

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS**

IN RE: PRADAXA (DABIGATRAN)
ETEXILATE) PRODUCTS LIABILITY)
LITIGATION)
_____)

3:12-md-02385-DRH-SCW
MDL No. 2385

Judge David R. Herndon

This Document Relates to: All Cases

CASE MANAGEMENT ORDER NUMBER 78
Requirements for Preservation of Records and *Prima Facie*
Evidence of Usage, Injury and Causation
(Implementation Order)

This Order applies to all Plaintiffs with personal injury claims pending in this MDL as of the entry of this Order who elect not to participate in the voluntary settlement program, and all Plaintiffs with personal injury claims later filed in, removed to, or transferred to this MDL after the entry of this Order. This Order requires all such Plaintiffs to comply with certain preservation obligations and to produce certain specified information regarding their claim. Plaintiffs who represent themselves *pro se* in this proceeding shall be bound by the requirements of this Order and shall fully comply with all obligations required of counsel by this Order, unless otherwise stated.

I. PRESERVATION NOTICE REQUIREMENT

A. For all cases pending in this MDL as of the entry of this Order or filed prior to the Opt In deadline in which the Plaintiff has elected to not participate in the Settlement Program, counsel for Plaintiff shall, no later than 10 days from the Opt In deadline send a written notice (the "Notice") by registered mail (with return receipt) to the following individuals or entities,

advising that the individual or entity may have records relevant to the Plaintiff's claim in this MDL proceeding ("Claim") and that any records relating to the Plaintiff must be preserved pending collection by Plaintiff:

1. All pharmacies that dispensed any medication to the Plaintiff for the period from five (5) years prior to the date of the alleged injury in the case to the present;
2. All physicians, medical facilities, other healthcare providers and/or other persons ("other providers") who prescribed Pradaxa for the Plaintiff, or provided any samples of Pradaxa to the Plaintiff; and
3. All physicians and/or other healthcare providers who treated Plaintiff for the period from five (5) years prior to the date of the alleged injury or any related injury to the present.

B. For all cases filed on or after the Opt In deadline, after the case is docketed in this Court (either through direct filing or JPML transfer), counsel for Defendants shall serve upon counsel for Plaintiff (or if a Plaintiff is proceeding *pro se*, the Plaintiff) a copy of this Order. Within ten (10) days of receipt of notice of this Order from counsel for Defendants, counsel for Plaintiff (or if a Plaintiff is proceeding *pro se*, the Plaintiff) shall send a Notice by registered mail (with return receipt) to the individuals or entities listed in Paragraph A above, advising that the individual or entity may have records relevant to the Plaintiff's Claim in this MDL proceeding and that any records relating to the Plaintiff must be preserved pending collection by Plaintiff.

C. Counsel for Plaintiff (or if a Plaintiff is proceeding *pro se*, the Plaintiff) shall serve a signed certification verifying that Notices were sent as required by this Order, listing the names and addresses of all individuals or entities to which Notices were sent, and providing copies of the Notices in accordance with the following schedule:

1. For all cases pending in this MDL as of the entry of this Order or filed prior to the Opt In deadline, Plaintiffs shall serve the certification required by this Paragraph no later than 20 days from the Opt In deadline.
2. For all cases filed on or after the opt-in deadline, Plaintiffs shall serve the certification required by this Paragraph within twenty (20) days of receipt of notice of this Order from counsel for the Defendants.
3. Plaintiffs shall serve the certification required by this Paragraph by one of the following methods:
 - a. By email to Robert Limbacher at rlimbacher@gdldlaw.com; or
 - b. By United States Mail or other carrier, post-marked on or before the deadlines set forth in this Paragraph (with return receipt) to the following: Robert Limbacher, Goodell DeVries, Two Commerce Square, 2001 Market Street, Suite 3700, Philadelphia, PA 19103

D. Any Plaintiff who fails to fully comply with the requirements of Paragraphs A, B, and C above shall be provided notice of such failure by email or fax from Defendants' counsel and shall be provided fourteen (14) additional days to cure such deficiency ("Cure Period") to be calculated from the receipt of such notice of deficiency from counsel for the Defendants. No other extensions will be granted unless agreed to by all parties. If a Plaintiff fails to cure the deficiency within the Cure Period, Defendants may file a Motion to Show Cause why the case should not be dismissed with prejudice. Plaintiff shall thereupon have twenty (20) days to respond to the Motion and show good cause why the case should not be dismissed. Any failure to respond to the Motion within the specified period shall lead to the dismissal of the case with prejudice.

E. A Plaintiff may not seek to introduce into evidence at trial any document or information asserting Pradaxa usage (either dispensed by a Pharmacy or provided to the Plaintiff as a sample), or asserting that Pradaxa caused or contributed to the Plaintiff's alleged injury, if

the Notice required by Paragraphs A or B above was not sent to the Plaintiff's pharmacy, physician, medical facility, other healthcare provider and/or other provider as required by this Order absent good cause shown. A Plaintiff who fails to act in good faith in compliance with this Order may also be subject to other sanctions or such orders deemed appropriate by this Court.

II. DISCOVERY REQUIREMENTS

A. All Plaintiffs who elect not to participate in the Settlement Program shall produce the following documents and/or information:

1. A Plaintiff Fact Sheet ("PFS") and authorizations in the forms previously approved by the Court, unless Plaintiff has already served a PFS that complies with the requirements of Case Management Order No. 15, and all amendments thereto;
2. All pharmacy records regarding the dispensation of medication to the Plaintiff for the period from five (5) years prior to the date of the alleged injury to the present;
3. All medical records relating to the Plaintiff from all healthcare providers listed in the PFS for the period from five (5) years prior to the date of the alleged injury to the present; and
4. An affidavit signed by the Plaintiff or his/her counsel (i) attesting that records have been collected from all pharmacies that dispensed drugs to, or for, the Plaintiff; (ii) attesting that all medical records described in subparagraph (3) above have been collected; and (iii) attesting that all records collected have been produced pursuant to this Order.

B. If any of the documents or records described in Sections II.A.2 and II.A.3 above do not exist, the signed affidavit by Plaintiff or Plaintiff's counsel shall state that fact and the reasons, if known, why such materials do not exist, and shall provide a "No Records Statement" from the pharmacy or healthcare provider.

C. Plaintiffs shall produce the items required in Sections II.A. and B. above in accordance with the following schedule:

1. For Plaintiffs with cases pending in this MDL as of the entry of this Order or filed prior to the opt-in deadline, the items required above shall be produced no later than 15 days from the opt-in deadline.
2. For Plaintiffs with cases filed in or transferred to this MDL on or after the opt-in deadline, items 1, 2 (as it relates to dispensing Pradaxa), 3 (as it relates to treatment for the injuries alleged in the law suit) and 4 above shall be produced within fifteen (15) days of receipt of notice of this Order from counsel for Defendants. For items 2 and 3 above, the plaintiff shall have sixty (60) days to provide records that do not relate to the prescribing of Pradaxa or the injuries at issue in the law suit.

D. All Plaintiffs shall also produce expert reports in compliance with Federal Rule of Civil Procedure 26 as follows:

1. A Rule 26(a)(2) expert report on general causation concerning the alleged injury.
2. A Rule 26(a)(2) case-specific expert report concerning the causation of the Plaintiff's alleged injury. The case-specific expert report should include, at a minimum, a precise identification of the Plaintiff's Pradaxa usage and the nature of the Plaintiff's alleged injury, along with the details of any medical exams, testing, diagnosis or treatment relied upon to support any claimed injury; a sworn statement by a competent medical expert that the expert believes to the appropriate degree of medical certainty that Plaintiff's use of Pradaxa caused the Plaintiff's alleged injury, along with a detailed description of all facts, medical and scientific literature or other authorities relied upon by the expert to support such opinion; and a complete set of medical records relied upon in forming the expert's opinion.

E. Plaintiffs shall produce expert reports required in Section II.D. above in accordance with the following schedule:

1. For Plaintiffs with cases pending in this MDL as of the entry of this Order or filed prior to the Opt In deadline, both the generic and case-specific expert reports described above shall be produced no later than thirty (30) days of the Opt In deadline.

2. For Plaintiffs with cases filed in or transferred to this MDL on or after the Opt In deadline, both the generic and case-specific expert reports shall be produced within thirty (30) days of receipt of notice of this Order from counsel for the Defendants.

F. Plaintiffs shall serve the items required in Section II in accordance with the service procedures set forth in Case Management Order No. 15.

G. Any Plaintiff who fails to comply with the requirements of Section II shall be given notice of such failure by email or fax from Defendants' counsel and shall be provided twenty (20) additional days to cure such deficiency ("Cure Period") to be calculated from the receipt of such notice of deficiency from counsel for the Defendants. No other extensions will be granted. If Plaintiff fails to cure the deficiency within the Cure Period, Defendants may file a Motion to Show Cause why the case should not be dismissed with prejudice. Plaintiff shall thereupon have twenty (20) days to respond to the Motion and show good cause why the case should not be dismissed. Any failure to respond to the Motion within the specified period shall result in automatic dismissal of the case with prejudice.

H. To the extent that this Order conflicts with any deadlines or provisions of CMO 15, this Order shall govern.

III. CERTIFICATION FOR CASES FILED AFTER THE OPT-IN DEADLINE

For all cases filed in or transferred to this MDL after the opt-in deadline, counsel for Plaintiff must serve a Certification as follows: (1) attesting that the Plaintiff had not retained counsel as of the claim registration deadline; (2) identifying the date on which counsel was retained by the Plaintiff; and (3) certifying that counsel did not intentionally delay being retained by the Plaintiff for any reason, including but not limited to attempting to avoid the opt-in deadline for the Settlement Program.

The Certification required by this Section must be served on Defendants within seven (7) days of receipt of notice of this Order from counsel for the Defendants by one of the following methods:

- a. By email to rlimbacher@gdlldlaw.com; or
- b. By United States Mail or other carrier, post-marked on or before the deadlines set forth in this Paragraph (with return receipt) to Robert Limbacher, Goodell DeVries, Two Commerce Square, 2001 Market Street, Suite 3700, Philadelphia, PA 19103.

Any counsel who fails to comply with the requirements of this Section shall be given notice of such failure by email or fax from Defendants' counsel and shall be provided ten (10) additional days to cure such deficiency ("Cure Period") to be calculated from the receipt of such notice of deficiency from counsel for the Defendants. No other extensions will be granted. If counsel fails to cure the deficiency within the Cure Period, Defendants may file a Motion to Show Cause why sanctions should not be imposed for failure to comply with this Order. Counsel shall thereupon have twenty (20) days to respond to the Motion and show good cause why sanctions should not be imposed.

IV. PENALTIES FOR FRAUD AND DECEPTION

Any party and/or counsel for that party who submits false or misleading information, or otherwise attempts to satisfy the documentation requirements of this Order through any form of deception, dishonesty or fraud, may be subject to appropriate sanctions, including monetary sanctions and costs, and dismissal with prejudice pursuant to Federal Rule of Civil Procedure 37.

SO ORDERED:

May 29, 2014

David R. Herndon
 Digitally signed by
David R. Herndon
Date: 2014.05.29
11:58:07 -05'00'

**Chief Judge
United States District Court**