

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

_____)	
IN RE: PRADAXA (DABIGATRAN)	3:12-MD-02385-DRH-SCW
ETEXILATE) PRODUCTS LIABILITY)	
LITIGATION)	MDL No. 2385
)	
_____)	

This Document Relates to:

All Cases

**CASE MANAGEMENT ORDER NO. 20
REGARDING DEFENDANT FACT SHEETS FOR BIPI**

1. BIPI shall serve a completed Defendant Fact Sheet ("DFS"), the form of which has been agreed to by the parties and approved by the Court, and which is attached hereto as Exhibit A, along with responsive documents, within sixty (60) days of receipt of any completed Plaintiff Fact Sheet ("PFS") for any case that is on file before this Order is duly entered. Further, the sixty (60) day time period shall run from the date the PFS was served (for example, for any PFS that has *already* been served the sixty (60) day period has already begun to run).

2. For cases filed after the date of this Order, the DFS shall be due forty-five (45) days following receipt of the PFS, along with responsive documents.

3. The completed DFS shall be served on the attorney identified on page one of the PFS as the "Principal Attorney". The method of service shall be the same as the method in which the PFS was served on BIPI. Additionally, a copy of the DFS and all supporting documents shall be emailed to Plaintiffs' Lead

Counsel at PRADAXA.MDL.DFS@wgclawfirm.com or a hard copy sent to: David Watts, at Watts Guerra Craft LLP, 5250 Prue Road, Suite 525, San Antonio, Texas 78240.

4. Defendant and its counsel shall use their best efforts to serve the completed DFS on a rolling basis prior to the deadlines set forth in Paragraph 1.

5. If Defendant does not submit a DFS within the time specified in this Order, Plaintiffs may send a Notice of Overdue Discovery letter to Defendant's counsel as follows: VLodato@sillscummis.com or by mail to Vincent Lodato, Esq., Sills Cummis & Gross P.C., One Riverfront Plaza, Newark, New Jersey 07102 ten (10) days after said deadline. Said Notice of Overdue Deficiency letter shall permit fourteen (14) days to cure the overdue DFS. In the event the completed DFS is not provided within such fourteen (14) day period, Plaintiff's counsel shall exercise all reasonable efforts to meet-and-confer with Defendant's counsel (for a period not to exceed five (5) days). If, after the meet-and-confer process, the discovery remains overdue, Plaintiff's counsel shall consult with MDL Lead/Liaison Counsel and may move for appropriate relief from the Court, which shall be on Notice filed by ECF, and permit fourteen (14) days for an opposition, if any. Plaintiffs' co-liaison shall be served (via e-mail) with a copy of all Notice of Overdue Discovery letters and copies of any and all motions under this paragraph.

6. If Plaintiff receives a DFS in the allotted time, but the DFS is not properly completed in Plaintiff's view, then Plaintiff shall send to defense counsel

(as identified in No. 5 above) a deficiency letter identifying the purported deficiencies, with a copy being contemporaneously sent to Plaintiffs' Liaison Counsel. If Defendant believes the DFS was properly completed, the parties shall meet and confer on the issue within fourteen (14) days of defendant's receipt of such notice. Subject to such meet and confer, Defendant shall then have twenty (20) days to serve an amended or supplemental response or advise that it is not amending/supplementing the response.

7. The admissibility of information in the DFS shall be governed by the Federal Rules and no objections are waived by virtue of any DFS response.

8. All information contained in the DFS is confidential and protected under the Protective Order (CMO 2).

So Ordered:

 Digitally signed by David
R. Herndon
Date: 2013.01.23
10:49:29 -06'00'

**Chief Judge
United States District Court**

Date: January 23, 2013

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

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IN RE: PRADAXA (DABIGATRAN)	3:12-MD-02385-DRH-SCW
ETEXILATE) PRODUCTS LIABILITY)	
LITIGATION)	MDL No. 2385
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This Document Relates to:

ALL CASES

DEFENDANT FACT SHEET FOR BIPI

For each case, Boehringer Ingelheim Pharmaceuticals, Inc. must complete this Defendant Fact Sheet (“DFS”) and identify or provide documents and/or data relating to each plaintiff, responsive to the questions set forth below, to the best of Defendant’s knowledge. In completing this DFS, you are under oath and must provide information that is true and correct to the best of your knowledge. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect. You must also supplement your responses in the event that additional information is provided from the Plaintiff. The DFS shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order. In the event the DFS does not provide you with enough space for you to complete your responses or answers, please attach additional sheets if necessary. Please identify any documents that you are producing as responsive to a question or request by bates-stamp identifiers.

This DFS must be completed and served on all counsel representing a plaintiff in the action identified in Section I below. This must be answered and served in accordance with CMO 20.

As used herein, the terms “you,” “your” or “yours” means the responding defendant.

As used herein, the phrase “provided” means sold, distributed, shipped, delivered or otherwise placed into the stream of commerce.

As used herein the phrase “Prescribing Health Care Provider” means each of Plaintiff’s physicians or medical providers who prescribed or dispensed Pradaxa to Plaintiff.

I. Case Information

This DFS pertains to the following case:

Case caption: _____

Civil Action No. _____

Name and Address of all persons who provided information responsive to the questions posed in this DFS:

A: _____
(Name)

(Address)

(Phone Number)

(Title within Defendant Company and
Company employed by)

B: _____
(Name)

(Address)

(Phone Number)

(Title within Defendant Company and
Company employed by)

II. Contacts With Prescribing Health Care Provider

In Section VII(A) of Plaintiff’s Fact Sheet, (s)he identifies persons or entities who prescribed or provided samples of Pradaxa to the Plaintiff. For each Prescribing Health Care Provider identified, please state the following:

A. Dear Doctor Letters:

1. Please identify the “Dear Doctor” or “Dear HealthCare Provider” letter that you contend was actually sent to the Plaintiff’s Prescribing Health Care Provider concerning Pradaxa.

NOTE: Please attach hereto a copy of each letter allegedly sent to Plaintiff's Prescribing Health Care Provider.

2. For each "Dear Doctor" or "Dear Healthcare Provider" letter that you contend was actually sent to Plaintiff's Prescribing Health Care Provider, please state the date that each "Dear Doctor" or "Dear HealthCare Provider" letter was actually sent to Plaintiff's Prescribing Health Care Provider and the person to whom each letter was sent.

3. For each "Dear Doctor" or "Dear HealthCare Provider" letter identified that you contend was actually sent to Plaintiff's Prescribing Health Care Provider, please identify any and all lists or databases which you contend demonstrate that these letters were actually sent, and please provide a relevant copy of same that identifies that the letter was sent.

B. Professional Information Request Letters:

1. Please identify any responses to any "Professional Information Request" letter that you contend was actually sent to the Plaintiff's Prescribing Health Care Provider concerning Pradaxa.

NOTE: Please attach hereto a copy of the letter addressed to Plaintiff's Prescribing Health Care Provider that you maintain was sent.

2. For each response to any “Professional Information Request” letter that you contend was actually sent to Plaintiff’s Prescribing Health Care Provider, please state the date that each “Professional Information Request” letter was actually sent to Plaintiff’s Prescribing Health Care Provider and the person to whom each letter was sent.

3. For each “Professional Information Request” letter identified that you contend was actually sent to Plaintiff’s Prescribing Health Care Provider, please identify any and all lists or databases which you contend demonstrate that these letters were actually sent.

C. Other Contacts

1. In Section VII(A) of Plaintiff’s Fact Sheet, Plaintiff identified Plaintiff’s Prescribing Health Care Provider(s). Please identify all known contacts between the Prescribing Health Care Provider and Defendant’s Sales Representatives / Sales and Marketing Organization / Employees, and please produce the following information:

Plaintiff’s Prescribing Health Care Provider	Identity and last known address of Defendant’s Sales Representative / Employee / “detail persons” who contacted Plaintiff’s Prescribing Health Care Provider about Pradaxa	The current relationship (e.g., employed, agent, independent contractor, co-promotional agreement(s)), if any, between Defendant and the Sales Representative or detail person	All dates of Contact¹

2. For each Prescribing Health Care Provider, please state whether Defendant or its representatives ever provided him/her (or anyone in their practice) Pradaxa samples. If the answer is “yes,” please state:²
 - (a). The number of sample packets provided and the dosages provided;
 - (b). The dates that they were shipped and/or provided; and
 - (c). The identity of the person or persons who provided the Samples.

3. For each Sales Representative or detail person identified in Section II (C) above, please identify and produce any and all notes or other documents of that person or persons, including all personal notes, calendar entries, and computer entries, that reflect or refer to any

¹ Information responsive to this request is contained in the VISTA database, which has been provided to the Plaintiff Steering Committee, and to which you are referred.

² Information responsive to this request is contained in the VISTA database, which has been provided to the Plaintiff Steering Committee, and to which you are referred.

communication with any of Plaintiff's Prescribing Health Care Providers.³

4. For each Sales Representative or detail person identified in Section II(C) above, please identify and produce any and all notes or other documents of that person or persons, including all personal notes, calendar entries, computer entries, backgrounder documents, marketing information, video and/or audio recordings and files, and/or tapes, email correspondence, text and/or audio messages, logs, database entry or other documents referred to in the sales call notes and other materials that is/was in their possession concerning Pradaxa or any other anticoagulant.⁴
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³ Information responsive to this request is contained in the VISTA database, which has been provided to the Plaintiff Steering Committee, and to which you are referred. However, BIPI shall supplement this response for cases selected as bellwether cases.

⁴ Information responsive to this request is contained in the VISTA database, which has been provided to the Plaintiff Steering Committee, and to which you are referred. However, BIPI shall supplement this response for cases selected as bellwether cases.

5. For each Sales Representative or detail person identified in Section II(C) above, please identify and produce all informational or promotional information that the Sales Representative or detail person distributed to any of Plaintiff's Prescribing Health Care Providers. Included in this request is information related to Pradaxa (*e.g.*, Patient information booklets, pamphlets or handouts) that is designed to be seen or possessed by the consumer that the Sales Representative left with the Health Care Provider or in the Health Care Provider's office.⁵
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6. For each Sales Representative or detail person identified in Section II(C) above, please identify and produce copies, in native format (or a format that makes any electronic information functional in the manner it was when utilized by the sales representative), of all information related to Pradaxa that the Sales Representative showed to Plaintiff's Health Care Provider via use of a tablet, mobile app., laptop computer, or any other mobile electronic device.⁶
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⁵ Information responsive to this request is contained in the VISTA and TEMPO databases, which have been provided to the Plaintiff Steering Committee, and to which you are referred. However, BIPI shall supplement this response for cases selected as bellwether cases.

⁶ Information responsive to this request is contained in the VISTA database, which has been provided to the Plaintiff Steering Committee, and to which you are referred. However, BIPI shall supplement this response for cases selected as bellwether cases.

7. For each Sales Representative or detail person, including third parties, identified in Section II(C) above, please identify and produce all information relating to any form of patient discount or coupon for the purchase of Pradaxa at a reduced price (or for free), including any information relating to rebates, that the Sales Representative or detail person distributed to any of Plaintiff's Prescribing Health Care Providers.⁷

⁷ Information responsive to this request is contained in the VISTA database, which has been provided to the Plaintiff Steering Committee, and to which you are referred. However, BIPI shall supplement this response for cases selected as bellwether cases.

III. Consulting With Plaintiff’s Prescribing Health Care Provider

- A. In Section VII(A) of Plaintiff’s Fact Sheet, Plaintiff identified his/her Prescribing Health Care Provider(s). If you have ever retained any of Plaintiff’s Prescribing Health Care Providers as a “key opinion leader,” a “thought leader,” a member of a “speaker’s bureau,” a “clinical investigator”, a “consultant”, or in any other capacity on the subject of anticoagulants (including Pradaxa) and/or the treatment of Atrial Fibrillation and/or stroke prevention from January 2008 until present, please provide the following information:

From January 2008 to present, identity of Plaintiff’s Prescribing Health Care Provider who was retained by Defendant	Date(s) that he or she was paid	All documents, if any, provided to health care provider by Defendant concerning Pradaxa

- B. In Section VII(A) of Plaintiff’s Fact Sheet, Plaintiff identified his/her Prescribing Health Care Provider(s). If you have ever retained any of Plaintiff’s Prescribing Health Care Providers as a “key opinion leader,” a “thought leader,” a member of a “speaker’s bureau,” a “clinical investigator,” a “consultant”, or in any other capacity on the subject of anticoagulants (including Pradaxa) and/or the treatment of Atrial Fibrillation and/or stroke prevention, from January 2002 until December 2007, please provide the following information:⁸

From January 2002 to December 2007, identity of Plaintiff’s Prescribing Health Care Provider who was retained by Defendant	Amount of Payments and Date(s) that he or she was paid

- C. For each of Plaintiff’s Prescribing Health Care Providers identified in Section III(A) and III(B) above, please state whether you have paid any money, and the amount thereof, for expenses, honoraria and/or fees per calendar year, and either produce all 1099 or other IRS tax forms issued by Defendant to Plaintiff’s Prescribing Health Care Providers evidencing such payments OR identify the reasons any money(ies) were paid and the reasons for each specific amount.

- D. For each of Plaintiff’s Prescribing Health Care Providers identified in Section III(A) and III(B) above, please provide all consulting agreements and contracts.

⁸ Per agreement reached between counsel, BIPI shall supplement this response for cases selected as bellwether cases so that further responsive information, as detailed below in Sections III(C)-(E), before 2008 will be provided.

E. For each of Plaintiff's Prescribing Health Care Providers identified in Section III(A) and III(B) above, Defendant shall do a reasonable search and then please state whether each physician identified attended any Defendant sponsored conferences or events ("Programs"). If your answer is "yes," please state:

1. The identity of the Prescribing Health Care Providers:

2. The title, location and date of the Program attended:

3. The topic of the Program:

4. Please provide or identify the agenda/brochure for the Program

F. Have any of Plaintiff's Prescribing Health Care Provider sever contacted you to request information concerning Pradaxa, its indications, its effects, and/or its risks? Yes____ No_____.

If Yes, please identify and attach any document which relates or refers to your communication with Plaintiff's Prescribing Health Care Providers.

IV. Plaintiff's Prescribing Health Care Provider's Prescribing Practices

In Section VII(A) of Plaintiff's Fact Sheet, Plaintiff identifies his/her Prescribing Health Care Providers. For each listed provider, please state and produce the following:

A. Do you have, or have you had, access to any database or information which purports to track any of Plaintiff's Prescribing Health Care Providers' prescribing practices with respect to Pradaxa or any other anticoagulant (including, but not limited to the product(s) prescribed, the number or prescriptions, the number of refills and the time frame when these products were prescribed or refilled). If your answer is "yes," please identify the database or document which captures that information and provide such information:

V. Plaintiff's Medical Condition

- A. After reasonable search, has Defendant determined if it has been contacted by Plaintiff, any of his/her physicians, or anyone on behalf of Plaintiff concerning Plaintiff (other than counsel for Plaintiff)?

_____ _____
Yes No

- B. If you have been contacted by any person or entity concerning Plaintiff, please state the name of the person(s) who contacted you and the person(s) who were contacted stating their name, address and telephone number.

- C. Please produce any and all documents which reflect any communication between any person and you, concerning Plaintiff.

- D. Please produce a copy of any MedWatch form and/or Adverse Event Report, including any update thereto, which refers or relates to Plaintiff and his/her use of Pradaxa, including back-up documentation concerning Plaintiff and any evaluation you did concerning Plaintiff, excluding any MedWatch form and/or Adverse Event Report created only as a result of the filing of Plaintiff's lawsuit.

VI. Advertising

- A. Did you advertise Pradaxa in the Media Market in which Plaintiff lived at the time that (s)he used Pradaxa?

_____ _____
Yes No

B. Did you advertise Pradaxa in the Media Market in which Plaintiff's Prescribing Health care provided office was located at the time that Plaintiff was prescribed Pradaxa?

Yes

No

VII. FACT WITNESSES

A. Please identify all persons you believe possess information concerning Plaintiff and/or any case-specific claims or case-specific defenses, other than plaintiff's than health care providers expert witnesses, and please state their name, address and his/her relationship to you (attach additional pages as necessary):

Name	Address, City, State, Zip	Relationship to you

B. If there are any individuals who witnessed the injury as it occurred, other than healthcare providers, who are not listed in the chart directly above, please identify them here by name, address and their relationship to you.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Relationship to Defendant(s): _____

VIII. Documents

- A. To the extent you have not already done so, please produce a copy of all documents and things that fall into the categories listed below. These include documents in the possession of any of your present and former employees, including information provided to your attorneys:
1. Any non-privileged document which relates to or refers to Plaintiff, other than documents received or produced in discovery in this matter.
 2. Subject to the limitations set forth in this fact sheet, any document sent to or received from any of Plaintiff's Prescribing Health Care Providers.
 3. Any and all documents reflecting any actual communication(s) between you and Plaintiff's Prescribing HealthCare Providers.
 4. Any documents reflecting any contracts or actual communications between you and any of Plaintiff's Prescribing Health Care Providers regarding Pradaxa.
 5. Any and all Adverse Event Reports for Plaintiff and all back-up data, including but not limited to any and all correspondence to/from the FDA regarding said AER and/or said Plaintiff, consistent with the information requested in Section III.F, above.
 6. Any document which purports to describe the prescribing practices of any of Plaintiff's Prescribing Health Care Providers, with the production of any such materials being subject to the express approval of the owner of such information to release the data without charge to Defendant, to the extent needed.

CERTIFICATION

Pursuant to 28 U.S.C § 1746, I declare under oath and do hereby swear and affirm that all of the information provided in this Defendant Fact Sheet is true and correct to the best of my knowledge, information and belief formed after due diligence and reasonable inquiry.

Signature

Print Name

Date