UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
NORTHERN DIVISION
(at Covington)

JUDITH ROMO, et al.,	)	Lead Case
	)	Civil Action No. 2: 15-089-DCR
Plaintiffs,	)	
	)	
V.	)	
	)	**CASE MANAGEMENT ORDER**
MCKESSON CORP., et al.,	)	**No. 5**
	)	**(Discovery Management Order)**
Defendants.	)	

*** *** *** ***

Being sufficiently advised, it is hereby **ORDERED** as follows:

I. SCOPE AND APPLICABILITY

A. Scope of the Plan - This Plan of Discovery ("Plan") is intended to conserve judicial resources, eliminate duplicative discovery, serve the convenience of the parties and witnesses, and promote the just and efficient conduct of this litigation. This Plan shall apply to all cases currently pending before this Court and consolidated under the caption *Romo, et al., v. McKesson Corp., et al.,* Civil Action No. 2: 15-cv-089-DCR.

For the purposes of this Plan, "Brand Defendants" shall mean defendants that sold propoxyphene-containing pain products pursuant to a New Drug Application ("NDA") at any time. "Generic Defendants" shall mean defendants that sold a "generic"[1] propoxyphene-containing product. Use of the term "parties" herein shall mean Plaintiffs and Defendants. This Plan shall not be construed to affect the governing law or choice-of-law rules in any

1 FDA defines "generic drug" as a drug that "is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use." *See* http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#G

case subject to the Plan. Notwithstanding the foregoing, discovery shall be governed by the Federal Rules of Civil Procedure except where specifically superseded by this Plan. This Plan shall not be construed to affect statutes of limitation, statutes of repose, or any other time bar. Unless expressly indicated, nothing in this Plan is intended or shall be deemed to amend or modify any prior order of the Court concerning discovery.

B. Use of Discovery in Federal and State Courts - Discovery conducted pursuant to this Plan may be utilized in federal court, in accordance with the applicable laws and rules of discovery and evidence. The use of any discovery conducted pursuant to this Plan in any state court proceeding will be addressed in separate orders or proceedings. Nothing in this Plan shall preclude any party from asserting in any action that any document, testimony, or other discovery produced pursuant to this Plan is inadmissible at any hearing or trial.

II. ORDER ADDRESSING EVIDENCE OF INJURY

A. Evidence Relevant to Contemporaneous Injury – Each plaintiff whose claims have not been dismissed in their entirety as of February 1, 2016, and who alleges ingestion of a propoxyphene-containing pain product ("Product") along with a "contemporaneous injury" shall produce the following evidence no later than March 2, 2016. The evidence that must be produced is as follows:

1. The dates of ingestion of a Product;

2. Prima facie evidence of acquisition of a Product, which shall take the form of pharmacy records with National Drug Codes ("NDCs") identifying a Product, pill bottles containing a Product with the Plaintiff's name, NDC or manufacturer name, and Product name clearly visible, or a pharmacist's affidavit setting forth the Product, NDC or

manufacturer of the Product, and the date each such Product was dispensed to the Plaintiff. Unless specifically ordered by this Court at a later date, no other forms of evidence will be sufficient to establish Product acquisition, including but not limited to: (1) medical record(s) denoting a prescription to plaintiff for the Product or notation of the Product as a current medication; (2) an affidavit from a healthcare provider attesting that he or she prescribed to plaintiff the Product; and/or (3) an affidavit from the plaintiff or a representative attesting that plaintiff ingested the Product; and

3. Prima facie evidence of the alleged injury, which shall take the form of a medical record which contains the date of the alleged injury or a signed affidavit from a physician which specifies the alleged injury and the date of the alleged injury.

B. Evidence Relevant to Cumulative/Latent Injury - Each plaintiff whose claims have not been dismissed in their entirety as of February 1, 2016, and who alleges ingestion of a propoxyphene-containing pain product ("Product") along with a "non-contemporaneous injury" shall produce the following evidence no later than March 2, 2016. The evidence that must be produced is as follows:

1. The dates of ingestion of a Product;

2. Evidence of acquisition of a Product, which shall take the form of pharmacy records with National Drug Codes ("NDCs") identifying a Product, pill bottles containing a Product with the Plaintiff's name, NDC or manufacturer name, and Product name clearly visible, or a pharmacist's affidavit setting forth the Product, NDC or manufacturer of the Product, and the date each such Product was dispensed to the Plaintiff. Unless specifically ordered by this Court at a later date, no other forms of evidence will be sufficient to establish Product acquisition, including but not limited to: (1) medical record(s)

denoting a prescription to plaintiff for the Product or notation of the Product as a current medication; (2) an affidavit from a healthcare provider attesting that he or she prescribed to plaintiff the Product; and/or (3) an affidavit from the plaintiff or a representative attesting that plaintiff ingested the Product; and

3. A signed certification from a licensed physician that includes: (a) the dates of alleged ingestion of the Product; a determination that the Plaintiff suffered an injury related to use of a specific Defendant's Product: identification of the specific injury alleged; a statement that the Product is capable of causing the specific injury alleged; a statement that the Product did cause the specific injury alleged; a listing of the records reviewed by the physician that document such injury; and the dates of the records that document such injury; and (b) copies of all records listed.

For purposes of this Plan, "non-contemporaneous injury" shall mean an injury that was first diagnosed by a health-care provider more than 10 days after a Plaintiff last ingested a propoxyphene-containing Product. Plaintiffs shall fulfill the requirements of this portion of this Order contemporaneously with the parties' other discovery obligations as outlined in this Order. Service of the information listed in this Section shall be made in writing, by email, upon the counsel listed in Section IV(A), below.

III. WRITTEN DISCOVERY

For all cases subject to this Plan, the parties are relieved of their obligation to comply with the requirements of Federal Rule of Civil Procedure 26(a).

IV. PRODUCTION OF DOCUMENTS

A. Plaintiffs' Production of Fact Sheets, Medical Authorizations, and Documents - No later than March 2, 2016, Plaintiffs shall serve, via email and regular

United States mail, on counsel of record for each defendant named in Plaintiff's case (1) a substantially complete "Plaintiff's Fact Sheet" in the identical form approved by this Court in MDL 2226, Dkt. No. 2089 and described herein; (2) the documents requested in the Plaintiff's Fact Sheet ("the responsive documents") including but not limited to the medical records and pharmacy records as set forth above in section II; and (3) the authorizations described herein. The Plaintiff Fact Sheet, the responsive documents, and the authorizations shall be emailed and mailed to Defendants' Counsel(s) at the following addresses:

For Xanodyne Pharmaceuticals, Inc.:

Gina M. Saelinger, Esq.
Ulmer & Berne LLP
600 Vine Street, Suite 2800
Cincinnati, OH 45202
gsaelinger@ulmer.com

For Eli Lilly:

Audra Ferguson-Allen, Esq.
Ice Miller LLP
One American Square, Suite 2900
Indianapolis, IN 46202-0200
Audra.Ferguson-Allen@icemiller.com

For Teva Pharmaceuticals USA, Inc. and Teva Biopharmaceuticals USA, Inc.:

Lori G. Cohen. Esq.
Greenberg Traurig LLP
Terminus 200
3333 Piedmont Road, NE Suite 2500
Atlanta, GA 30305
cohenl@gtlaw.com

For Endo Pharmaceuticals Inc., Endo Pharmaceuticals Holdings Inc., Generics International (US Parent), Inc., Generics International (US), Inc., Generics Bidco I, LLC, Generics Bidco II, LLC, and Vintage Pharmaceuticals, LLC:

Rachel B. Passaretti-Wu, Esq.
Quinn Emanuel Urquhart & Sullivan, LLP

51 Madison Avenue, 22nd Floor
New York, New York 10010
rachelpassarettiwu@quinnemanuel.com

For Watson Pharmaceuticals Inc.:

Margaret E. Keane
Bingham, Greenebaum, Doll LLP
3500 National City Tower
101 South Fifth St.
Louisville, KY 40202
mkeane@bgdlegal.com

For Mylan Inc. and Mylan Pharmaceutical Inc.

Clem C. Trischler, Esq.
Bradley A. Matta, Esq.
Pietragallo Gordon Alfano Bosick and Raspanti LLP
One Oxford Centre. 38th Floor
Pittsburgh, PA 15219
CCT@Pietragallo.com
BAM@Pietragallo.com

Counsel for Covidien Inc.; Mallinckrodt Inc.

Bryan T. Pratt
SHOOK, HARDY & BACON L.L.P.
2555 Grand Blvd.
Kansas City, MO 64108
(816) 474-6550
bpratt@shb.com

For Cornerstone Biopharma, Inc.; Cornerstone Biopharma Holdings, LLC (formerly known as and sued herein as Cornerstone Biopharma Holdings, Inc.); and Aristos Pharmaceuticals, Inc.:

Kai Peters, Esq.
GORDON & REES, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111
kpeters@gordonrees.com

For Brenn Pharmaceuticals, Inc. f/k/a Propst Distribution, Inc. f/k/a/ Qualitest Pharmaceuticals, Inc. and Brenn Manufacturing, Inc. f/k/a Vintage Pharmaceuticals, Inc.:

Tammara Bokmuller
600 West Broadway, Suite 500
San Diego, CA 92101
tbokmuller@mpplaw.com

B. Content of Plaintiff Fact Sheet and Authorizations

1. Signature of Fact Sheet and Amendments by Plaintiff. All responses in a Plaintiff Fact Sheet or an amendment thereto are binding on the Plaintiff as if they were contained in answers to interrogatories. Each Plaintiff Fact Sheet and amendment thereto shall be signed and dated by the Plaintiff or the proper Plaintiff representative under penalty of perjury.

2. Five Blank Medical Authorizations Served with Fact Sheet. Each individual Plaintiff shall serve along with his or her Plaintiff's Fact Sheet five originals of the "Authorization for the Release of Medical Records" of all health-care providers and other sources of information and records (including but not limited to pharmacies, insurance companies, and/or any applicable state or federal government agencies) (collectively, "custodian of records"). The authorizations shall be dated and signed without setting forth the identity of the custodian of the records or provider of care. Defendants may use the blank authorizations to obtain records only from any custodians of records or providers listed in the Plaintiff's Fact Sheet without further notice. Defendants may use the blank authorizations to obtain records from other custodians or providers by providing Plaintiff's counsel of its intent to do so five business days prior to requesting any record.

3. Three Blank Employment Authorizations. Each individual Plaintiff shall serve along with his or her Plaintiff's Fact Sheet three originals of the "Authorization for the Release of Employment Records" of all employers. The authorizations shall be dated

and signed without setting forth the identity of the custodian of the records. Defendants may use the blank authorization to obtain records from any employer listed in the Plaintiff's Fact Sheet without further notice. Defendants may use the blank authorizations to obtain records from other employers by providing Plaintiff's counsel of its intent to do so five business days prior to requesting any record.

4. Blank Worker's Compensation Authorization. Each individual Plaintiff shall serve along with his or her Plaintiff's Fact Sheet an original of the "Authorization for the Release of Worker's Compensation Records." The authorizations shall be dated and signed without setting forth the identity of the custodian of the records. Defendants may use the blank authorization to obtain records from any agency administering a claim for worker's compensation benefits listed in the Plaintiff's Fact Sheet without further notice. Defendants may use the blank authorizations to obtain records from other worker's compensation agencies by providing Plaintiff's counsel of its intent to do so five business days prior to requesting any record.

5. Two Blank Tax Return Authorizations. Each individual Plaintiff shall serve along with his or her Plaintiffs Fact Sheet two originals of the "Authorization for the Release of Tax Return Records." The authorizations shall be dated and signed without setting forth the identity of the custodian of the records. Defendants may use the blank authorization to obtain records from any taxing agency for a jurisdiction reasonably implicated by the information listed in the Plaintiff's Fact Sheet without further notice. Defendants may use the blank authorizations to obtain records from other taxing authorities by providing Plaintiff's counsel of its intent to do so five business days prior to requesting any record.

6. Obligation to Cooperate by Providing Additional Authorizations. If Defendants wish to obtain records from a custodian of records who will not accept the authorizations Plaintiff has submitted, Plaintiff will cooperate with Defendants and provide the necessary authorization(s).

C. Case-Specific Discovery Upon Plaintiffs - In addition to the Plaintiff Fact Sheets, authorizations, and documents that are the subject of this Plan, for any Plaintiff remaining at the conclusion of Phase I and proceeding to Phase II, further case-specific discovery on such Plaintiff may be provided for in a subsequent scheduling order for Phase II and may include Interrogatories, Requests for Production, Requests for Admission, and Depositions.

D. Preservation - The Preservation Order entered in MDL 2226 (Dkt. No. 387) and adopted in these cases pursuant to Case Management Order No. 2 shall apply to this Discovery Plan.

E. Confidentiality - The Confidentiality Order entered in MDL 2226 (Dkt. No. 1513) and adopted in these cases in Case Management Order No. 3, "Protective Order" shall apply to this Discovery Plan.

F. Duplicates - Where a single document custodian has more than one identical copy of a document (the documents are the same and neither contain different marginalia), Defendant need only produce a single copy of that document. Where multiple document custodians each possess their own copies of an identical document, the document may be produced once for each custodian in possession of the document.

G. Original Documents - The parties shall, upon reasonable request, make originals of any produced document available for inspection and copying by the requesting

party. If either party requests production of an electronic document in native format, the parties shall meet and confer regarding the request.

H. Format of Production - The protocol for and format of production of documents shall be in accordance with the Document Production Protocol and Cost of Production Order, entered in MDL 2226 (Dkt. No. 2290), and adopted in these cases pursuant to Case Management Order No. 4.

I. Cost of Production - The costs that will be assessed for production of documents by both Plaintiffs and Defendants shall be in accordance with the Document Production Protocol and Cost of Production Order, entered in MDL 2226 (Dkt. No. 2290), and adopted in these cases pursuant to Case Management Order No. 4.

J. Bates Numbering - All documents produced during discovery shall have their pages numbered sequentially by the party producing the documents. Each page of a produced document shall have a legible, unique page identifier ("Bates Number") electronically "burned" onto the image at a location that does not obliterate, conceal or interfere with any information from the source document. No other legend or stamp will be placed on the document image other than a confidentiality legend (where applicable), redactions (consistent with applicable law or Court order), and the Bates Number identified above.

K. Assertion of Privilege - Any party that withholds the production of requested documents or materials on the ground of any privilege or application of the work product doctrine must provide a Privilege Log. Each Privilege Log shall describe each document or thing for which a privilege or the work product doctrine is asserted in sufficient detail to reasonably permit the party seeking discovery to assess whether or not to dispute any such

assertion of privilege or application of the work product doctrine. This will include but is not limited to information regarding the document's subject, date, author, and all recipients the specific privilege asserted, and the basis for the privilege. Each party withholding materials shall provide opposing counsel a copy of the Privilege Log in electronic form contemporaneously with each production whenever possible, and in all circumstances, within sixty (60) days after the production absent agreement of the parties. In the case of production by Defendants of custodial or departmental files, however, Defendant shall produce the Privilege Log within sixty (60) days after the production of custodian or departmental files is fully complete. Without waiving any argument regarding the scope of any privilege, the parties shall not be required to log communications with outside counsel that occurred after the first Darvon, Darvocet and/or propoxyphene lawsuit was filed against the respective Defendant.

L. Search Terms for Electronically Stored Information ("ESI") – All search terms used or agreed to for the Brand Defendants' production of documents during the proceedings in MDL 2226, including those set forth in Minute Entry Order for Status Conference, Dkt. No. 2768, shall be adopted for the Brand Defendants in these cases.

V. DEPOSITIONS

Case Management Order No. 6, Abbreviated Deposition Protocol, shall apply.

VI. ADDITIONAL CASE-SPECIFIC DISCOVERY

No case-specific discovery, other than as provided for above, may occur without further order of this Court.

VII. FAILURE TO COMPLY WITH ABOVE PROVISIONS REGARDING WRITTEN PHASE I DISCOVERY

A. **Failure to Provide Physician Certification regarding Non-Contemporaneous Injury** - On or before March 17, 2016, counsel for defendants shall notify the Court of the names of plaintiffs who allege a non-contemporaneous injury but who did not provide the requisite physician certifications on or before March 2, 2016. Thereafter, the Court will enter a Show Cause Order as to why those plaintiffs' claims should not be dismissed. In order to adhere to the other deadlines in this Order, extensions to the March 2, 2016 deadline may not be agreed to by the parties.

B. **Failure to Serve Plaintiff Fact Sheets** - On or before March 17, 2016, counsel for defendants shall notify the Court of the name of any plaintiff who did not serve a Plaintiff Fact Sheet by the March 2, 2016 deadline. Thereafter, the Court will enter a Show Cause Order as to why those plaintiffs' claims should not be dismissed. In order to adhere to the other deadlines in this Order, extensions to the March 2, 2016 deadline may not be agreed to by the parties.

C. **Incomplete Plaintiff Fact Sheets** - For those plaintiffs who serve a Plaintiff Fact Sheet, but who fail to provide a substantially complete Plaintiff Fact Sheet, defendants shall send deficiency letters outlining the missing information ("Deficiency Letter"). Plaintiffs shall have thirty (30) days after the date on the deficiency letter to provide the missing information. Upon the request of defendants, this Court will hold a Show Cause hearing regarding those plaintiffs who failed to comply after the thirty (30) day Deficiency Letter time period has lapsed.

D. Failure to Provide Prima Facie Evidence of Acquisition and Injury - For each plaintiff who fails to provide prima facie evidence of acquisition and injury, defendants shall provide a rejection letter to plaintiff's counsel noting that plaintiff has failed to provide the requisite prima facie records ("Rejection Letter"). The Rejection Letter will state that the failure to cure the rejection by producing the requisite prima facie record(s) within thirty (30) days of the date of the letter will be deemed an admission that the plaintiff lacks the requisite proof to proceed with his or her claims and that the defendants will thereafter seek immediate dismissal. If plaintiff's counsel intends to proceed against any defendant under an alternate theory of liability besides ingestion of the defendant's product, plaintiff's counsel may indicate such in a written response to defendant's counsel. Any plaintiff who responds to the Rejection Letter by producing the requisite prima facie record(s) within thirty (30) days of the date of the letter, or any plaintiff who identifies an alternate theory of liability, will then, as appropriate, be subject to the deficiency letter process outlined in Section IV.B.3. above. Upon the request of defendants, this Court will hold a Show Cause hearing regarding those plaintiffs who failed to comply after the thirty (30) day Rejection Letter time period has lapsed.

VIII. DECEASED PLAINTIFFS

In the event a plaintiff dies before his or her individual action is concluded, or has died since his or her complaint was filed, and his or her claim is not extinguished under applicable state law, the following procedures shall govern the substitution of a proper party in the place of the deceased plaintiff.

A. Suggestion of Death - By March 17, 2016 or within thirty (30) days of the death of any plaintiff, whichever is later, plaintiff's counsel shall file a formal "Suggestion of

Death" with this Court that identifies the deceased plaintiff and describes the date, time, and circumstances of the plaintiff's death.

B. **Failure to File Suggestion of Death** - If any defendant learns that a plaintiff is deceased, and a Suggestion of Death was not timely filed, defendants may file with the Court a motion to dismiss the deceased plaintiff's individual action with prejudice pursuant to Federal Rule of Civil Procedure 25(a).

C. **Motion for Substitution** - Within forty-five (45) days of filing a Suggestion of Death, plaintiff's counsel shall file a Motion for Substitution, as required by the Federal Rules of Civil Procedure 25(a), and identify the proposed substitute plaintiff by name, describe why the proposed substitute plaintiff is a proper party under applicable state law, and explain why the deceased plaintiff's claim has not been extinguished under applicable law.

1. In the event that applicable state law requires the opening of an estate and the appointment of a personal representative to pursue the claims of a deceased plaintiff, plaintiff's counsel shall initiate or cause to be initiated proceedings to open an estate and/or obtain the appointment of a personal representative for the deceased plaintiff by April 1, 2016 or within thirty (30) days from the death of the plaintiff, whichever is later.

2. If available at the time of filing, plaintiff's counsel shall attach as an exhibit to the Motion for Substitution a copy of any Order appointing the proposed substitute plaintiff as the personal representative of the deceased plaintiff.

3. In the event that no personal representative has been appointed by the deadline to file a Motion for Substitution, plaintiff's counsel shall describe in the Motion for Substitution the steps taken to obtain the appointment of a personal representative and state

whether there are any competing applications. If the Court determines that the proposed substitute plaintiff would be a proper party if appointed a personal representative of the deceased plaintiff and that the provisions of this Order and Federal Rules of Civil Procedure 25(a) have otherwise been complied with, the Court will provisionally grant the Motion for Substitution on the condition that the substituted plaintiff submit to the Court, prior to the conclusion of the case, a copy of the Order appointing him or her as the deceased plaintiff's personal representative.

4. Nothing in this Order shall preclude any defendant from challenging the authority or capacity of the proposed substitute plaintiff.

D. Failure to File Motion for Substitution - If a Motion for Substitution is not made within forty-five (45) days after service of a Suggestion of Death or the Motion for Substitution otherwise fails to comply with the provisions of this Order, defendants may file with the Court a motion to dismiss the deceased plaintiff's individual action with prejudice pursuant to Federal Rule of Civil Procedure 25(a).

This 26th day of January, 2016.

Signed By:
Danny C. Reeves DCR
United States District Judge