that identifies any information or documents withheld on the basis of privilege, except for work-product prepared by or at the direction of counsel after the institution of this action for purposes of the litigation and privileged communications with counsel after the institution of this action. Within forty-five (45) days after producing documents for an agreed-upon custodian, the Producing Party shall complete its

production of documents for that custodian and provide a privilege log[2]. At that time, the Producing Party will send a letter to Plaintiffs' co-lead counsel identifying each custodian for which it believes-- to the best of the signatory's knowledge, information, and belief formed after a reasonable inquiry, pursuant to the terms of FRCP 26(g)-- it has completed its document production from data sources identified in the letter and based on the selected search terms and the ESI protocol. The letter will be signed by an attorney with first-hand knowledge of the production process for that custodian(s). The letter will be sent via email and U.S. Mail and/or Federal Express. By the terms of this paragraph, it is not the intent of the parties to limit or expand what is required of the parties by law.

b. **Attorney's Ethical Responsibilities.** Nothing in this order overrides any attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows to be privileged and to inform the Disclosing Party that such materials have been produced. Any party receiving materials that that party knows to be covered by a privilege, shall not copy, distribute, or otherwise use in any manner such materials and shall provide prompt notice of the disclosure to the Producing Party to afford the Producing Party the

[2] For any document or portion of any document the Producing Party designates as subject to a claim of privilege, immunity or work product protection that is responsive to a discovery request, the Producing Party shall supply a Privilege Log in the manner to be addressed by separate Order. If documents are produced on a rolling basis, a corresponding privilege log for all redactions or withheld documents shall be produced within forty-five (45) days of the production of documents from each wave.

opportunity to request return of the materials, in accordance with the terms of this paragraph.

c. If a Disclosing Party notifies the Receiving Party of Inadvertently Disclosed Information, the Receiving Party shall, within ten (10) court days: (i) return or destroy (or in the case of electronically stored information, delete) all copies of such information (including all notes or other work product of the Receiving Party reflecting the contents of the Inadvertently Disclosed Information) within their possession, custody, or control— and instruct experts, consultants, or others to whom the Inadvertently Disclosed Information was provided that all copies must be destroyed—and (ii) provide a certification of counsel that all such Inadvertently Disclosed Information has been returned or destroyed.

d. If the Receiving Party contests the claim of attorney-client privilege or work product protection, the Receiving Party may—within 10 business days of receipt of the notice of disclosure—move the Court for an Order compelling production of the Inadvertently Disclosed Information ("Disclosure Motion"). Such a Disclosure Motion shall be filed or lodged conditionally under seal. Pending resolution of the Disclosure Motion, the Receiving Party must not use the challenged information in any way or disclose it to any person other than those required by law to be served with a copy of the sealed Disclosure Motion. On any such Disclosure Motion, the Disclosing Party shall retain the burden of establishing its privilege or work product claims. Nothing in this

paragraph shall limit the right of any Party to petition the Court for an *in camera* review of the Inadvertently Disclosed Information.

e. **Rule 502(b)(2).** The provisions of Federal Rule of Evidence 502(b)(2) are inapplicable to the production of Protected Information under this Order.

16. **Inadvertent Production or Disclosure of Confidential Material.**

a. Inadvertent or unintentional disclosure, without the required confidentiality designation, of any Document, Testimony, or Information that the Disclosing Party intended to designate as Confidential Material ("inadvertent production") shall not be deemed a waiver in whole or in part of the producing Party's claim of confidentiality, either as to specific documents and information disclosed or as to the same or related subject matter. In the event that a Designating Party makes such an inadvertent production, that Party shall promptly inform the receiving Party or Parties in writing of the inadvertent production and the specific material at issue and promptly reproduce the Confidential Material with the required legend.

b. Upon receipt of such notice, the receiving Party or Parties shall treat the material identified in the notice as confidential; within ten court days of receiving notice of the inadvertently disclosed Confidential Material the receiving Party shall destroy all copies of such Confidential Material and instruct any parties to whom it has disclosed Confidential Material to destroy all copies of such Confidential Material.

SO ORDERED, this 17th day of September, 2020

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

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

SHERYL MCCALL and DAVID MCCALL,	:	
	:	**Case Nos.**
	:	**3:20-cv-08074; 3:20-cv-12605;**
Plaintiffs,	:	**3:20-cv-07758; 3:20-cv-07756;**
	:	**3:20-cv-09530; 3:20-cv-10080;**
v.	:	**3:20-cv-07753; 3:20-cv-12328;**
	:	**3:20-cv-11913; 3:20-cv-11912;**
JANSSEN PHARMACEUTICALS, INC., *et al.,*	:	**3:20-cv-12608; 2:20-cv-07079;**
	:	**3:20-cv-11921; 3:20-cv-12421;**
	:	**3:20-cv-07750; 3:20-cv-10966;**
Defendants.	:	**3:20-cv-11919; 3:20-cv-10968;**
	:	**3:20-cv-12264; 3:20-cv-06070;**
This Document Relates to All Cases[3]	:	**3:20-cv-10960**
		ENDORSEMENT OF PROTECTIVE ORDER

[3] (1) *Rebecca Anthony and Carlie Anthony v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12605-BRM-ZNQ; (2) *Lynn Brewer and William Brewer v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07758-BRM-ZNQ; (3) *Harriet Comstock v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07756-BRM-ZNQ; (4) *Sherry Dobbins and James Dobbins v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-09530-BRM-ZNQ; (5) *Carol Dubois v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10080-BRM-ZNQ; (6) *Deborah Edwards v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07753-BRM-ZNQ; (7) *Margaret Emmons v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12328-BRM-ZNQ; (8) *Marilyn J. Evans v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11913-BRM-ZNQ; (9) *Iris Groudan v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11912-BRM-ZNQ; (10) *Carol Hardy and Roger Hardy v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12608-BRM-ZNQ; (11) *Valerie Hull and Edward Hull v. Teva Branded Pharmaceuticals USA, Inc., et al.*, 2:20-cv-07079-BRM-JAD; (12) *Tiffany Kotz v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11921-BRM-ZNQ; (13) *Elizabeth Lafave v. Teva Branded Pharmaceutical Products R&D, Inc., et al.*, 3:20-cv-12421-BRM-ZNQ; (14) *Barbara Mayou and Keith Mayou v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-07750-BRM-ZNQ; (15) *Sheryl McCall and David McCall v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-08074-BRM-ZNQ; (16) *Maria A. Rodgers v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10966-BRM-ZNQ; (17) *Michelle Scott v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-11919-BRM-ZNQ; (18) *Heather E. Shaffer v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-10968-BRM-ZNQ; (19) *Cynthia Vescio v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-12264-BRM-ZNQ; (20) *Becky Worden v. Janssen Pharmaceuticals, Inc., et al.*, 3:20-cv-06070-BRM-ZNQ; (21) *Ronna York v. Janssen Pharmaceuticals, Inc., et al*, 3:20-cv-10960-BRM-ZNQ.

EXHIBIT A

ENDORSEMENT OF PROTECTIVE ORDER

I hereby attest to my understanding that information or documents designated as Confidential Discovery Material are provided to me subject to the Protective Order dated _____, 2020 (the "Order"), in the above-captioned litigation ("Litigation"); that I have been given a copy of and have read the Order; and, that I agree to be bound by its terms. I also understand that my execution of this Endorsement of Protective Order, indicating my agreement to be bound by the Order, is a prerequisite to my review of any information or documents designated as Confidential Discovery Material pursuant to the Order.

I further agree that I shall not disclose to others, except in accord with the Order, any Confidential Discovery Material, in any form whatsoever, and that such Confidential Discovery Material may be used only for the purposes authorized by the Order.

I further agree to return all copies of any Confidential Discovery Material or any document or thing containing Confidential Discovery Material I have received to counsel who provided them to me, or to destroy such materials, upon completion of the purpose for which they were provided and no later than the conclusion of this Litigation.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such Confidential Discovery Material will continue even after this Litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the District of New Jersey for the purposes of any proceedings relating to enforcement of the Order. I further agree to be bound by and to comply with the terms of the Order as soon as I sign this Agreement, regardless of whether the Order has been entered by the Court.

Date: _____

By: _____

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

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

MDL Docket No.: 2973

PROOF OF SERVICE

In compliance with Rule 4.1(a) of the Rules of Procedure for the United States Judicial Panel on Multidistrict Litigation, I hereby certify that a copy of Defendant Janssen Pharmaceuticals, Inc.'s Response to Motion to Transfer Actions to the District of New Jersey Pursuant To 28 U.S.C. § 1407 For Consolidated Pretrial Proceedings and Proof of Service were served on all counsel of record electronically using the JPML's CM/ECF system on October 15, 2020.

Dated this 15th day of October 2020

Respectfully Submitted,

/s/ R. Bruce Hurley
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