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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

IN RE: CHANTIX (VARENICLINE) PRODUCTS LIABILITY LITIGATION

Master File No.: 2:09-CV-2039-IPJ
MDL No. 2092

This Order Relates To:

ALL CASES

PRETRIAL ORDER NO. 4: DISCOVERY PLAN

I. SCOPE AND APPLICABILITY.

A. **Scope of Plan**. This Joint Coordinated Plan of Discovery ("Plan") is intended to conserve judicial resources, eliminate duplicative services by all counsel and co-counsel; 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 October 1, 2009, 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: Chantix (Varenicline) Products Liability Litigation, MDL No. 2092. This Plan may also apply to state court actions provided that the parties thereto so agree or the applicable court so

orders. Plaintiffs' State/Federal Liaison Counsel agree that they will support this Plan being entered as an order in any coordinated proceeding involving Chantix in New York state court. This Plan shall not be construed to affect the governing law or choice of law rules in any case subject to the Plan.

B. 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. This provision shall not preclude third party discovery; provided, however, that any party intending to serve third party discovery shall give ten (10) days written notice to the other party of the third party discovery to be served.

C. Use of Discovery in Federal and State Courts. Discovery conducted pursuant to this Plan may be utilized in state or federal court, in accordance with the applicable laws and rules of discovery and evidence. This provision shall not preclude any party from asserting in any action that any document, testimony, or other discovery produced pursuant to this Plan is inadmissible at trial.

II. WRITTEN DISCOVERY

A. Waiver of Initial Disclosures. For all cases subject to this Plan, the parties are relieved from complying with the requirements of Federal Rule of Civil Procedure 26(a) or any similar state court rule.

B. Master Written Discovery by Plaintiffs. Plaintiffs may serve Master Set(s) of Requests for Production, Master Set(s) of Interrogatories (not to exceed fifty interrogatories, including all discrete subparts, except by leave of this Court upon good cause shown), and Set(s) of Requests for Admission on Pfizer. Absent leave of Court, other than these Master Sets of Production, Master Sets of Interrogatories, and Sets of Requests for Admission, no other requests for production, interrogatories, or requests for admission may be propounded on Pfizer.

C. Master Written Discovery by Pfizer. In addition to the Plaintiff Fact Sheets, authorizations, and documents that are the subject of this Plan, for cases selected for trial or included in a discovery or trial pool, Pfizer may serve Requests for Production, Set(s) of Interrogatories (not to exceed twenty-five interrogatories, including all discrete subparts, except by leave of this Court upon good cause shown), and Set(s) of Requests for Admission.

III. PRODUCTION OF DOCUMENTS

A. Plaintiffs' Production of Fact Sheets, HIPAA Authorizations, and Documents. Plaintiffs shall produce to Defendant a "Plaintiff's Fact Sheet" for each Plaintiff, in the form attached hereto as Exhibit 1, the documents requested at the end of 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 Defendant's Counsel at the following address:

F.M. ("Tripp") Haston, III
Bradley Arant Boult Cummings LLP
One Federal Place
1819 Fifth Avenue North
Birmingham, AL 35203
Phone: (205) 521-8303
Fax: (205) 488-6303

1. Content of Fact Sheet and Authorizations.

a. 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 responses 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.

b. 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"), in the form attached hereto as Exhibit 2. The authorizations shall be dated and signed without setting forth the identity of the custodian of the records or provider of care. Pfizer may use the blank authorizations to obtain records from any custodian of record listed in the Plaintiff's Fact Sheet and may use the blank authorizations to obtain records from other custodians by providing Plaintiffs' counsel notice of its intent to do so.

c. Three Blank Employment Authorizations Served with Fact Sheet. 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, in the form attached hereto as Exhibit 3.

d. Medicare Authorizations. Pursuant to the reporting and other requirements of Medicare, Medicaid, and SCHIP Extension Act of 2007, each individual Plaintiff shall complete the Medicare Request for Information Form attached hereto as Exhibit 4.

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

2. Schedule for Production of Plaintiff's Fact Sheets.

a. For all cases filed on or before the date on which this Order is entered ("the entry date"), Plaintiffs shall produce the Plaintiff's Fact Sheet, HIPAA authorizations, and related documents within sixty (60) days from the entry date.

b. For any case filed after the entry date, Plaintiffs shall produce the Plaintiff's Fact Sheet, HIPAA authorizations, and related documents for such case within sixty (60) days of docketing of the case in the MDL. If a complaint is filed directly in the MDL, "docketing" will mean the day the complaint is filed; if a complaint is not filed directly in the MDL, "docketing" will mean the date that the Panel issues a Conditional Transfer Order transferring the case to this MDL.

B. Defendant's Production of Fact Sheets. Within 60 days of receipt of a substantially complete Plaintiff's Fact Sheet and substantially complete authorizations in a particular case, Defendant shall serve on Plaintiff's counsel of

record a Defendant's Fact Sheet in the form attached hereto as Exhibit 5. Because Defendant is providing a Defendant's Fact Sheet, absent leave of Court, the Plaintiff in that case may not serve on Defendant any case-specific interrogatories or requests for production.

C. Defendant's Production of Documents. Defendant shall produce (or where the parties agree it is appropriate, make available for review and/or inspection) a common set of documents to Plaintiffs as follows:

1. On or before March 5, 2010, Defendant shall produce the regulatory file regarding Chantix.

2. On or before April 1, 2010, Defendant shall produce the adverse events database regarding Chantix and the medical inquiry database regarding Chantix.

3. On or before May 17, 2010, Defendant shall produce the SAS datasets, study protocols, and final study reports for agreed-upon studies regarding Chantix. The parties shall meet and confer regarding the list of studies for which Defendant shall produce such documents and data, and Plaintiffs shall identify those studies for which Defendant shall produce documents and data by March 15, 2010.

4. The terminal date for documents subject to production under

the immediately preceding subparagraphs (1)-(3) shall be July 31, 2008. Defendant shall make a supplemental production of these documents with a terminal date for supplementation of July 31, 2009, on the following dates: (a) regulatory file – May 1, 2010; (b) adverse events database and medical inquiry database – June 1, 2010; (c) clinical study documents – July 1, 2010. The parties will meet and confer regarding any further supplemental production of these documents.

5. On or before August 1, 2010, Defendant shall produce the custodial files regarding Chantix for the 30 individuals who were identified in the list of thirty witnesses previously provided by Pfizer to Plaintiffs' Lead Counsel.

6. On or before August 1, 2010, Defendant shall produce all remaining documents responsive to Plaintiffs' Master Written Discovery.

7. Defendant's initial production of documents shall include documents generated on or before July 31, 2009 ("black box" label change).

8. The parties agree to meet and confer concerning a supplemental production of Defendant's documents generated on or after August 1, 2009 and on or before December 31, 2009, and are hereby **ORDERED** to do so. The production of these documents will not interfere with the deadline dates

as outlined below.

9. Defendant shall have an ongoing duty to supplement its production in a timely manner pursuant to Fed.R.Civ.P. 26(e)(1), including all data from ongoing safety and surveillance studies.

D. Preservation. The parties shall maintain and preserve documents produced pursuant to this Plan and/or in response to requests for production of documents so that they shall be available to all attorneys, on reasonable terms and conditions, and to the Courts in which the actions subject to this Plan are pending.

E. 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.

F. 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.

G. Format of Production. The protocol for and format of production of documents shall be in accordance with the Document Production Protocol, attached hereto as Exhibit 6.

H. Bates Numbering.

1. Bates Numbering Generally. 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.

2. Defendant's Bates Numbers to Reflect Source of Documents. Defendant's documents shall bear bates numbers that identify the individual from whom the document was collected, or, where the document was collected from files maintained other than by an individual, with some other bates number that identifies the file from which the document was collected.

3. **Production of Documents by Non-Parties**. The parties shall meet and confer regarding the production of any documents by non-parties in response to subpoenas or authorizations to identify an appropriate page numbering system prior to the production of any such documents.

I. **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 factual 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 within sixty (60) days after the production absent agreement of the parties. In the case of production by Pfizer 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. The parties

shall not be required to log communications with outside counsel that occurred after the first Chantix lawsuit was filed.

IV. DEPOSITIONS.

A. Commencement of Depositions.

1. Depositions of common fact witnesses currently or formerly employed by Pfizer, including any depositions conducted pursuant to Federal Rule of Civil Procedure 30(b)(6) (collectively "common Pfizer witnesses"), shall commence on September 1, 2010, but may commence earlier if the parties so desire.

2. Depositions of plaintiffs; plaintiffs' physicians; family members of plaintiffs; sales representatives and other relevant third party witnesses may commence on December 1, 2010.

B. Number of Depositions. No more than twenty-five depositions of common Pfizer witnesses shall be taken in total, and no more than five such depositions per month, absent agreement of the parties or good cause shown by Plaintiffs. This limitation includes any depositions conducted pursuant to Federal Rule of Civil Procedure 30(b)(6) or any comparable state rule of civil procedure.

C. Deposition Notices. A single deposition notice shall apply in all

cases governed by this Plan. Additional notices or cross-notices shall not be required. For cases pending in state court, the parties will consent to out-of-state commissions for the depositions of non-party witnesses (including physicians, family members, and others), subject to an expedited procedure to be negotiated by the parties.

D. **Deposition Scheduling**. Depositions must be noticed pursuant to Federal Rule of Civil Procedure 30 at least thirty (30) calendar days in advance, with notice served upon counsel. Absent extraordinary circumstances, counsel shall consult with opposing counsel and proposed deponents in advance in an effort to schedule depositions at mutually convenient times and places. Depositions should be scheduled by agreement of the parties based upon the availability of documents relevant to the specific witness and the availability of the witness and counsel. No more than one (1) deposition may be scheduled on the same day. Absent leave of court, no witness currently or formerly employed by Pfizer may be deposed more than once.

E. **Deposition Week**. In any week in which depositions will be taken, such depositions shall commence no earlier than 9:30 a.m. on Monday and end no later than 3:00 p.m. on Friday of that week, unless by agreement of the parties or court order.

F. **Deposition Day**. Except as stated above, the deposition day shall commence at 9:30 a.m. and terminate no later than 5:30 p.m., unless by agreement of the parties or court order.

G. **Locations for Taking Depositions**. Unless otherwise agreed by counsel for Plaintiffs, depositions of Plaintiffs will take place in each plaintiff's home district or jurisdiction. Unless otherwise agreed by counsel for Pfizer, depositions of Pfizer employees (past and current) will take place in one of the following locations, as designated by Pfizer: DLA Piper's offices in New York, NY, Williams & Connolly LLP's or DLA Piper's officer in Washington, D.C., and other locations as designated by Williams & Connolly LLP and/or DLA Piper. Unless otherwise agreed by the parties and the witness, depositions of prescribing physicians, treating physicians, family members, and other relevant third party witnesses shall take place in the district or jurisdiction in which those witnesses reside.

H. **Attendance at Depositions**. Unless otherwise agreed by the parties, depositions may be attended only by the parties, the deponent, the deponent's attorney, attorneys representing any party in any action governed by this Plan (including any employee or retained consultant of such attorney who is assisting in the litigation and whose presence is reasonably required by the

attorney), in-house counsel for Pfizer, the court reporter, and the videographer.

I. Sequence of Examination. Questioning at the depositions will be conducted in the following sequence: (1) the examiner designated by counsel noticing the deposition, (2) any physician or healthcare provider's counsel, (3) the examiner designated by the opposing counsel; (4) individual counsel for the deponent, if any, other than counsel above; and (5) any re-cross and/or redirect by such counsel, in the above order.

J. Use of Confidential Documents. While a deponent is being examined about any document that is confidential (or highly confidential, or otherwise subject to designation under the terms of the Protective Order entered in this litigation) because (i) the parties have so agreed, (ii) a party has designated the document confidential (or highly confidential, or otherwise designated the document) under the terms of the Protective Order, or (iii) a Court has so ordered, attendance at that deposition by persons to whom disclosure is not authorized by agreement of the parties, the terms of the Protective Order, or by court order shall be prohibited. Any portion of the deposition transcript containing confidential information (or highly confidential information or information otherwise subject to the Protective Order) shall be sealed as set forth in the Protective Order. Sealed portions of deposition transcripts may be opened,

read, and utilized for all purposes as permitted by the terms of the Protective Order entered in this litigation.

K. Objections at Depositions. All objections as to relevance and admissibility (i.e., objections other than to the form of the question) shall be preserved for later ruling by the court in which the action is pending. As soon as any one attorney representing a party to this litigation states the word "objection," all parties shall be deemed to have preserved all possible objections to the form of the question or the responsiveness of the answer. Counsel for other parties shall not repeat the objection.

L. Deposition Exhibits.

1. Provision of Hard Copies. Extra hard copies of documents about which counsel expect to examine the deponent should be provided to the reporter, the deponent, deponent's counsel, and a reasonable number of copies for counsel for the other party participants during the deposition.

2. Use of Bates Numbers. To the extent possible, all exhibits shall have printed bates numbers affixed. Documents that have not been previously produced shall be assigned a Bates number from a range of numbers reserved for this purpose. The first time a document is marked as a deposition exhibit, it shall be referred to by the Bates number appearing on the document.

3. Marking of Deposition Exhibits. All documents marked as exhibits shall be attached to the original transcript and retained with the original transcript. Copies of exhibits may be attached to copies of the transcript where the party ordering the transcript pays for the costs of copying those exhibits.

M. Videotaped Depositions. The provisions of this Plan regarding examination of deponents apply to videotaped depositions. Any deposition may be videotaped at the request of a party pursuant to the following terms and conditions:

1. Stenographic Recording. A certified court reporter shall simultaneously record stenographically all deposition proceedings and testimony. The court reporter shall administer the oath or affirmation to the deponent on camera. The written transcript by the court reporter shall constitute the official record of the deposition for purposes of Federal Rule of Civil Procedure 30(e) (submission to the witness) and 30(f) (filing; exhibits).

2. Cost of Deposition. The noticing party shall bear the expense of videotaping and stenographic recording. Motions to recover these costs and expenses may be made at the conclusion of the litigation in accordance with applicable law.

3. Videotape Operator. The video camera shall be operated by

an experienced video camera operator ("videotape operator"). In all cases subject to this Plan, including those cases pending in state court, the operator shall be subject to the provisions of Federal Rule of Civil Procedure 28(c). The videotape operator shall not distort the appearance or the demeanor of participants in the deposition by the use of camera or sound recording techniques.

4. **Interruptions**. The video camera operation will be suspended during the deposition only by agreement of counsel examining and defending the deposition, and "off the record" discussions shall not be videotape recorded. The video camera operator shall record on camera the time of suspension and any subsequent reconvening of the deposition.

5. **Index**. The videotape operator shall use a counter on the recording equipment and after completion of the deposition shall prepare a log, cross-referenced to counter numbers, that identifies the positions on the tape at which examination by different counsel begins and ends, at which objections are made and examination resumes, at which exhibits are identified, and at which any interruption of continuous tape recording occurs, whether for recesses, "off the record" discussion, mechanical failure, or otherwise.

6. **Certification**. After the deposition is completed, the video

operator shall certify on camera the correctness, completeness, and accuracy of the videotape recording in the same manner as a stenographic court reporter.

7. **Technical Data**. Technical data, such as recording speeds and other information needed to replay or copy the tape, shall be included with copies of the videotapes.

8. **Exhibits**. If examining counsel uses an Elmo or other device to capture document images during a videotaped deposition and incorporate the image into the videotape, such counsel may highlight or underline portions of the document but may not otherwise manipulate the document, such as by writing on or otherwise altering the document.

9. **No Distortion**. The camera operators shall not distort the appearance or the demeanor of participants in the deposition by the use of camera or sound recording techniques.

N. **Services of Deposition Officer**. Services and products offered or provided by a deposition officer (i.e., a court reporter or videotape operator) or the entity providing the services of a deposition officer to any party or to any party's attorney or non-party who is financing all or part of the deposition shall be offered or provided to all parties or their attorneys attending the deposition.

O. **Real-Time Transcription**. Any party may arrange for "real-time"

transcription of a deposition at its cost.

P. Correction and Signing of Deposition. The transcript of a deposition shall be submitted to the deponent for correction and signature within sixty (60) days after receipt of the transcript from the court reporter. The deposition may be signed by the deponent before any notary or pursuant to 28 U.S.C. § 1746. If no corrections are made within sixty (60) days after completion of the deposition, the transcript will be deemed accurate and the parties shall have the right to use a copy of the transcript in any further proceedings as though the copy were the original transcript. In the event the original transcript is unsigned, lost, stolen, or inadvertently destroyed, a certified copy reflecting any changes made to the original transcript may be used in place of the original.

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 at an appropriate time concerning the number of experts to be designated by each side.

B. Production and Discoverability of Expert Materials. Each expert will produce his or her final report and a copy of all documents that the expert has considered in preparing and/or rendering the expert's opinion. No other documents relating to expert reports will be produced, provided, however, that nothing in this agreement is intended to bar discovery of documents that are otherwise discoverable from a party or third party outside of the context of expert discovery. No party will seek discovery of any experts' notes, drafts of expert reports, or communications with counsel, provided, however, that counsel may inquire at deposition about any facts provided to the expert by counsel and upon which such expert is relying in expressing the expert's opinions.

C. Plaintiffs' Designation of General Causation and Liability Experts. Plaintiffs shall designate general causation and liability experts on or before April 1, 2011.

D. Defendant's Designation of General Causation and Liability Experts. Defendant shall designate general causation and liability experts on or before May 2, 2011.

E. Plaintiffs' Designation of Rebuttal Experts. Plaintiffs shall

designate rebuttal experts on or before June 1, 2011.

F. Depositions of General Causation and Liability Experts. Depositions of Plaintiffs' general causation and liability experts may commence on July 2, 2011. Depositions of Defendant's general causation and liability experts may commence fifteen days after the completion of depositions of Plaintiffs' general causation and liability experts. All depositions of general causation and liability experts shall be completed by October 3, 2011.

G. Motions Relating to General Causation and Liability. Any *Daubert* or other motion directed to causation issues of general applicability, or any other dispositive motions must be filed by October 31, 2011. Oppositions to such motions must be filed by November 30, 2011, and any reply briefs must be filed by December 15, 2011.

H. "General Causation and Liability Experts." The term "General Causation and Liability Experts" refers to those experts who will testify on causation and liability issues of general or widespread applicability (i.e., issues that are not specific to an individual plaintiff).

I. Coordinated Discovery and Hearings Regarding General Causation Experts. Where the parties engage in generally applicable expert discovery and/or hearings (e.g., relating to issues of general or widespread

applicability), the parties consent to coordinate such discovery and hearings for all Plaintiffs subject to this Plan.

J. Case-Specific Experts. Case-specific expert discovery will occur after the Court decides motions relating to causation issues of general applicability.

VI. CASE-SPECIFIC DISCOVERY.

This Plan sets forth a schedule for common discovery and for certain case-specific discovery, as described herein. The Parties shall meet and confer at a later date, once discovery that is the subject of this Plan is substantially complete, to discuss a schedule for further case-specific discovery. Until that time, absent court order, no discovery other than that permitted by this Plan may be conducted.

DONE and **ORDERED** this 24th day of February, 2010.

INGE PRYTZ JOHNSON
U.S. DISTRICT JUDGE

General Information

Court	United States District Court for the Northern District of Alabama; United States District Court for the Northern District of Alabama
Federal Nature of Suit	Personal Injury - Product Liability[365]
Docket Number	2:09-cv-02039
Status	CLOSED