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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

IN RE: LIPITOR (ATORVASTATIN
CALCIUM) MARKETING, SALES
PRACTICES AND PRODUCTS LIABILITY
LITIGATION

)
)
) MDL No. 2:14-mn-02502-RMG
)
) JOINT PROPOSED CASE
) MANAGEMENT ORDER NO. 16
)
)
) This Order relates to All Actions.
)

DEFENDANT'S FACT SHEET AND SUPPLEMENTAL PROTECTIVE ORDER

1. The parties have agreed upon the use of a form Defendant's Fact Sheet, with accompanying instructions and definitions, which is attached to this Order as Attachment A and shall be subject to the provisions set forth in Case Management Order No. 6, paragraph 4(k), except as otherwise set forth in the Defendant's Fact Sheet as to the timing for service.

2. The parties and non-party IMS Health Inc. ("IMS) have also agreed to be governed by a Supplemental Protective Order Concerning Use of Certain Third-Party Information, which is attached to this Order as Attachment B and shall apply to information requested in Part IV of the Defendant's Fact Sheet.

3. The attached Defendant's Fact Sheet and Supplemental Protective Order Concerning Use of Certain Third-Party Information are hereby adopted in this MDL and shall govern the applicable cases according to their terms.

AND IT IS SO ORDERED.



Richard Mark Gergel
United States District Court Judge

August 14, 2014
Charleston, South Carolina

ATTACHMENT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION**

**IN RE: LIPITOR (ATORVASTATIN
CALCIUM) MARKETING, SALES
PRACTICES AND PRODUCTS
LIABILITY LITIGATION** : **MDL NO. 2502**
: :
: **2:14-mn-02502-RMG**
:

THIS DOCUMENT RELATES TO: :
ALL ACTIONS :
:

DEFENDANT’S FACT SHEET

For each Plaintiff in the Discovery Pool from whom a substantially completed Plaintiff Fact Sheet (“PFS”) has been received, Defendant Pfizer Inc. and, where named as a Defendant in the Complaint or Short Form Complaint, Defendant Greenstone LLC (“DEFENDANTS”) will complete this Defendant Fact Sheet (“DFS”) and identify or provide documents and/or information responsive to the questions set forth below to the best of their knowledge. Defendants will provide as much information as they can based on searches of reasonably accessible information and will supplement their responses if they learn that they are incomplete or incorrect in any material respect, including in the event that additional information is provided from Plaintiffs that relates to the questions raised in the DFS. The DFS shall be completed in accordance with the requirements and guidelines set forth in the applicable Pretrial or Case Management Orders. Because the answers, responses and productions made pursuant to this DFS are in lieu of interrogatories and requests for production of documents and things, all answers and responses provided shall be verified to be true, complete and accurate by a properly designated representative of the Defendant, and shall be binding upon Defendants as if they were contained in responses to interrogatories and/or requests for production of documents and things.

Defendants will attach additional sheets of paper if necessary and will identify any documents they are producing as responsive to a question or request by bates number. Defendants must supplement their responses if they learn that any response is incomplete or incorrect in any material respect.

Defendants will serve a completed DFS on Plaintiff’s primary counsel as identified in the PFS on or before August 15, 2014, or in the case of any Discovery Pool case selected after June 23, 2014, within thirty (30) days of selection of the case or within thirty (30) day of service of a substantially completed PFS, whichever is later, but in no case shall a DFS be due prior to August 15, 2014. Defendants shall make their best effort to produce the documents requested

herein, to the extent they are reasonably accessible and identifiable, with the completed DFS. If Defendants are not able to produce certain documents requested herein with the completed DFS, they shall so advise in the DFS and shall provide an estimated date for producing any such documents.

DEFINITIONS

As used herein, “YOU,” “YOUR,” or “YOURS” means the responding Defendants.

“DEFENDANTS” shall refer to Pfizer Inc. (“PFIZER”), and, where applicable (as described above), Greenstone, LLC, (“GREENSTONE”).

As used herein, the phrase “TREATING HEALTHCARE PROVIDER” means: (1) any physician or other individual medical provider identified by full name and address in the PFS who prescribed and/or dispensed Lipitor® to the Plaintiff; and (2) up to three additional healthcare providers who treated Plaintiff either prior to or for her alleged injuries. Counsel for Plaintiffs shall, within four calendar days of her case being selected for inclusion in the Discovery Pool, provide to Defendant’s counsel the full names and business addresses of no more than three additional treating healthcare providers.

As used herein, the term “DOCUMENT” shall, consistent with Federal Rule of Civil Procedure 34(a)(1)(A), refer to any “designated documents or electronically stored information—including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations—stored in any medium from which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form.”

I. CASE INFORMATION

This DFS pertains to the following case:

Case caption: _____

Civil Action No.: _____

Court in which action was originally filed: _____

Date this DFS was completed: _____

II. CONTACTS WITH TREATING HEALTHCARE PROVIDERS

For each Treating Healthcare Provider identified in the PFS, please provide the following:

A. Dear Doctor Letters: For each “Dear Doctor,” “Dear Healthcare Provider,” “Dear Colleague,” or other similar type of document or letter sent to the Treating Healthcare Provider concerning Lipitor®, please:

1. Identify the master letter sent, including bates number.
2. State the date the master letter was sent to the Treating Healthcare Provider(s), and provide the name and address to whom the letter was sent.

Response:

Date Letter Sent	Bates Number of Master Letter	Recipient (Name and Address)

B. Physician’s Information Request Letters (“PIR”): If any Treating Healthcare Provider has ever initiated a PIR or any other similar information request related to Lipitor®, please produce any request and:

1. Identify the date of the request and the recipient.
2. Provide the name and address of the sender or requestor.
3. Provide the bates number of the request.
4. State whether or not a response to the PIR was sent or provided.

Response:

Date of Request	Recipient (Name and Address)	Sender (Name and Address)	Bates Number of Request	Response? (Yes/No)

In addition, for each PIR or similar information request to which a response was sent as indicated by a “Yes” above, please produce any response and:

1. Identify the format of the response.
2. Identify the date the response was sent or provided.
3. Provide the name and address of the sender of the response.
4. Provide the name and address of the recipient of the response.
5. Provide the bates number of the response.

Response:

Format of Response	Date Sent	Sender (Name and Address)	Recipient (Name and Address)	Bates Number of Response

C. Other Contacts: For each Treating Healthcare Provider identified in the PFS:

1. Identify by name all of Defendants’ Sales Representatives, Marketing Organization Representatives, medical liaisons, and/or any other detail persons (“Representative”) who came in contact with any of Plaintiff’s Treating Healthcare Provider in connection with Lipitor® during the timeframe for which such records are available.
2. Identify the time period, and specifically the dates, during which the Representative had any such contact with the Treating Healthcare Provider.
3. If the Representative is no longer an employee, Pfizer will provide the dates of employment for the employee and will also provide, within ten (10) days of a request for the deposition of a former Representative outside of Pfizer’s control, the last known address, telephone number and email address for the Representative.
4. For each representative, provide the names of the Representative’s Supervising/District Sales Manager. If the Representative’s Supervising/District Sales Manager is no longer an employee, Pfizer will provide the dates of employment for the employee and will also provide, within 10

days of a request for the deposition of a former Manager/District Sales Manager outside of Pfizer’s control, the last known address, telephone number, and email address for the former employee.

5. For each Sales Representative identified in response to paragraph II.C.1, please produce the most current Curriculum Vitae or Resume. If the company is not in possession of a Curriculum Vitae or Resume, please produce the portion of the Sales Representative’s personnel file that reflects their educational background.
6. For each Representative identified in response to II.C.1, produce complete “call” notes for each such contact that relates to: (1) Lipitor®; and/or (2) statin therapy generally; and/or (3) the risks of elevated cholesterol.
7. Produce all annual, semi-annual or quarterly Plans of Action (“POA”) documents used to set out the performance goals and expectations of for sales representatives/teams/territories/company (whether in terms of market share, total prescriptions/new prescriptions, or dollar sales volume); the approved messaging for sales representatives; and that sets out all approved promotional materials (whether approved for “leave behind” or not). Defendant’s response should include all sales pieces, “Slim Jims,” POA training aids, medical journal publications/articles approved for dissemination to or use in discussions with physicians, and any other promotional items or things.

Response:

Healthcare Provider	Name of Representative	Date(s) of Contact	Current or Former Employee	Supervising/ District Sales Manager	

D. Samples: If Defendants or their Representatives ever provided any Treating Healthcare Provider with Lipitor® samples, please provide the following to the extent reasonably accessible:

1. Identify the Treating Healthcare Provider who received the samples.
2. Identify the date on which such samples were provided.
3. Identify the amount, dosage, and lot numbers of such samples.
4. Identify the name of the Representative who provided the samples.

Response:

Healthcare Provider	Date Shipped/Provided	Amount, Dosage, and Lot Numbers	Representative who Provided

III. CONSULTING WITH PLAINTIFF’S TREATING HEALTHCARE PROVIDER

For each Treating Healthcare Provider identified in the PFS, please state the following:

A. Consulting and Professional Relationships: If the Treating Healthcare Provider has been consulted, retained, or compensated by Defendant as a “key opinion leader,” “thought leader,” member of a “speaker’s bureau,” “clinical investigator,” “consultant,” or in a similar capacity or otherwise has or had a financial relationship with Defendant, regarding Lipitor® :

1. Identify the Treating Healthcare Provider.
2. Identify the date(s) that the Treating Healthcare Provider was consulted, retained, or compensated.
3. State the nature of the affiliation.
4. State the amount of money paid to the Treating Healthcare Provider, if available.

Response:

Treating Healthcare Provider	Date(s) Consulted, Retained, or Compensated	Nature of Affiliation	Remuneration

- B. For any Treating Healthcare Provider identified in response to III.A., please identify and produce all documents or correspondence provided to the Treating Healthcare Provider by Defendant concerning the potential benefits and/or risks of statin therapy (including Lipitor®), or lowering levels of cholesterol generally.

Response:

- C. For each Treating Healthcare Provider identified in Section III.A., please identify and produce all consulting agreement contracts and/or retainer agreement contracts entered into by Defendant with the Treating Healthcare Provider.

Response:

- D. Provide a complete list of all persons identified by Pfizer as Key Opinion Leaders (“KOLs”) relative to Lipitor, including in your list the names and business address of the KOL.

IV. PLAINTIFF’S TREATING HEALTHCARE PROVIDERS’ PRACTICES

For each Treating Healthcare Provider identified in the PFS, please state whether you have in your possession prescriber-level information concerning the physician’s prescribing of Lipitor®, and or statins generally?

Yes _____ No _____

If “Yes,” please produce such information.

Such production will be made pursuant to a protective order signed by the Court, in order to protect the proprietary information and processes of the third party. Such protective order will be presented to the court separate from the present motion to approve DFS.

- a. State the names and address of all third party companies from whom Lipitor®-related prescriber-level information has been obtained .

Response:

- b. Provide all Lipitor®-related prescriber-level data obtained on Plaintiff’s Treating Healthcare Providers.

Such production will be made pursuant to a protective order signed by the Court, in order to protect the proprietary information and processes of the third party. Such protective order will be presented to the court separate from the present motion to approve DFS.

V. PLAINTIFF’S MEDICAL CONDITION

- A. To your knowledge, have you been contacted by Plaintiff, any of her Treating Healthcare Providers, or anyone acting on behalf of Plaintiff (other than Plaintiff’s counsel) concerning Plaintiff, other than in connection with the present lawsuit?

Yes _____ No _____

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

Response:

- C. Please identify all non-privileged documents that reflect any communication between any person identified in Section V.A. or V.B. above and you concerning Plaintiff.

Response:

D. Please produce a copy of any Adverse Event Report or MedWatch form that refers or relates to Plaintiff, as well as any underlying documentation (e.g., the adverse event source file, medical records, and non-privileged investigative reports) that refers or relates to Plaintiff.

Response:

CERTIFICATION

I declare under penalty of perjury that the information provided in this Defendants' Fact Sheet is true and correct to the best of my knowledge and belief and the same provides all accessible responsive information and documents unless otherwise specified above.

Further, on behalf of the responding Defendant, I acknowledge the continuing obligation to supplement these responses if it is discovered that any response is materially incomplete or incorrect.

Signature
On behalf of Defendant Pfizer Inc.

Print Name

Date

ATTACHMENT B

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION**

IN RE: LIPITOR (ATORVASTATIN CALCIUM) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	: : : :	MDL NO. 2502 2:14-mn-02502-RMG
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THIS DOCUMENT RELATES TO: ALL ACTIONS	: :
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**SUPPLEMENTAL PROTECTIVE ORDER
CONCERNING USE OF CERTAIN THIRD-PARTY INFORMATION**

Whereas, the parties to this Supplemental Protective Order Concerning Use of Certain Third Party Information (the “Supplemental Order”), have stipulated that certain discovery material is and should be treated as confidential, and have agreed to the terms of this order; accordingly, it is this ____ day of _____, 2014, ORDERED:

1. This Supplemental Order shall apply in the above-captioned MDL proceeding (the “MDL”) and is intended to supplement the Joint Confidentiality and Protective Order (the “Joint Order”), made applicable to all actions in the MDL by Case Management Order No. 4, dated April 25, 2014. This Supplemental Order shall apply where discovery implicates proprietary data licensed by Pfizer Inc. (“Pfizer”) from IMS Health Incorporated (“IMS”). The terms of the Joint Order are incorporated herein, except as specified herein.

2. This Supplemental Order shall govern the treatment of IMS information in the MDL. “IMS Information” shall refer to any electronic data, software or documentation related thereto purchased from or licensed from IMS or any of its affiliated companies, which is produced, used or distributed in the MDL. “IMS Information” shall also include any data,

abstracts, or summaries (including copies) derived by the parties, their attorneys or experts in whole or in part from production of any of the IMS Information in the MDL.

3. IMS hereby provides its consent, subject to the terms of this Supplemental Order, to the release by Pfizer to counsel of record for plaintiffs in the Lipitor® MDL of the following IMS Information: Data from IMS's Xponent® suite of services for the treating healthcare providers identified pursuant to the Defendant's Fact Sheet and relative to the fourteen Discovery Pool cases. Pfizer must notify IMS prior to any further production of IMS Information to counsel of record for any plaintiffs in the MDL. IMS's consent does not transfer any right, title, license, or other interest in any IMS Information. Further, such consent does not extend to the copying or transfer of any IMS Information except as expressly provided herein. The terms of any license agreements between IMS and any of the parties shall remain in effect.

4. All IMS Information is hereby designated as CONFIDENTIAL pursuant to the terms of this Order. No further designation is necessary, and no party shall object to the propriety of this designation. Notwithstanding the foregoing, the IMS Information shall be marked using the methods in paragraphs 7-9 of this Supplemental Order.

5. To the extent that any IMS Information contains personally identifiable information subject to various privacy laws, including but not limited to state data breach laws, the Receiving Party shall comply with all such relevant laws. In the event of any loss of IMS Information it shall be the obligation of the Receiving Party to comply with notice and other requirements of any applicable privacy or data breach laws.

6. Any IMS Information received by a party shall be used by that party solely for the purposes of the MDL and shall in no event be used for any business, competitive, personal, private, public or other purpose, except as required by law and in that event in accordance with

paragraph 15. IMS Information shall not be placed in any information repository accessible to any person or entity not directly involved in the MDL.

Marking IMS Information as Confidential

7. IMS Information produced in hard-copy form, and any copies thereof, shall be marked CONFIDENTIAL pursuant to paragraph 2 of the Joint Order. IMS Information produced in electronic form shall be designated as CONFIDENTIAL by marking the outside of the storage medium on which the IMS Information is produced.

8. Notwithstanding anything to the contrary in paragraph 4 of the Joint Order, IMS Information disclosed at a deposition taken in connection with the MDL shall be marked as CONFIDENTIAL on the record during the taking of the deposition, and the transcript shall be treated as CONFIDENTIAL without need for further designation. The party who noticed the deposition shall be responsible for ensuring that the court reporter marks the transcript as such.

9. Inadvertent production of IMS Information without a confidentiality marking will not be deemed to waive the confidential nature of the information or preclude a later marking of information as CONFIDENTIAL.

Authorized Recipients of IMS Information

10. Any party receiving IMS Information (“a Receiving Party”) shall treat it as proprietary information and shall disclose the information only to Qualified Persons, as defined in paragraph 5(b) of the Joint Order, and pursuant to the procedures in that paragraph 5(b).

11. Counsel shall take all reasonable and necessary steps to assure the security of IMS Information and to limit access to Qualified Persons. If a Receiving Party learns of any

unauthorized disclosure of IMS Information, it shall immediately upon learning of such disclosure inform IMS or its counsel of the disclosure.

12. In no event shall any disclosure of IMS Information be made to any competitor of IMS, or to any person who, upon reasonable and good faith inquiry, could be determined to be an employee of any competitor of IMS, irrespective of whether that person is retained as an expert in this action. No person or entity that obtains access to any IMS Information shall in any manner whatsoever attempt to reverse engineer or disassemble such information or attempt to ascertain the methodologies by which such information was obtained, sorted, projected or manipulated.

13. No person or entity that obtains access to IMS Information shall attempt to identify any person or entity (including any patient, consumer, outlet, supplier, plan, pharmacy or prescriber) that is not readily identifiable in the IMS Information. No person or entity that obtains access to IMS Information shall attempt to contact, for the purposes of obtaining testimony or otherwise, any person or entity (including any patient, consumer, outlet, supplier, plan, pharmacy or prescriber) identified or identifiable from the IMS Information. In the event that any party determines that there is an unavoidable litigation need that makes the foregoing limitations unworkable the parties reserve the right to seek modification of this Supplemental Order upon good cause shown and after reasonable notice to IMS. Notwithstanding the foregoing, if any of the aforementioned have been or can be independently derived from sources other than IMS Information, then the foregoing limitations shall not apply to such independently derived information.

14. Testimony, reports, deliverables, and analyses produced by using, or referring to, IMS Information that is used or presented at deposition, trial, or hearing shall always be used or

presented on an anonymous basis to ensure the privacy of any individual prescriber. In particular, names of prescribers shall be redacted or referred to on a de-identified basis and shall not be combined with other demographic fields of data, including but not limited to zip code or specialty, in order to avoid the risk of re-identification; however, preparation and use of non-discoverable reports, deliverables and analyses which contain prescriber identifiable IMS Information is limited to the Qualified Persons and is subject to the security, document management and other obligations contained in this Supplemental Order. Notwithstanding the foregoing, if the parties determine that there is an unavoidable litigation need to use the IMS Information supporting any such reports, deliverables and analyses (the "Reliance Materials") on an identifiable basis for cross examination of persons who relied on Reliance Materials, then the parties will, as soon as practicable, provide notice to IMS or its counsel, and in good faith, meet and confer with IMS or its counsel to determine the limitations, if any, on the use of such Reliance Materials. In that instance, the parties agree to negotiate, in good faith, reasonable limitations which will ensure the confidentiality of the data and the privacy of individual prescribers. In the event the parties are unable to reach an agreement, the parties reserve the right to seek modification of this Protective Order after reasonable notice to IMS.

15. Within three days after any party is served with a subpoena or other notice compelling the production of IMS Information, that party must give written notice of such subpoena or other notice to IMS or its counsel. IMS shall bear the burden of opposing, if it deems appropriate, the subpoena on grounds of confidentiality.

Submitting IMS Information to Court

16. In the event a party seeks to file any IMS Information with the court, that party shall take appropriate steps to file the IMS Information under seal pursuant to paragraph 6 of the

Joint Order. If, for any reason, the court does not give permission for the IMS Information to be filed under seal, the party that seeks to file the IMS Information shall provide notice to IMS and consult in good faith to determine how the IMS Information can be filed with appropriate protection.

Downloading and Electronic Transmission of IMS Information

17. To the extent that any party or counsel for any party transmits, creates, develops or otherwise establishes on any digital or analog machine-readable device, recording media, computers, discs, networks or tapes any information, files, databases or programs that contain IMS Information, that party and/or its counsel must take all necessary steps to insure that access to that transmission, electronic or magnetic media is properly restricted to those persons who, by the terms of this Supplemental Order, may have access to IMS Information. When transmitted electronically, IMS Information shall be transmitted through secured electronic communication channels and in encrypted format. In each instance, the encryption credentials (*e.g.*, log-in and password) shall be provided separately.

18. The Receiving Party of any IMS Information must ensure that any downloading to desktop platforms will be made only to password-protected or otherwise secure desktops or laptops. Users will be advised that they are prohibited from downloading IMS Information to any removable storage device.

19. If IMS Information is made available or contained in hard copy or printed format, then the Receiving Party must take reasonable steps to ensure that access to such hard copies is limited to authorized recipients under the terms of this Supplemental Order and to ensure the secure management, protection and destruction of IMS Information. The Receiving Party may maintain no more than 4 copies of the data.

IMS Shall Not Be Called to Provide Testimony Concerning IMS Information

20. The parties acknowledge that IMS Information, although appropriate for its intended purpose of supporting business and marketing analyses in industries such as the pharmaceutical industry, contains data that is susceptible to error or variance, as set forth in the documentation accompanying the IMS Information, and was not compiled and/or created by IMS for the purposes of establishing any legal fact. The parties agree that IMS shall not be called by any party to provide testimony to substantiate IMS Information with respect to any particular prescriber or any other matter.

Destruction of IMS Information Upon Resolution of this Action

21. Within thirty days after the final resolution of the MDL, all IMS Information, including all copies, abstracts and/or summaries, that is not retained as privileged communications, work product or court-filed documents, shall be destroyed. The parties shall certify such destruction and send such certifications to IMS or its counsel. If the parties hereto receive notice from the Court that the IMS Information filed with the Court will or may be released, the parties will immediately notify IMS or its counsel.

22. Upon the final resolution of the MDL, the provisions of this Supplemental Order shall continue to be binding. This Court expressly retains jurisdiction over the MDL for the purpose of enforcing the provisions of this Supplemental Order following the final resolution of the MDL.

Miscellaneous

23. IMS shall be notified if the terms of the Joint Order are amended or modified.

When notice is required to be given to IMS, it shall be provided to:

Dana B. Klinges
DUANE MORRIS LLP
30 South 17th Street
Philadelphia, PA 19103

SO ORDERED:

Dated: _____, 2014 _____