

DOCKETED
COMPLEX LIT CENTER

JAN 11 2011

IN RE	J. STEWART	COURT OF COMMON PLEAS
	:	PHILADELPHIA COUNTY
REGLAN/METOCLOPRAMIDE	:	
LITIGATION	:	
	:	JANUARY TERM, 2010
<i>This Document Relates to All Cases</i>	:	NO. 1997

CASE MANAGEMENT ORDER NO. 14:
DISCOVERY ORDER GOVERNING REGLAN/METOCLOPRAMIDE CASES
WITH PATIENT EDUCATION MONOGRAPH DEFENDANTS

I. SCOPE OF THIS ORDER

This Case Management Order No. 14 (“CMO No. 14”) shall govern all cases that are presently pending or hereafter filed in the Philadelphia Court of Common Pleas, which become part of the program of coordinated pretrial proceedings relating to the prescription drug Reglan® and/or metoclopramide (the “Reglan®/metoclopramide Litigation”).

This CMO No. 14 discusses the Patient Education Monograph (“PEM”) identification procedure and plaintiff and defendant fact sheets specific to claims against PEM Defendants. For purposes of this CMO No. 14, the PEM Defendants are First DataBank, Inc., Wolters Kluwer Health, Inc., Thomson Reuters (Healthcare) Inc., Elsevier Inc., Gold Standard, Inc., and Cerner Multum, Inc. Other methods of discovery will be addressed in subsequent case management orders.

II. DISCOVERY PROVIDED BY PLAINTIFFS

A. PLAINTIFFS’ PEM FACT SHEETS

1. In every case currently part of the Reglan/metoclopramide Litigation in which claims are being asserted against a PEM Defendant and in all other cases that become part of the Reglan/metoclopramide Litigation by virtue of being filed in or transferred to this Court in which claims are being asserted

In Re: Reglan Litigation-ORDER



10010199700158

against a PEM Defendant, each Plaintiff shall complete and submit a Plaintiff PEM Fact Sheet (“PPFS”) to the Defendants’ counsel in the individual Plaintiff’s cases by the method discussed below. A copy of the agreed to PPFS is attached hereto as Exhibit “A.”

2. Within sixty (60) days of PEM Defendant’s filing of an entry of appearance in the matter or sixty (60) days from entry of this CMO No. 14, whichever is later, each Plaintiff shall serve all named Defendants in that individual Plaintiff’s case with a completed PPFS. Accordingly, each Plaintiff shall sign the completed PPFS and provide an executed Declaration attesting under penalty of perjury that the information contained therein is true and correct to the best of the Plaintiff’s knowledge, information, and belief, formed after due diligence and reasonable inquiry. A completed PPFS shall be treated the same as interrogatory answers and responses to requests for production under the Pennsylvania Rules of Civil Procedure, and will be governed by the standards applicable to written discovery under the Pennsylvania Rules of Civil Procedure. The questions and requests for production in the PPFS are non-objectionable and shall be answered by each Plaintiff without objection. Each Plaintiff shall comply with his or her obligation to supplement their document production by making regular additional productions within reasonable timeframes in accordance with the Pennsylvania Rules of Civil Procedure.

3. Service of the PPFS shall be via email, addressed to Defendants’ counsel named in each individual Plaintiff’s case.

4. This Section does not prohibit a Plaintiff from withholding or

redacting information based upon a recognized privilege. If information is withheld or redacted on the basis of privilege, Plaintiff shall provide Defendants with a privilege log in accordance with a subsequent Case Management Order. In the event that a dispute arises concerning the completeness or adequacy of a Plaintiff's response to any request contained in the PPFS, this Section shall not prohibit Plaintiff from asserting that his or her response is adequate.

5. Each Plaintiff is required to provide Defendants with a PPFS that is "substantially complete in all respects." "Substantially complete in all respects" requires that a Plaintiff:

a. Answer every question in the PPFS and leave no blanks, even if a Plaintiff can only answer the question in good faith by indicating "not applicable" or "I don't know";

b. Produce the documents subject to the Requests for Production at Part II of the PPFS or a statement certifying that there are no such responsive documents.

6. Remedies to address a deficient PPFS will be addressed in a subsequent Case Management Order.

III. PEM IDENTIFICATION AND DISMISSAL PROCESS

A. IDENTIFICATION OF PEM DEFENDANTS

1. In cases where Plaintiffs do not have copies of actual PEMs received during the ingestion period identifying the PEM Defendant named in a Writ of Summons or SFC, the Plaintiff may avail itself of the PEM ID discovery procedures below and the named PEM Defendant may avail itself of the PEM ID dismissal procedures below.

B. PEM ID DISCOVERY

1. Simultaneously with or subsequent to service of the PPFS, but not later than 60 days after service of the DPFS (“Supplemental PEM ID Discovery Period” or “SPEMIDDP”), a Plaintiff with a claim against a PEM Defendant may supplement missing or incomplete PEM records with other documentary support of PEM ID and/or with affidavit or deposition testimony of a dispensing pharmacist, pharmacy manager or other responsible person. Any party in a case including one or more PEM Defendants may pursue discovery, including the service of limited interrogatories by Plaintiff upon the PEM Defendant(s) against which Plaintiff has asserted claims in that case, in the SPEMIDDP, to confirm whether a PEM Defendant authored the PEM allegedly received by Plaintiff in furtherance of PEM ID. Disputes as to the discovery served or pursued in the SPEMIDDP may be submitted to Discovery Master Bock.

C. PEM DISMISSAL PROTOCOL

1. Plaintiff may certify at any time after service of the PPFS that no PEM ID discovery is required or that all reasonably feasible PEM ID discovery has been completed. Upon the earlier of Plaintiff’s certification or the expiration of the SPEMIDDP (“PEM ID Discovery Closure Date”), a PEM Defendant named by Plaintiff and not identified through any reasonably supported basis (including statements or documents from a pharmacy or pharmacist), or who otherwise believes in good faith that the supplemental discovery does not support its identification, may avail itself of the PEM ID dismissal motion procedure described below. Plaintiff may seek an extension of the SPEMIDDP from the PEM Defendant upon good cause shown, which shall include, but not be limited

to, the inability to confirm who authored the Plaintiff's PEM. Any disputes over good cause shall be heard by Discovery Master Bock.

2. At any time after the PEM ID Discovery Closure Date, and so long as a dispute regarding an extension of the SPEMIDDP is not pending, a PEM Defendant may inform a Plaintiff by a PEM ID Dismissal Letter directed to Plaintiff's individual representative counsel via email that such PEM Defendant has not been identified as an author of a PEM provided to Plaintiff. The PEM Defendant must also copy all counsel of record on the letter.

a. Absent objection from any party within twenty (20) days of delivery of the PEM ID Dismissal Letter, Plaintiff may file a voluntary dismissal of the PEM Defendant from the case in its entirety, which is deemed to be on consent of all parties.

3. If Plaintiff does not file a voluntary dismissal of the PEM Defendant within thirty (30) days of delivery of the PEM ID Dismissal Letter, the PEM Defendant may file a motion to dismiss on grounds of no PEM ID, unless there is a dispute regarding PEM Defendant's compliance with discovery requests issued pursuant to Part B above, in which case the motion may be filed within thirty (30) days of resolution of the discovery dispute.

4. Plaintiff shall have thirty (30) days to oppose PEM Defendant's motion to dismiss, and PEM Defendant shall have fourteen (14) days to file reply papers if any.

5. Should the PEM Defendant's motion for PEM ID Dismissal be denied, the PEM Defendant reserves its right to file a motion for summary

judgment at a later date.

6. Dismissal pursuant to this procedure shall be without prejudice as to a Plaintiff's right to reinstate a dismissed PEM Defendant in the event PEM identification can be properly established for the dismissed PEM Defendant at a later date. In this instance, the date of commencement of the action as to the reinstated PEM Defendant for statute of limitations purposes shall be considered to be the original date of service on such defendant, service of which may be made by certified mail upon PEM Defendant with a copy to counsel of record.

a. Plaintiff's right to reinstate a dismissed PEM Defendant more than 90 days after the dismissal without prejudice shall be conditioned upon a good faith showing by Plaintiff that the basis upon which reinstatement is premised was not reasonably discoverable prior to the dismissal without prejudice. Disputes as to the adequacy of Plaintiff's showing shall be resolved by Judge Moss after receiving a recommendation from Discovery Master Bock.

IV. DISCOVERY PROVIDED BY PEM DEFENDANTS

A. DEFENDANTS' PEM FACT SHEETS

1. A copy of the agreed to DPFS is attached hereto as Exhibit "B."
2. Within sixty (60) days of being identified in a PPFS, each identified PEM Defendant shall serve Plaintiff and all other named Defendants in that individual Plaintiff's case with a completed DPFS. A completed DPFS shall be treated the same as interrogatory answers and responses to requests for production under the Pennsylvania Rules of Civil Procedure, and will be governed by the standards applicable to written discovery under the Pennsylvania Rules of

Civil Procedure. The questions and requests for production in the DPFS are non-objectionable and shall be answered by identified PEM Defendants without objection. Each PEM Defendant shall comply with its obligation to supplement its document production by making regular additional productions within reasonable timeframes in accordance with the Pennsylvania Rules of Civil Procedure.

3. Service of the DPFS shall be via email, addressed to Plaintiff's counsel and other Defendants' counsel named in each individual Plaintiff's case.

4. This Section does not prohibit a PEM Defendant from withholding or redacting information based upon a recognized privilege. If information is withheld or redacted on the basis of privilege, the PEM Defendant shall provide Plaintiff with a privilege log in accordance with a subsequent Case Management Order. In the event that a dispute arises concerning the completeness or adequacy of a PEM Defendant's response to any request contained in the DPFS, this Section shall not prohibit the PEM Defendant from asserting that its response is adequate.

5. DPFS must be "substantially complete in all respects."
"Substantially complete in all respects" requires that a PEM Defendant:

a. Answer every question in the DPFS and leave no blanks, even if a PEM Defendant can only answer the question in good faith by indicating “not applicable” or “unknown”;

b. Produce the documents requested in the DPFS or a statement certifying that there are no such responsive documents or that document collection and review is ongoing.

6. Remedies to address a deficient DPFS will be addressed in a subsequent Case Management Order.

SO ORDERED:

DATE: 4/11/11


THE HONORABLE SANDRA MAZER MOSS

IN RE REGLAN/METOCLOPRAMIDE LITIGATION	: : : : : : :	COURT OF COMMON PLEAS PHILADELPHIA COUNTY JANUARY TERM, 2010 NO. 1997
---	---------------------------------	--

PLAINTIFF'S PEM FACT SHEET

PLAINTIFF'S NAME: _____

Plaintiff's Attorney (include email address): _____

By Order of the Court and agreement of the Parties, you are required to answer each and every question set forth in this document to the best of your knowledge; no question is to be left blank. To the extent that you do not know or cannot remember the answer to a given question, you must state that in your response to the question. Similarly, to the extent a question does not apply to your claim, you must state that in your response to the question. If the space provided does not allow for a complete answer, please attach additional sheets so that your answer to each question is complete. This Fact Sheet shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order.

Please note that your answers to each question set out in this Fact Sheet constitute answers to written interrogatories pursuant to Rule 4006 of the Pennsylvania Rules of Civil Procedure. In that respect, when completing this Fact Sheet you will be under an oath to tell the truth, and the information you provide must be true and accurate to the best of your knowledge. Further, pursuant to Rule 4007.4 of the Pennsylvania Rules of Civil Procedure, you must supplement your responses to the questions set forth in this Fact Sheet if you, at any time, learn that any of your responses are incomplete or inaccurate in any respect. You must also supplement your responses in the event that additional information is provided from a PEM Defendant.

Please identify any documents that you are producing responsive to a question or as required with Bates-Stamp identifiers.

To the extent that a response to this Fact Sheet is contained in previously produced documents, the responding Plaintiff may answer by referencing the previously produced document(s). Such reference must contain sufficient information and/or instructions, including Bates numbers, to allow a PEM Defendant to access the answer requested with minimal effort.

I. CASE INFORMATION

A. Please state the following for the lawsuit that you filed:

Case caption and number: _____

Court in which action is pending: _____

Your name: _____

Social Security Number: _____

Current street address: _____

City: _____

State: _____

Zip: _____

B. If you are completing this questionnaire in a representative capacity for a minor or for the estate of a deceased person, please complete the following:

The name of the person you are representing: _____

If you were appointed by a court, state the:

State, County, Court Term, and Case Number: _____

Date of Appointment: _____

Your relationship to the represented person: _____

If you represent a decedent's estate, state the date of death of the decedent and the address of the place where the decedent died: _____

C. PEM Identification

Using the table on the following pages, identify each and every Patient Education Monograph(s) you claim to have received, including how, from where, and from whom you received each Monograph, when you received it, any copyright and date information on the Monograph, the company you believe authored the Monograph and the basis for this belief, a description of the Monograph's appearance and contents, and a listing of all other information provided with the Monograph (such as package inserts, medication guides, other literature, or oral advice or counseling).

If you have a copy of any Patient Education Monograph(s), please attach it.

DATE(S) PEM RECEIVED	MANNER OF RECEIPT (including from where and from whom received)	DESCRIPTION OF PEM APPEARANCE AND CONTENTS	COPYRIGHT INFORMATION AND DATE(S) LISTED ON PEM	PEM AUTHOR (including basis for this belief)	OTHER INFORMATION PROVIDED WITH PEM (including information received orally)

(If additional space is needed, please use additional sheets)

lawyers, please attach a copy to this Fact Sheet. This does not include privileged materials. If you do not have any documents in a particular category, please include a certification that no such documents are in your custody, possession or control, or in the possession, custody or control of your lawyers.

- A. Copies of all Reglan/metoclopramide PEMs received by you.
- B. Copies of all documents including correspondence relating to Reglan/metoclopramide PEMs received by you.
- C. Copies of all drug information concerning Reglan/metoclopramide received by you.

DECLARATION

I, _____, **declare under penalty of perjury subject to 18 Pa. C.S. §4904** that all of the information provided in this Plaintiff Fact Sheet is true and correct to the best of my knowledge, information and belief formed after due diligence and reasonable inquiry, that I have supplied all the documents requested in Part VI of this Plaintiff Fact Sheet, to the extent that such documents are in my possession or in the possession of my lawyers, and that I have supplied the authorizations attached to this declaration.

Signature

Date

Sworn and subscribed before me
This ____ day of _____

Notary Public

As used herein, the terms, “you,” “your”, or “yours” means the responding Defendant, and Defendant’s employees or agents over which Defendant has control, unless defined to include a third party.

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

As used herein, the phrase “Prescribing Healthcare Provider and Entity” means each of Plaintiff’s physicians, medical providers, practices, clinics, persons or entities who prescribed and/or dispensed Reglan[®]/Metoclopramide to Plaintiff.

As used herein, the phrase “Dispensing Pharmacy” means each of Plaintiff’s pharmacies which filled Plaintiff’s Reglan[®]/Metoclopramide prescriptions.

As used herein, the phrase “Licensee” means each of the licensees to you whom you provided your patient education monograph that was ultimately provided to the pharmacies where Plaintiff filled her Reglan[®]/Metoclopramide prescriptions.

As used herein, the phrase “Defendant Manufacturers” means each of the Defendants that manufacture(d) Reglan/ Metoclopramide, brand or generic, named as Defendants in this lawsuit by the Plaintiff.

I. CASE INFORMATION

This DFS pertains to the following case:

Case Caption: _____

Civil Action No: _____

Date DFS completed: _____

A. Please provide the following information on the person or persons who provided information responsive to the questions posed in this DFS.

1. _____

Name

Current Position (If no longer employed, last position with Defendant)

City of Employment (If no longer employed, city of residence)

2. _____
Name

Current Position (If no longer employed, last position with Defendant)

City of Employment (If no longer employed, city of residence)

3. _____
Name

Current Position (If no longer employed, last position with Defendant)

City of Employment (If no longer employed, city of residence)

4. _____
Name

Current Position (If no longer employed, last position with Defendant)

City of Employment (If no longer employed, city of residence)

5. _____
Name

Current Position (If no longer employed, last position with Defendant)

City of Employment (If no longer employed, city of residence)

6. _____
Name

Current Position (If no longer employed, last position with Defendant)

City of Employment (If no longer employed, city of residence)

(Please attach additional sheets if necessary)

II. CONTACT REGARDING THE PLAINTIFF

1. Have you initiated contact with any of Plaintiff's physicians or pharmacies concerning the Plaintiff?

_____ Yes _____ No

2. Have you been contacted by any of Plaintiff's physicians, pharmacists, hospitals or pharmacies, or anyone on behalf of Plaintiff's physicians, pharmacists, hospitals or pharmacies concerning the Plaintiff?

_____ Yes _____ No

If applicable,

3. Provide the details, including dates and individuals involved in contact. Identify and provide documents.
4. Identify the person or persons who provided information responsive to this Section or any of its subparts.

III. CONTACT WITH DISPENSING PHARMACY(IES) OR LICENSEE

In Plaintiff's Fact Sheet, Plaintiff identified the pharmacy(ies) where she/he filled his/her Reglan/Metoclopramide prescription. Please identify all significant contacts and/or relationships between the identified Dispensing Pharmacy(ies) or Your Licensee and You concerning Reglan/metoclopramide patient education materials and/or Plaintiff, for the time period during which Plaintiff allegedly received Defendant's patient education monograph, by providing the following information for EACH Dispensing Pharmacy:

1. Name of Dispensing Pharmacy or Licensee;
2. Date(s) of contact or relationship;
3. Reason for or nature of contact or relationship (i.e. sales call, contract discussion, etc.);
4. Name and position of person (at the time) who was the primary contact person or the person primarily responsible on Defendant's behalf, for the relationship or contact;

5. Provide any correspondence, communications, notes, documents or other materials reflecting such contact or relationship, including but not limited to electronic data, but excluding data for non-Reglan/metoclopramide patient education materials;
6. Provide a list and brief description of the Reglan/Metoclopramide patient education materials you provided to the Dispensing Pharmacy or Licensee and dates provided;
7. Provide contracts, agreements, and/or licenses entered with the Dispensing Pharmacy or Licensee in place for the time period during which Plaintiff allegedly received Defendant's patient education monograph(s);
8. Provide copies of any and all Reglan/Metoclopramide patient education materials provided to the Dispensing Pharmacy or Licensee for the time period(s) during which Plaintiff allegedly received Defendant's patient education monograph(s); and
9. Provide copies of any and all promotional, advertisement and sales materials provided by you to the Dispensing Pharmacy or Licensee for the time period(s) during which Plaintiff allegedly received Defendant's patient education materials.

IV. CONTACT WITH DEFENDANT MANUFACTURERS

In Plaintiff's Fact Sheet, Plaintiff identified the Defendant Manufacturers from which Plaintiff received Reglan/metoclopramide. Please identify all significant contacts and/or relationships between the Defendant Manufacturers and You relating to Reglan/Metoclopramide patient education materials, for the time period(s) during which Plaintiff allegedly received Defendant's patient education monograph, by providing the following information for EACH Defendant Manufacturer:

1. Name of Defendant Manufacturer contacted.
2. Date(s) of contact or relationship;
3. Reason for or nature of contact or relationship (i.e. sales call, response to adverse event report, etc.);
4. Name and position of person (at the time) who was the primary contact person or the person primarily responsible on Your behalf, for the relationship or contact; and
5. Provide any correspondence, communications, notes, documents or other materials reflecting such contact or relationship, including but not limited

to electronic data, but excluding data for non-Reglan/metoclopramide patient education materials;

6. Provide a list and brief description of the patient education materials you provided to the Defendant Manufacturer relating to Reglan/metoclopramide and dates provided;
7. Provide contracts, agreements, and/or licenses relating to Reglan/metoclopramide patient education materials entered with the Defendant Manufacturer and documents reflecting payments made to you under those contracts, agreements, and/or licenses;
8. Provide copies of any and all Reglan/Metoclopramide patient education materials that you provided to the Defendant Manufacturer; and
9. Provide copies of any and all promotional, advertisement and sales materials relating to Your Reglan/metoclopramide patient education materials provided by you to Defendant Manufacturer.

DECLARATION

I, _____, **declare under penalty of perjury subject to 18 Pa. C.S. §4904** that all of the information provided in this Plaintiff Fact Sheet is true and correct to the best of my knowledge, information and belief formed after due diligence and reasonable inquiry, that I have supplied all the documents requested in Part VI of this Plaintiff Fact Sheet, to the extent that such documents are in my possession or in the possession of my lawyers, and that I have supplied the authorizations attached to this declaration.



Signature

Date

Sworn and subscribed before me
This ____ day of _____

Notary Public