

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

IN RE:)
) MDL Docket No. 1953
)
)
)
)
HEPARIN PRODUCTS) CHIEF JUDGE JAMES G. CARR
LIABILITY LITIGATION) CASE NO. 1:08-60000

)
)
) ALL CASES

PRETRIAL ORDER NO. 15

Upon agreement of the Parties, the Court hereby enters an Order pertaining to the Defendant Fact Sheet which is attached hereto as Exhibit "A".

1) For each action currently pending before the Court in MDL 1953 in which Baxter Healthcare Corporation ("Baxter") is named as a Defendant, and for which Baxter has received a completed Plaintiff Fact Sheet ("PFS") as of the date of this Order establishing injury or wrongful death occurring after September 12, 2007 allegedly related to contaminated Heparin, Baxter shall complete and serve upon the Plaintiffs' Attorney who is identified in the Heparin Plaintiff Fact Sheet at Part I(b) the completed Defendant Fact Sheet within 60 days of the entry of this Order. In addition, a copy of the Defendant Fact Sheet, plus attachments shall be served on Plaintiffs' Federal Court Liaison Counsel (David W. Zoll, Esquire, ZOLL KRANZ & BORGESS, LLC, 6620 West Central Ave., Suite 200, Toledo, OH 43617).

2) As for those matters not currently filed, but for which an MDL 1953 Tolling Agreement has been sought by a potential Claimant, and such Claimant has completed and served the Plaintiff Fact Sheet as of the date of this Order establishing injury or wrongful death

occurring after September 12, 2007 allegedly related to contaminated Heparin manufactured by Baxter, Baxter shall, within 60 days of the entry of this Order, serve a copy of the completed Defendant Fact Sheet upon the attorney identified in Part 1(b) of the Plaintiff Fact Sheet or if no counsel is listed to the person identified in Part 2 of the Plaintiff Fact Sheet, and upon Plaintiffs' Federal Court Liaison Counsel.

3) For all completed Plaintiff Fact Sheets received after the date of the entry of this Order from claimants with cases pending in before the Court in MDL 1953 or who have sought an MDL 1953 Tolling Agreement, Baxter shall complete and serve upon the Plaintiffs' Attorney who is identified in the Heparin Plaintiff Fact Sheet at Part I(b) the completed Defendant Fact Sheet within 45 days of the receipt of the completed Plaintiff Fact Sheet. In addition, a copy of the Defendant Fact Sheet, plus attachments shall be served on Plaintiffs' Federal Court Liaison Counsel (David W. Zoll, Esquire, ZOLL KRANZ & BORGESS, LLC, 6620 West Central Ave., Suite 200, Toledo, OH 43617).

4) Notwithstanding the foregoing, for those cases in which claimant/plaintiff alleges injury or wrongful death from contaminated heparin **prior to September 13, 2007**, Baxter shall complete and serve upon the Plaintiffs' Attorney who is identified in the Heparin Plaintiff Fact Sheet at Part I(b) the completed Defendant Fact Sheet within 60 days of the receipt of the completed Plaintiff Fact Sheet or within 60 days after June 30, 2009, whichever is later. In addition, a copy of the Defendant Fact Sheet, plus attachments shall be served on Plaintiffs' Federal Court Liaison Counsel (David W. Zoll, Esquire, ZOLL KRANZ & BORGESS, LLC, 6620 West Central Ave., Suite 200, Toledo, OH 43617).

5) Plaintiffs and Claimants reserve their rights to seek any and all relief available under applicable federal rules and applicable state rules for failure to timely comply with the completion of this Fact Sheet (subject to any extensions issued by the Court or agreements among the Parties).

6) Nothing in the Defendants Fact Sheet shall be deemed to limit the scope of inquiry at depositions or admissibility of evidence at trial. The scope of inquiry at depositions shall remain governed by the Federal Rules of Civil Procedure. The admissibility of information in the Defendants Fact Sheet shall be governed by the Federal Rules of Evidence and no objections are waived by virtue of any Fact Sheet response.

7) All completed Defendants Fact Sheet are subject to the confidentiality provisions of Pretrial Order No. 7, as amended.

Accordingly, it is hereby ORDERED, ADJUDGED and DECREED this 29th day of April, 2009.

s/ James G. Carr

Chief Judge James G. Carr
United States District Court

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO**

IN RE: HEPARIN PRODUCT
LIABILITY LITIGATION

MASTER DOCKET NO.: 08-CV-60000

MDL NO.: 1953

THIS RELATES TO
MDL CASE NO.: _____

PLAINTIFF: _____
(NAME)

DEFENDANT, BAXTER HEALTHCARE CORPORATION,
BAXTER INTERNATIONAL INC. FACT SHEET
(EXHIBIT A TO PTO 15)

Defendant Baxter Healthcare Corporation states as follows:

I. CASE INFORMATION

This Defendant Fact Sheet pertains to the following case:

A. Name of Plaintiff (person who claims injury or who it is alleged died from contaminated heparin): _____

B. Northern District of Ohio Case No. or date of Tolling Agreement:

C. Name and address of facilities or locations where Plaintiff allegedly received contaminated Heparin (“Physician/clinic” identified in Part VI.A of Plaintiff Fact Sheet --hereinafter referred to as the “Heparin Location”):

1. _____

2. _____

3. _____

II. BAXTER HEPARIN SHIPMENTS AND RECALLS

As to each Heparin Location identified above, state as follows:

A. Is the Heparin Location a Direct Purchaser (“Direct Purchaser” is any purchaser of heparin from Baxter or any Baxter owned or controlled entity) of Heparin?

Yes _____ No _____

If yes, please provide the following:

1. Sales Information:

Please identify all Baxter Heparin supplied to each Heparin Location by date of shipment for the period of 6 months prior to the date(s) the Plaintiff allegedly received contaminated heparin, including but not limited to:

- a. the amounts of Heparin supplied by date of shipment;
- b. the units of Heparin supplied by date of shipment;
- c. the NDC numbers of Heparin supplied by date of shipment; and
- d. the manufacturing lot identification numbers of Heparin supplied by date of shipment; and
- e. any contracts, invoices or other documents evidencing heparin sales to such Heparin Location.
- f. please provide copies of any documents or print outs that confirm the information provided in response to (a) - (e) above.

2. Recall Information:

Please provide documentation of the following concerning any Baxter recall of Heparin:

- a. All evidence of recall notices sent to the Heparin Location;
- b. All records of any contacts or communications between the Heparin Location and Baxter concerning Heparin Recalls;
- c. All records from Heparin Location of returns, product quarantine, containment, destruction or consumption concerning recalled Heparin;

d. All records from Heparin Location concerning inability to trace or locate recalled Heparin.

B. Is Heparin Location a customer of a Baxter wholesaler or distributor [Baxter Supplier], also known as a Trace Sales Customer? As used herein the term “Trace Sales Customer” refers to any indirect purchaser of heparin for whom Baxter has a record of sales.

Yes _____ No _____

If yes, please provide the following:

1. Sales Information:

Please identify all Baxter Heparin supplied to the Heparin Location by the Baxter Supplier (“Baxter Supplier” refers to the wholesaler, distributor or other entity who purchased Heparin from Baxter for distribution or sale to the Heparin Location) by date of shipment for the period of 6 months prior to the date(s) the Plaintiff allegedly received contaminated heparin, including but not limited to:

- a. the amounts of Heparin supplied by date of shipment;
- b. the units of Heparin supplied by date of shipment;
- c. the NDC numbers of Heparin supplied by date of shipment; and
- d. the manufacturing lot identification numbers of Heparin supplied by date of shipment;
- e. please provide copies of any documents or print outs that confirm the information provided in response to (a) - (d) above.

2. Manufacturing Lot Identification:

If Baxter records do not indicate the lot numbers of Heparin shipped to Heparin Location by Baxter Supplier for the six month period prior to the date(s) the Plaintiff allegedly received contaminated heparin, then please provide the following as to the Heparin supplied by Baxter Supplier to Plaintiff’s Heparin Location for the six month period by date of shipment prior the date(s) the Plaintiff allegedly received contaminated heparin:

- a. the amounts of Heparin supplied by date of shipment;
- b. the units of Heparin supplied by date of shipment;
- c. the NDC numbers of Heparin supplied by date of shipment; and

- d. the manufacturing lot identification numbers of Heparin supplied from Baxter to the Baxter Supplier by date of shipment for the period of six months prior to plaintiff's injury
- e. please provide copies of any documents or print outs that confirm the information provided in response to (a) - (d) above.

3. Recall Information:

Please provide documentation of the following concerning any Baxter recall of Heparin:

- a. All recall notices sent to the Heparin Location;
- b. All records of any contacts or communications between the Heparin Location and Baxter concerning Heparin Recalls;
- c. All records from Heparin Location of returns, product quarantine, containment, destruction or consumption concerning recalled Heparin;
- d. All records from Heparin Location concerning inability to trace or locate recalled Heparin;
- e. All communications between Baxter Supplier and Heparin Location concerning Baxter Heparin recalls.

C. If Heparin Location is a Trace Sales Customer of Baxter, please state as follows:

- 1. Identify any other manufacturer(s) of Heparin of the strength and quantity administered to Plaintiff who sold product through the Baxter Supplier to the plaintiff's Heparin Location for the six month period prior to Plaintiff's alleged receipt of contaminated heparin on a weekly basis and state the quantity of Heparin sold by week;
- 2. State the percentage of Baxter Heparin (compared to Heparin made by other manufacturers) sold by Baxter Supplier to plaintiff's Heparin Location for the strength and quantity of Heparin administered to plaintiff for the six month period prior to Plaintiff's alleged receipt of contaminated heparin on a weekly basis.

III. CONTACT WITH PLAINTIFF/CLAIMANT OR REPRESENTATIVE

A. Did Defendant or anyone else, to Defendant's knowledge, make a report to the FDA regarding this Plaintiff/Claimant?

___ Yes ___ No

B. If Yes, identify the person and organization making the report, produce a copy of the report and/or form, as well as all underlying and/or supporting data, communications and/or other materials that comprise said submission.

C. Did you or any consultant, in the normal course of business (excluding attorney work product), perform an analysis or review of medical or scientific information concerning the Plaintiff/Claimant who is the subject of this case?

___ Yes ___ No

If Yes, identify: (1) the person who performed the analysis or review, (2) the person's current address, and (3) produce all documents relating to the analysis performed concerning the Plaintiff/Claimant.

(1) _____

(2) _____

D. Prior to this litigation, was Defendant contacted by Plaintiff/Claimant or anyone acting on his/her behalf concerning Plaintiff's/Claimant's injury (other than contacts between counsel for the parties during the course of this litigation and other than any contacts that were identified or would be reflected in materials produced in response to questions III.A-C, above)?

___ Yes ___ No

E. If Yes, please identify (1) the person who contacted you; (2) the person who was contacted; and (3) the date of the contact.

(1) _____

(2) _____

(3) _____

F. To the best of your knowledge, has any physician or healthcare provider from Plaintiff/Claimant's Heparin Location ever contacted you to request information concerning contaminated Heparin?

___ Yes ___ No

1. If Yes, identify and attach any document which refers to communication between any Defendant and Plaintiff/Claimant's dispensing healthcare provider.

(Name)

(Address)

(Address)

(Phone)

V. CONTACTS WITH PLAINTIFF/CLAIMANT'S HEALTHCARE PROVIDERS

Baxter affirmatively states that, as a general matter, prior to February 29, 2008, Baxter's "sales" activities with respect to heparin sodium injection vials or HEP-LOCK products were neither focused on these products' therapeutic indications nor were they targeted to physicians or clinicians. Instead (with the exception of promotional activities related to the launch of enhanced labeling that provided additional safeguards to assist clinicians in the correct of identification of medications), heparin was "sold" as one of more than 100 generic products offered by Baxter Healthcare Corporation, primarily on the basis of availability and price and/or Group Purchasing Organization (GPO) contract arrangements.

VI. DOCUMENTS

- A. To the extent you have not already done so, produce a copy of all paper and electronic documents in your custody and possession that are responsive to the categories listed below and that were created prior to the initiation of Plaintiff/Claimant's lawsuit or assertion of a claim on his/her behalf:
 1. Any document that relates or refers to Plaintiff/Claimant.
 2. Any document reflecting any contracts or actual communications between you and any of Plaintiff/Claimant's healthcare providers regarding heparin as set forth in the PFS.
 3. Any and all Adverse Event Reports for Plaintiff/Claimant and all back-up data, including but not limited to, any and all correspondence to or from the FDA regarding Plaintiff/Claimant.

VERIFICATION

I, _____, make this verification on behalf of Defendant(s) _____, being authorized to do so. I declare under the penalty of perjury that all of the above information provided in this Defendant Fact Sheet is true and correct to the best of my knowledge. I have supplied all the documents requested in Section VI of this document, to the extent that such documents are in my possession, custody, or control, or in the possession, custody or control of the Defendants or its attorneys.

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

Date

(Name)

(Position with Defendant)

(Signature)