

SUPREME COURT OF THE STATE OF NEW YORK  
COUNTY OF NEW YORK

-----X	:	Index No. 774000/2011
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IN RE: NEW YORK CHANTIX PRODUCT	:	CASE MANAGEMENT
LIABILITY LITIGATION	:	ORDER NO. 4
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THIS DOCUMENT APPLIES TO ALL CASES	:	
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**Discovery Plan and Coordination with Federal Multidistrict Litigation No. 2092**

**I. Applicability of This Order**

1. Scope of Order. This Order applies to pretrial procedures for cases involving the prescription medication Chantix that are presently or hereafter assigned to this Court (“New York Coordinated Proceeding”). This Order shall apply to all discovery conducted by the New York Coordinated Proceeding Plaintiffs’ Steering Committee (“New York PSC”) on behalf of all plaintiffs (including any committees or sub-committees specifically authorized by the New York PSC to conduct such discovery) and that conducted by Defendant Pfizer Inc (“Pfizer”) in these proceedings; neither individual Plaintiffs’ counsel nor any committees or sub-committees created by the New York PSC shall be entitled to conduct additional non-case-specific discovery in these proceedings other than as permitted by this Order or any subsequent Order of this Court.

2. Coordination with Chantix MDL. The Court is aware that product liability cases involving Chantix are pending in the federal multidistrict litigation entitled *In Re: Chantix (Varenicline) Products Liability Litigation*, MDL No. 2092, in the United States District Court for the Northern District of Alabama (“the MDL”). It is the intent and objective of this Court to allow discovery to proceed in the New York Coordinated Proceeding in coordination with the MDL where possible in order to conserve judicial resources, eliminate duplicative discovery,

serve the convenience of the parties and witnesses, and promote the fair and efficient conduct of this litigation.

## **II. The Parties' Agreement Regarding MDL Coordination**

3. Pfizer Voluntarily Agrees to Refrain from Filing FNC Motions. In consideration for Pfizer's agreement to refrain from filing motions to dismiss for *forum non conveniens* against any plaintiff who is a resident of the United States but not a resident of New York (including the forty-nine states other than New York, the District of Columbia, and Puerto Rico), except as may be further allowed under this (or any future) Case Management Order, the New York Coordinated Proceeding Plaintiffs consent and agree to the following pretrial procedures to be applied in the New York Coordinated Proceeding.

4. Adoption of MDL Discovery Plan. On February 24, 2010, the MDL Court issued Pretrial Order No. 4: Discovery Plan, and on March 11, 2010, the Court issued six exhibits to that order, all of which are attached hereto as Exhibit 1 ("MDL PTO 4"). The Court subsequently amended MDL PTO 4 on three occasions: (1) on April 30, 2010, when it issued Pretrial Order No. 4A: Amendment to Pretrial Order No. 4: Discovery Plan, which is attached hereto as Exhibit 2 ("MDL PTO 4A"); (2) on October 5, 2010, when it issued Pretrial Order No. 4B: Second Amendment to Pretrial Order No. 4: Discovery Plan, which is attached hereto as Exhibit 3 ("MDL PTO 4B"); and (3) on March 10, 2011, when it issued Pretrial Order No. 4C: Third Amendment to Pretrial Order No. 4: Discovery Plan, which is attached hereto as Exhibit 4 ("MDL PTO 4C") (collectively, all four orders referred to as "the MDL Discovery Plan"). The parties to the New York Coordinated Proceeding hereby agree to adopt the MDL Discovery Plan in its entirety, and hereby incorporate those orders by reference, except as specified below. No

party may conduct any discovery other than that permitted by the MDL Discovery Plan or this Order or subsequent case management orders issued by this Court.

5. Use of MDL Written Discovery and Documents. In the MDL, the MDL Plaintiffs' Leadership Structure ("MDL PLS") has issued Master Requests for Production of Documents and a Master Set of Interrogatories. To date, Pfizer has responded to the Master Requests for Production of Documents and the Master Set of Interrogatories and has produced more than 22 million pages of documents to the MDL PLS. To save the parties the unnecessary expense of re-producing those documents, and any future discovery Pfizer produces in the MDL, the New York PSC and the MDL PLS shall meet and confer with respect to the sharing of those documents. Consistent with Section I.B of MDL Pretrial Order No. 7 ("MDL PTO 7"), the MDL PLS shall not impose any assessment on a Non-Participating State Court Counsel who has access to such documents, so long as such counsel does not receive Common Benefit Work Product, as that term is defined in MDL PTO 7. In exchange for Pfizer's consent to such sharing, the New York PSC will not issue any additional requests for the production of documents or interrogatories other than in conjunction with the MDL PLS.

6. Plaintiff Fact Sheets, Authorizations, and Responsive Documents. Plaintiffs shall provide Plaintiff Fact Sheets, authorizations, and responsive documents required by the MDL Discovery Plan to:

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

7. Participation in MDL Depositions of Common Pfizer Witnesses. The New York PSC shall designate one examiner for each deposition of common Pfizer witnesses, pursuant to MDL PTO 4B. Plaintiffs' State / Federal Liaison Counsel in the MDL shall provide notice of any depositions of common Pfizer witnesses noticed by the MDL PLS in the MDL to all Plaintiffs' counsel in the New York Coordinated Proceeding. After a deposition of a common Pfizer witness has been noticed and taken in the MDL, then Plaintiffs in the Coordinated Proceeding may not take a subsequent deposition of that witness, except for good cause shown as determined by this Court or upon consent of the parties. In such instances, the subsequent deposition shall be restricted to such additional inquiry as permitted by the Court or agreed upon by the parties.

8. Depositions of Case-Specific Witnesses. The parties consent to the depositions of Plaintiffs' prescribing and treating physicians and other medical providers, as well as other relevant non-party witnesses, and consent to and shall negotiate an expedited procedure for the issuance of out-of-state commissions for the depositions of non-party witnesses, which shall be the subject of a future Case Management Order by this Court. The parties shall meet and confer with respect to a procedure for selecting the cases in which the parties shall conduct such discovery.

9. Expert Disclosures and Depositions. The parties shall provide disclosures of any expert who will testify at trial pursuant to N.Y. C.P.L.R. 3101(d) at least thirty days in advance of the expert's deposition (and, for any expert on general causation and/or liability, pursuant to the schedule established by the MDL Discovery Plan). Federal Rule of Civil Procedure 26 reports shall not be required for experts testifying only in the New York Coordinated Proceeding; provided, however, that any Rule 26 reports authored by an expert in connection

with the MDL may be used in the New York Coordinated Proceeding where that expert also is designated in the New York Coordinated Proceeding. As provided in the MDL Discovery Plan, the parties' testifying experts may be deposed as permitted under Federal Rule of Civil Procedure 26(b)(4)(A) and federal law. Where a party designates an expert for both the MDL and the New York Coordinated Proceeding, the parties shall meet and confer to identify a mutually convenient date for the expert's deposition in both the MDL and the New York Coordinated Proceeding.

10. Joint Hearing Regarding Admissibility of Expert Testimony. The parties consent to a joint hearing between this Court and the MDL Court on the admissibility of any expert testimony on general causation and/or liability issues, subject to both Courts' approval and subject to the parties' right to designate separate experts for the MDL and the New York Coordinated Proceeding. This provision shall not be construed to alter the law that governs the admissibility of expert testimony in the respective proceedings.

11. Negotiation of Further MDL Pretrial Orders and Case Management Orders. Representatives of the New York PSC shall be entitled to participate in the negotiation of future Pretrial Orders in the MDL so as to avoid duplicative negotiations in the New York Coordinating Proceeding and to promote efficiency and coordination between the MDL and the New York Coordinated Proceeding.

12. Pretrial Exchange of Witness & Exhibit Lists. The parties shall exchange witness lists and exhibit lists at least thirty days before any trial in the New York Coordinated Proceeding.

DONE and ORDERED this 15 day of  
April, 2011.

  
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HONORABLE CAROL E. HUFF  
Justice of the Supreme Court

# Exhibit 1

**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:

**PRETRIAL ORDER  
NO. 4: DISCOVERY PLAN**

ALL CASES

**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 35206  
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 office 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 24<sup>th</sup> day of February, 2010.



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INGE PRYTZ JOHNSON  
U.S. DISTRICT JUDGE

Exhibit 1 to MDL  
Pretrial Order No. 4

# Exhibit 1

**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 Fact Sheet Relates To:  
MDL Case No. \_\_\_\_\_

Plaintiff: \_\_\_\_\_  
(full name)

**PLAINTIFF'S FACT SHEET**

This Fact Sheet must be completed by each plaintiff who has filed a lawsuit related to his/her use of Chantix or as the representative of a person or the estate of a deceased person who used Chantix. Please answer every question to the best of your knowledge. In completing this Fact Sheet, you are under oath and must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details requested, please provide as much information as you can. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect. For each question, where the space provided does not allow for a complete answer, please attach additional sheets so that all answers are complete.

Information provided by plaintiff will only be used for purposes related to this litigation and may be disclosed only as permitted by the protective order in this litigation. This Fact Sheet is completed pursuant to the Federal Rules of Civil Procedure governing discovery (or, for state court cases, the governing rules of civil procedure of the state in which the case is pending).

**I. CASE INFORMATION**

A. Please provide the following information for the civil action which you filed:

1. Case Caption: \_\_\_\_\_
2. Court Case Number: \_\_\_\_\_
3. Court in which action was originally filed: \_\_\_\_\_
4. Court in which action is pending now: \_\_\_\_\_

5. Please state the name, address, telephone number, fax number, and e-mail address of principal attorney representing you:

Attorney Name: \_\_\_\_\_

Firm: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

Fax Number: \_\_\_\_\_

E-Mail Address: \_\_\_\_\_

B. If you are completing this questionnaire in a representative capacity (e.g., on behalf of the estate of a deceased person), please complete the following:

Your name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

In what capacity are you representing the individual? \_\_\_\_\_

If you were appointed by a court, state the:

State, Court Term and Number: \_\_\_\_\_

Date of Appointment: \_\_\_\_\_

Your relationship to the represented person: \_\_\_\_\_

If applicable, state the date and place of death of the decedent:

\_\_\_\_\_

If you are claiming the wrongful death of a family member, identify any and all heirs of that person:

\_\_\_\_\_

\_\_\_\_\_

[If you are completing this questionnaire in a representative capacity, please respond to the remaining questions with respect to the person who used Chantix. Those questions using the term "You" refer to the person who used Chantix. If the individual is deceased, please respond as of the time immediately prior to his or her death unless a different time period is specified.]

**II. CLAIM INFORMATION**

A. Do you claim that you suffer or have suffered any physical, mental, psychological, psychiatric, cognitive, or emotional injuries, illnesses, or disabilities that you believe were caused by Chantix? Yes: \_\_\_\_\_ No: \_\_\_\_\_

If yes, for each injury, please provide the following information:

Describe the nature of your injury, illness or disability: \_\_\_\_\_

\_\_\_\_\_

When did you first experience any symptoms you believe are related to that injury?

\_\_\_\_\_

What is the name and address of the first person you contacted about your symptoms?

\_\_\_\_\_

Date(s) of diagnosis (if any): \_\_\_\_\_

Medications prescribed: \_\_\_\_\_

Did you receive any treatment other than medication? Yes: \_\_\_\_\_ No: \_\_\_\_\_

If yes, please describe the other treatment received:

\_\_\_\_\_

Name of physician, psychiatrist, or other health care provider who first diagnosed you:

\_\_\_\_\_

Address: \_\_\_\_\_

Treating physician (if different): \_\_\_\_\_

Address: \_\_\_\_\_

Were you hospitalized at the time of the diagnosis? Yes: \_\_\_\_\_ No: \_\_\_\_\_

If yes, please provide the following information:

Hospital name and address: \_\_\_\_\_

\_\_\_\_\_

Date of admission: \_\_\_\_\_ Date of discharge: \_\_\_\_\_

B. Does the injury, illness, or disability persist today? Yes: \_\_\_\_\_ No: \_\_\_\_\_

If yes, identify the current symptoms, the treatment you continue to receive, and the physician(s) providing treatment:

Current symptoms: \_\_\_\_\_

Medications currently taking: \_\_\_\_\_

Other treatment currently receiving: \_\_\_\_\_

Treating physician (if different from above): \_\_\_\_\_

Address (if not otherwise provided): \_\_\_\_\_

\_\_\_\_\_

C. Do you allege that Chantix caused you to attempt suicide (or caused the decedent to commit suicide)? Yes: \_\_\_\_\_ No: \_\_\_\_\_

If you answered "Yes," please complete the following:

Date you attempted suicide / decedent committed suicide: \_\_\_\_\_

Means by which you attempted suicide / decedent committed suicide: \_\_\_\_\_

\_\_\_\_\_

Were any toxicology tests performed? Yes: \_\_\_\_\_ No: \_\_\_\_\_

If so, what were the results? \_\_\_\_\_

If decedent committed suicide: Was an autopsy performed? Yes: \_\_\_\_\_ No: \_\_\_\_\_

Was any law enforcement official, governmental official, or other individual present at the time of the incident or respond to the incident? If yes, please list such persons.

\_\_\_\_\_

\_\_\_\_\_

Were there any individuals who had contact with you or would have knowledge of your behavior or mental state in the 72 hours immediately preceding your suicide attempt (or decedent's suicide)? If so, please identify their name, address, and relationship to you.

\_\_\_\_\_

\_\_\_\_\_

D. Lost Earnings: Do you claim that you lost earnings or suffered impairment of earning capacity as a result of any condition that you believe was caused by Chantix?  
Yes: \_\_\_\_\_ No: \_\_\_\_\_ If you answered "Yes," please answer the following:

State the total amount of time you have lost from work as a result of any condition you claim was caused by Chantix.

\_\_\_\_\_  
State the annual gross income you derived from your employment for each of the last five (5) years (or attach your federal tax returns for each of the last five (5) years).

\_\_\_\_\_  
State the amount of income you claim you lost as a result of any condition you claim was caused by Chantix.

E. Medical Expenses: Please list all of your medical expenses, including amounts billed or paid by insurers and other third-party payors, which are related to any condition which you claim was caused by Chantix for which you seek recovery in the action which you have filed. \$ \_\_\_\_\_

F. Chantix Use: Identify by name and address the physician, psychiatrist, or other health care professional(s) who prescribed Chantix for you, the dosage and date(s) during which he or she prescribed Chantix, and the dosage and date(s) you took Chantix:

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_  
City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_ Phone: \_\_\_\_\_

Hospital Affiliation (if any): \_\_\_\_\_

Reason for Prescription: \_\_\_\_\_

Date Prescribed: \_\_\_\_\_ Dosage Prescribed: \_\_\_\_\_

Date(s) Used: \_\_\_\_\_

During your visit to the prescribing doctor's office, were you provided any written information about Chantix by the doctor or his or her staff?

Yes: \_\_\_\_\_ No: \_\_\_\_\_ Do Not Recall: \_\_\_\_\_

If you answered "Yes," please describe the document you received:

\_\_\_\_\_  
\_\_\_\_\_

During your visit to the prescribing doctor's office, were you told anything about Chantix by the doctor or his / her staff?

Yes: \_\_\_\_\_ No: \_\_\_\_\_ Do Not Recall: \_\_\_\_\_

If you answered "Yes," please identify each person who told you anything about Chantix and describe what he or she told you:

\_\_\_\_\_  
\_\_\_\_\_

G. Have you had discussions with any physician, psychiatrist, or other health care professional about whether your condition is related to Chantix?

Yes: \_\_\_\_\_ No: \_\_\_\_\_ Don't know: \_\_\_\_\_ If yes, please identify:

Name of health care professional: \_\_\_\_\_

Address: \_\_\_\_\_

Date of discussion: \_\_\_\_\_

What were you told? Please check one of the following:

- 1. \_\_\_\_\_ I was told my condition is related to Chantix.
- 2. \_\_\_\_\_ I was told my condition is not related to Chantix.
- 3. \_\_\_\_\_ I was told my condition may be related to Chantix.
- 4. \_\_\_\_\_ I was told by the doctor that he or she does not know whether my condition is related to Chantix.
- 5. \_\_\_\_\_ I don't recall what I was told.
- 6. \_\_\_\_\_ Other (describe discussion regarding Chantix):

\_\_\_\_\_

(If discussed with more than one doctor, please answer for each doctor, using additional pages as necessary.)

**III. PERSONAL INFORMATION OF CHANTIX USER**

**A. Background Information:**

Name: \_\_\_\_\_

Maiden or other names used or by which you have been known:  
\_\_\_\_\_

Social Security Number: \_\_\_\_\_

Medicare Health Insurance Claim Number (if applicable): \_\_\_\_\_

Identify each address at which you have resided during the last ten (10) years and the approximate dates during which you lived at each one (most recent first):

Street Address	City, State, Zip	Dates Resided	
		From	To

Date and Place of Birth: \_\_\_\_\_

Sex: Male \_\_\_\_\_ Female \_\_\_\_\_

Do you have a driver's license? Yes: \_\_\_\_\_ No: \_\_\_\_\_

Have you ever had your driving privileges suspended or limited based on your health or physical condition? Yes: \_\_\_\_\_ No: \_\_\_\_\_

If so, when and for what reason(s)? \_\_\_\_\_  
\_\_\_\_\_

B. Family Information:

1. Have you ever been married? Yes: \_\_\_\_\_ No: \_\_\_\_\_

If you have been married, for each spouse, state:

Spouse's Name	Date of Marriage	Date Marriage Ended	Spouse's Date of Birth	Spouse's Occupation	Spouse's Present Address

2. Has your spouse filed a loss of consortium or other claim in this lawsuit?

Yes: \_\_\_\_\_ No: \_\_\_\_\_

3. If you have children, please identify each child's name and date of birth:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

C. Employment History:

Current occupation: \_\_\_\_\_

Please identify each of your employers over the past ten (10) years, including the dates of each such employment and positions held (most recent first):

Employer	Address	Type of Business & Position	Dates of Employment

Have you ever been out of work for more than thirty (30) days for reasons related to your health? Yes: \_\_\_\_\_ No: \_\_\_\_\_

If yes, please state the dates, employer, and health condition:

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In the year prior to any injury you claim was caused by Chantix:

Were you fired, demoted, or suspended? Yes: \_\_\_\_\_ No: \_\_\_\_\_

Did you receive any negative performance reviews? Yes: \_\_\_\_\_ No: \_\_\_\_\_

If you answered "Yes" to any of the above questions, please describe the circumstances:

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D. Educational History:

Identify each high school, vocational school, college, university or other post-secondary educational institution you have attended, the dates of attendance, and diplomas or degrees awarded:

School	Dates of Attendance	Diplomas/Degree Awarded

E. Military Service:

1. Have you ever served in any branch of the military? Yes: \_\_\_\_\_ No: \_\_\_\_\_

2. Branch and dates of service:

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3. Were you discharged for any reason relating to your health (whether physical, psychiatric or other health condition)?

Yes: \_\_\_\_\_ No: \_\_\_\_\_

If yes, state the condition:

\_\_\_\_\_

4. Have you ever been rejected from military service for any reason relating to your health (whether physical, psychiatric, or other health condition)?

Yes: \_\_\_\_\_ No: \_\_\_\_\_

F. Worker's Compensation Claims: Have you ever filed a worker's compensation claim?

Yes: \_\_\_\_\_ No: \_\_\_\_\_ If yes, please state:

Year claim was filed: \_\_\_\_\_

Where claim was filed: \_\_\_\_\_

Claim/docket number, if applicable: \_\_\_\_\_

Nature of claimed injury: \_\_\_\_\_

Period of disability: \_\_\_\_\_

[Attach additional sheets as necessary to describe more than one claim.]

G. Social Security Disability Claims: Have you ever made a social security disability claim?

Yes: \_\_\_\_\_ No: \_\_\_\_\_ If yes, please state:

Year claim was filed: \_\_\_\_\_

Where claim was filed: \_\_\_\_\_

Nature of disability: \_\_\_\_\_

Period of disability: \_\_\_\_\_

[Attach additional sheets as necessary to describe more than one clam.]

H. Other Disability Claims: Have you ever made any other form of disability claim?

Yes: \_\_\_\_\_ No: \_\_\_\_\_ If yes, please state:

Year claim was filed: \_\_\_\_\_

Where claim was filed: \_\_\_\_\_

Name of insurer/employer or other party to whom claim was made:

\_\_\_\_\_

Nature of disability: \_\_\_\_\_

Period of disability: \_\_\_\_\_

I. Life Insurance: Have you ever been denied life insurance? Yes: \_\_\_\_\_ No: \_\_\_\_\_

If yes, please state when, the name of the company, and the company's stated reason for denial (if any).

\_\_\_\_\_

\_\_\_\_\_

J. Other Lawsuits: Within the last ten (10) years, have you filed a lawsuit or made a claim, *other than* in the present suit? Yes: \_\_\_\_\_ No: \_\_\_\_\_

If yes, state: (1) the state and county in which claim was filed, (2) the caption, case name and/or names of adverse parties, (3) the civil action or docket number assigned to each such claim, action or suit, (4) the claims you made in that suit, and (5) the current status of the claim.

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

K. Prior Convictions: Have you ever been convicted of, or pled guilty (or no contest) to, a felony and/or a crime involving fraud or dishonesty within the last ten (10) years?

Yes: \_\_\_\_\_ No: \_\_\_\_\_ If so, please describe: (1) the crime or offense, (2) the state and county in you were which convicted or pled, (3) the date on which you were convicted or pled guilty, and (4) the sentence or other outcome.

\_\_\_\_\_

\_\_\_\_\_

- L. Computer Use: Have you had access to a computer at any time during the past five (5) years? Yes: \_\_\_\_\_ No: \_\_\_\_\_ If “yes,” then answer the following:

Did you ever visit any website containing information regarding Chantix, other smoking cessation products, help quitting smoking, or the risks of smoking?

Yes: \_\_\_\_\_ No: \_\_\_\_\_ Do Not Recall: \_\_\_\_\_

Did you ever communicate via email or visit any chat rooms regarding Chantix, other smoking cessation products, help quitting smoking, or the risks of smoking?

Yes: \_\_\_\_\_ No: \_\_\_\_\_ Do Not Recall: \_\_\_\_\_

**IV. LIST OF HEALTHCARE PROVIDERS**

- A. Health Care Providers (Including Mental Health Care Providers): Identify each physician, doctor, or other health care provider (including any psychiatrist, psychologist, therapist, counselor, or other mental health care provider) who has provided treatment to you for any reason in the past ten (10) years and the reason for consulting the health care provider or mental health care provider (attach additional sheets as needed).

Name	Address	Approximate Dates	Reason for Consultation

- B. Hospitals, Clinics, & Other Facilities: Identify each hospital, clinic, or healthcare facility where you have received inpatient or outpatient treatment (including emergency room treatment) in the past ten (10) years (attach additional sheets as needed):

Name	Address	Approximate Dates	Reason for Treatment

- C. Pharmacies: Identify each pharmacy, drugstore and/or other supplier (including mail order) where you have had prescriptions filled or from which you have ever received any prescription medication since in the past ten (10) years (attached additional sheets as needed):

Name of Pharmacy	Address of Pharmacy	Approximate Dates

- D. Insurance Carriers: Identify each health insurance carrier which provided you with medical coverage and/or pharmacy benefits for the last ten (10) years, with the named insured and named insured's social security number (attach additional sheets as needed).

Carrier	Address	Name of Insured & SSN (if not Chantix user)	Policy Number

- E. Other Witnesses: Other than those previously identified, please identify all persons who you believe possess information concerning your injury and/or your current medical condition. For each person, please state their name, address, phone number, relationship to you, and the information you believe they possess (attach additional sheets as needed).

Name	Address (including City, State, Zip) and Phone Number	Relationship	Information you believe they possess

Name	Address (including City, State, Zip) and Phone Number	Relationship	Information you believe they possess

**V. PLAINTIFF'S HEALTH HISTORY**

- A. Over the past ten (10) years, have you experienced or been diagnosed or treated for any injuries, illnesses or disabilities (whether physical, psychiatric, or otherwise) *other than* those that you believe were caused by Chantix? Yes: \_\_\_\_\_ No: \_\_\_\_\_

If yes, for each injury, please provide the following information (attach additional sheets as needed):

Injury, illness, or disability	When first experienced symptoms	When first diagnosed	Name(s) of health care provider(s) who treated and/or diagnosed	Treatment received (including medications, if any)	Do you suffer from this condition today (Y/N)?

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B. Please indicate whether to the best of your knowledge you have ever experienced or been diagnosed or treated for:

1. Mental health conditions, including but not limited to:

- Aggressive/violent behavior Yes: \_\_\_\_\_ No: \_\_\_\_\_
- Anxiety (on at least a periodic basis) Yes: \_\_\_\_\_ No: \_\_\_\_\_
- Attention Deficit/Hyperactivity Disorder Yes: \_\_\_\_\_ No: \_\_\_\_\_
- Bi-polar disorder Yes: \_\_\_\_\_ No: \_\_\_\_\_
- Depression (on at least a periodic basis) Yes: \_\_\_\_\_ No: \_\_\_\_\_
- Personality disorders Yes: \_\_\_\_\_ No: \_\_\_\_\_
- Psychosis or psychiatric illnesses Yes: \_\_\_\_\_ No: \_\_\_\_\_
- Schizophrenia Yes: \_\_\_\_\_ No: \_\_\_\_\_
- Suicide attempt Yes: \_\_\_\_\_ No: \_\_\_\_\_
- Suicidal behavior Yes: \_\_\_\_\_ No: \_\_\_\_\_
- Suicidal ideation (e.g., fantasies, dreams, thoughts, premonitions, or fears relating to death, accident, or suicide) Yes: \_\_\_\_\_ No: \_\_\_\_\_

2. Epilepsy and/or seizure disorder Yes: \_\_\_\_\_ No: \_\_\_\_\_

3. Alcoholism Yes: \_\_\_\_\_ No: \_\_\_\_\_

4. Drug Abuse Yes: \_\_\_\_\_ No: \_\_\_\_\_

If you answered yes to any of the above, for each condition, please describe your symptoms, the date you first experienced symptoms, the date you were diagnosed, the name and address of the physician(s) who diagnosed and/or treated you, the treatment you received, and the current status of the condition, to the extent not already answered in Section V.A above:

Condition / Symptoms	When first experienced symptoms	When first diagnosed	Name(s) of health care provider(s) who treated and/or diagnosed	Treatment received (including medications, if any)	Do you suffer from this condition today (Y/N)?

If you ever have attempted suicide in the past, please complete the following for each and every suicide attempt:

Date you attempted suicide	Method by which you attempted suicide	Were any toxicology tests performed (Y/N)?

C. Smoking History:

1. State amount smoked up until you began using Chantix:

Packs per Day	Number of Years Smoked	Dates of Years You Smoked

2. Has any doctor ever advised you that any health condition you had was caused or exacerbated by smoking? Yes: \_\_\_\_\_ No: \_\_\_\_\_

If so, what health condition did your doctor tell you was caused or exacerbated by smoking?

\_\_\_\_\_

\_\_\_\_\_

3. Has any doctor ever advised you to quit smoking for health reasons?

Yes: \_\_\_\_\_ No: \_\_\_\_\_ If so, what health reasons did your doctor give in advising you to quit smoking?

\_\_\_\_\_

\_\_\_\_\_

4. During the time that you were using Chantix, did you continue to smoke ?

Yes: \_\_\_\_\_ No: \_\_\_\_\_ Do Not Recall: \_\_\_\_\_

If yes, state amount smoked: \_\_\_\_\_ packs per day from \_\_\_\_\_ to \_\_\_\_\_

If no, state date on which smoking ceased: \_\_\_\_\_

5. Did you smoke cigarettes on the day of your alleged injury?

Yes: \_\_\_\_\_ No: \_\_\_\_\_ Do Not Recall: \_\_\_\_\_

6. Indicate whether you have smoked cigarettes since you stopped using Chantix:

Yes: \_\_\_\_\_ No: \_\_\_\_\_ If yes, state amount smoked:

\_\_\_\_\_ packs per day during the period \_\_\_\_\_ to \_\_\_\_\_

7. Had you ever tried to stop smoking before you used Chantix?

Yes: \_\_\_\_\_ No: \_\_\_\_\_ If yes, identify the date and duration of your quit attempt, the amount you smoked prior the quit attempt, how you tried to quit (e.g., Zyban, nicotine gum, cold turkey, other), and why you resumed smoking:

Date and Duration of Quit Attempt	Packs Smoked per Day in Month Leading up to Quit Attempt	Method of Quit Attempt	Reason(s) Why You Resumed Smoking

D. Drinking History:

1. Do you currently or have you in the past drank alcohol (beer, wine, whiskey, etc.)? Yes: \_\_\_\_\_ No: \_\_\_\_\_

2. If yes, please check which represents your typical alcohol consumption in the six (6) months leading up the date on which you first experienced any symptoms you believe are related to the injury/ies alleged in your Complaint:

- \_\_\_\_\_ 1 - 2 drinks per week
- \_\_\_\_\_ 3 - 6 drinks per week
- \_\_\_\_\_ 7 - 10 drinks per week
- \_\_\_\_\_ 10 or more drinks per week
- \_\_\_\_\_ Other (explain: \_\_\_\_\_)

3. If yes, please check which represents your typical alcohol consumption over the past ten (10) years:

- 1 - 2 drinks per week
- 3 - 6 drinks per week
- 7 - 10 drinks per week
- 10 or more drinks per week
- Other (explain: \_\_\_\_\_)

E. Illegal Drug Use:

1. At any time, have you ever been arrested for, charged with, tested positively for, and/or treated for use of an illegal drug of any kind (i.e., cocaine, ecstasy, heroin, marijuana, methamphetamines, etc.)? Yes  No
2. At any time, have you ever frequently used an illegal drug? Yes  No
3. Have you used any illegal drug more than ten times per year in any of the past fifteen (15) years? Yes  No
4. Since one year before you started taking Chantix to the present, have you used (even one time) any illegal drug? Yes  No

If you answered yes to any of the above questions, please: (1) identify each substance, (2) when you first and last used it, and (3) how frequently you used it.

F. Family Medical History: Please indicate whether, to the best of your knowledge, your *parents, siblings, children, or grandparents* have experienced, been diagnosed with, or treated for any of the following conditions:

1. Mental health conditions, including but not limited to:

- |   |                               |                              |                                      |
|---|-------------------------------|------------------------------|--------------------------------------|
| Aggressive/violent behavior   | Yes: <input type="checkbox"/> | No: <input type="checkbox"/> | Don't Know: <input type="checkbox"/> |
| Anxiety (on at least a periodic basis)  | Yes: <input type="checkbox"/> | No: <input type="checkbox"/> | Don't Know: <input type="checkbox"/> |
| Attention Deficit/Hyperactivity Disorder  | Yes: <input type="checkbox"/> | No: <input type="checkbox"/> | Don't Know: <input type="checkbox"/> |
| Bi-polar disorder   | Yes: <input type="checkbox"/> | No: <input type="checkbox"/> | Don't Know: <input type="checkbox"/> |
| Depression (on at least a periodic basis)   | Yes: <input type="checkbox"/> | No: <input type="checkbox"/> | Don't Know: <input type="checkbox"/> |
| Personality disorders   | Yes: <input type="checkbox"/> | No: <input type="checkbox"/> | Don't Know: <input type="checkbox"/> |
| Psychosis or psychiatric illnesses  | Yes: <input type="checkbox"/> | No: <input type="checkbox"/> | Don't Know: <input type="checkbox"/> |
| Schizophrenia   | Yes: <input type="checkbox"/> | No: <input type="checkbox"/> | Don't Know: <input type="checkbox"/> |
| Suicide attempt / completed suicide   | Yes: <input type="checkbox"/> | No: <input type="checkbox"/> | Don't Know: <input type="checkbox"/> |
| Suicidal behavior   | Yes: <input type="checkbox"/> | No: <input type="checkbox"/> | Don't Know: <input type="checkbox"/> |
| Suicidal ideation (e.g., fantasies, dreams, thoughts, premonitions, or fears relating to death, accident, or suicide) | Yes: <input type="checkbox"/> | No: <input type="checkbox"/> | Don't Know: <input type="checkbox"/> |

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- 2. Epilepsy and/or seizure disorder Yes: \_\_\_ No: \_\_\_ Don't Know: \_\_\_
- 3. Alcoholism Yes: \_\_\_ No: \_\_\_ Don't Know: \_\_\_
- 4. Drug Abuse Yes: \_\_\_ No: \_\_\_ Don't Know: \_\_\_

If you answered yes to any of the preceding, please identify: (1) the person(s) who experienced, was diagnosed with, or was treated for that condition, (2) that person's relationship to you, (3) the condition that person experienced, and (4) whether that person died from the condition or complications related to the condition.

Person	Relationship to You	Condition	Death from Condition?

- G. Medications: List all prescription medications you have taken in the past ten (10) years, including the name of the medication, the time period(s) you took it (including the dates first and last taken), and the reasons your physician prescribed it, if known:

Medication	Date First Taken	Date Last Taken	Reason for Prescription/Use

**VI. DOCUMENTS**

- A. Authorizations: Please sign and attach to this Fact Sheet the authorizations for the release of records appended hereto.
- B. Documents in your possession: If you have any of the following materials in your custody or possession, or in the possession, custody or control of your lawyers, please attach a copy to this Fact Sheet.
1. If you have been the claimant or subject of any worker's compensation, Social Security or other disability proceeding, all documents relating to such proceeding.
  2. Copies of all medical records, bills, and any other documents from physicians, psychiatrists, healthcare providers (including mental health care providers), hospitals, pharmacies, insurance companies, or others who have provided treatment to you in the past ten (10) years or that you otherwise identified in this Fact Sheet, including but not limited to documents relating to your purchase of Chantix such as receipts, prescriptions, or records of purchase.
  3. All documents constituting, reporting, summarizing, or referring to any medical test, psychological test, psychiatric test, or mental health test of any kind ever taken by or administered to plaintiff over the past ten (10) years.
  4. All documents that describe, refer to, or record any conviction of plaintiff for a: (1) felony, (2) crime of dishonesty, (3) crime involving the use of, possession of, addiction to, intoxication with, or abuse of any form of alcohol, controlled substance, mind-altering substance, illegal drug, or medication, or (4) act of violence against or abuse of another person over the past ten (10) years.
  5. All notes, reports, recommendations, memoranda, correspondence, and other documents in which any person, including, but not limited to, school administrators, counselors, health care providers, and/or law enforcement personnel, described, warned about, opined on, or in any way referred to any actual, observed, or possible behavioral problem, deportment problem, psychological or psychiatric problem, mental problem, mental illness, alcohol problem, suicidal ideation, or substance-abuse problem of or with respect to plaintiff for a period of ten (10) years prior to the date of the alleged injury.
  6. All documents constituting, concerning, or relating to product use instructions, product warnings, package inserts, pharmacy handouts, or other materials distributed with or provided to you in connection with your use of Chantix, including but not limited to documents which mention Chantix or any alleged health risks or hazards related to Chantix in your possession at or before the time of the injury alleged in your Complaint.
  7. Copies of advertisements, brochures, pamphlets, web pages, or other promotional material for Chantix, as well as any other documents related to Chantix.

8. Any articles, web pages, books, or other documents discussing smoking and/or smoking cessation.
9. Copies of the entire packaging, including the bottle, box and label for the Chantix you allege caused you injury and any remaining medication. (To the extent these items already are in your possession, you or your attorney must maintain the originals of the items requested in this subpart.)
10. Copies of any document written or prepared by plaintiff, including but not limited to any journal(s), diary(ies), note(s), letter(s), and/or email(s), that mentions, discusses, or refers to any thought, expression, or act of suicide, depression, anxiety, grief, hostility, troubled behavior, or violence, including, but not limited to, any suicide note(s) and/or letters, emails, or other communications around the time of the incident or at any other time, or that refers to any injuries or illnesses you allege were caused by Chantix.
11. Copies of all documents you (not your lawyer) obtained from any source related to Chantix or to the alleged effects of ingesting Chantix, including but not limited to documents obtained directly or indirectly from Pfizer.
12. All documents relating to any web sites you have viewed, chat rooms, web logs (or "blogs"), electronic mail, or other Internet activity in which you have engaged related to your use of Chantix, smoking cessation, and/or the injuries you allege Chantix caused.
13. All documents relating to any communication by any person, including your attorneys, to or from the Food & Drug Administration ("FDA"), including but not limited to on-line, telephoned, mailed, or faxed communications to the FDA's MedWatch program regarding Chantix, including the dates of such communications.
14. If you claim you have suffered a loss of earnings or earning capacity, your W-2s for each of the last five (5) years.
15. Copies of letters testamentary or letters of administration relating to your status as plaintiff (if applicable).
16. Decedent's death certificate and autopsy report (if applicable).

**VERIFICATION**

I declare under penalty of perjury subject to 28 U.S.C. § 1746 that all of the information provided in this Plaintiff's Fact Sheet is true, complete, and correct to the best of my knowledge, information, and belief, and that I have supplied all the documents requested in Part VI of this Plaintiff's Fact Sheet, to the extent that such documents are in my possession or in the possession of my lawyers, and that I have signed and supplied the authorizations attached to this Verification.

Further, I acknowledge that I have an obligation to supplement the above responses if I learn that they are in any material respect incomplete or incorrect.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Print Name: \_\_\_\_\_

Exhibit 2 to MDL  
Pretrial Order No. 4

## Exhibit 2

**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 Fact Sheet Relates To:  
MDL Case No. \_\_\_\_\_

Plaintiff: \_\_\_\_\_  
(full name)

**HIPAA COMPLIANT AUTHORIZATION FOR USE AND DISCLOSURE  
OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION**

**Person/Entity from Whom  
Records are Requested:**

\_\_\_\_\_  
Provider Name ("Provider")

\_\_\_\_\_  
Address                      City, State and Zip Code

**Patient:**

\_\_\_\_\_  
Patient Name

\_\_\_\_\_  
Address                      City, State and Zip Code

\_\_\_\_\_  
Date of Birth                      Social Security Number

**Information Authorized To Be Disclosed:** I authorize the Provider to furnish copies of my entire medical record and all of my individually identifiable health information, to include but not be limited to: x-ray reports, CT scan reports, echocardiographic recordings, radiographic films, blood tests, MRI scans, MRA films, EEGs, EKGs, sonograms, arteriogram, pathology specimens, discharge summaries, photographs, videos, DVDs, emails, or other electronically stored information, data, or images, surgery consent forms, admission and discharge

records, operation records, doctor and nurses notes, progress notes, prescriptions, medical bills, medical reports and records, invoices, histories, diagnoses, narratives, correspondence, memoranda, and billing information, pharmacy records, prescription records including NDC numbers and drug information handouts and/or monographs. If the Provider is in possession of records from any other source, I authorize release of those records under this authorization.

This authorization includes records for treatment of psychological, psychiatric and emotional problems. It also includes, to the extent such records exist and are in the Provider's possession, employment records, workers' compensation records, disability records, social security records, and insurance records, including Medicare/Medicaid and other public assistance claims applications, statements, eligibility material, claims or claim disputes, resolutions and payments, medical records provided as evidence of services provided, and any other documents or things pertaining to services furnished under Title XVII of the Social Security Act or other forms of public assistance (federal, state, local, or other). This listing is not meant to be exclusive.

**Person to Whom Records are to be Disclosed ("Recipient"):** I authorize disclosure of the above specified information to the defendant in the above-captioned litigation, in which I am a plaintiff, and its authorized agent as set forth below:

Medical Research Consultants – Attn: RECORD RETRIEVAL

---

Name of Recipient or Recipient's Agent

Agent for Service of Record on Behalf of Defendant Pfizer Inc

---

Relationship to Recipient

10114 Sam Houston Parkway South, Suite 200, Houston, TX 77099

---

Address

City, State and Zip Code

I further authorize disclosure to any counsel for Pfizer Inc in the above-captioned litigation, as well as any employees, agents, or independent contractors retained by such counsel and including but not limited to counsel for Pfizer's insurers. The Recipient has agreed to pay reasonable charges incurred by the Provider to supply copies of such records.

**Purpose of Disclosure:** I am requesting disclosure of these records in connection with the above-referenced litigation in which I am a plaintiff.

**Acknowledgements:**

I understand that once information covered by this authorization has been disclosed, redisclosure of that information by the Recipient is possible, and the information may no longer be protected by federal or state law, including the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).

I understand that information disclosed under this authorization could relate to, and I hereby authorize the disclosure of, information regarding treatment and testing for (please initial):

- \_\_\_\_\_ Drug or alcohol abuse
- \_\_\_\_\_ Acquired Immunodeficiency Syndrome (AIDS), Human Immunodeficiency Virus (HIV), and other sexually transmitted diseases
- \_\_\_\_\_ Sickle Cell Anemia
- \_\_\_\_\_ Tuberculosis
- \_\_\_\_\_ Genetic testing and counseling

I understand that my signing of this authorization is voluntary. Refusing to sign or revoking this authorization will not affect my health care treatment, enrollment in my health plan, or eligibility for payment and benefits under my health plan.

I further understand that, pursuant to applicable state law, I may have a right to receive a copy of this authorization as provided in 45 CFR 164.524.

**Term:** This authorization shall be valid through December 31, 2015 or the conclusion of my case, whichever occurs first. This authorization remains in full force and effect until such expiration, and further authorizes the Provider to release to the Recipient any additional records created or obtained by the Provider after the date hereof.

**Revocation:** I understand that I may revoke this authorization at any time by writing to the Provider at the Provider’s above address, but my revocation will not apply to information that has already been released before the Provider receives notice of any revocation. Cancellation, revocation, or modification will only be valid once the Provider receives written notification of such cancellation, revocation or modification. A copy of said notification shall also be sent to the

Recipient identified above. I also understand that provision of this signed authorization is required by Order of the Court in the litigation to which this authorization pertains, and that such revocation, without good cause, may consequently lead to sanctions.

**Copies:** Any photostatic copy of this document shall have the same authority as the original, and may be substituted in its place.

Date: \_\_\_\_\_

\_\_\_\_\_  
Signature of Patient or Legal/Personal Representative

\_\_\_\_\_  
Description of Representative's Authority to Act for Patient, if Applicable

**FOR RECIPIENT'S USE ONLY –**

**Plaintiff's Lawyer(s) to Receive Notices of Receipt of Requests and Records:**

Lawyer's Name(s): \_\_\_\_\_

Firm Name: \_\_\_\_\_

Lawyer's Email(s) (Required): \_\_\_\_\_

Exhibit 3 to MDL  
Pretrial Order No. 4

## Exhibit 3

**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 Fact Sheet Relates To:  
MDL Case No. \_\_\_\_\_

Plaintiff: \_\_\_\_\_  
(full name)

**AUTHORIZATION FOR RELEASE OF RECORDS FROM EMPLOYER,  
EDUCATIONAL INSTITUTION, AND OTHER PROVIDERS**

**Person/Entity from Whom  
Records are Requested ("Provider"):**

\_\_\_\_\_  
Name of Employer/Educational Institution

\_\_\_\_\_  
Address                      City, State and Zip Code

**Employee:**

\_\_\_\_\_  
Employee Name ("Employee")

\_\_\_\_\_  
Address                      City, State and Zip Code

\_\_\_\_\_  
Date of Birth                      Social Security Number

**Information Authorized To Be Disclosed:** I authorize the Provider to furnish all records and information in its possession including but not limited to: Copies of all applications for employment, unemployment benefits, resumes, records of all positions held, job descriptions of positions held, salary and/or compensation records, performance evaluations and reports, statements and comments of fellow employees, attendance records, W-2's, worker's compensation files, all health care

records, including all hospital, physician, clinic, infirmary, nurse and dental records, x-rays, test results, physical examination records, any records pertaining to claims made relating to health, disability or accidents in which I was involved including correspondence, reports, claim forms, questionnaires, records of payments made to me or on my behalf, and any other records relating to my employment with the above-named institution, including records regarding the Employee's employment, income, and education, including attendance reports, performance reports, W-4 and W-2 forms, medical reports, workers' compensation claims, and all other records relating to employment, past and present, and claims for disability. This listing is not meant to be exclusive.

**Person to Whom Records are to be Disclosed ("Recipient"):** I authorize disclosure of the above specified information to the defendant in the above-captioned litigation, in which I am a plaintiff, and its authorized agent as set forth below:

Medical Research Consultants – Attn: RECORD RETRIEVAL

---

Name of Recipient or Recipient's Agent

Agent for Service of Record on Behalf of Defendant Pfizer Inc

---

Relationship to Recipient

10114 Sam Houston Parkway South, Suite 200, Houston, TX 77099

---

Address

City, State and Zip Code

I further authorize disclosure to any counsel for Pfizer Inc in the above-captioned litigation, as well as any employees, agents, or independent contractors retained by such counsel and including but not limited to counsel for Pfizer's insurers. The Recipient has agreed to pay reasonable charges incurred by the Provider to supply copies of such records.

**Purpose of Disclosure:** I am requesting disclosure of these records in connection with the above-referenced litigation in which I am a plaintiff.

**Acknowledgements:**

I understand that once information covered by this authorization has been disclosed, redisclosure of that information by the Recipient is possible, and the information may no longer be protected by federal or state law, including the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

I understand that my signing of this authorization is voluntary. Refusing to sign or revoking this authorization will not affect my health care treatment, enrollment in my health plan, or eligibility for payment and benefits under my health plan.

I further understand that, pursuant to applicable state law, I may have a right to receive a copy of this authorization as provided in 45 CFR 164.524.

**Term:** This authorization shall be valid through December 31, 2014 or the conclusion of my case, whichever occurs first. This authorization remains in full force and effect until such expiration, and further authorizes the Provider to release to the Recipient any additional records created or obtained by the Provider after the date hereof.

**Revocation:** I understand that I may revoke this authorization at any time by writing to the Employer at the Employer's above address, but my revocation will not apply to information that has already been released before the Employer receives notice of any revocation. Cancellation, revocation, or modification will only be valid once the Employer receives written notification of such cancellation, revocation or modification. A copy of said notification shall also be sent to the Recipient identified above. I also understand that provision of this signed authorization is required by Order of the Court in the litigation to which this authorization pertains, and that such revocation, without good cause, may consequently lead to sanctions.

**Copies:** Any photostatic copy of this document shall have the same authority as the original, and may be substituted in its place.

Date: \_\_\_\_\_

\_\_\_\_\_  
Signature of Employee or Legal/Personal Representative

\_\_\_\_\_  
Description of Personal Representative's Authority to Sign for Employee

**FOR RECIPIENT'S USE ONLY –**

**Plaintiff's Lawyer(s) to Receive Notices of Receipt of Requests and Records:**

Lawyer's Name(s): \_\_\_\_\_

Firm Name: \_\_\_\_\_

Lawyer's Email(s) (Required): \_\_\_\_\_

Exhibit 4 to MDL  
Pretrial Order No. 4

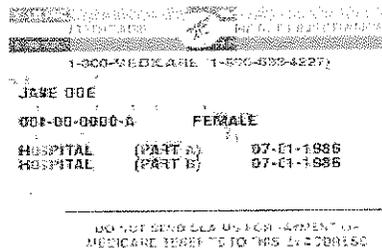
## Exhibit 4

The Centers for Medicare & Medicaid Services (CMS) is the federal agency that oversees the Medicare program. Many Medicare beneficiaries have other insurance in addition to their Medicare benefits. Sometimes, Medicare is supposed to pay after the other insurance. However, if certain other insurance delays payment, Medicare may make a "conditional payment" so as not to inconvenience the beneficiary, and recover after the other insurance pays.

Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA), a new federal law that became effective January 1, 2009, requires that liability insurers (including self-insurers), no-fault insurers, and workers' compensation plans report specific information about Medicare beneficiaries who have other insurance coverage. This reporting is to assist CMS and other insurance plans to properly coordinate payment of benefits among plans so that your claims are paid promptly and correctly.

We are asking you to the answer the questions below so that we may comply with this law.

**Please review this picture of the Medicare card to determine if you have, or have ever had, a similar Medicare card.**



**Section I**

Are you presently, or have you ever been, enrolled in Medicare Part A or Part B?												<input type="checkbox"/> Yes		<input type="checkbox"/> No			
<i>If yes, please complete the following. If no, proceed to Section II.</i>																	
<b>Full Name:</b> <i>(Please print the name exactly as it appears on your SSN or Medicare card if available.)</i>																	
<b>Medicare Claim Number:</b>										<b>Date of Birth (Mo/Day/Year)</b>			- -				
<b>Social Security Number:</b> <i>(If Medicare Claim Number is Unavailable)</i>										- -			<b>Sex</b>		<input type="checkbox"/> Female	<input type="checkbox"/> Male	

**Section II**

I understand that the information requested is to assist the requesting insurance arrangement to accurately coordinate benefits with Medicare and to meet its mandatory reporting obligations under Medicare law.

\_\_\_\_\_  
**Claimant Name (Please Print)**

\_\_\_\_\_  
**Claim Number**

\_\_\_\_\_  
**Name of Person Completing This Form If Claimant is Unable (Please Print)**

\_\_\_\_\_  
**Signature of Person Completing This Form**

\_\_\_\_\_  
**Date**

*If you have completed Sections I and II above, stop here. If you are refusing to provide the information requested in Sections I and II, proceed to Section III.*

Form 1001

\_\_\_\_\_  
**Claimant Name (Please Print)**

\_\_\_\_\_  
**Claim Number**

For the reason(s) listed below, I have not provided the information requested. I understand that if I am a Medicare beneficiary and I do not provide the requested information, I may be violating obligations as a beneficiary to assist Medicare in coordinating benefits to pay my claims correctly and promptly.

**Reason(s) for Refusal to Provide Requested Information:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
**Signature of Person Completing This Form**

\_\_\_\_\_  
**Date**

Exhibit 5 to MDL  
Pretrial Order No. 4

# Exhibit 5

**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 Fact Sheet Relates To:  
MDL Case No. \_\_\_\_\_

Plaintiff: \_\_\_\_\_  
(full name)

**DEFENDANT'S FACT SHEET**

For each Plaintiff from whom it has received a substantially complete and verified Plaintiff Fact Sheet ("PFS") and substantially complete authorizations, Defendant Pfizer Inc ("Pfizer") must complete this Defendant Fact Sheet ("DFS"). Pfizer shall serve a complete and verified DFS and responsive documents on Plaintiffs' counsel of record within sixty (60) days after receipt of a substantially complete and verified PFS and substantially complete authorizations. Pfizer shall attach additional sheets of paper (or documents) if that is necessary to completely answer the following questions.

**I. CASE INFORMATION**

This Defendant Fact Sheet pertains to the following Plaintiff:

Case Caption: \_\_\_\_\_

Court Case No.: \_\_\_\_\_

Court in which action was originally filed: \_\_\_\_\_

Court in which action is pending now: \_\_\_\_\_

**II. CONTACTS WITH PRESCRIBING HEALTH CARE PROVIDER**

In Section II.F of the PFS, Plaintiff identified person(s) who prescribed CHANTIX® to Plaintiff (hereinafter "Prescribing Health Care Provider"). For each Prescribing Health Care Provider identified, please state the following:

A. Dear Doctor or Dear Healthcare Provider Letters: For each and every "Dear Doctor" or "Dear Healthcare Provider" letter that was sent to Plaintiff's Prescribing Health Care Provider regarding CHANTIX®, if any, please:

1. Identify the master letter sent, including bates numbers.
2. State the date of each master letter sent.

3. State the person to whom the letter was sent.
  4. State the address to which the master letter was sent.
- B. Other Contacts: For each Prescribing Health Care Provider identified, please produce complete “call” notes, if any (subject to any redactions permitted by the protective order in this litigation), from or of any CHANTIX®-related “sales” visits or contact calls made by Pfizer sales representatives or employees of Pfizer before or during the prescription period to each Prescribing Health Care Provider identified in the PFS of which you have knowledge and which are available to you.
- C. Consulting with Plaintiff’s Prescribing Health Care Provider(s):
1. For each Prescribing Health Care Provider(s) to whom Pfizer paid consideration on the subject of CHANTIX® as: (1) a “key opinion leader” or (2) a member of Pfizer’s Speaker Program, please state:
    - a. The name of the Prescribing Health Care Provider(s).
    - b. The dates the Prescribing Health Care Provider(s) was affiliated with Pfizer with respect to CHANTIX®.
    - c. The amount of money paid to the Prescribing Health Care Provider(s) with respect to CHANTIX®, if available.
  2. For each Prescribing Health Care Provider(s) to whom Pfizer paid consideration on any subject other than CHANTIX®, or to whom Pfizer made payments relating to CHANTIX® other than any listed in your answer to Section II.C.1 above, please state:
    - a. The name of the Prescribing Health Care Provider(s).
    - b. The date(s) on which the Prescribing Health Care Provider(s) received any payment from Pfizer.
    - c. The amount(s) paid to the Prescribing Health Care Provider(s), if available.
    - d. The purpose of or reason for such payment, if available.
  3. To your knowledge, has Plaintiff’s Prescribing Health Care Provider(s) ever contacted you to request information concerning CHANTIX®, its indications, its effects and/or its risks? Yes: \_\_\_\_\_ No: \_\_\_\_\_

If your answer is “yes,” please identify the Prescribing Health Care Provider and attach any document which refers to any such communication from or to Plaintiff’s Prescribing Health Care Provider.

**III. PLAINTIFF COMMUNICATIONS**

A. To your knowledge, have you been contacted by Plaintiff, any of his/her physicians, or anyone on behalf of Plaintiff concerning Plaintiff regarding CHANTIX®, other than in connection with the present lawsuit?

Yes: \_\_\_\_\_ No: \_\_\_\_\_

If your answer is “yes,” please state:

1. The name of the person(s) who contacted you.
2. The person(s) who was contacted.
3. Please attach any document which refers to any such communication.

B. Please produce a copy of any FDA Adverse Event report or MedWatch form which refers or relates to Plaintiff, as well as any underlying documentation (e.g., the adverse event source file, medical records, and non-privileged investigative reports) which refer or relate to Plaintiff.

**CERTIFICATION**

I declare under penalty of perjury subject to 28 U.S.C. § 1746 that all of the information provided in this Profile Form is true and correct to the best of my knowledge and that I have supplied all requested documents to the extent that such documents are in my possession, custody and control (including the custody and control of my lawyers).

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date

Exhibit 6 to MDL  
Pretrial Order No. 4

## Exhibit 6

**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 Document Relates To:  ALL CASES	<b>DOCUMENT PRODUCTION PROTOCOL (EXHIBIT 6 TO PRETRIAL ORDER NO. 4)</b>

This Document Production Protocol (“Protocol”) 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 (“the MDL proceedings”). This Protocol also may apply to state court actions provided that the parties thereto so agree or the applicable court so orders. This Protocol shall apply to the production of hard-copy and electronic documents by Pfizer Inc and its agents, employees (current and former), representatives, subsidiaries, and other affiliated entities (collectively, “Pfizer”).

1. Document Images.

a. Document Images Generally. All documents that originally existed in either hard-copy or native electronic form that are not privileged or otherwise protected from production and are responsive to discovery requests or Court order (or are otherwise produced in these proceedings) shall be produced in electronic image form in

the manner provided herein, except where otherwise indicated. Each document's electronic image shall convey the same information and image as the original document. The parties shall meet and confer promptly to address any documents that present imaging or formatting problems to attempt to resolve any such problems.

b. Image Format. All production document images will be provided as single-page "TIFFs" utilizing Group 4 compression. All images generated from hard-copy documents shall be scanned as single page black and white images at 300 d.p.i. resolution. All native electronic documents shall reflect how the source document would have appeared if printed out to a printer attached to a computer.

c. Color Images. Where the Plaintiffs' Steering Committee ("PSC") wishes to obtain color images of a document that contains color, the parties shall meet and confer regarding the production of color images for such documents and the format for such production. Pfizer shall honor reasonable and specific requests for the production of color image(s) of such documents.

2. Information Accompanying Document Images.

a. Load Files. Pfizer shall provide documents with a Concordance delimited file and an Opticon delimited file. Examples of such files are listed below:

Example of Opticon Delimited File:

MSC000001,MSC001,D:\IMAGES\001\MSC000001.TIF,Y,,,3  
MSC000002,MSC001,D:\IMAGES\001\MSC000002.TIF,Y,,,,  
MSC000003,MSC001,D:\IMAGES\001\MSC000003.TIF,Y,,,,  
MSC000004,MSC001,D:\IMAGES\001\MSC000004.TIF,Y,,,2  
MSC000005,MSC001,D:\IMAGES\001\MSC000005.TIF,Y,,,,

Example of Concordance Delimited File :

 BegDocp\_ EndDocp\_ BegAttachp\_ EndAttachp\_ Custodianp

b. Document Unitization. Each page of a hard copy document shall be scanned or electronically saved into an image. If a document is more than one page, the unitization of the document and any attachments and/or affixed notes shall be maintained as it is kept in the ordinary course of business. Distinct documents should not be merged into a single record, and single documents should not be split into multiple records. The parties will make their best efforts to have their vendors unitize documents correctly and will commit to address situations where there are improperly unitized documents.

c. File Naming Conventions. Each page image file shall be named with the unique Bates Number of the page of the document in the case of single-page TIFFs, followed by the extension "TIF." In the event the Bates Number contains a symbol and/or character that cannot be included in a file name, the symbol and/or character will be omitted from the file name.

d. Production Media. Pfizer shall produce documents on CD-ROM, DVD, external hard drive (with standard PC compatible interface formatted using NTFS with a firewire and/or USB 2.0 interface), or such other readily accessible computer or electronic media as the parties agree upon ("the Production Media"). Each piece of Production Media shall identify a production number corresponding to the production "wave" with which the documents on the Production Media are associated (e.g., "Pfizer-CX 001," "Pfizer-CX 002"), as well as the volume of the material in that production wave (e.g., "-001," "-002"). For example, if the first production wave by Pfizer comprises document images on three hard drives, Pfizer shall label each hard drive in the following manner: "Pfizer-CX 001-001," "Pfizer-CX 001-002," and "Pfizer-CX 001-

003.” The Production Media also shall bear a label indicating: (1) that it was produced in MDL No. 2092, (2) the producing party’s name, (3) the production date (including the day, month, and year that the production was created on the disk or hard drive), (4) where practicable, the type of materials on the media (*e.g.*, “Images,” “OCR text,” or “load files”), and (5) where practicable, the Bates Number range of the materials contained on the Production Media. If any such information cannot be placed on the label on the Production Media, it shall be provided in an accompanying letter. Should any single “wave” produced by Pfizer exceed five (5) DVDs, the production shall be made by hard drive, which will be supplied and/or paid for by the PSC.

e. Objective Coding. If either party objectively codes the documents Pfizer produces in this litigation, that party shall produce with each production of documents (or upon creation of such coding) an ASCII text file, appropriately delimited, setting forth the objective coding for each document (the “Objective Coding”). The datafile shall include the fields and type of content set forth in Exhibit A to this Order, if available. If Pfizer produces the Objective Coding, the Objective Coding shall be labeled and produced on Production Media in accordance with the provisions stated herein. If the PSC has problems importing and using the Objective Coding for document management, the parties shall meet and confer to attempt to resolve the problems. Neither party’s production of Objective Coding shall constitute any certification as to the reliability, accuracy or completeness of the coding, nor shall it constitute any waiver of work product protection or the attorney-client privilege with respect to that coding.

3. Text Files Accompanying Document Images.

a. Unredacted Electronic Text Files. For documents that exist natively in electronic format that Pfizer has not redacted in any part and that Pfizer produces as images, Pfizer shall produce extracted text files reflecting the full text that has been electronically extracted from the original, native electronic files (“Extracted Text”).

b. Redacted Electronic Text Files and Text Files Accompanying Hard-Copy Documents. For documents that exist natively in electronic format that Pfizer has redacted in any part or for hard-copy documents, Pfizer shall produce corresponding Optical Character Recognition (“OCR”) text files (“OCR Text”).

c. Format of Production of Extracted Text or OCR Text. The Extracted Text and/or OCR Text (collectively, “the Text Files”) shall be provided in ASCII text format and shall be labeled and produced on Production Media. The Text Files will be named with the unique Bates Number of the first page of the corresponding document followed by the extension “.TXT”.

d. No Certification as to Text Files. Pfizer’s production of the Text Files shall not constitute any certification as to the reliability, accuracy or completeness of the Extracted Text or the OCR Text.

e. Meta-Data. For images generated from native electronic documents, Pfizer shall produce meta-data corresponding to the fields in Exhibit A to this Protocol, where available.

4. Original Documents. Pfizer shall retain the original hard-copy and native electronic source documents for all documents produced in this MDL proceeding. Pfizer

shall make reasonable efforts to maintain the original native electronic source documents in a manner so as to preserve the “meta-data” associated with these electronic materials. Subject to preservation of appropriate privileges and other protections of Pfizer’s information from production in accordance with applicable law, Pfizer shall, upon reasonable request, make originals of any produced document available for inspection by the requesting party in the form in which such documents are kept in the ordinary course of business.

5. Databases. Where Pfizer is producing a database, it shall provide the PSC with the data contained in the database in a fully searchable format which mirrors the fields of the original database to the extent possible using SQL. Contemporaneously with the production, Pfizer will provide to the PSC a description of the fields in each database, where available. The parties will meet and confer regarding which, if any, fields Pfizer claims are protected or privileged and should be withheld from production if such fields are not already addressed by the protective order in this litigation.

6. Searches to Identify Discoverable Materials. The parties will meet and confer regarding the individuals, databases, and locations (collectively “sources”) which have been and will be searched for potentially discoverable materials. The parties also will confer regarding the method which Pfizer has and shall use in searching those sources, including the use of an agreed set of search terms. Should the PSC identify additional sources or request additional searches, the parties shall meet and confer regarding such sources and searches before seeking relief from the Court.

7. Use of Documents. When documents produced in accordance with this Protocol are used in any proceeding, including depositions, hearings, or trial, the image

copy of the document shall be the copy used. OCR or extracted text shall not be used in any proceeding as a substitute for the image of any document.

**Exhibit A**

<b><u>Coding Field</u></b>	<b><u>Description</u></b>
BegBates; EndBates	The beginning and ending Bates numbers for the document at issue.
BegAttach; EndAttach	The beginning and ending Bates numbers of the collection to which the document and any attachments thereto are associated ( <i>i.e.</i> , for an email that is bates stamped ABC0001 – ABC0002, with two attachments bates stamped ABC0003 – ABC0004 and ABC0005 – ABC0008, the BegAttach and EndAttach for all three documents would be ABC0001 – ABC0008).
DocDate	The date of the document, formatted as follows: MM/DD/YYYY, with leading zeros as appropriate ( <i>e.g.</i> , 01/01/2010). For emails, the field will reflect the date the email was sent; for other documents, the field will reflect the last date on which the document was saved.
DocType	The type of document ( <i>e.g.</i> , email, Microsoft Word 2000, Microsoft Excel, etc.).
Document Title	The title of the document, if any, including any meta-data title field of the native file.
AuthorName	The author(s) of a document, including the display name or author field value, pulled from the meta-data of an ESI document.
To	The addressed recipient(s) of a document.
CC	The addressed recipient(s) of copies of a document.
BCC	The addressed recipient(s) of blind copies of a document.
Subject	Subject of an email message or on the face of the document.
DocID	The unique number of a document assigned by a document management system, if available with the extracted meta-data.
Comments	The comments embedded in the document, if available with the extracted meta-data and it is technologically feasible to include with the meta-data load file.
Attachment List	Document names of responsive and non-privileged attachments to emails or other documents, if available with the extracted meta-data and it is technologically feasible to include with the meta-data load file.
Custodian	The name of the individual whose electronic or hardcopy custodial file contained the document at issue.
Importance	For Outlook emails, “High,” “Low,” or “Normal.”

<b><u>Coding Field</u></b>	<b><u>Description</u></b>
Sensitivity	For Outlook emails, “Normal,” “Private,” “Personal,” or “Confidential.”
Marginalia	For hard-copy documents, yes or no indication of whether the document at issue contains handwritten notations, notes, or marginalia.
Redacted	Yes or no indication of whether the document at issue is redacted.
Confidential	Yes or no indication of whether the document at issue was designated as confidential or highly confidential as of the date of production.
MD5 Hash code	Unique identifier, extracted from all files; the Hash value or “de-duplication key” assigned to a document.

# Exhibit 2

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 Document Relates To:

**PRETRIAL ORDER NO. 4A:  
AMENDMENT TO PRETRIAL  
ORDER NO. 4: DISCOVERY PLAN**

ALL CASES

On February 24, 2010, the Court issued Pretrial Order No. 4: Discovery Plan. Section III.C of the Discovery Plan, which set forth certain dates for Pfizer's production of documents, hereby is amended as follows:

1. On or before June 15, 2010, Pfizer has agreed to produce custodial files regarding Chantix for five of the individuals who were identified in the list of thirty witnesses previously provided by Pfizer to Plaintiffs' Lead Counsel.
2. On or before July 1, 2010, Pfizer has agreed to produce custodial files regarding Chantix for five more individuals on the list of thirty witnesses previously provided by Pfizer to Plaintiffs' Lead Counsel.
3. On or before August 1, 2010, Pfizer has agreed to produce custodial files regarding Chantix for the remaining twenty individuals on the

list of thirty witnesses previously provided by Pfizer to Plaintiffs' Lead Counsel.

4. The terminal date for documents subject to production under the immediately preceding subparagraphs (1)-(3) shall be July 31, 2009. For any such custodians who continued to work on Chantix after July 31, 2009, Pfizer has agreed to make a supplemental production of those documents with a terminal date of December 31, 2009; the supplemental production will be due on September 1, 2010. Absent agreement of the parties or order of the Court for good cause shown, Pfizer shall not be required to produce any custodial documents dated after December 31, 2009.

5. On or before October 1, 2010, Pfizer has agreed to produce custodial files regarding Chantix for the seven additional individuals agreed to by the parties.

6. Absent agreement of the parties or order of the Court for good cause shown, Pfizer shall not be required to produce more than 50 custodial files in total. For the 13 remaining custodial files regarding Chantix whose deadline for production is not otherwise specified in this Order, absent agreement of the parties or order of the Court for good cause shown, Pfizer has agreed to produce such custodial files 60 days after Plaintiffs' Lead Counsel identifies the custodian and requests production of his or her

custodial file, except that the earliest date for such production(s) shall be October 1, 2010.

**DONE** and **ORDERED** this the 30<sup>th</sup> day of April, 2010

A handwritten signature in cursive script, reading "Inge Prytz Johnson".

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INGE PRYTZ JOHNSON  
U.S. DISTRICT JUDGE

# Exhibit 3

**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. 4B:  
SECOND AMENDMENT TO  
PRETRIAL ORDER NO. 4:  
DISCOVERY PLAN**

On February 24, 2010, the Court issued Pretrial Order No. 4: Discovery Plan (“PTO 4”). On April 30, 2010, the Court issued Pretrial Order No. 4A: Amendment to Pretrial Order No. 4: Discovery Plan (“PTO 4A”). Section IV of PTO 4 set forth certain requirements for depositions, and Section V of PTO 4 set forth certain requirements relating to expert discovery.

At the request of the parties, the Court hereby amends and supplements Section IV and Section V of PTO 4 as outlined herein. This order shall not be construed to amend PTO 4 or PTO 4A in any respect other than as specified in this order.

**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”), may commence on January 3, 2011.

2. Depositions of plaintiffs, plaintiffs’ physicians, family members of plaintiffs, sales representatives, and other relevant third party witnesses may commence on April 1, 2011; provided, however, that: (a) by February 1, 2011, the parties shall submit to the Court a joint proposal (or, to the extent they cannot reach agreement, their competing proposals) regarding the process for selecting a pool of initial cases eligible for such discovery (and, if necessary, trial), and such discovery may not commence until the Court issues an order regarding that process; and (b) no case will be eligible to be included in the initial pool of cases set for discovery and/or trial if the plaintiff has not filed a complaint in this MDL and served a substantially complete Plaintiff Fact Sheet, authorizations, and responsive documents by January 3, 2011.

**Q. Coordination of Depositions with State Court Litigation.**

1. Coordination of MDL with New York & Other State Court Litigation. To facilitate the coordination of these MDL

proceedings with state court product liability cases involving Chantix, the parties have agreed to modify PTO 4 and agree to request the entry of orders adopting PTO 4 and this order in applicable state court litigations.

2. Deposition Length Generally. All depositions shall be limited to one seven-hour day of examination by the noticing side, absent good cause shown or agreement of the parties. Examination by the non-noticing side shall not count against the seven-hour limit. The parties shall endeavor to limit duplicative questioning so as to be as efficient as possible with respect to deposition time.

3. Request for Additional Deposition Time for Common Pfizer Witnesses or Expert Witnesses. For any common Pfizer witness or expert witness (both those pertaining to general liability or case-specific experts), if Lead Counsel for either side believes that the deposition will or may last beyond one day, Lead Counsel shall notify opposing Lead Counsel at the time of issuing the deposition notice or within a reasonable time thereafter, so that the parties may meet and confer with respect to whether any additional deposition time is warranted and schedule the deposition accordingly. Consent to additional deposition time shall not be unreasonably withheld. Absent exceptional circumstances or agreement of the parties, neither side may obtain additional deposition time if they do not request the additional time at the time of issuing the deposition notice or within a reasonable time thereafter.

4. Sequence of Examination of Common Pfizer Witnesses.

Consistent with Section IV.I of PTO 4, questioning of common Pfizer witnesses will be conducted in the following sequence: (1) examination by one attorney designated by MDL Plaintiffs' Lead Counsel; (2) examination by one attorney designated by New York Plaintiffs' Liaison Counsel; (3) examination by plaintiffs' counsel in any other state court litigations, provided that such counsel do not exceed one counsel per state; (4) examination by one attorney designated by Defendants' Lead Counsel; (5) any physician or healthcare provider's counsel, provided that such counsel do not exceed one counsel per state; (6) examination by individual counsel for the deponent, if any, other than counsel above; and (7) any re-examination by the counsel listed above, provided that time remains within the Plaintiffs' seven-hour limit. Plaintiffs' counsel shall cooperate with respect to the division of time so as to ensure that the interests of the state court plaintiffs' counsel are adequately addressed, and the Plaintiffs' attorneys designated to conduct the examinations shall coordinate with each other so as to conduct as thorough and non-duplicative an examination as is practicable. The parties shall leave sufficient time for examination by the attorney designated by Defendants' Lead Counsel, but such time shall not count against the Plaintiffs' seven hours.

5. Questions by Non-Designated Examiners. Any Plaintiffs' counsel not designated to examine a deponent may suggest matters for inquiry in any deposition by providing to the designated examiners a written list of questions and a brief explanation of such matters. Any Defendants' counsel in any related state action not designated to examine a deponent may suggest matters for inquiry in any deposition by providing to the examiner designed by Defendants' Lead Counsel a written list of questions and a brief explanation of such matters.

6. Use of Depositions in MDL and State Court Proceedings. Any examination conducted by any examiner may be used in the MDL proceedings, consistent with the law, rules of procedure and evidence, and orders of this Court. Any depositions taken in these MDL proceedings may be used in any state court action, in accordance with that State's law and rules of procedure and evidence.

**V. REVISED SCHEDULE FOR EXPERT DISCOVERY.**

**K. Revised Schedule for Designations and Depositions of Experts.**

Plaintiffs shall designate general causation and liability experts (as that term is used in Section V.H of PTO 4) on or before August 5, 2011. Defendant shall designate general causation and liability experts on or before September 2, 2011.

Plaintiffs shall designate rebuttal experts on or before September 30, 2011.

Depositions of Plaintiffs' general causation and liability experts may commence on October 31, 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 February 24, 2012.

**L. Revised Schedule for Motion Practice Involving Experts.** Any *Daubert* or other motion directed to causation issues of general applicability, or any other dispositive motions must be filed by March 23, 2012. Oppositions to such motions must be filed by April 20, 2012, and any reply briefs must be filed by May 11, 2012.

**DONE and ORDERED** this the 5<sup>th</sup> day of October, 2010.



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INGE PRYTZ JOHNSON  
U.S. DISTRICT JUDGE

# Exhibit 4

**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. 4C: THIRD  
AMENDMENT TO PRETRIAL  
ORDER NO. 4: DISCOVERY PLAN**

On February 24, 2010, the Court issued Pretrial Order No. 4: Discovery Plan (“PTO 4”). On April 30, 2010, the Court issued Pretrial Order No. 4A: Amendment to Pretrial Order No. 4: Discovery Plan (“PTO 4A”). On October 5, 2010, the Court issued Pretrial Order No. 4B: Second Amendment to Pretrial Order No. 4: Discovery Plan (“PTO 4B”). Section IV of PTO 4 set forth certain requirements for depositions, and Section V of PTO 4 set forth certain requirements relating to expert discovery.

At the request of the parties, the Court hereby amends and supplements Section IV and Section V of PTO 4 as outlined herein. This order shall not be construed to amend PTO 4 or PTO 4A or PTO 4B in any respect other than as specified in this order.

**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”), may commence on May 16, 2011.
2. Depositions to be conducted in the pool of initial cases eligible for discovery and trial (hereinafter referred to as “Bellwether Cases”) will be governed by the provisions set forth in Pretrial Order No. 9.

**V. REVISED SCHEDULE FOR EXPERT DISCOVERY.**

**K. Revised Schedule for Disclosures and Depositions of Experts.**

The following schedule is limited to experts in cases involving suicide, attempted suicide and neuropsychiatric events. The Court will enter a separate Order pertaining to experts for any other category of injury at a later date or upon motion by the parties.

1. General Causation and Liability Experts. Plaintiffs shall disclose general causation and liability experts (as that term is used in Section V. H of PTO 4) in accordance with FRCP 26(a)(2) on or before November 7, 2011. Defendant shall disclose general causation and liability experts in accordance with

FRCP 26(a)(2) on or before December 5, 2011. Plaintiffs shall designate rebuttal experts on or before December 30, 2011.

Depositions of Plaintiffs' general causation and liability experts may commence on January 16, 2012. Depositions of Defendant's general causation and liability experts may commence after the completion of the depositions of Plaintiffs' general causation and liability experts. All depositions of general causation and liability experts for initial Bellwether Cases shall be completed by March 30, 2012.

2. Specific Causation and Liability Experts. The scheduling and procedures regarding specific causation and liability experts for Bellwether Cases will be governed by the provisions set forth in Pretrial Order No. 9.

**L. Revised Schedule for Motion Practice Involving Experts.**

The following schedule is limited to experts in cases involving suicide, attempted suicide and neuropsychiatric events. The Court will enter a separate Order pertaining to expert motion practice for cases with any other category of injury at a later date or upon motion by the parties.

1. General Causation and Liability. Any *Daubert* or other motion directed to causation issues of general applicability must be filed by April 30, 2012. Oppositions to such motions must be filed by May 18, 2012, and any reply briefs must be filed by June 1, 2012.

2. Specific Causation and Liability. The scheduling and procedures regarding any *Daubert* or other motion directed to causation issues of specific applicability, or any other dispositive motions applicable to the initial Bellwether Cases will be governed by the provisions set forth in Pretrial Order No.

**DONE** and **ORDERED** this the 10<sup>th</sup> day of March, 2011.



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INGE PRYTZ JOHNSON  
U.S. DISTRICT JUDGE