

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

IN RE: DARVOCET, DARVON AND	)	
PROPOXYPHENE PRODUCTS	)	Master File No. 2: 11-md-2226-DCR
LIABILITY LITIGATION	)	MDL Docket No. 2226
	)	
	)	ALL CASES

**PROCEDURES GOVERNING DISCOVERY**

**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 transferred to this Court by the Judicial Panel on Multidistrict Litigation (“Panel”) pursuant to its order of August 16, 2011, any tag-along actions transferred to this Court by the Panel, and any related actions that have been or will be originally filed in, transferred to, or removed to this Court and assigned thereto as part of In re: Darvocet, Darvon and Propoxyphene Products Liability Litigation, MDL No. 2226.

For the purposes of this Plan, “Brand Defendants” shall mean defendants that sold propoxyphene-containing pain products pursuant to an NDA at any time. Use of the term “parties” herein shall mean Plaintiffs and Brand Defendants. This Plan shall not be construed to affect the governing law or choice-of-law rules in any 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Rules of Civil Procedure except where specifically superseded by this Plan.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 amended or modify any prior order of the Court concerning discovery, including, but not limited to, the provisions of CMO 1.

**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.

**C. Discovery Under the Plan** - No party to the Plan may conduct any discovery not expressly authorized by the Plan absent further order of this Court or express agreement of the parties. Nothing in this Plan is intended to govern the scope of discovery against non-Brand Defendants (“Generic Defendants”) and the Court will not permit such discovery to go forward. If the Court orders discovery at any time in the future as to Generic Defendants, Plaintiffs and the Generic Defendants will be given an opportunity to propose a revised discovery plan and/or case management order.

## **II. ORDER ADDRESSING EVIDENCE OF CUMULATIVE/LATENT INJURY**

**A. Evidence Relevant to Cumulative/Latent Injury** - Each Plaintiff who alleges ingestion of a propoxyphene-containing pain product manufactured or sold by a Brand Defendant along with a non-contemporaneous injury shall produce the following

evidence within 60 days of this Order. All other Plaintiffs who allege a non-contemporaneous injury shall produce the following evidence within 60 days after the Court denies a motion to dismiss or a motion for judgment on the pleadings filed by a Brand Defendant, or within 60 days after a Brand Defendant provides written notice that it does not plan to file a motion to dismiss or a motion for judgment on the pleadings. 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 may take the form of pharmacy records with NDCs identifying a Product; pill bottles containing a Product; or a health-care provider or Plaintiff's affidavit of prescription or use of a Product (in the event that an affidavit is provided, it shall not be sufficient to implicate any particular defendant to state only that "Darvon" or "Darvocet" was acquired);
3. A signed certification from a licensed physician that includes: (a) the dates of ingestion; a determination that the Plaintiff suffered an injury related to use of a specific Brand Defendant's Product (if the Plaintiff alleges use of a Brand Defendant's Product) or, if not, that the Plaintiff suffered an injury related to use of a propoxyphene-containing pain product; identification of the specific injury; a statement that a propoxyphene pain product is capable of causing, and 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 pain product manufactured or sold by Lilly or Xanodyne. 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 upon the counsel listed in Section IV(A), below.

### **III. WRITTEN DISCOVERY**

**A. Waiver of Initial Disclosures** - 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).

**B. Master Written Discovery by Plaintiffs** - Plaintiffs collectively may serve one Master Set of Requests for Production, one Master Set of Interrogatories (not to exceed seventy-five interrogatories, including all discrete subparts, except by consent of the parties or leave of this Court upon good cause shown), and one Master Set of Requests for Admission (not to exceed twenty-five requests, including all discrete subparts, except by consent of the parties or leave of this Court upon good cause shown) on each Brand Defendant. Absent leave of Court, other than these Master Sets of Production, Master Sets of Interrogatories, and Master Sets of Requests for Admission, no other requests for production, interrogatories, or requests for admission may be propounded on Brand Defendants without leave of court.

#### **IV. PRODUCTION OF DOCUMENTS**

##### **A. Plaintiffs' Production of Fact Sheets, Medical Authorizations, and Documents -**

Plaintiffs in the categories included within Section IV(C) below shall produce to Defendants a "Plaintiff's Fact Sheet" (in a form to be established by agreement of the parties or later order of the Court), the documents requested in the Plaintiff's Fact Sheet ("the responsive documents"), and the authorizations described herein. Plaintiff's Fact Sheets, the responsive documents, and the authorizations shall be 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

For Eli Lilly:

Kimberly C. Metzger, Esq.  
Ice Miller LLP  
One American Square, Suite 2900  
Indianapolis, IN 46202-0200

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

For 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.  
Skadden, Arps, Slate, Meagher & Flom LLP  
Four Times Square  
New York, NY 10036  
Rachel.Passaretti@skadden.com

For Watson Pharmaceuticals, Inc.:

Summer McMillan, Esq.  
Baker, Donelson, Bearman, Caldwell & Berkowitz, PC  
265 Brookview Center Way, Suite 600  
Knoxville, TN 37919  
smcmillan@bakerdonelson.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, 38<sup>th</sup> Floor  
Pittsburgh, PA 15219  
CCT@Pietragallo.com  
BAM@Pietragallo.com

## **B. Content of Fact Sheet and Authorizations -**

1. Signature of Fact Sheet and Amendments by Plaintiff All responses in a Plaintiff's Fact Sheet or an amendment thereto are binding on the Plaintiff as if they were contained in answers to interrogatories. Each Plaintiff's 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. Brand 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. Brand 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. Brand Defendants may use the blank authorization to obtain records from any employer listed in the Plaintiff’s Fact Sheet without further notice. Brand 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. Brand 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. Brand 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 Plaintiff's 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. Brand 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. Brand 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. Form of Fact Sheets The parties shall agree on a form of Fact Sheet within 30 days of the date of this Order.
7. Obligation to Cooperate by Providing Additional Authorizations If Brand Defendants wish to obtain records from a custodian of records who will not accept the authorizations Plaintiff has submitted, Plaintiff will cooperate with Brand Defendants and provide the necessary authorization(s).

**C. Schedule for Production of Plaintiff's Fact Sheets** - For all cases filed on or before the date on which this Order is entered ("the Entry Date"), Plaintiff shall produce the



Plaintiff's Fact Sheet (substantially complete), medical authorizations, employment authorizations and related documents within sixty (60) days from the Entry Date if the Plaintiff alleges ingestion of a propoxyphene-containing pain product manufactured or sold by a Brand Defendant, and for all other Plaintiffs, within 60 days after the Court denies a motion to dismiss or motion for judgment on the pleadings filed by a Brand Defendant, or within 60 days after a Brand Defendant provides written notice that it does not plan to file a motion to dismiss or motion for judgment on the pleadings. For any case filed after the Entry Date, Plaintiff shall produce the Plaintiff's Fact Sheet (substantially complete), medical authorizations, employment authorizations and related documents for such case within sixty (60) days of docketing of the case in the MDL if Plaintiff alleges ingestion of a propoxyphene-containing pain product manufactured or sold by a Brand Defendant, and for all other Plaintiffs, within 60 days after the Court denies a motion to dismiss or motion for judgment on the pleadings filed by a Brand Defendant, or within 60 days after a Brand Defendant provides written notice that it does not plan to file a motion to dismiss or motion for judgment on the pleadings.

Under this Plan, "docketing" shall mean the date that the Member Case number is opened on the In Re: Darvocet, Darvon and Propoxyphene Product Liability Litigation MDL 2226 (2:11-md-02226-DCR) docket. If deficiencies exist in a Fact Sheet, Defendants shall communicate such deficiencies to Plaintiffs in writing and Plaintiffs shall respond within fourteen calendar days. If additional time is needed to gather the information, the parties shall confer in good faith at least five (5) days before the due date to determine and agree whether and how much additional time is

needed. This shall constitute a “meet and confer” process, upon completion of which Defendants may, if deficiencies remain, move the Court to compel Plaintiffs to cure deficiencies. A Fact Sheet shall be served upon all Defendants named in the relevant case.

**D. Case-Specific Discovery Upon Plaintiffs** - In addition to the Plaintiff’s Fact Sheets, authorizations, and documents that are the subject of this Plan, for cases that may be selected for trial or included in a discovery or trial pool, each Brand Defendant may serve one set each of Requests for Production, Interrogatories (not to exceed twenty-five interrogatories, including all discrete subparts, except by consent of the parties or leave of this Court upon good cause shown), and Requests for Admission (not to exceed twenty-five requests, including all discrete subparts, except by consent of the parties or leave of this Court upon good cause shown).

**E. Brand Defendants’ Production of Documents** - Each Brand Defendant shall produce (consistent with a “Document Production Protocol” and a “Cost of Production Order” as described below) a common set of documents to Plaintiffs as follows:

1. On or before August 1, 2012, Each Brand Defendant shall produce its entire regulatory file, including but not limited to the IND, the FDA-approved NDAs, and all communications with the FDA in its possession for Darvon, Darvocet, and/or any other propoxyphene-containing pain product that the Brand Defendant actually marketed in the United States, or any part thereof.
2. On or before August 1, 2012, Lilly shall produce documents in its possession sufficient to show the dates that Lilly contract-manufactured any propoxyphene-containing pain products for a third party.

3. On or before November 1, 2012, the Brand Defendants shall produce a listing of adverse event reports in its possession for propoxyphene-containing pain products that reasonably relate to cardiac-related symptoms, events or injuries. Selection of responsive adverse event reports shall be according to MedDRA or other terms upon which the parties agree.
4. On or before February 1, 2013, each Brand Defendant shall produce a list and description of all study proposals or final study reports in its possession regarding Darvon, Darvocet and/or any other propoxyphene-containing pain product that the Brand Defendant actually manufactured or sold, to the extent such documents are not otherwise included in the materials produced to Plaintiffs. The parties shall meet and confer regarding the study protocols and study reports from the list that the Brand Defendants shall produce. The parties will meet and confer regarding the timing and nature of production of any other documents responsive to Master Requests to Produce or responsive to other discovery requests that may be propounded.
5. Defendants shall have an ongoing duty to supplement production in a timely manner pursuant to Fed. R. Civ. P. 26(e)(1).
6. The parties acknowledge that the document production will include documents containing personally identifiable information and that the parties shall redact such information in accordance with applicable laws and regulations.
7. Within sixty days of receipt of a substantially complete Plaintiff's Fact Sheet and substantially complete authorizations in a particular case, each Brand Defendant shall serve on Plaintiff's counsel of record a Defendant's Fact

Sheet. The parties shall agree on the form of a Defendant's Fact Sheet within 30 days of the date of this Order. Because Defendant is providing a Defendant's Fact Sheet, absent consent of the parties or leave of Court, the Plaintiff in that case may not serve on Defendant any case-specific interrogatories or requests for production.

**F. Preservation** -The previously entered Preservation Order shall apply to this Discovery Plan.

**G. Confidentiality** - The previously entered Confidentiality Order shall apply to this Discovery Plan.

**H. Duplicates** - Where a single document custodian has more than one identical copy of a document (i.e., 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.

**I. 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.

**J. Format of Production** - The protocol for and format of production of documents shall be in accordance with an agreed-upon "Document Production Protocol."

**K. Cost of Production** -The costs that will be assessed for production of documents by both Plaintiffs and Defendants shall be in accordance with a "Cost of Production

Order” to be entered separately.

**L. 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.

**M. 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.

## **V. DEPOSITIONS**

### **A. Commencement of Depositions -**

1. Defendants Depositions of common fact witnesses currently or formerly employed by a Brand Defendant, including any depositions conducted pursuant to Federal Rule of Civil Procedure 30(b)(6) (collectively “common Brand Defendant witnesses”), may commence on September 3, 2012, but may commence earlier if the parties agree. Plaintiffs may serve each Defendant with a single 30(b)(6) notice, or may separate the topics over two or more notices. All such depositions shall be scheduled through the respective Defendant’s counsel.

2. Plaintiffs, Spouses, Prescribing Physicians, Treating Health-Care Providers, Medical Examiners and Toxicologists To allow for completion of Plaintiff’s Fact Sheets and the gathering and review of documents obtained in accordance with the releases described in Part III above, Defendants may commence depositions of plaintiffs, spouses, prescribing physicians, treating health-care providers, medical examiners and toxicologists upon the receipt of a Plaintiff’s Fact Sheet and relevant records.

**B. Deposition Protocol** - On or before September 1, 2012, the parties shall meet and confer regarding the creation of a Deposition Protocol, which will govern all

depositions taken in this litigation. The Deposition Protocol will govern the details of all depositions taken in this litigation, including, but not limited to, scheduling of depositions, length of depositions, location of depositions, and recording of depositions.

## **V. EXPERT WITNESSES**

**A. Expert Reports and Depositions** - The designation of experts whose opinions may be submitted at trial must be accompanied by a report that complies with Federal Rule of Civil Procedure 26(a)(2)(B). The report must be provided contemporaneously with the expert designation. All parties' experts whose opinions may be submitted at trial shall be subject to deposition as directed in Federal Rule of Civil Procedure 26(b)(4)(A) prior to the close of expert discovery. The parties will meet and confer prior to September 1, 2012, concerning the timing of identification of experts, the number of experts to be designated by each side, and the protocol for expert depositions. The parties agree, however, that plaintiffs will identify their experts, provide expert reports, and produce their experts for deposition before Defendants are required to identify their experts, provide expert reports, and produce their experts for deposition.

**B. Production and Discoverability of Expert Materials** - Unless superseded by the foregoing section, discovery regarding expert opinions and related materials shall be governed by Rule 26(b)(4) of the Federal Rules of Civil Procedure.

**C. Motions Relating to Expert Testimony** - The parties will meet and confer regarding scheduling for any *Daubert* or other motion directed to causation issues of general applicability or any other dispositive motions.

**VI. ADDITIONAL CASE-SPECIFIC DISCOVERY**

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

This 25<sup>th</sup> day of May, 2012.



**Signed By:**

**Danny C. Reeves** DCR

**United States District Judge**