CASE 0:15-md-02642-JRT Document 234 Filed 08/01/16 Page 1 of 11

UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

In re: FLUOROQUINOLONE PRODUCTS

LIABILITY LITIGATION

MDL No. 15-2642 (JRT)

This Document Relates to All Actions

PRETRIAL ORDER NO. 10 DEFENDANT FACT SHEET

1. SCOPE OF ORDER

This Order shall apply to all product liability cases currently pending in the MDL 2642 and to all related actions that have been or will in the future be originally filed in, transferred to, or removed to this Court and assigned thereto (collectively, "these MDL proceedings"). This Order is binding on all parties and their counsel in all such case.

2. DEFENDANT FACT SHEET

The form Defendant Fact Sheet ("DFS") that shall be used in MDL 2642 and all member actions is attached as Exhibit A. In accordance with the schedule set forth in Exhibit A, every Defendant in each Member Action shall:

- a) Complete and execute a DFS or provide a certification that the Defendant has no relevant information or responsive materials required by the DFS;
- **b**) Serve the completed and executed DFS or certification upon counsel for Plaintiff named in the Member Action;
- c) Produce to Plaintiff's counsel all responsive, non-privileged documents in his/her possession and custody that are requested in the DFS.

CASE 0:15-md-02642-JRT Document 234 Filed 08/01/16 Page 2 of 11

3. SERVICE OF DFS

Defendant shall serve the completed DFS or certification upon Plaintiff by emailing it to

Plaintiff's counsel. Concurrent with service to Plaintiff, Defendant shall serve the completed DFS or

certification upon the PEC by emailing it to Thomas Sims, at Baron & Budd, P.C., at

tsims@baronbudd.com.

DATED: July 29, 2016 at Minneapolis, Minnesota.

JOHN R. TUNHEIM
Chief Judge

United States District Court

EXHIBIT A

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

| IN RE: FLUOROQUINOLONE PRODUCTS LIABILITY LITIGATION |) MDL No. 15-2642 (JRT) |
|--|-------------------------|
| TILL D D. I | _) |
| This Document Relates to: | |

DEFENDANT FACT SHEET

Within sixty (60) days of receiving a substantially completed and verified Plaintiff Fact Sheet ("PFS"), in which the Plaintiff identifies a fluoroquinolone manufactured and/or marketed by one or more of the Defendants, each such Defendant ("Defendant") with relevant information must complete and serve the following Defendant Fact Sheet ("DFS") and identify or provide documents and/or data responsive to the questions set forth below to the best of their knowledge. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect. Service of the DFS shall be made on all counsel representing a plaintiff in the action identified in Section I. The DFS shall be supplemented in accordance with Fed. R. Civ. P.26.

A substantially complete PFS shall include fully completed sections II(1-3) and VIII(1-9). A substantially complete PFS shall also include a written representation from plaintiff's counsel identifying: 1) the physician(s) or medical provider(s) who prescribed or dispensed the fluoroquinolone(s) plaintiff alleges caused his/her injury; 2) the address of said physician(s) or medical provider(s); and 3) the institution and address with which said physician(s) or medical provider(s) is/are affiliated (if any).

A Defendant who, after a reasonably diligent search, did not locate any relevant information or responsive materials will not be required to respond to each PFS, and will instead provide a certification from counsel that the Defendant has no relevant information or responsive materials required by the DFS. 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 in your answers below the Bates numbers of any documents that you are producing as responsive to a question or request.

For each chart included in the questions below, the Defendant may either fill out the chart, produce responsive information in a standard report from a structured database, or indicate that no data was found if applicable.

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 term "fluoroquinolone" refers to the following antibiotics in the fluoroquinolone class of drugs: Avelox®, Cipro®, Floxin®, and Levaquin®.

CASE 0:15-md-02642-JRT Document 234 Filed 08/01/16 Page 5 of 11

As used herein, the phrases "Prescribing Health Care Provider" and "PHCP" means only Plaintiff's physicians or medical providers identified in PFS Section II(3) who prescribed or dispensed the fluoroquinolone(s) to Plaintiff that allegedly caused Plaintiff's injury and that was manufactured and/or marked by Defendant.

As used herein, the phrase "Relevant Time Period" means through August 17, 2015, unless otherwise specifically noted.

Case Information This DFS pertains to the following case: Case Caption: Civil Action No.:

Date that this DFS was completed:

II. **Contacts With Prescribing Health Care Provider**

For each Prescribing Health Care Provider, please provide the following by either completing each chart below as requested, producing responsive information in a standard report from a structured database, or indicating that no data was found if applicable. Any of these options is an acceptable method of compliance with Sections A-C:

A. **Dear Doctor Letters**:

T.

Please identify the "Dear Doctor" or "Dear HealthCare Provider" or similar letter that 1. you contend was sent to the Plaintiff's Prescribing Health Care Provider concerning any fluoroquinolone(s). To the extent not previously produced, please produce a copy of each letter sent to Plaintiff's Prescribing Health Care Provider.

| Sender (Name and Address) | Letter or Document Date | Recipient (Name and Address) | Basis for Contending Letter Was Sent to Plaintiff's PHCP | Bates Number |
|---------------------------------|-------------------------------|------------------------------|--|-----------------|
| | | | | |
| | | | | |
| | | | | |

Physician or Medical Information Request Letters ("PIR" or "MIR"): В.

Please indicate if any of the Prescribing Health Care Provider(s) has (have) ever initiated 1. a PIR or MIR concerning any fluoroquinolone(s) during the Relevant Time Period by identifying the name and address of the sender of the PIR or MIR; the date it was sent; the name and address of the recipient and whether or not a response to the PIR or MIR or similar document was sent. To the extent not previously produced, please produce a copy of each PIR or MIR as well as the response sent (if any) to Plaintiff's Prescribing Health Care Provider.

| Sender | PIR or MIR | Recipient | Response Sent? |
|--------------------|------------|--------------------|----------------|
| (Name and Address) | Date | (Name and Address) | (Yes or No) |
| | | | |
| | | | |
| | | | |

CASE 0:15-md-02642-JRT Document 234 Filed 08/01/16 Page 7 of 11

2. For each MIR or PIR in which a response was sent, provide the following information regarding the response:

| Original MIR or PIR Request document Date | Format of Response (Letter or Otherwise) | Date Response Sent | Response Sender (Name and Address) | Response Recipient (Name and Address) | Bates Number of Supporting Documentation |
|---|---|--------------------------|---|--|--|
| | | | | | |
| | | | | | |

C. Other Contacts

1. For each Prescribing Health Care Provider, please identify all known contacts between the Prescribing Health Care Provider and Defendant's Detail Representatives during the Relevant Time Period concerning fluoroquinolone(s) and please produce the following information from structured databases and central repositories that can be queried using standard search techniques for the information requested by Plaintiffs (in other words, Defendants shall not be required to harvest, process and search documents to comply with this request).

| Name of Representative | Current or Former Employee | Date(s) of Each Contact with Prescribing Health Care Provider |
|---------------------------|----------------------------------|---|
| | | |
| | | Name of Former |

| 2. | If section II.6 of | the PFS indicates | that the Pla | aintiff received | samples of the |
|----|---|-------------------|-----------------|-------------------|-------------------|
| | fluoroquinolone(s) a identified in PFS sect | | * | 0 | |
| | provided him/her any Section VIII(2) of PF | - | imples prior to | o the date of sym | nptoms alleged in |
| | Yes | No | _ | | |

If the answer is "yes," please state:

| Prescribing Health Care Provider(s) | Date Shipped to and/or Provided | Amount and Dosage | Representative Who Provided |
|--|---------------------------------|--------------------------|--------------------------------|
| | | | |
| | | | |
| | | | |

In the event that discovery determines that a Prescribing Health Care Provider identified in PFS section II.6.a used samples from another member of their practice, the parties will meet & confer over additional reasonable discovery

3. Please produce any and all information that reflects or refers to any contacts or communications with Plaintiff's Prescribing Health Care Provider during the Relevant Time Period regarding fluoroquinolone(s) to the extent maintained in a structured database structured databases and central repositories that can be queried using standard search techniques for the information requested by Plaintiffs (in other words, Defendants shall not be required to harvest, process and search documents to comply with this request).

III. Consulting With Plaintiff's Prescribing Health Care Provider

For each Prescribing Health Care Provider, please provide the following by either completing the chart below as requested, producing responsive information in a standard report from a structured database, or indicating that no data was found if applicable. Any of these options is an acceptable method of compliance with Sections A & B:

A. If you have ever retained or compensated 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 fluoroquinolone(s) you marketed and/or the treatment of infectious diseases during the Relevant Time Period, please provide the following information from structured databases and central repositories that can be queried using standard search techniques for the information requested by Plaintiffs (in other words, Defendants shall not be required to harvest, process and search documents to comply with this request):

| Prescribing Health Care Provider(s) | Date(s) that Prescribing Health Care Provider Was Retained or Compensated | Nature of Affiliation | Compensation and/or Reimbursement |
|-------------------------------------|---|-----------------------|-----------------------------------|
| | | | |
| | | | |
| | | | |

B. If your records indicate Plaintiff's Prescribing Health Care Provider attended any Defendant-sponsored conferences or events ("Programs") on the subject of fluoroquinolone(s) or infectious diseases, please provide the following information from structured databases and central repositories that can be queried using standard search techniques for the information requested by Plaintiffs (in other words, Defendants shall not be required to harvest, process and search documents to comply with this request):

| | | | Date(s) that Prescribing Health |
|--------------------|--|--------------|------------------------------------|
| Prescribing Health | Title, Location and Date of the Program | Topic of the | Care Provider Attended the |
| Care Provider(s) | Attended | Program | Program |
| | | | |
| | | | |

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

For each Plaintiff's Prescribing Health Care Provider, please provide data pertaining to or reflecting his/her dispensing/prescribing practices with respect to Defendant's fluoroquinolone(s) during the Relevant Time Period to the extent: 1) that information is in Defendant's possession, custody or control (Defendant has no obligation to obtain and/or purchase additional data from IMS beyond that currently maintained in Defendant's internal company data sources); 2) Defendant is able to obtain express approval from IMS and AMS to release the data (if there is a charge levied by IMS and/or AMA, then the parties will meet and confer regarding which party shall be responsible for paying the charge); and 3) Plaintiffs enter into a confidentiality or consent agreement with IMS and AMA prior to production here (to the extent requested by IMS and/or AMA). Specifically, if available, Defendant will provide: 1) product(s) prescribed, 2) the number of new prescriptions, and 3) the number of total prescriptions.

V. Plaintiff's Medical Condition

| Δ. | Based on reasonable search by Defendant, has Defendant been contacted during the Relevance Period by Plaintiff, Plaintiff's Prescribing Health Care Provider, Plaintiff's Treat Physicians (as identified in Section IV of the PFS) or anyone on behalf of Plaintiff concern Plaintiff (other than counsel for Plaintiff) regarding fluoroquinolone(s) based on informat maintained in structured databases and central repositories that can be queried using standard techniques for the information requested by Plaintiffs (in other words, Defendants standard to harvest, process and search documents to comply with this request)? | ting ning tion dard |
|----|--|------------------------------|
| | Yes No | |
| | If Yes, please provide the name, address and telephone number of the person(s) who contacted you and to the extent in the data returned by the reasonable search, the name of the person(s) who were contacted. | d |
| | | |

- B. Please produce all documents that reflect any communications between any person (other than counsel for Plaintiff) and you during the Relevant Time Period, concerning Plaintiff and his/her use of fluoroquinolone(s) to the extent maintained in structured databases and central repositories that can be queried using standard search techniques for the information requested by Plaintiffs (in other words, Defendants shall not be required to harvest, process and search documents to comply with this request).
- C. Please identify the information in Defendant's Adverse Event database prior to the date that Plaintiff's complaint was filed in this action that refers or relates to Plaintiff and his/her use of any fluoroquinolone(s).

VI. <u>Documents</u>

- A. To the extent you have not already done so and subject to the limitations set forth in this fact sheet concerning the data sources, timeframes, and categories of relevant information, please produce a copy of all documents and things that are responsive to the categories listed below to the extent maintained in structured databases and central repositories that can be queried using standard search techniques. Defendants shall not be required to harvest, process and search documents to comply with these requests.
 - 1. Any non-privileged document created before August 14, 2014 that relates or refers to Plaintiff.
 - 2. Any document sent to or received from any of Plaintiff's Prescribing Health Care Provider(s) during the Relevant Time Period that concerns any fluoroquinolone(s).
 - 3. Any document reflecting or referring to any contacts or communications between you and Plaintiff's Prescribing Health Care Provider(s) during the Relevant Time Period that concerns any fluoroquinolone(s).

CERTIFICATION

I am employed by [INSERT DEFENDANT], one of the Defendants in this litigation. I am authorized by [INSERT DEFENDANT(S)] to execute this certification on each corporation's behalf. The foregoing answers were prepared with the assistance of a number of individuals, including counsel for [INSERT DEFENDANT], upon whose advice and information [INSERT DEFENDANT] I relied.

I declare under penalty of perjury that all of the information provided in this Defendant Fact Sheet is true and correct to the best of my knowledge upon information and belief.

| Signature | | |
|------------|--|--|
| Print Name | | |
| Date: | | |