# UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

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

: Case No. 2:20-md-02973 (BRM)(ESK)

: MDL No. 2973

JUDGE BRIAN R. MARTINOTTI

JUDGE EDWARD S. KIEL

THIS DOCUMENT RELATES TO: ALL CASES

# CASE MANAGEMENT ORDER #1 Initial Case Management Order

These matters having been transferred to this Court by order of the Judicial Panel on Multidistrict Litigation pursuant to its order of December 15, 2020 (ECF No. 1), meriting special attention as complex litigation, the Court *sua sponte* enters the following Order:

#### 1. PREAMBLE

The Court asserts its expectation that professionalism, courtesy, and civility will endure throughout these proceedings. The Manual for Complex Litigation, Fourth (hereinafter "MCL 4th") states the spirit in this language:

Judicial involvement in managing complex litigation does not lessen the duties and responsibilities of the attorneys. To the contrary, complex litigation places greater demands on counsel in their dual roles as advocates and officers of the court. The complexity of legal and factual issues makes judges especially dependent on the assistance of counsel.

MCL 4th, *supra*, § 10.21. Counsel is further reminded of the parameters of Federal Rule of Civil Procedure 11, namely Rule 11(b) regarding representations to the Court.

#### 2. APPLICABILITY AND EFFECT

- **Applicability of Order.** Prior to the Initial Case Management Conference and entry of a comprehensive order governing all further proceedings in this case, subject to the provisions of Section 2(c), *infra*, the provisions of this Order shall govern the practice and procedure in those actions that were filed in or transferred to this Court by the Judicial Panel on Multidistrict Litigation pursuant to its order of December 15, 2020, and listed in Schedule A of that order. This Order also applies to all related cases filed in all vicinages of the District of New Jersey and will also apply to any "tag-along actions" later filed in, removed to, or transferred to this Court.
- **b.** <u>Consolidation.</u> The civil actions listed on Schedule A are consolidated for pretrial purposes. Any "tag-along actions" later filed in, removed to or transferred to this Court, or directly filed in the District of New Jersey, will automatically be consolidated with this action without the necessity of future motions or orders. This consolidation, however, does not constitute a determination that the actions should be consolidated for trial, nor does it have the effect of making any entity a party to any action in which he, she or it has not been named, served or added in accordance with the Federal Rules of Civil Procedure.
- c. <u>Prior Orders.</u> This Court was managing forty-five (45) *Elmiron* cases filed in the District of New Jersey as of December 11, 2020, and entered the following orders, which are attached hereto and incorporated herein:

<sup>&</sup>lt;sup>1</sup> The attached orders are from *McCall v. Janssen Pharmaceuticals, Inc.*, Case No. 20-8074, the first-filed case in this district. Upon the filing of new cases, but prior to the creation of the MDL, the Court posted, to the new individual dockets, all orders signed to date.

- i. Case Management Order No. 1 (Ex. 1)
- ii. Case Management Order No. 2 (Ex. 2)
- iii. Protective Order (Ex. 3)
- iv. Case Management Order No. 3 (Ex. 4)
- v. Privilege Order (Ex. 5)
- vi. Case Management Order No. 4 (Ex. 6)
- vii. Case Management Order No. 5 Regarding Dismissal of Bayer Defendants (Ex. 7)
- viii. Case Management Order No. 6 for the Production of Physically and Electronically Stored Information (Ex. 8)
- ix. Case Management Order No. 7 (Ex. 9)
- x. Case Management Order No. 8 (Ex. 10)

Counsel with cases transferred to this district are advised to review all orders previously entered by this Court.

d. <u>Extension and Stay.</u> Each defendant is granted an extension of time for responding by motion or answer to the complaint(s) until a date to be set by this Court. Pending the Initial Case Management Conference and further orders of this Court, all outstanding discovery proceedings are stayed, and no further discovery shall be initiated. All previously filed motions not directly filed to this MDL Master Docket are hereby administratively terminated. The parties shall re-file any such motions, if applicable and as necessary, as directed by the Court following the Initial Case Management Conference.

#### 3. INITIAL CASE MANAGEMENT CONFERENCE

a. Date of Initial Case Management Conference and Agenda for Conference.
 Matters relating to pretrial and discovery proceedings in these cases will be addressed at an Initial

Case Management Conference to be held on January 8, 2021, at 12:00 p.m. via Zoom² before Judge Martinotti (information to follow). Counsel are expected to familiarize themselves with the MCL 4th and be prepared at the conference to suggest procedures that will facilitate the expeditious, economical, and just resolution of this litigation, including but not limited to procedures for selecting lead counsel, liaison counsel, and chairs of certain committees and subcommittees. The items listed in MCL 4th Sections 22.6, 22.61, 22.62, and 22.63 shall, to the extent applicable, constitute a tentative agenda for the conference. Counsel shall meet and confer and seek consensus to the extent possible with respect to the items on the agenda, if not previously addressed, including but not limited to, fact sheets, a proposed discovery plan including ESI orders and protective orders, amendment of pleadings, consideration of any class action allegations and motions, the mode of trial, and any other case-management-related orders and procedures. If the parties have any suggestions as to any case management orders or additional agenda items, these shall be emailed to the Court via Chambers\_of\_Judge\_Brian\_Martinotti@njd.uscourts.gov and Chambers\_of\_Magistrate\_Judge\_Edward\_Kiel@njd.uscourts.gov on or before January 5, 2021.

**b.** Attendance.<sup>3</sup> To minimize costs and facilitate a manageable conference, counsel are encouraged, but not required, to attend the conference, and parties with similar interests are expected to agree to the extent practicable on a single attorney to act on their joint behalf at the conference. A party will not, by designating an attorney to represent its interests at the conference, be precluded from other representation during the litigation. Attendance at the conference will not waive objections to jurisdiction, venue, or service.

<sup>&</sup>lt;sup>2</sup> **PLEASE NOTE**: This MDL is being initiated in the midst of the COVID-19 pandemic. Pursuant to the Standing Orders of this Court and the CARES Act, and until further notice, all court appearances will be via video or telephone, and all court-ordered meetings should be conducted in the safest manner practicable to ensure meaningful and effective participation.

<sup>&</sup>lt;sup>3</sup> See supra n.2.

Counsel appearing at the Initial Case Management Conference, held via Zoom, shall email their appearances to Michael Zogby, Esq. at michael.zogby@faegredrinker.com, who shall collect same and provide them to the Court.

# c. <u>Preparations for Conference.</u>

- Procedures for Complex Litigation. Counsel are expected to be prepared at the conference to suggest procedures that will facilitate the just, speedy, and inexpensive resolution of this litigation.
- ii. <u>Initial Conference of Counsel</u>. Before the conference, counsel shall meet and confer by any means practicable and seek consensus to the extent possible with respect to the items on the agenda, including a proposed discovery plan and a suggested schedule for joinder of parties, amendment of pleadings, motions, and trial.
- iii. <u>List of Affiliated Companies and Counsel.</u> To assist the Court in identifying any problems of recusal or disqualification, counsel will submit with its statement under this section, by January 5, 2021, a list of all companies affiliated with the parties and all counsel associated in the litigation.
- iv. <u>List of Related Actions</u>. Counsels' statements under this Section shall include a list of all related actions pending in state or federal court and their current status, including the status of discovery, to the extent known.
- v. <u>Position Statement and Introductory Letter.</u> Plaintiffs and defendants shall submit to the Court via email<sup>4</sup> on or before January 5, 2021, a brief written

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<sup>&</sup>lt;sup>4</sup> Chambers\_of\_Judge\_Brian\_Martinotti@njd.uscourts.gov and Chambers\_of\_Magistrate\_Judge \_Edward\_Kiel@njd.uscourts.gov

statement, not more than three (3) pages, indicating their preliminary understanding of the facts involved in the litigation and the critical factual and legal issues. These statements will <u>NOT</u> be filed with the Clerk, will not be binding, will not waive claims or defenses, and may not be offered in evidence against a party in later proceedings. The parties' statements shall list: the approximate number of cases; the nature of the claims; any previously pending motions or existing deadlines; any discovery taken to date; and any discovery believed to be reasonably necessary in advance of settlement discussions. The parties shall be limited to one such submission for all plaintiffs and one such submission for all defendants.

vi. Service list. A service list will be maintained by the Clerk of the Court during the course of this litigation by adding parties/attorneys to the master docket. Any attorney who wishes to have his/her name added to or deleted from the master docket may do so upon request to the Clerk of this Court and notice to all other persons on such master docket. Parties who are not named as parties in this litigation but may later be joined as parties or who are parties in related litigation pending in other federal or state courts are invited to attend on their own behalf or through counsel. Interim liaison counsel shall present to the Court at the Initial Case Management Conference a list of attorneys and their office addresses, phone and fax numbers, and e-mail addresses.

## 4. FUTURE CASE MANAGEMENT CONFERENCES

**a.** The Court will conduct [it is anticipated these conferences will be held every 30 to

45 days], and the parties may request, periodic status, scheduling, and case management conferences to assess the progress regarding the matters scheduled herein. Reasonable notice of all such conferences will be provided to all counsel of record.

- **b.** In anticipation of all future case management conferences, liaison counsel shall email to Judge Martinotti and Judge Kiel a joint proposed agenda and updated case list no fewer than five (5) days before any scheduled conference.
- c. All conferences or parts thereof will be on the record and recorded. Anyone desiring a transcript may order one directly from Court Reporter Megan McKay-Soule via email at Megan\_McKay-Soule@njd.uscourts.gov.
- **d.** Counsel appearing at each conference shall sign an attendance sheet or otherwise submit their appearance as instructed, be familiar with the issues to be discussed, and not schedule other matters for the date and time of the conference.
- **e.** All counsel are required to comply with the provisions of each order whether or not he or she was in attendance at the conference giving rise to the order.

#### 5. MASTER DOCKET AND FILING

a. Any pleading or document which is to be filed in any of these actions shall be e-filed with the Clerk of this Court and not in the transferor court. The Clerk of this Court will maintain a master docket case file under the style "In Re: ELMIRON (PENTOSAN POLYSULFATE SODIUM) MDL No. 2973 PRODUCTS LIABILITY LITIGATION" and the identification "MDL No. 2973." When a pleading is intended to be applicable to all actions, this shall be indicated by the words: "This Document Relates to All Cases." When a pleading is intended to apply to fewer than all cases, this Court's docket number for each individual case to

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<sup>&</sup>lt;sup>5</sup> The Clerk of the Court shall continue to maintain a separate civil action number and case file for each case filed in, removed to, or transferred to this Court.

which the document number relates shall appear immediately after the words "This Document

Relates to." The following is a sample of the pleading caption style:

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

Case No. 2:20-md-02973 (BRM)(ESK)

**MDL No. 2973** 

JUDGE BRIAN R. MARTINOTTI

JUDGE EDWARD S. KIEL

THIS DOCUMENT RELATES TO:

**b.** All documents filed in this Court must be filed electronically pursuant to Local Rule

5.1 and 7.1(d), this Court's Electronic Case Filing Policies and Procedures

(http://www.njd.uscourts.gov/cmecf-policies-and-procedures), Judge Martinotti's Judicial

Preferences (http://www.njd.uscourts.gov/content/brian-martinotti), and Judge Kiel's Judicial

Preferences (https://www.njd.uscourts.gov/content/edward-s-kiel). Attorneys may register for

electronic filing at http://www.njd.uscourts.gov/cmecf-information. An attorney who, due to

exceptional circumstances, is unable to comply with the requirements of electronic filing, may

apply to the Court for an order granting an exemption. The application shall be in writing, filed

with the Clerk of Court, and shall state the reason for the attorney's inability to comply.

**c.** *Pro se* litigants who have not been authorized to file electronically shall continue

to file their pleadings and other documents with the Clerk of this Court in the traditional manner,

on paper.

**d.** When an action that properly belongs as part of *In Re: Elmiron (Pentosan* 

Polysulfate Sodium) Products Liability Litigation is hereinafter filed in the District of New Jersey

or transferred here from another court, the Clerk of this Court shall:

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- Make a docket entry on the individual docket, directing the parties to this
   Order and all prior Orders; and
- ii. Make an appropriate entry on the master docket sheet.

#### 6. APPEARANCES IN LITIGATION

Counsel who appeared in a transferor court prior to transfer need not enter an additional appearance before this Court. Moreover, attorneys (in "tag-along actions") admitted to practice and in good standing in any United States District Court are admitted *pro hac vice* in this litigation, and the requirements of Local Rules 101.1(c) are waived. Such counsel are subject to the New Jersey Rules of Professional Conduct, The Guidelines for Litigation Conduct, L.Civ.R. 103.1(c), and the disciplinary jurisdiction of this Court. Association of local counsel is not required.

#### 7. DISCOVERY

Judge Kiel shall preside over all discovery matters. In accordance with Rule 5(d) of the Federal Rules of Civil Procedure, discovery requests and responses are <u>not to be filed with the Clerk nor sent to the Judge's Chambers</u>, except when specifically ordered by the Court to the extent needed in connection with a motion.

#### 8. LIAISON COUNSEL AND STEERING COMMITTEES

a. <u>Interim Liaison Counsel.</u> This Court may be appointing, *sua sponte*, plaintiffs' attorneys as co-interim liaison counsel for the sole purpose of organizing plaintiffs' counsel in an attempt to arrive at a consent regarding plaintiffs' leadership, including liaison counsel and committees, as described below. Leadership and the committees are expected to be diverse in gender, ethnicity, geography, and experience. In the event counsel cannot agree, the Court will make appointments.

At the Initial Case Management Conference, the parties should be prepared to discuss any

additional needs for an organizational structure or any additional matters consistent with the efficient handling of this matter.

b. Liaison Counsel. Liaison counsel shall be authorized to receive orders and notices from the Court on behalf of all parties within their liaison group, and pending further orders of the Court, shall be responsible for the preparation and transmittal of copies of such orders and notices to the parties in their liaison group and perform other tasks determined by the Court. Liaison counsel shall be required to maintain complete files with copies of all documents served upon them and shall make such files available to parties within their liaison group upon request. Liaison counsel are also authorized to receive orders and notices from the Judicial Panel on Multidistrict Litigation pursuant to Rule 5.2(e) of the Panel's Rules of Procedure or from the transferee court on behalf of all parties within their liaison group and shall be responsible for the preparation and transmittal of copies of such orders and notices to the parties in their liaison group. Plaintiffs' liaison counsel shall coordinate the establishment of a document depository, real or virtual, to be available to all participating plaintiffs' counsel. The expenses incurred in performing the services of liaison counsel shall be shared equally by all members of the liaison's group in a manner agreeable to the parties or set by the Court failing such agreement.

Henceforth, interim lead counsel or liaison counsel for all parties shall meet and confer prior to the Court conferences; prepare agendas for the conferences and submit them to the Court three days before the conferences; and report at the conferences regarding the status of the case.

c. <u>Plaintiffs' Steering Committee.</u> Plaintiffs' Steering Committee ("PSC") shall conduct and coordinate the discovery stage of this litigation with the defendants' representatives or committee. The main criteria for membership in the PSC will be: (a) willingness and availability to commit to a time-consuming project; (b) ability to work cooperatively with others; and (c)

professional experience in this type of litigation (d) willingness to commit the necessary resources to pursue this matter.

The PSC will have the following responsibilities:

### **Discovery**:

- Initiate, coordinate, and conduct all pretrial discovery on behalf of plaintiffs
  in all actions which are consolidated with the instant multidistrict
  litigation.
- ii. Develop and propose to the Court schedules for the commencement, execution, and completion of all discovery on behalf of all plaintiffs.
- iii. Cause to be issued in the name of all plaintiffs the necessary discovery requests, motions, and subpoenas pertaining to any witnesses and documents needed to properly prepare for the pretrial discovery of relevant issue found in the pleadings of this litigation. Similar requests, notices, and subpoenas may be caused to be issued by the PSC upon written request by an individual attorney in order to assist him/her in the preparation of the pretrial stages of his/her client's particular claims.
- iv. Conduct all discovery in a coordinated, efficient, and consolidated manner on behalf and for the benefit of all plaintiffs. No attorney for a plaintiff may be excluded from attending the examination of witnesses and other proceedings. Such attorney may suggest questions to be posed to deponents through the designated PSC members provided that such questions are not repetitious.

### **Hearings and Meeting:**

- i. Call meetings of counsel for plaintiffs for any appropriate purpose, including coordinating responses to questions of other parties or of the Court. Initiate proposals, suggestions, schedules, or joint briefs, and any other appropriate matter(s) pertaining to pretrial proceedings.
- ii. Examine witnesses and introduce evidence at hearings on behalf of plaintiffs.
- iii. Act as spokesperson for all plaintiffs at pretrial proceedings and in response to any inquiries by the Court, subject of course to the right of any plaintiff's counsel to present non-repetitive individual or different positions.

#### Miscellaneous:

- i. Submit and argue any verbal or written motions presented to the Court on behalf of the PSC as well as oppose when necessary any motions submitted by the defendant or other parties which involve matters within the sphere of the responsibilities of the PSC.
- ii. Negotiate and enter into stipulations with Defendants regarding this litigation. All stipulations entered into by the PSC, except for strictly administrative details such as scheduling, must be submitted for Court approval and will not be binding until the Court has ratified the stipulation. Any attorney not in agreement with a non-administrative stipulation shall file with the Court a written objection thereto within ten (10) days after he/she knows or should have reasonably become aware of the stipulation.

- Failure to object within the term allowed shall be deemed a waiver and the stipulation will automatically be binding on that party.
- iii. Explore, develop, and pursue all settlement options pertaining to any claim or portion thereof of any case filed in this litigation.
- iv. Maintain adequate files of all pretrial matters and have them available, under reasonable terms and conditions, for examination by plaintiffs or their attorneys.
- v. Prepare periodic status reports summarizing the PSC's work and progress.

  These reports shall be submitted to the Plaintiffs' Liaison Counsel who will promptly distribute copies to the other plaintiffs' attorneys.
- vi. Perform any task necessary and proper for the PSC to accomplish its responsibilities as defined by the Court's orders.
- vii. Perform such other functions as may be expressly authorized by further orders of this Court.
- viii. Reimbursement for costs and/or fees for services will be set at a time and in a manner established by the Court after due notice to all counsel and after a hearing.
- **d.** <u>Defendants' Steering Committee.</u> The Court will consider at the Initial Case Management Conference the recommendations of the defendants for a procedure to form the Defendants' Steering Committee. Defendants' Steering Committee will have the duties and responsibilities described in Section 8(b) of this order as it pertains to this respective group.

# **9. MDL 2973 WEBSITE**

A website particular to MDL 2973 has been created and can be accessed by going to this

Court's website located at www.njd.uscourts.gov and clicking on "MDL/Notable Cases" and then

clicking on the link to "Elmiron MDL 2973" located under the "MDL Cases" heading. The MDL

2973 website may also be accessed directly by going to https://www.njd.uscourts.gov/elmiron-

pentosan-polysulfate-sodium-products-liability-litigation. The website will contain forms, court

orders, minute entries, a calendar of upcoming events, and other relevant information.

10. COMMUNICATION WITH THE COURT

Unless otherwise ordered by this Court, all substantive communications with the Court

shall be in writing, with copies to opposing counsel. Nevertheless, the Court recognizes that

cooperation by and among plaintiffs' counsel and by and among defendants' counsel is essential

for the orderly and expeditious resolution of this litigation. The communication of information

among and between plaintiffs' counsel and among and between defendants' counsel shall not be

deemed a waiver of the attorney-client privilege or the protection afforded attorney's work

product, and cooperative efforts contemplated above shall in no way be used against any plaintiff

by any defendant or against any defendant by any plaintiff. Nothing contained in this provision

shall be construed to limit the rights of any party or counsel to assert the attorney-client privilege

or attorney work product doctrine.

Counsel may contact ex parte, for the purpose of settlement discussions only, Judge

Martinotti via email at brian\_martinotti@njd.uscourts.gov or Judge Kiel via email at

Chambers\_of\_Magistrate\_Judge\_Edward\_Kiel@njd.uscourts.gov.

Date: December 18, 2020

/s/Brian R. Martinotti

BRIAN R. MARTINOTTI

UNITED STATES DISTRICT JUDGE

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

SHERYL MCCALL and DAVID MCCALL, 1

Case No. 3:20-cv-08074 Plaintiffs,

> JUDGE BRIAN R. MARTINOTTI JUDGE ZAHID N. QURAISHI

JANSSEN PHARMACEUTICALS, INC., et al.,

Defendants.

This Document Relates to All Cases

v.

# 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

As of August 26, 2020, 14 cases alleging products liability claims relating to use of A.

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) Valerie Hull and Edward Hull v. Janssen Pharmaceuticals, Inc., et al., 2:20-v-07079; (7) Clara Johns v. Alza Corp., et al, 3:20-cv-10341-BRM-ZNQ; (8) Shirley Ruth Levy v. Alza Corp., et al., 3:20-cv-10342-BRM-ZNQ; (9) Sheryl McCall and David McCall v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-08074-BRM-ZNQ; (10) Barbara Mayou and Keith Mayou v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-07750-BRM-ZNQ; (11) Maria Rogers v. Janssen Pharmaceuticals, Inc., et al., 3:20cv-10966; (12) Heather Shaffer v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-10968; (13) Becky Worden v. Janssen Pharmaceuticals, Inc., et al. 3:20-cv-06070-FLW-TJB; (14) Ronna York v. Janssen Pharmaceuticals, Inc., et al, 3:20-cv-10960

Elmiron have been filed in the District of New Jersey with 9 complaints having being served. Thirteen out of the 14 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 <u>28,</u> 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, 1

Plaintiffs, : Case No. 3:20-cv-08074(BRM)

υ. : JUDGE BRIAN R. MARTINOTTI

: JUDGE ZAHID N. QURAISHI

JANSSEN PHARMACEUTICALS, INC., et al.,

Defendants.

This Document Relates to All Cases :

#### **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

<sup>&</sup>lt;sup>1</sup>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) 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-cv-07079-BRM-ZNQ; (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-BRM-ZNQ; (13) Heather Shaffer v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-10968-BRM-ZNQ; (14) Becky Worden v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-06070-FLW-TJB (Wolfson, J.); (15) Ronna York v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-10960-BRM-ZNQ; (16) Iris Groudan v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-11912-BRM-ZNQ; (17) Marilyn Evans v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-11913-BRM-ZNQ; (18) Cynthia Vescio v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-12264.

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") 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 8th, 2020

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

Zou What

# 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;

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-1733; 3:20-cv-12323; : 3:20-cv-11913; 3:20-cv-11912;

JANSSEN PHARMACEUTICALS, INC., : 3:20-cv-12608; 2:20-cv-07079;

et al., : 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;

Defendants. : 3:20-cv-11919; 3:20-cv-10968; : 3:20-cv-12264; 3:20-cv-06070;

This Document Relates to All Cases<sup>1</sup> : 3:20-cv-10960

JUDGE BRIAN R. MARTINOTTI JUDGE ZAHID N. QURAISHI

<sup>1</sup> 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-ZNO; (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-ZNO; (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.
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- 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. <u>Designation of Documents</u>. 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. <u>Designation of Deposition Transcripts</u>.

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. <u>Written Pleadings, Motion Papers, and Discovery Materials</u>. 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 webenabled 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").
  - The Designating Party shall have the burden of establishing the applicability of its "confidential" designation.
- 10. <u>Use of Confidential Material in Court in Pretrial Proceedings.</u> 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:
  - 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. <u>Disposition of Confidential Material.</u>

- 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.
- 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.
  - 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<sup>2</sup>. 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

<sup>&</sup>lt;sup>2</sup> 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. <u>Inadvertent Production or Disclosure of Confidential Material.</u>

- 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  $\underline{17t}$ hday of  $\underline{\hspace{0.3cm}}$  September $\underline{\hspace{0.3cm}}$  , 2020

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

SHERYL MCCALL and DAVID :

MCCALL, : Case Nos.

: 3:20-cv-08074; 3:20-cv-12605;

Plaintiffs, : 3:20-cv-07758; 3:20-cv-07756;

2 3:20-cv-09530; 3:20-cv-10080; 2 3:20-cv-07753; 3:20-cv-12328;

: 3:20-cv-1733; 3:20-cv-12323; : 3:20-cv-11913; 3:20-cv-11912;

JANSSEN PHARMACEUTICALS, INC., : 3:20-cv-12608; 2:20-cv-07079;

et al., : 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<sup>3</sup> : 3:20-cv-10960

ENDORSEMENT OF PROTECTIVE

ORDER

<sup>3</sup> (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-ZNO; (9) Iris Groudan v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-11912-BRM-ZNO; (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 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:	 	 	

SHERYL MCCALL and DAVID : MCCALL, :

:

Plaintiffs, : Case Nos.

3:20-cv-08074; 3:20-cv-12605; 3:20-cv-07758: 3:20-cv-07756:

v. : 3:20-cv-07758; 3:20-cv-07756; : 3:20-cv-09530; 3:20-cv-10080;

JANSSEN PHARMACEUTICALS, INC., : 3:20-cv-07753; 3:20-cv-12328;

et al., : 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.

<sup>&</sup>lt;sup>1</sup> 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.

ZNO; (5) Carol Dubois v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-10080-BRM-ZNO; (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., 3:20cv-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 <u>Dana\_Sledge-Courtney@njd.uscourts.gov</u>.

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.

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Case Nos.

SHERYL MCCALL and DAVID : 3:20-cv-08074; 3:20-cv-12605; MCCALL, : 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-12008, 2:20-cv-07079, : 3:20-cv-10341; 3:20-cv-11921;

JANSSEN PHARMACEUTICALS, INC., : 3:20-cv-12421; 3:20-cv-10342;

et al., : 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<sup>1</sup> : JUDGE BRIAN R. MARTINOTTI

JUDGE ZAHID N. QURAISHI

<sup>1</sup> (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-ZNO; (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-ZNO; (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., "attorneyclient 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.

Law Mat

Case Nos.

SHERYL MCCALL and DAVID : 3:20-cv-08074; 3:20-cv-12605; MCCALL, : 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;
3:20-cv-12608; 3:20-cv-07079;

: 3:20-cv-10341; 3:20-cv-11921; JANSSEN PHARMACEUTICALS, INC., : 3:20-cv-12421; 3:20-cv-10342;

et al., : 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 JUDGE BRIAN R. MARTINOTTI

JUDGE ZAHID N. QURAISHI

<sup>&</sup>lt;sup>1</sup> 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-ZNO; (15) Shirley Ruth Levy v, ALZA Corp., et al., 3:20cv-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

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 13th2020

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

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Case Nos.

SHERYL MCCALL and DAVID : 3:20-cv-08074; 3:20-cv-12605; MCCALL, : 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; : 3:20-cv-12608; 3:20-cv-07079;

v. : 3:20-cv-12608; 3:20-cv-07079;

: 3:20-cv-10341; 3:20-cv-11921; JANSSEN PHARMACEUTICALS, INC., : 3:20-cv-12421; 3:20-cv-10342;

et al., : 3:20-cv-12421, 3:20-cv-12547;

2 3:20-cv-10966; 3:20-cv-11919; 2 3:20-cv-10968; 3:20-cv-12264; 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

<sup>1</sup> 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., 3:20cv-10342-BRM-ZNQ; (16) Barbara Mayou and Keith Mayou v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-07750-BRM-ZNO; (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<sup>2</sup> 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<sup>3</sup> 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.

<sup>&</sup>lt;sup>2</sup> All cases served and currently pending before Judge Brian Martinotti are identified in footnote 1.

<sup>&</sup>lt;sup>3</sup> 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 15thday of October, 2020

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

SHERYL MCCALL and DAVID : Case Nos.

MCCALL, : 3:20-ev-08074; 3:20-ev-12605;

: 3:20-cv-07758; 3:20-cv-07756;

*Plaintiffs*, : 3:20-cv-09530; 3:20-cv-10080;

: 3:20-cv-07753; 3:20-cv-12328; : 3:20 cv 11913; 3:20 cv 11912;

v. : 3:20-cv-11913; 3:20-cv-11912; : 3:20-cv-12608; 3:20-cv-07079;

JANSSEN PHARMACEUTICALS, INC., : 3:20-cv-10341; 3:20-cv-11921;

et al., : 3:20-cv-12421; 3:20-cv-13940;

: 3:20-cv-10342; 3:20-cv-07750;

Defendants. : 3:20-cv-12547; 3:20-cv-10966;

: 3:20-cv-11919; 3:20-cv-10968;

This Document Relates to All Cases<sup>1</sup> : 3:20-cv-12264; 3:20-cv-13596;

3:20-cv-06070; 3:20-cv-10960

JUDGE BRIAN R. MARTINOTTI JUDGE ZAHID N. QURAISHI

<sup>1</sup> 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-ZNO; (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-ZNO; (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) Velma Lehmann v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-13940-BRM-ZNQ; (16) Shirley Ruth Levy v. ALZA Corp., et al., 3:20-cv-10342-BRM-ZNO; (17) Barbara Mayou and Keith Mayou v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-07750-BRM-ZNQ; (18) Sheryl McCall and David McCall v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-08074-BRM-ZNQ; (19) Loretta Reid v. Janssen

## CASE MANAGEMENT ORDER NO. 6

## ORDER FOR THE PRODUCTION OF PHYSICALLY AND ELECTRONICALLY STORED INFORMATION

The Parties hereby agree to the following protocol for production of electronically stored information ("ESI") and paper ("Hardcopy") documents. Subject to the Protective Order entered in this action, this protocol governs all productions in the matter. This protocol has the objective to facilitate the just, and speedy completion of effective and comprehensive discovery of ESI and Hardcopy documents and to promote, whenever possible, the early resolution of disputes regarding discovery without Court intervention. Nothing in this protocol shall limit a party's right to seek or object to discovery as set out in applicable rules, to rely on any protective order entered in this action, or to object to the authenticity or admissibility of any Hardcopy document or ESI produced in accordance with this protocol except as otherwise set forth in this stipulation. The mere production of ESI as part of a mass production shall not itself constitute a waiver for any purpose.

### **DEFINITIONS**

1. "**Defendants**" means and refers to the named Defendants in the above-captioned matter, as well as any later added Defendants, as well as their directors, principals, employees, agents, and affiliated companies.

Pharmaceutical, Inc., et al., 3:20-cv-12547-BRM-ZNQ; (20) Maria A. Rodgers v. Janssen

Pharmaceuticals, Inc., et al., 3:20-cv-10966-BRM-ZNQ; (21) Michelle Scott v. Janssen

Pharmaceuticals, Inc., et al., 3:20-cv-11919-BRM-ZNQ; (22) Heather Shaffer v. Janssen

Pharmaceuticals, Inc., et al., 3:20-cv-10968-BRM-ZNQ; (23) Cynthia Vescio v. Janssen

Pharmaceuticals, Inc., et al., 3:20-cv-12264-BRM-ZNQ; (24) Deborah F. Weiner v. Janssen

Pharmaceuticals, Inc., et al., 3:20-cv-13596-BRM-ZNQ; (25) Becky Worden v. Janssen

Pharmaceuticals, Inc., et al., 3:20-cv-06070-BRM-ZNQ; (26) Ronna York v. Janssen

Pharmaceuticals, Inc., et al., 3:20-cv-10960-BRM-ZNQ.

- 2. "**Document**" is defined to be synonymous in meaning and equal in scope to the usage of this term in Rules 26 and 34 of the Federal Rules of Civil Procedure. The term "Document" shall include Hardcopy Documents, Electronic Documents, and ESI as defined herein.
- 3. "Electronic Document or Data" means Documents or Data existing in electronic form at the time of collection, including but not limited to: e-mail or other means of electronic communications, word processing files (e.g., Microsoft Word), computer presentations (e.g., PowerPoint files), spreadsheets (e.g., Excel), and image files (e.g., jpg).
- 4. "Electronically stored information" or "ESI," as used herein has the same meaning as in Federal Rules of Civil Procedure 26 and 34.
- 5. "**Hardcopy Document**" means Documents existing in paper form at the time of collection.
- 6. "Native Format" means and refers to the format of ESI in which it was generated and/or as used by the producing party in the usual course of its business and in its regularly conducted activities. For example, the Native format of an Excel workbook is a .xls or .xslx file.
- 7. "Metadata" means: (i) structured, i.e., fielded, information embedded in a Native file which describes, *inter alia*, the characteristics, origins, usage, and/or validity of the electronic file; (ii) information generated automatically by the operation of a computer or other information technology system when a Native file is created, modified, transmitted, deleted, or otherwise manipulated by a user of such system; (iii) information, such as Bates numbers, created during the course of processing documents or ESI for production; and (iv) information collected during the course of collecting documents or ESI, such as the name of the Media device, or the custodian or non-custodial data source from which it was collected.
- 8. "**Media**" means an object or device, real or virtual, including but not limited to a disc, tape, computer, or other device on which data is or was stored.
- 9. "Optical Character Recognition" or "OCR" means the process of recognizing, and creating a file containing, visible text within an image.

- 10. "Confidentiality Designation" means the legend affixed to Documents for Confidential Discovery Material as defined by, and subject to, the terms of the Protective Order in this Litigation.
- 11. "Searchable Text" means the Native text extracted from an Electronic Document and any Optical Character Recognition text ("OCR text") generated from a Hardcopy Document or electronic image.
- 12. "**Load Files**" means electronic files provided with a production set of documents and images used to load that production set into a receiving party's document review platform, and correlate its data within that platform.
- 13. "And" and "or" shall be construed conjunctively or disjunctively as necessary to make their use inclusive rather than exclusive, e.g., "and" shall be construed to mean "and/or".
- 14. "**Include**" and "**including**" shall be construed to mean "include, but not be limited to" and "including, but not limited to,".
  - 15. Reference to the singular shall also be deemed to refer to the plural, and vice-versa.
- 16. "Responsive," "Relevant" and "Discoverable" are used interchangeably and each shall be construed to encompass the broadest possible scope.

## A. GENERAL AGREEMENTS

1. Ongoing Cooperation among the Parties. The parties are aware of the importance the Court places on cooperation and commit to continue to consult and cooperate reasonably as discovery proceeds. An attorney's zealous representation of a client is not compromised by conducting discovery in a cooperative manner.

## 2. Discovery.

a. <u>Meet and Confer</u>. The Parties will meet and confer to discuss any issues arising with respect to discovery in this case. After such a meet and confer, a Party may bring any disagreements to the Court for resolution.

- b. <u>Discoverable Custodians and Non-Custodial Data Sources</u>. Within thirty (30) days from entry of this Order, or, for a Defendant served after the entry of this Order, within thirty (30) days from entry of an appearance in this litigation, each Defendant shall identify and describe all custodial and non-custodial data sources which Defendant reasonably believes contain responsive information.
  - (1) Custodians shall be identified by name, current or last-known title, dates of employment by the Party, and a brief description of current or last-known employment duties. Absent a showing of good cause, and subject to any further agreement among the Parties, the list(s) provided pursuant to this paragraph shall be the presumptive limit on ESI discovery. If any identified custodian or data source is located outside the United States, the Parties shall meet and confer regarding such matters as relevancy and privacy of the data at issue and, as applicable, the timing of production of any such data.
  - (2) Plaintiffs reserve the right to request, at any time prior to the close of discovery, inclusion of additional custodians or non-custodial data sources whose relevance was discovered after the initial designations, or for other reasonable cause shown. If the Defendants object to the inclusion of such non-custodial or custodial sources, the Parties will meet and confer to resolve the matter; if the Parties cannot reach resolution, the Court or its designee will determine the matter.
  - (3) Documents and ESI from identified custodial and non-custodial data sources will be preserved pending identification of data to be produced into this litigation consistent with obligations pursuant to applicable laws and rules.

- (4) Defendants have a continuing obligation to identify any other custodial and non-custodial data sources that may contain information relevant to this litigation, and preserve them consistent with obligations pursuant to applicable laws and rules.
- c. <u>Discovery Concerning Preservation and Collection Efforts</u>. If there is a reasonable dispute concerning the scope of a party's preservation or collection efforts, before discovery about such efforts is initiated, the Parties or their counsel shall meet and confer to address the specific stated need for such discovery, its relevance to claims and defenses, and the availability and suitability of alternative, less burdensome means to obtain the information.
- d. On-Site Inspections of ESI. On-site inspections of ESI under Rule 34(b) shall be permitted, if at all, only upon a good faith showing by the Requesting Party of good cause and specific need or upon agreement of the Parties. As appropriate, the Court may condition on-site inspections of ESI, as authorized in the preceding sentence, to be performed by independent third-party experts, and the Court may set other conditions deemed appropriate.
- e. <u>Non-Discoverable ESI</u>. Absent a Party's specific written notice for good cause, the following categories of ESI are presumed to be inaccessible and not discoverable:
  - (1) ESI deleted in the normal course of business before the time a preservation obligation came into effect;
  - (2) Backup data files that are maintained in the normal course of business for purposes of disaster recovery, including (but not limited to) backup tapes, disks, SAN, and other forms of Media, and that are duplicative of data more accessible elsewhere;
  - (3) Deleted, "slack," fragmented, or unallocated data only accessible by forensics;

- (4) Random access memory (RAM), temporary files, or other ephemeral data that are difficult to preserve without disabling the operating system;
- (5) On-line access data such as (without limitation) temporary internet files, history files, cache files, and cookies;
- (6) Data in Metadata fields frequently updated automatically, such as last-opened or last-printed dates;
- (7) Electronic data (*e.g.*, call logs, email, calendars, contact data, notes, *etc.*) sent to or from mobile devices (*e.g.*, iPhone, iPad, Android, and Blackberry devices), if a copy of such electronic data is saved elsewhere (such as on a server, laptop, desktop computer, or "cloud" storage);
- (8) Voicemail, including Telephone or VOIP voice messages kept on a cell phone, tablet, or other portable device;
- (9) Text messages and instant messages not retained in the ordinary course of business;
- (10) Server, system, network, or software application logs;
- (11) Electronic data temporarily stored by laboratory equipment or attached electronic equipment, provided that such data is not ordinarily preserved as part of a laboratory report, including any report relating to statistical analysis;
- (12) Software files included on the National Institute of Standards and Technology

  (NIST) Modern RDS (minimal) list obtained from https://www.nist.gov/itl/ssd/software-quality-group/national-software-reference-library-nsrl/nsrl-download/current-rds;

- (13) Structural files not material to individual file contents (e.g. .CSS, .XSL, .DTD,) unless such files contain substantive data (for example when used for data storage or transmission);
- (14) Operating System files that do not store substantive content (e.g. CAT, DLL, DMP, EXE, FON, PNF, OPS, SYS.);
- (15) Application source code, configuration, and other similar files necessary for the function of an application that do not store user-created content during ordinary use (*E.g.* BAK, BIN, CFG, DBF, DAT, JS, JAR, LUA, MSB, RES, WINNT, YTR), and are not user-created programs (for example SAS programs).
- f. <u>Disaster-Recovery Backup Data</u>. Absent a Party's specific written notice for good cause, no Party shall be required to modify or suspend procedures, including rotation of backup Media, used in the normal course of business to back up data and systems for disaster recovery purposes. Absent a showing of good cause, such backup Media shall be considered to be not reasonably accessible. Notwithstanding anything contained herein to the contrary, before any non-duplicative, discoverable data that Defendants have a reasonable and good faith belief would potentially contain responsive information is erased, overwritten, destroyed or otherwise made unavailable or unusable, the Defendants will identify in sufficient detail what potentially relevant data is on such Media and which is no longer available on other systems or other Media.
- 3. Procedures for redactions and for the handling of materials subject to claims of attorneyclient privilege, work-product, and privacy shall be set out in the Protective Order to be entered in this action.

#### B. <u>ELECTRONICALLY STORED INFORMATION</u>

- 1. Production in Reasonably Usable Form.
  - a. The Parties shall produce electronically stored information in a reasonably usable form. Except as stated in Paragraphs B.2 and B.3 below or as agreed hereafter by the Parties, such reasonably usable form shall be the single-page TIFF-image format with extracted text to the extent available or OCR text if extracted text is not available, and associated Metadata set out in Attachment A, which is incorporated in full in this protocol ("TIFF-Plus format"). If the Receiving Party seeks production in Native format of specifically identified ESI produced originally in TIFF-Plus format, the Producing Party shall respond reasonably and in good faith to any such request. Procedures for production of a Native file in response to any such request are set out in Attachment A, Paragraph A.25.b.
  - b. All documents containing color which are produced in native format shall be produced in color. PDFs and PowerPoints shall be produced in color. To the extent a document produced in TIFF or TIFF-*Plus* format is illegible, unable to be properly evaluated, or otherwise unacceptable due to the fact that it was produced in black and white rather than color, the Parties shall meet and confer concerning a supplemental production of that document in color.
  - c. If electronically stored information discoverable in this proceeding was previously produced in another legal proceeding, the Parties shall meet and confer to discuss the proposed format of any production of that ESI in this proceeding, and the particulars of how the information was collected and identified.

- 2. <u>Native Files</u>. Electronic spreadsheets (*e.g.*, Excel), electronic presentations (*e.g.*, PowerPoint), word processing files with tracked changes, comments, or hidden text (*e.g.*, Word), desktop databases (*e.g.*, Access), Portable Document Format files ("PDF") (including IND and NDA files), and audio/video multimedia files shall be produced in Native format as described in Paragraph A.25.a of Attachment A. If a native document type referenced herein requires redactions it can be produced in TIFF-*Plus* format.
- 3. Enterprise Databases, Database Management Systems, and Other Structured Data ("Structured Data Systems"). The Parties will meet and confer to address the production and production format of any responsive data contained in a database or other structured or aggregated data source or otherwise maintained by an application. The Parties will cooperate in the exchange of information concerning such databases and data sources to facilitate discussions on productions and production format.
- 4. <u>Use of Native Files in Proceedings in the Case</u>. The Parties shall meet and confer to address any issues concerning the use of Native files in proceedings in the Case. Such discussions may address issues including printing, the use or nonuse of slip-sheets, alterations of Native files to facilitate their use with a witness or to use as an exhibit, including hiding columns or rows that contain no information or information not relevant to the columns presented and not otherwise reasonably relevant for context, the use of reports or summaries created from Native file data, and timing for objections to admissibility of Natives used in proceedings.
- Technology and Methodology for the Collection and Identification of Defendant's ESI for Production.

- a. The Parties shall meet and confer to address the method(s) the Defendants will use relating to the collection and production of responsive documents, including consideration of the best methods available given the various locations and formats of potentially relevant and responsive documents that may be collected. Methods to be considered during such discussions may include the use of reasonable search term filters, file types, and date ranges or the use of advanced search and retrieval technologies, including predictive coding or other technology-assisted review ("TAR"). If there are any issues that cannot be resolved regarding search and retrieval methods, the Parties shall bring any disputes to the attention of the Court. In any such discussion,
  - (1) After the Parties have agreed upon collection and identification methods, and only if a party believes in good faith that use of the disclosed methods would result in deficiencies in production, the Parties will work collaboratively on any revisions to such methods, on the understanding that this may be an iterative process.
  - (2) Nothing in this Order shall be deemed to be a waiver of any right or responsibility of the Producing Party to manage and control searches of its data files, including the right, upon notice to the Receiving Party, to make good-faith revisions to search filters. Once search and retrieval methods have been agreed to or otherwise ordered by the Court, if changes to such methods are deemed necessary by the Producing Party the Producing Party will so notify the Requesting Party and the Parties shall meet and confer regarding the revisions if the Requesting Party does not agree to them.

- (3) The technology and methodology the Parties agree to use to identify and classify potentially responsive documents in connection with Defendants' production may be jointly set out in a separate, formal protocol agreed upon by the Parties.
- b. The fact that any electronic file has been identified in an agreed-upon collection and identification method shall not prevent any Party, after attorney review on good-faith basis, from withholding such file from production on the grounds that the file is not responsive, that it is protected from disclosure by applicable privilege or immunity, that it is governed by any applicable privacy law or regulation, that it contains proprietary non-responsive information, or that the Protective Order entered in this Action allows the file to be withheld.
- c. Nothing in this section shall limit a Party's right reasonably to seek agreement from the other Parties or a court ruling to modify previously agreed-upon collection and identification methodology.
- 6. <u>Plaintiffs' Identification and Classification of Documents and ESI</u>. The Parties shall meet and confer with respect to the identification and classification of Plaintiffs' documents and ESI.
- 7. <u>Discrete Document Collections</u>. Identified discrete document collections, such as, by way of example only, documents submitted to and exchanged with FDA, shall be produced in their entirety without regard to whether or not each document in the collection has been identified as possibly responsive, or deemed to be or classified as, responsive, or, if search terms are used, contains a search term, except that privileged documents in such a

collection may be withheld and listed in a privilege log as specified elsewhere in this proceeding.

- a. Adverse events of interest: To the extent a relevant, responsive clinical adverse event report is produced by Defendants and identified by Plaintiffs as an adverse event of interest, the Parties agree to meet and confer concerning production of full backup files associated with that particular adverse event.
- 8. <u>Documents with Insufficient Text</u>. Documents that are reasonably believed to be responsive and for which text-based search technologies may be ineffective, such as images, spreadsheets, etc., must be reviewed without culling by search terms, predictive coding, or other technologies that rely primarily on text.
- 9. <u>Known Responsive Materials Must Be Produced</u>. Documents and ESI known to Defendants to be non-privileged and responsive to a discovery request and/or relevant to the litigation shall be produced without regard to the collection and identification methods agreed upon by the Parties unless a good faith objection has been made, including, but not limited to, that production of such materials would be unreasonably burdensome, in which case, the parties shall meet and confer and raise any disputes with the Court.
- 10. <u>Email Threading</u>. The Parties shall meet and confer to address the use of email threading in the Case.
- 11. Avoidance of Duplicate Production.
  - a. "Duplicate ESI" means files that are exact duplicates based on the files' MD5 or SHA-1 hash values. The Producing Party need produce only a single copy of responsive

Duplicate ESI. A Producing Party shall take reasonable steps to de-duplicate ESI globally (*i.e.*, both within a particular custodian's files and across all custodians). Entire document families may constitute Duplicate ESI. De-duplication shall not break apart families. When the same Duplicate ESI exists in the files of multiple custodians, the additional custodians shall be listed in the OTHER\_CUSTODIANS field identified in Paragraph A.24(c) of Attachment A.

b. If the Producing Party makes supplemental productions following an initial production, that Party also shall provide with each supplemental production an overlay file to allow the Receiving Party to update the OTHER\_CUSTODIANS field. The overlay file shall include both all custodians listed in the OTHER\_CUSTODIANS field in prior productions and any custodians newly identified in the current supplemental production.

## C. DOCUMENTS THAT EXIST ONLY IN HARDCOPY (PAPER) FORM

<u>Hardcopy Document Production</u>. Hardcopy documents shall be scanned and produced in TIFF image format as set forth in Attachment A.

#### D. INFORMATION NOT ADDRESSED IN THIS STIPULATION

To expedite discovery of relevant evidence, the Parties will discuss and attempt in good faith to resolve all issues involving information not addressed in this Stipulation for the Production of Physically and Electronically Stored Information before bringing these issues to the Court.

#### E. NO WAIVER

By complying with this Stipulation for the Production of Physically and Electronically Stored Information, no Party waives any objection to the production of the documents, tangible items or things, and ESI that is preserved.

# F. <u>ALTERNATE FORMATS</u>

Notwithstanding the Parties' stipulations herein, upon reasonable request made by the Receiving Party, the Parties shall confer regarding the production in an alternate format of a document previously produced in accordance with this Order.

## G. LIMITATIONS AND NON-WAIVER

This protocol provides a general framework for the production of ESI and paper documents on a going forward basis. The Parties and their attorneys do not intend by this protocol to waive their rights to the attorney-client or work-product privileges, and any such waiver shall be strictly and narrowly construed and shall not extend to other matters or information not specifically described herein.

# H. GENERAL PROVISIONS

- 1. Any practice or procedure set forth herein may be varied by agreement of the Parties, and first will be confirmed in writing, where such variance is deemed appropriate to facilitate the timely and economical exchange of electronic data or other covered discovery materials.
- 2. Should any Party subsequently determine in good faith that it cannot proceed as required by this Order or that the order requires modification, the Parties will meet and confer to resolve any dispute before seeking Court intervention.
- 3. The Parties agree that e-discovery will be conducted in phases and the Parties will meet and confer regarding discovery of data sources not listed herein.

	4.	Regardless of the foregoing, the Parties retain the obligation to produce, or log for
privi	lege, all	responsive documents of which they are aware consistent with obligations pursuant
to ap	plicable	laws and rules.

SO ORDERED, this 19th day of October, 2020

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

Brukht

# **Attachment A**

- A.1. <u>Image Files</u>. Files produced in \*.tif format will be single page black and white \*.tif images at 300 DPI, Group IV compression. To the extent possible, original orientation will be maintained (i.e., portrait-to-portrait and landscape-to-landscape). Each \*.tif image will be assigned a unique name matching the production number of the corresponding page. Such files will be grouped in folders of no more than 1,000 \*.tif files each unless necessary to prevent a file from splitting across folders. If a file, *e.g.*, a PDF file, exceeds 500 \*.tif images, the producing party may produce the file Natively rather than in \*.tif format. Files will not be split across folders and separate folders will not be created for each file. Production ("Bates") numbers shall be endorsed on the lower right corner of all images. This number shall be a unique, consistently formatted identifier that will:
  - (i) be consistent across the production;
  - (ii) contain no special characters or spaces; and
  - (iii) be numerically sequential within a given file.

Bates numbers should be a combination of an alpha prefix along with an 8-digit number (e.g. ABC0000001). The number of digits in the numeric portion of the Bates number format should not change in subsequent productions. Confidentiality Designations, if any, will be endorsed on the lower left corner of all images and shall not obscure any portion of the original file.

- A.2. <u>TIFFs of Redacted ESI</u>. TIFFs of redacted ESI shall include all non-redacted elements and formatting which are visible in its Native application, and each redacted area must bear a label containing the reason for the redaction. Parties will meet and confer to the extent there is a request for alternative views of documents.
- A.3. <u>Date Fields Time Zone</u>. All documents shall be processed so as to show fielded dates and times in UTC.

- A.4. Exception Files. The Parties will use reasonable efforts and standard industry practices to address Documents that present imaging or form production problems (including encrypted and/or protected files identified during the processing of ESI) ("Exception Files"). The Parties will meet and confer regarding procedures that will be used to identify, access, and process Exception Files. If the Parties cannot reach agreement on the handling of Exception Files through the meet and confer process, the matter may be submitted to the Court for determination.
- A.5. Native File Identification. A producing party may provide a Bates-stamped placeholder TIFF, bearing the legend "This document has been produced in Native format" for ESI produced in Native format; these placeholders will be Bates numbered in the same way as any other TIFF, and the Bates number of that single page shall be used as the BegBates and EndBates of the associated document. Otherwise, the Native document shall be provided a Single Bates number that will be used as the BegBates and EndBates of the associated document. If no placeholder page has been provided, a party using the document in court proceedings, depositions, or trial, shall either create and attach a placeholder page as described above, or shall stamp the Bates number in the border of the Native document.
- A.6. <u>File Text</u>. Except where a file's full text cannot be extracted (*e.g.*, when a file has been redacted under assertion of privilege or other protection from disclosure), full text will be provided in the format of a single \*.txt file for each file (*i.e.*, not one \*.txt file per \*.tif image). Where ESI contains text that cannot be extracted, the available \*.tif image will be OCR'd or, as applicable, the redacted Native file will have its text re-extracted, and file-level text will be provided. Searchable Text will be produced as single file UTF-8 text files with the text file named to match the beginning production number of the file. The full path of the text file must be provided in the \*.dat data Load File.

- A.7. <u>Text Extracted from Emails</u>. Text extracted from emails shall include all header information that would be visible if the email was viewed in Outlook including: (1) the individuals to whom the communication was directed ("To"), (2) the author of the email communication ("From"), (3) who was copied and blind copied on such email ("CC" and "BCC"), (4) the subject line of the email ("RE" or "Subject"), (5) the date and time of the email, and (6) the names of any attachments.
- A.8. OCR software should be set to the highest quality setting during processing. Documents containing foreign language text shall be OCR'ed using the appropriate settings for that language, e.g., OCR of German documents will use settings that properly capture umlauts. Settings such as "auto-skewing" and "auto-rotation" should be turned on during the OCR process.
- A.9. <u>De-NISTing</u>. Electronic files will be De-NISTed, removing commercially available operating system and application file information contained on the current NIST file list.
- A.10. <u>Lost, Destroyed or Irretrievable ESI</u>. If a Defendant learns that responsive ESI that once existed was lost, destroyed, or is no longer retrievable as a result of acts or circumstances not occurring in the ordinary course of business, the Defendant shall comply with its obligations under the Federal Rules of Civil Procedure to explain where and when the responsive ESI was last retrievable in its original format and to disclose the circumstances surrounding the change in status of that responsive ESI, whether that information is available from other sources, and whether any backup or copy of such original responsive ESI exists. Nothing in this paragraph is intended to expand or limit the obligations under the Federal Rules of Civil Procedure.
- A.11. <u>Proprietary Software</u>. To the extent that relevant ESI cannot be rendered or reviewed without the use of proprietary software, the Parties shall meet and confer to minimize any expense

or burden associated with the production of such documents in an acceptable format, including issues as may arise with respect to obtaining access to any such software and operating manuals.

A.12. Redactions. Redactions shall be made consistent with the Protective Order in this Action. For redacted items which were originally ESI, all Metadata fields required herein will be provided and will include all non-redacted data consistent with the Protective Order and Privilege Order in this litigation. Redacted documents shall be identified as such in the Load File provided with the production. A document's status as redacted does not relieve the producing party from providing all of the Metadata required herein.

A.13. <u>Word Processing Files</u>. If word processing files, including without limitation Microsoft Word files (\*.doc and \*.docx), are produced in \*.tif image format, such \*.tif images will display all content and data visible in any view in the Native application, including tracked changes, comments, and hidden text.

A.14. <u>Presentation Files</u>. If presentation files, including without limitation Microsoft PowerPoint files (\*.ppt and \*.pptx), are produced in \*.tif image format, such \*.tif images will display all content and data visible in any view in the Native application, including comments, hidden slides, speakers' notes, and similar data in such files.

A.15. <u>Spreadsheet or Worksheet Files</u>. If spreadsheet files, including without limitation Microsoft Excel files (\*.xls or \*.xlsx), are produced in \*.tif image format, such \*.tif images will display all content and data visible in any view in the Native application including hidden rows, columns, and worksheets, if any, in such files.

A.16. <u>Parent-Child Relationships</u>. Parent-child relationships (*e.g.*, the associations between emails and their attachments) will be preserved. Email and other ESI attachments will be produced

as independent files immediately following the parent email or ESI record. Parent-child relationships will be identified in the data Load File pursuant to Paragraph A.24 below.

- A.17. <u>Family Groups</u>. A document and all other documents in its attachment range, emails with attachments, and files with substantive extracted embedded OLE documents all constitute family groups. If any member of a family group is produced, all members of that group must also be produced, or, if privileged, so logged, except as set forth in Paragraph A. 20 below.
- A.18. <u>Dynamic Fields</u>. Files containing dynamic fields such as file names, dates, and times will be produced showing the field type (e.g., "[FILENAME]" or "[AUTODATE]"), rather than the values for such fields existing at the time the file is processed.
- A.19. <u>Foreign Language</u>. Hardcopy documents and ESI that contains languages other than English, in whole or in part, shall be produced in the original language(s), along with all existing translations of the Searchable Text to the extent maintained in the ordinary course of business and reasonably available.
- A.20. Embedded Objects. Some Microsoft Office and .RTF files may contain embedded objects. Such objects typically are the following file types: Microsoft Excel, Word, PowerPoint, Project, Outlook, and Access; and PDF. Subject to claims of privilege, as applicable, objects with those identified file types shall be extracted as separate files and shall be produced as attachments to the file in which they were embedded. If the file with the embedded object is produced in native format, the embedded object need not be extracted. Images embedded in emails may not be produced separately as attachments.
- A.21. <u>Compressed Files</u>. Compressed file types (i.e., .CAB, .GZ, .TAR. .Z, .ZIP) shall be decompressed in a reiterative manner to ensure that a zip within a zip is decompressed into the lowest possible compression resulting in individual files.

- A.22. <u>Scanned Hardcopy Documents</u>. Hardcopy documents shall be scanned and produced in TIFF image format. In scanning and production of Hardcopy documents:
  - a. Documents are to be produced as they were kept. For documents found in folders or other containers with labels, tabs, indexes or other identifying information, such indexes, labels and tabs shall be scanned. Pages with Post-It notes shall be scanned both with and without the Post-it, with the image of the page with the Post-it preceding the image of the page without the Post-It.
  - b. Defendants will use best efforts to unitize documents (*i.e.*, distinct documents should not be merged into a single record, and a single document should not be split into multiple records) and maintain document relationships, *i.e.*, attachment status.
  - c. In the case of an organized compilation of separate Hardcopy documents—for example, a binder containing several separate documents behind numbered tabs—the document behind each tab should be scanned separately, but the relationship among the documents in the binder should be reflected in proper coding of the family fields set out below.
  - document level and provided in document-level \*.txt files named to match the production number of the first page of the document to which the OCR text corresponds. OCR text should not be delivered in the data load file or any other delimited text file. OCR software must be set to the highest quality setting for any previously-unscanned paper documents and reasonable quality control measures shall be used to ensure that the integrity of scanned copies of previously unscanned paper documents are preserved for OCR (e.g., pages are not angled or skewed, text

is not blurred or obscured, etc.). Settings such as "auto-deskewing" and "auto-rotation" must be turned on during the OCR process to maximize text recognition on any given page. Documents containing foreign language text must be OCR'ed using the appropriate settings for that language, (*e.g.*, OCR of German documents must use settings that properly capture umlauts).

- e. To the extent objective non-privileged metadata as set forth in A.24.c was created as part of the collection, processing, scanning, and/or production of hardcopy documents, such metadata shall be provided to Plaintiffs at the time of production.
- A.23. <u>Production Numbering</u>. The Producing Party shall take reasonable steps to ensure that attachments to documents or electronic files are assigned production numbers that directly follow the production numbers on the documents or files to which they were attached.

# A.24. Data and Image Load Files

a. <u>Load Files Required</u>. Unless otherwise agreed, each production will include a data

Load File in Concordance (\*.dat) format and an image Load File in Opticon (\*.opt)

format.

#### b. Load File Formats.

- Load File names should contain the volume name of the production media.
   Additional descriptive information may be provided after the volume name.
   For example, both ABC001.dat or ABC001\_metadata.dat would be acceptable.
- ii. Unless other delimiters are specified, any fielded data provided in a Load

  File should use Concordance default delimiters. Semicolon (;) should be
  used as multi-entry separator.

- iii. Any delimited text file containing fielded data should contain in the first line a list of the fields provided in the order in which they are organized in the file.
- c. Fields to be Included in Data Load File. For all documents or electronic files identified as relevant, not privileged, and produced, the following Metadata fields for each document or electronic file, if available at the time of collection and processing and unless such Metadata fields are protected from disclosure by attorney-client privilege or work-product immunity or otherwise prohibited from disclosure by law or regulation, will be provided in the data Load File pursuant to subparagraph (a). The term "Scanned Docs" refers to documents that are in Hardcopy form at the time of collection and have been scanned into \*.tif images. The term "Email and E-Docs" refers to files that are in electronic form at the time of their collection, irrespective of the form (TIFF-Plus or Native format) in which they are produced.

	Sample		Email and E-	
Field	Data	<b>Scanned Docs</b>	Docs	Comment
PRODBEG	ABC00000	Yes	Yes	Beginning production
[Key Value]	001			number
PRODEND	ABC00000	Yes	Yes	Ending production
	008			number
PRODBEGATT	ABC00000	Yes	Yes	Beginning production
	009			number of parent in a
				family
PRODENDATT	ABC00001	Yes	Yes	Ending production
	005			number of last page of
				the last attachment in a
				family
CUSTODIAN	Smith, John	Yes	Yes	Custodian who
				possessed the document
				or electronic file

	Sample		Email and E-	
Field	Data	<b>Scanned Docs</b>	Docs	Comment
OTHER_CUSTO DIANS	Doe, Jane; Jones, James	N/A	Yes	When global de- duplication is used, these are custodians whose file has been de- duplicated; multiple custodians separated by semicolons
NATIVEFILE	Natives\ 001\001\ ABC 00000001.x	N/A	Yes	Path and file name for Native file on production media
FILEDESC	Microsoft Office 2007 Document	N/A	Yes	Description of the type file for the produced record
FOLDER	\My Documents\ Document1 .doc	N/A	Yes	Original source folder for the record produced
FILENAME	Document1 .doc	N/A	Yes	Name of original electronic file as collected
DOCEXT	DOC	N/A	Yes	File extension for email or e-doc
PAGES	2	Yes	Yes	Number of pages in the produced document or electronic file (not applicable to Native file productions)
AUTHOR	John Smith	Yes	Yes	Author information as derived from the properties of the document
DATECREATED	10/09/2005	Yes	Yes	Date on which non- email file was created as extracted from file system Metadata or bib coding
DATELASTMOD	10/09/2005	N/A	Yes	Last date on which non- email file was modified as extracted from file system Metadata

	Sample		Email and E-	
Field	Data	<b>Scanned Docs</b>	Docs	Comment
SUBJECT	Changes to	Yes	Yes	"Subject" field
	Access			extracted from email
	Database			message or Metadata
				properties of the
				document or Title as bib
EDOM	T 1 D 1	***	37	coded
FROM	John Beech	Yes	Yes	"From" field extracted
				from email message or as bib coded
TO	Janice	Yes	Yes	"To" field extracted
	Birch			from email message or
				as bib coded
CC	Frank	Yes	Yes	"Cc" or "carbon copy"
	Maple			field extracted from
				email message or as bib
				coded
BCC	John	Yes	Yes	"Bcc" or "blind carbon
	Oakwood			copy" field extracted
				from email message or
				as bib coded
DATESENT	10/10/2005	N/A	Yes	Sent date of email
				message (mm/dd/yyyy
				format)
TIMESENT	10:33 am	N/A	Yes	Sent time of email
				message, time zone set
				to GMT
DATERCVD	10/10/2005	N/A	Yes	Received date of email
				message (mm/dd/yyyy
				format)
TIMERCVD	10:33 am	N/A	Yes	Received time of email
				message, time zone set
		27/1		to GMT
ALL_PARTICIPA	John Beech,	N/A	Yes	For emails only; lists all
NTS	Janice			participants in lesser-
	Birch,			included emails that,
	Frank			without ====email
	Maple			threading, would have
CONFIDENCIAL	IIIOIII V	37	37	been subject to review
CONFIDENTIAL	HIGHLY	Yes	Yes	Text of Confidentiality
ITY	CONFIDE			Designation, if any
	NTIAL			

TEXTPATH		Sample		Email and E-	
O01\  ABC00000   O01.txt   Containing extracted or OCR text	Field	Data	<b>Scanned Docs</b>	Docs	Comment
ABC00000	TEXTPATH	Text\001\	Yes	Yes	
Oil		,			_
FILE_PRODUCE D_IN_NATIVE_ AND_TIFF					OCR text
D_IN_NATIVE_ AND_TIFF					
AND_TIFF   Support	_	Yes	N/A	YES	
MD5_HASH   309997447f   N/A   Yes   MD5_Hash value for ESI					
PRODVOL VOL001 Yes Yes Name of the Production Volume  CREATEDBY John Smith NA Yes Who the document was created by  DUPELOCATIO My N/A Yes Filepaths of all duplicates  Document documents Documents Document document attached to a document Attachment Count 1 N/A Yes File Name of all attachments  Attachment Names Document N/A Yes File Name of all attachments  LastModifiedBy John Smith N/A Yes File Name of all attachments  Redacted Y/N Yes Yes Identifies documents with redactions  Redaction Reason Privacy Yes Yes Identifies the type of redaction  ConversationID 309997447f N/A Yes  HASREVISIONS Yes N/A Yes  HASHIDDENTE XT  HASHIDDENSLI Yes N/A Yes  HASSPEAKERN Yes N/A Yes					
PRODVOL VOL001 Yes Yes Name of the Production Volume  CREATEDBY John Smith NA Yes Who the document was created by  DUPELOCATIO NS Documents, Document doc; VDesktop\Documents, Document l. doc; VDesktop\Documents, Document l. doc  FILEPATH NMY Documents, Document l. doc  Attachment Count 1 N/A Yes Path to collection source  Attachment Names Document l. doc  LastModifiedBy John Smith N/A Yes File Name of all attachments  LastModifiedBy John Smith N/A Yes Identifies document was created by  N/A Yes File Name of all attachments  Last were to modify document lidentifies documents with redactions  Redacted Y/N Yes Yes Identifies the type of redaction  Redaction Reason Privacy Yes Yes Identifies the type of redaction  ConversationID 309997447f N/A Yes  HASREVISIONS Yes N/A Yes  HASHIDDENTE XT  HASHIDDENSLI Yes N/A Yes  HASSPEAKERN Yes N/A Yes  HASSPEAKERN Yes N/A Yes  HASSPEAKERN Yes N/A Yes	MD5_HASH	309997447f	N/A	Yes	
CREATEDBY John Smith NA Yes Who the document was created by DUPELOCATIO   My   Documents   Documents   Document   doc;   Desktop\Documents   Documents   Documents   Documents   Document   doc;   Documents   Document   doc   Documents   Document   doc   doc   Attachment Count   1   N/A   Yes   Number of document attached to a document   doc   Attachment Names   Document   doc   document   doc	DDODIJOI		37	37	
DUPELOCATIO NS    NA   Yes   Filepaths of all duplicates	PRODVOL	VOL001	Yes	Yes	
DUPELOCATIO NS    My   Documents   Documents   doc;   Desktop   Documents   doc;   Desktop   Documents   Documents   doc   doc	CREATEDBY	John Smith	NA	Yes	
NS    Documents   Document   doc;   Desktop   Document   doc;   Desktop   Document   doc	DUDELOCATIO	\Mx	NI/A	Voc	•
Document I .doc; \Desktop\D ocument I .doc; \Desktop\D ocument I .doc  FILEPATH \My \ Documents\D Documents\D Document I .doc  Attachment Count I \ N/A \ Yes \ Number of document attached to a document attached to a document attachment Names Document I .doc  Attachment Names Document I .doc \ Yes \ File Name of all attachments  LastModifiedBy John Smith N/A Yes Last user to modify document  Redacted Y/N Yes Yes Identifies documents with redactions  Redaction Reason Privacy Yes Yes Identifies the type of redaction  ConversationID 309997447f N/A Yes  HASREVISIONS Yes N/A Yes  HASHIDDENTE XT N/A Yes  HASHIDDENSLI Yes N/A Yes  HASHIDDENSLI Yes N/A Yes  HASSPEAKERN Yes N/A Yes			IN/A	ies	1
.doc;   Desktop\D ocument1.d oc   Path to collection	IND				uupiicates
Desktop\D ocument1.d oc					
FILEPATH    My   Documents   Documents   Locuments   Documents   D					
FILEPATH    My   Documents   Document   .doc					
FILEPATH \  \My \\ Documents \\ Document \					
Documents\ Document	FILEPATH		N/A	Yes	Path to collection
Attachment Count 1 N/A Yes Number of documents attached to a document Attachment Names Document 1 N/A Yes File Name of all attachments  LastModifiedBy John Smith N/A Yes Last user to modify document  Redacted Y/N Yes Yes Identifies documents with redactions  Redaction Reason Privacy Yes Yes Identifies the type of redaction  ConversationID 309997447f N/A Yes HASREVISIONS Yes N/A Yes N/A Yes SHASHIDDENTE Yes N/A Yes SHASHIDDENTE Yes N/A Yes SHASHIDDENSLI Yes N/A Yes HASHIDDENSLI Yes N/A Yes HASHIDDENSLI Yes N/A Yes SHASSPEAKERN YES N/A YES SH					
Attachment Count  Attachment Names  Document1  Attachment Names  LastModifiedBy  LastModifiedBy  John Smith  Redacted  Y/N  Yes  Yes  Last user to modify document  With redactions  Redaction Reason  Privacy  Yes  HASREVISIONS  HASHIDDENTE  XT  HASHIDDENSLI  DES  HASSPEAKERN  Yes  N/A  Yes  Number of documents attached to a document  Yes  File Name of all attachments  Last user to modify document  Identifies documents with redactions  Redaction  Yes  Identifies the type of redaction  Yes  Yes  Yes  Yes  Yes  HASHIDDENSLI  Yes  N/A  Yes  HASSPEAKERN  Yes  N/A  Yes  Yes  Yes  N/A  Yes  Yes		,			
Attachment Names   Document 1   N/A   Yes   File Name of all attachments    LastModifiedBy   John Smith   N/A   Yes   Last user to modify document    Redacted   Y/N   Yes   Yes   Identifies documents with redactions    Redaction Reason   Privacy   Yes   Yes   Identifies the type of redaction    ConversationID   309997447f   N/A   Yes    HASREVISIONS   Yes   N/A   Yes    HASHIDDENTE   Yes   N/A   Yes    HASHIDDENSLI   Yes   N/A   Yes    HASSPEAKERN   Yes   N/A   Yes		.doc			
Attachment Names Document   N/A   Yes   File Name of all attachments    LastModifiedBy John Smith   N/A   Yes   Last user to modify document    Redacted   Y/N   Yes   Yes   Identifies documents with redactions    Redaction Reason   Privacy   Yes   Yes   Identifies the type of redaction    ConversationID   309997447f   N/A   Yes    HASREVISIONS   Yes   N/A   Yes    HASCOMMENT   Yes   N/A   Yes    HASHIDDENTE   Yes   N/A   Yes    HASHIDDENSLI   Yes   N/A   Yes    HASHIDDENSLI   Yes   N/A   Yes    HASSPEAKERN   Yes   N/A   Yes    HASHIDDENSLI   Yes   N/A   Yes    HASSPEAKERN   Yes   N/A   Yes    HASSPEAKERN   Yes   N/A   Yes    HASSPEAKERN   Yes   N/A   Yes    HASHIDDENSLI   Yes   N/A   Yes    HASSPEAKERN   Yes   N/A   Yes    HASHIDDENSLI   Yes   N/A   Yes    HASSPEAKERN   Yes   N/A   Yes	Attachment Count	1	N/A	Yes	Number of documents
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HASSPEAKERN Yes N/A Yes					
		Yes	N/A	Yes	

	Sample		Email and E-	
Field	Data	<b>Scanned Docs</b>	Docs	Comment
HASHIDDENRO	Yes	N/A	Yes	
WS				
HASHIDDENCO	Yes	N/A	Yes	
LUMNS				
HASHIDDENWO	Yes	N/A	Yes	
RKSHEETS				
HASVERYHIDD	Yes	N/A	Yes	
ENWORKSHEET				
S				
SCANNEDIMAG	Yes	Yes	NO	Indicates whether
Е				document is Hardcopy
				document that was
				scanned for production
HASHANDWRIT	Yes	Yes	NO	Indicates whether
ING				document contains
				handwriting

## A.25. Files Produced in Native Format.

a. For any electronic file produced initially as a Native file in accordance with Paragraph B.2 of the Protocol above, the file shall be given a file name consisting of a unique Bates number and, as applicable, a suitable confidentiality designation; for example, "ABC00000002\_Confidential." For each such Native file, the production will include a \*.tif image slipsheet (i) indicating the production number of the Native file, (ii) with respect to any confidential document, setting forth the full confidentiality language applicable to the Native file as set out in the Protective Order, and (iii) stating "File Provided Natively." To the extent that it is available, the original or redacted file text shall be provided in a file-level multi-page UTF-8 text file with a text path provided in the \*.dat file; otherwise the text contained on the slipsheet shall be provided in the \*.txt file with the text path provided in the \*.dat file.

- b. For any electronic file produced in native file format following production of a TIFF-image in accordance with Paragraph B.1, the file shall be given a file name consisting of (i) the Bates number of the first page of the associated TIFF-image and (ii) as applicable, a suitable confidentiality designation. For each such Native file, the production will include a new .DAT file (i) indicating the production number of the Native file, (ii) identifying the path to the Native file, (iii) adding a field stating "Yes," indicating that the file was produced in both Native and TIFF formats, and (iv) linking the Metadata associated with the originally produced TIFF image to the newly produced Native file.
- A.26. <u>Production Media</u>. Unless otherwise agreed, documents and ESI will be produced on optical media (CD/DVD), external hard drive, secure FTP site, or similar electronic format. Such Media should have an alphanumeric volume name; if a hard drive contains multiple volumes, each volume should be contained in an appropriately named folder at the root of the drive. Volumes should be numbered consecutively (ABC001, ABC002, etc.). Deliverable Media should be labeled with the name of this action, the identity of the producing Party, and the following information: Volume name, production range(s), and date of delivery.
- A.27. Encryption of Production Media. To maximize the security of information in transit, any Media on which documents or electronic files are produced may be encrypted by the producing Party. In such cases, the producing Party shall transmit the encryption key or password to the requesting Party, under separate cover, contemporaneously with sending the encrypted Media. The receiving Parties in this matter are on notice that certain data produced may originate from custodians in the European Union and the receiving Parties therefore agree to follow the strictest security standards in guarding access to said data.

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

Case Nos.

SHERYL MCCALL and DAVID 3:20-cv-08074; 3:20-cv-12605; MCCALL, 3:20-cv-07758; 3:20-cv-14668;

3:20-cv-07756; 3:20-cv-14663;

Plaintiffs, 3:20-cv-14447; 3:20-cv-09530;

3:20-cv-10080; 3:20-cv-07753; 3:20-cv-12328; 3:20-cv-11913; v.

3:20-cv-11912; 3:20-cv-12608;

JANSSEN PHARMACEUTICALS, INC., 3:20-cv-07079; 3:20-cv-10341;

3:20-cv-11921; 3:20-cv-12421; et al., 3:20-cv-13940; 3:20-cv-10342;

Defendants. 3:20-cv-07750; 3:20-cv-14448;

3:20-cv-14450; 3:20-cv-12547; 3:20-cv-10966; 3:20-cv-11919;

This Document Relates to All Cases<sup>1</sup>

<sup>1</sup> 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) Connie Combs and Roy Combs v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-14668-BRM-ZNQ; (4) Harriet Comstock v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-07756-BRM-ZNQ; (5) Amanda Cooper v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-14663-BRM-ZNQ; (6) Vanessa L. Davis v. ALZA Corporation, et al., 3:20-cv-14447-BRM-ZNQ; (7) Sherry Dobbins and James Dobbins v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-09530-BRM-ZNQ; (8) Carol Dubois v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-10080-BRM-ZNQ; (9) Deborah Edwards v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-07753-BRM-ZNQ; (10) Margaret Emmons v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-12328-BRM-ZNQ; (11) Marilyn J. Evans v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-11913-BRM-ZNQ; (12) Iris Groudan v. Janssen Pharmaceuticals Inc., et al., 3:20-cv-11912-BRM-ZNQ; (13) Carol Hardy and Roger Hardy v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-12608-BRM-ZNQ; (14) Valerie Hull and Edward Hull v. Teva Pharmaceuticals, Inc., et al., 3:20-cv-07079-BRM-ZNQ; (15) Clara Johns v. ALZA Corp., et al., 3:20-cv-10341-BRM-ZNQ; (16) Tiffany Kotz v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-11921-BRM-ZNO; (17) Elizabeth Lafave v. Teva Branded Pharmaceutical Products R&D, Inc., et al., 3:20-cv-12421-BRM-ZNQ; (18) Velma Lehmann v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-13940-BRM-ZNQ; (19) Shirley Ruth Levy v. ALZA Corp., et al., 3:20-cv-10342-BRM-ZNQ; (20) Barbara Mayou and Keith Mayou v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-07750-BRM-ZNQ; (21) Sheryl McCall and David McCall v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-08074-BRM-ZNQ; (22) Dawn Petrovia v. ALZA Corporation, et al., 3:20-cv-14448-BRM-ZNQ; (23) Susan Preece v. ALZA Corporation, et al., 3:20-cv-14450-BRM-ZNQ; (24) Loretta Reid v. Janssen Pharmaceutical, Inc., et al., 3:20-cv-12547-BRM-ZNO; (25) Maria A. Rodgers v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-10966-BRM-ZNQ; (26) Michelle Scott v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-11919-

: 3:20-cv-10968; 3:20-cv-12264; 3:20-cv-13596; 3:20-cv-14452; 3:20-cv-14670; 3:20-cv-06070; 3:20-cv-10960 JUDGE BRIAN R. MARTINOTTI JUDGE ZAHID N. QURAISHI

# CASE MANAGEMENT ORDER NO. 7

The Court having held a case management conference on October 26, 2020, and for good cause shown, enters the following Order:

## I. STATUS OF LITIGATION AND COORDINATION

A. As of October 29, 2020, 37 cases alleging products liability claims relating to use of Elmiron have been filed in the District of New Jersey with 33 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

BRM-ZNQ; (27) Heather Shaffer v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-10968-BRM-ZNQ; (28) Cynthia Vescio v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-12264-BRM-ZNQ; (29) Deborah F. Weiner v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-13596-BRM-ZNQ; (30) Dondra White v. ALZA Corporation, et al., 3:20-cv-14452-BRM-ZNQ; (31) Maria Windham v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-14670-BRM-ZNQ; (32) Becky Worden v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-06070-BRM-ZNQ; (33) Ronna York v. Janssen Pharmaceuticals, Inc., et al., 3:20-cv-10960-BRM-ZNQ.

- A. The parties are meeting and conferring regarding a plaintiff fact sheet/defense fact sheet ("PFS" and "DFS") and process, as well as 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. The parties are coordinating with plaintiffs' counsel in other jurisdictions, primarily the Court's designated liaison counsel from Philadelphia, to coordinate content of the PFS and DFS submissions and the processes.
- B. The parties are meeting and conferring on a deposition protocol, including the detail of same and whether it simply needs to govern remote deposition protocols given the COVID-19 global pandemic.
- C. The parties continue to meet and confer on the scheduling of the Rule 30(B)(6) most knowledgeable deposition relating to Bayer as further outlined in CMO 5. The parties now report that they have agreed for the deposition to take place on November 11, 2020. The Court confirmed with Defendants and Pennsylvania liaison counsel that the invitation to the Pennsylvania litigants was offered, which it had been.
  - 1. Related to Bayer, the appointed Pennsylvania liaison advised of its third-party subpoena that they had planned to issue to Bayer. She also advised the court that Janssen agreed to facilitate such discovery without the need for a subpoena because in accordance with this Court's CMO the former Bayer Defendants have agreed and are under Court Order to make discovery available to the New Jersey litigants, and this discovery should also be provided to the Pennsylvania liaison counsel for use with

the Pennsylvania plaintiffs.

- D. The parties also continue to meet and confer on the dismissal of additional Teva entities, and shall report on the status of their discussions at the next case management conference.
- E. Plaintiffs indicated that they intend to propound on the Janssen Defendants a master set of discovery requests, including interrogatories and document demands, within the next week.
- F. The parties continue to meet and confer on search terms, document production issues, and the scheduling of depositions, and shall provide an update at the next case management conference; Plaintiffs' counsel advised that they were seeking input from all other Plaintiffs' counsel with cases filed in New Jersey so as to capture more issues, and hopefully avoid the necessity of propounding more discovery after a MDL is created and the need for supplementation of discovery responses and associated costs therein.
- G. The Janssen Defendants produced their first installment of their rolling production, including the majority of the NDA as mandated by this Court, on October 23, 2020, and plan to make a production each month. They are currently planning on making their next installments on November 13, 2020, and December 11, 2020, and will provide an update later this year regarding additional installments.

## IV. COORDINATION/COOPERATION

A. The parties are continuing 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. 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.

**SCHEDULING** V.

В.

A. The next case management conference is scheduled for November 16, 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.

В. 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 30th2020

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

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