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IN RE PROPECIA ® LITIGATION

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THIS DOCUMENT APPLIES TO
ALL CASES

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SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY

Case No. 623

Civil Action

FILED

NOV 07 2016

JUDGE JESSICA R. MAYER

**ORDER REGARDING PRODUCTION
OF DEFENSE FACT SHEETS**

Upon Stipulation of the parties, and for good cause shown, the Court issues the following Order Regarding the Production of Defense Fact Sheets:

1. On or before December 9, 2016, Defendants shall provide to Plaintiff’s individual attorney as identified in the Plaintiff Fact Sheet (PFS) and to Plaintiffs’ Liaison Counsel, complete Defense Fact Sheets (DFS) in the form attached hereto as Exhibit “A”, along with responsive documents, for each of the ten (10) cases included in the “Trial Pool” as defined in Case Management Order No. 6. The production of Defense Fact Sheets shall be made in the Trial Pool selection cases and their appropriate substitutions, only.

2. In the event a case initially included in the “Trial Pool” is replaced with a new case from the “Case Pool”, Defendants shall have sixty (60) days from the date that the new case is selected for inclusion in the “Trial Pool” to provide a complete DFS to Plaintiff’s individual attorney and to Plaintiffs’ Liaison Counsel.

3. If Defendants fail to provide a complete DFS within the time period specified in paragraphs 1 or 2, above, notice shall be given to Defendants from either Plaintiff’s individual counsel or Plaintiff’s Liaison Counsel within fifteen (15) days after said deadline or receipt of the DFS by email or mail. The notice shall permit Defendants thirty (30) days to cure the

purported deficiencies and produce a completed DFS and documents. In the event a completed DFS is not provided within such thirty (30) day period, Plaintiffs shall exercise all reasonable efforts to meet-and-confer with Defendants' counsel, for a period of not less than twenty (20) days before failing any motion with the Court. No treating or prescribing health care provider or sales representative deposition in a particular case will proceed before 10 days after service of the completed Merck Profile Form in that case unless otherwise agreed upon by counsel.

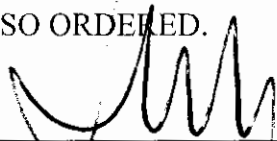
4. The admissibility of information in the DFS shall be governed by the New Jersey Rules of Civil Procedure and no objections are waived by virtue of any DFS response.

5. All information contained in the DFS is confidential and protected under any applicable Stipulation and Order Regarding Confidential Information.

6. Plaintiffs' use of the DFS shall be without prejudice to the right of the Plaintiffs in a specific case to serve additional discovery.

7. A copy of this order shall be posted online by the Court.

IT IS SO ORDERED.



JESSICA R. MAYER, J.S.C.

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NO OBJECTION TO THE FORM OF
JUDGEMENT ENTERED PER B. 4:42-1(c)

IN RE: PROPECIA® LITIGATION

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SUPERIOR COURT OF NEW JERSEY

LAW DIVISION: MIDDLESEX COUNTY

CASE NO. 623

CIVIL ACTION

Merck's Profile Form

For each case in which it is ordered, Defendant Merck must complete this Profile Form ("MPF"). Defendant must serve the complete and verified MPF and responsive documents by the date established in the Order Regarding Production of Defense Fact Sheets, dated 11/16 on all counsel identified therein.

Defendant Merck shall attach additional sheets of paper, if necessary, to completely answer the questions below. When producing any documents that are responsive to a question, or as required, the documents shall be identified by the MPF Bates Number.

If the response to any question is that of "no data found," that response should be entered in the appropriate location(s). If "no data found" is provided in response to a given section, a query of the systems yielded no data. It is a data limitation of any system that, in certain circumstances, reliable data simply cannot be obtained. The unavailability of such data is not an MPF deficiency.

Databases routinely return data that is non-responsive or otherwise irrelevant to Plaintiff/Prescriber. Such data is excluded or redacted in the MPF package, and the MPF is not deficient in this regard. MPF productions include redactions relating to privacy information (e.g., social security numbers) and other Merck Products.

Certain output from databases cannot be provided on a single page and cannot be manipulated and so are divided into multiple pages for production purposes.

Data output produced in the MPF may be responsive to more than one section of the MPF form.

Merck does not have an obligation to review medical records to identify the Prescribing Healthcare Provider(s) or otherwise respond to this MPF, but rather shall respond to information provided in the Plaintiff Profile Form ("PPF"). Unless otherwise specified, the relevant time period for responsive information is from 5 years prior to the Plaintiff's

first prescription period of Propecia and/or Proscar, as identified in Plaintiffs' Profile Form, until the filing of the Complaint ("Prescription Period").

Merck shall produce available responsive information for this MPF that can be reasonably searched and obtained from Merck's readily accessible electronic database(s) maintained in the ordinary course of business. Merck does not have an obligation to review or produce information for this MPF from any other source, including, but not limited to, department or custodial files.

Many databases at Merck require input of very limited identifying information relating to a patient or prescriber, so it is often impossible to determine with the certainty required by the Certification that the data output generated is, indeed, the specific individual identified in the PPF.

Nothing contained in this MPF prohibits Merck from withholding materials on the basis of privilege, provided a privilege log is provided according to the Privilege log protocol. The Parties agree that post-complaint materials need not be logged.

I. CASE INFORMATION

A. This MPF pertains to the following case:

1. Case caption: _____
2. Current Civil Action No.: _____
3. Court in which action was originally filed: _____
4. Original Civil Action No.: _____
5. Date that Plaintiff's Complaint was filed: _____
6. Date that this MPF was completed: _____

II. CONTACTS WITH PRESCRIBING HEALTH CARE PROVIDER

Prescribing Health Care Provider

Plaintiff has identified in the Plaintiff's Profile Form persons or entities which prescribed or dispensed Propecia/Proscar to the Plaintiff (hereinafter "Prescribing Health Care Provider.") For each such Prescribing Health Care Provider identified in the PPF, please provide the following:

A. Dear Doctor Letters

1. For each "Dear Doctor" or "Dear Health Care Provider" letter that was sent during the Prescription Period to the plaintiff's Prescribing Health Care Provider(s), as identified in the PPF, related to Propecia and/or Proscar, please identify the letter sent and provide a copy.

Merck states that the following Bates range corresponds to results generated after a search of the relevant Merck systems:

RESPONSE

Merck states that if information is not provided in response to this portion of the MPF, a query of the relevant systems yielded no responsive information or the requested information was otherwise unavailable or inaccessible to Merck and the MPF is not deficient in this regard.

2. Please identify any "Professional Information Request" letters related to Propecia and/or Proscar that Merck sent during the Prescription Period related to Propecia and/or Proscar to the Prescribing Health Care Provider(s) as identified in the PPF and provide a copy.

Merck states that the following Bates range corresponds to a report generated after a search of the relevant Merck systems and provides data relating to "Professional Information Requests" (PIRs) sent to Plaintiff's Prescribing Health Care Provider(s), as identified in the PPF, during the Prescription Period:

RESPONSE

Merck states that if information is not provided in response to this portion of the MPF, a query of the relevant systems yielded no responsive information or the requested information was otherwise unavailable or inaccessible to Merck and the MPF is not deficient in this regard. To the extent Merck has a record of a written PIR(s) being sent to Plaintiff's Prescribing Health Care Provider(s) during the Prescription Period, the documents will be included in the accompanying MPF data package.

B. Other Contacts

1. For each Prescribing Health Care Provider identified in the PPF, produce or identify all call notes between the Prescribing Health Care Provider and Merck's sales representatives related to Propecia and/or Proscar during the Prescription Period.

Merck states that the MPF obligates it to provide all Propecia and/or Proscar-related call notes between the Prescribing Health Care Provider(s) and Merck's sales representatives during the Prescription Period. The following Bates range corresponds to a report generated after a search of the relevant Merck systems and provides data relating to Propecia and/or Proscar-related sales calls on Plaintiff's Prescribing Health Care provider(s), as identified in the PPF:

RESPONSE

Merck states that if information is not provided in response to this portion of the MPF, a query of the relevant systems yielded no responsive information or the requested information was otherwise unavailable or inaccessible to Merck and the MPF is not deficient in this regard. To the extent Merck has a record of Propecia and/or Proscar-related call notes between Plaintiff's Prescribing Health Care Provider(s) and Merck's sales representatives during the Prescription Period, the documents will be included in the accompanying MPF data package.

2. Please identify Merck's sales representatives who had contact with each Prescribing Healthcare Provider identified in the PPF related to Propecia and/or Proscar during the Prescription Period, including the current relationship, if any, between Merck and the sales representative and the sales representative's last known residence or mailing address.

Merck states that the MPF obligates it to provide the identity, current relationship with Merck, and the last know residence or mailing address of any sales representative who called on Plaintiff's Prescribing Health Care Provider(s) for Propecia and/or Proscar during the Prescription Period as identified in Section B(1) to the extent such data exists:

RESPONSE

Merck states that if information is not provided in response to this portion and Section B(1) of the MPF, a query of the relevant systems yielded no responsive information or the requested information was otherwise unavailable or inaccessible to Merck and the MPF is not deficient in this regard. To the extent Merck has a record of call notes between Plaintiff's Prescribing Health Care Provider(s) and Merck's sales representatives, data responsive to this portion of the MPF will be included in the accompanying MPF package.

3. For each Prescribing Health Care Provider identified in the PPF, please state whether Merck or its representatives provided him/her with Propecia/Proscar samples during the Prescription Period.

Yes No

- i. If the answer is "yes," please state for each: (a) the number of sample packets provided and their dosages; (b) the dates that they were shipped and/or provided; (c) the lot numbers for the samples provided on each date identified; and (d) the identity of the person or persons who provided the samples.

Merck states that limited historic electronic data prior to April 2002 relating to Merck's sample disbursements cannot be reliably linked to a specific Plaintiff's Prescribing Health Care Provider(s). Merck will provide sample disbursement data, to the extent the data in Merck's relevant databases and systems can be reliably related to Plaintiff's Prescribing Health Care Provider(s).

Merck also states that its system of record for tracking product samples contains certain historical inaccuracies and/or omissions relating to lot numbers.

The following Bates range corresponds to a report generated after a query of Merck's systems and identifies responsive data relating to Propecia and/or Proscar samples distributed to Plaintiff's Prescribing Health Care Provider(s) during the Prescription Period:

RESPONSE

Merck states that if information is not provided in response to this portion of the MPF, a query of the relevant systems yielded no responsive information or the requested information was otherwise unavailable or inaccessible to Merck and the MPF is not deficient in this regard. To the extent Merck has a record of Propecia and Proscar samples being provided to Plaintiff's Prescribing Health Care Provider(s) during the Prescription Period, the documents will be included in the accompanying MPF data package.

4. For each Prescribing Health Care Provider identified by Plaintiff in the PPF, state whether Merck or its representatives provided him/her with data or documentation (including without limitation published studies or journal articles) relating in any way to Propecia/Proscar during the Prescription Period.
- Yes No

- i. If the answer is "yes," please provide a copy.

Merck states that the MPF obligates it to identify any Propecia and/or Proscar-related documentation that Merck's sales representatives provided to Plaintiff's Prescribing Health Care Provider(s), as identified in the PPF, during the Prescription Period to the extent such data exists:

RESPONSE

Merck states that if information is not provided in response to this portion of the MPF, a query of the relevant systems yielded no responsive information or the requested information was otherwise unavailable or inaccessible to Merck and the MPF is not deficient in this regard. To the extent Merck has a record

of Propecia and/or Proscar-related documentation provided to Plaintiff's Prescribing Health Care Provider(s) by Merck's sales representatives, data responsive to this portion of the MPF will be included in the accompanying MPF data package.

III. CONSULTING WITH PRESCRIBING HEALTH CARE PROVIDER

- A. For each Prescribing Health Care Provider identified in the PPF, please state whether Merck retained him/her as a member of Merck's Speaker Program, a Merck Clinical Investigator, or a consultant during the Prescription Period.

_____ Yes _____ No

1. If the answer is "yes," please state/provide for each: (a) the dates of payments; (b) the amounts he/she was paid by Merck, including fees, expenses, honoraria, or any other form of payment, and copies of all documents evidencing such payments; (c) copies of documents, if any, related to Propecia/Proscar that he/she was provided, including cover letters accompanying such materials; and (d) copies of contracts, consultancy agreements or any other agreements related to Propecia and/or Proscar.

Merck will provide payments made to Plaintiff's Prescribing Health Care Provider(s), as identified in the PPF, and will provide such payment information in response to this portion of the MPF. Merck states that payments made to third-party entities on behalf of the Plaintiff's Prescribing Health Care Provider(s) may not be linked back to the Plaintiff's Prescribing Health Care Provider(s). Merck will provide all payments made to the Plaintiff's Prescribing Health Care Provider(s) regardless of the purpose for which payments were made.

Merck further states that because of reporting mechanisms in the systems for reporting payment data, payments to physicians cannot always be reliably linked to a specific product or therapeutic area. Accordingly, to the extent that such payment information is provided in responses to this portion of the MPF, it, in whole or part, is not necessarily related to Propecia and/or Proscar.

Merck also states that to provide the most comprehensive reporting of payment data, multiple source systems are queried that may contain the same data. This is due to standard industry practices to ensure continuity of data and business processes. As a result, certain payment data may be redundant in nature and are, therefore, potentially over-reported in the MPF data package.

In addition, Merck states that the report provided in response to this portion of the MPF is generated directly from Merck's systems maintaining payments to physicians and tracks standard bookkeeping and accounting conventions. Certain outputs from Merck's databases and systems cannot be provided on a

single page. Accordingly, certain reports provided in the MPF data package cannot be divided into multiple pages.

Finally, Merck states that different business units at Merck have different standards for maintaining contracts and agreements in the ordinary course of business. Accordingly, some of the documents are unavailable. Available contracts will be identified and produced. If no data is attached hereto, a query of Merck's systems produced no data responsive to this portion of the MPF during the Prescription Period, and the MPF is not deficient in this regard.

RESPONSE

This data identifies the entirety of data responsive to this portion of the MPF. If data is not provided in response to this portion of the MPF, a query of the relevant systems yielded no responsive information or the requested information was otherwise unavailable or inaccessible to Merck and the MPF is not deficient in this regard.

- B. For each Prescribing Health Care Provider identified in the PPF, please state whether he/she was ever invited to any of Merck's sponsored conferences or events. ___ Yes ___ No

1. If the answer is "yes," please state/provide for each: (a) the title, date and location of the event; (b) the topic(s) of the event; (c) the names of all speakers at the event; and (d) a copy, if any, of the agenda, brochure, and/or other written materials concerning or handed out at the event.

Merck states that it does not maintain, in the ordinary course of business, records of physicians who were invited to a Merck sponsored conference or event. Merck further states that data relating to "titles," "date," "location," "topic(s)," and/or "speakers" at conferences and events are not recorded and cannot be provided. The following Bates range corresponds to a report(s) generated after a query of Merck's systems and identifies responsive data relating to Plaintiff's Prescribing Health Care Provide(s) during the Prescription Period:

RESPONSE

Merck states that if information is not provided in response to his portion of the MPF, a query of the relevant systems yielded no responsive information or the requested information was otherwise unavailable or inaccessible to Merck and the MPF is not deficient in this regard.

IV. PLAINTIFF'S PRESCRIBING HEALTH CARE PROVIDER'S DISPENSING / PRESCRIBING PRACTICES

- A. For each Prescribing Health Care Provider identified in the PPF, please provide data pertaining to or reflecting his/her dispensing/prescribing practices with respect to Propecia/Proscar, including, but not limited to, the number of prescriptions, the number of refills, the number of pills, the dosage and date of the packaging or date of expiration on the pills.
1. Data from Section IV(A) is subject to the execution of an appropriate third party data sharing agreement, which Merck and Plaintiffs shall reasonably cooperate to secure.

Merck has received consent from IMS Health, Inc. ("IMS") to produce certain prescription data relating to Plaintiff's Prescribing Health Care Provider(s), as identified in the PPF, in the MPF for this case. Use of IMS prescription data is subject to the terms of IMS' consent.

The following Bates range corresponds to a report generated after a query of Merck's systems and identifies responsive IMS prescription data relating to Plaintiff's Prescribing Health Care Provider(s):

RESPONSE

The report identifies the entirety of data responsive to this portion of the MPF. Merck states that if data is not provided in response to this portion of the MPF, a query of the relevant systems yielded no information or the requested information was otherwise unavailable or inaccessible to Merck and the MPF is not deficient in this regard. If the results provided do not relate to all Plaintiff's Prescribing Health Care Provider(s) identified by Plaintiff, such data represents the entirety of information that can be reliably related to those physicians in Merck's databases and systems, and the MPF is not deficient in this regard.

- B. For each Prescribing Health Care Provider identified in the PPF, produce or identify all notes between the Prescribing Health Care Provider and Merck's Health Science Associates ("HSA") related to Propecia and/or Proscar.

Merck states that the MPF obligates it to provide all Propecia and/or Proscar-related notes between the Prescribing Health Care Provider(s) and Merck's HSAs during the prescription period. The following Bates range corresponds to a report generated after a search of the relevant Merck systems and provides data relating to Merck's HSAs and Plaintiff's Prescribing Health Care Provider(s), as identified in the PPF:

RESPONSE

Merck states that if information is not provided in response to this portion of the MPF, a query of the relevant systems yielded no responsive information or the requested information was otherwise unavailable or inaccessible to Merck and the MPF is not deficient in this regard. To the extent Merck has a record of notes between Plaintiff's Prescribing Health Care Provider(s) and Merck's HSAs during the Prescription Period, the documents will be included in the accompanying MPF data package.

V. PLAINTIFF'S MEDICAL CONDITION

- A. Has Merck had contact with the Prescribing Health Care Provider identified in the PPF concerning Plaintiff's injuries in relation to Plaintiff's alleged use of Propecia and/or Proscar?
_____ Yes _____ No

See, Merck's response under Section V (C), below.

- B. Has Merck been contacted by Plaintiff, the Prescribing Health Care Provider(s) identified in the PPF, or anyone on behalf of Plaintiff concerning Plaintiff (other than counsel for Plaintiff) in relation to Plaintiff's alleged use of Propecia and/or Proscar?
_____ Yes _____ No

See, Merck's response under Section V (C), below.

- C. If your answer to A or B above is "yes," please (a) state the name, address and telephone number of each individual who contacted Merck or has been contacted by Merck; (b) produce any documents that reflect any communication between Plaintiff, any of his physicians, or anyone on behalf of Plaintiff (other than counsel for Plaintiff), and Merck, concerning Plaintiff; (c) dates you contacted or were contacted; (d) how you were contacted (i.e. email, phone, cell phone, text message, mail).

Merck states that because many Merck database require the input of very limited identifying information relating to a patient or Prescribing Health Care Provider(s) (and there is no standard or consistent formatting convention used for names), it is often impossible to determine with the certainty required by the Certification that the data output generated is, indeed, the specific individual identified in a PPF.

Merck further states that the queries run on Merck's databases and systems to respond to this portion of the MPF include communications between Merck's National Service Center for data relating to Plaintiff in this case to the extent the data can be reliably related to Plaintiff and falls within the Prescription Period.

RESPONSE

D. Please produce a copy of any of the following materials in relation to Plaintiff's alleged use of Propecia and/or Proscar:

1. FDA Adverse Event report which refers to or relates to Plaintiff;

As outlined above, Merck states that because many Merck databases require the input of very limited identifying information relating to a patient or Prescribing Health Care Provider(s) (and there is no standard or consistent formatting convention used for names), it is often impossible to determine with the certainty required by the Certification that the data output generated is, indeed, the specific individual identified in a PPF.

Merck further states that the queries run on Merck's database and systems to respond to this portion of the MPF were not limited to adverse event reporting data and include communications between Merck's National Service Center for data relating to Plaintiff in this case to the extent the data can be reliably related to Plaintiff.

RESPONSE

If no adverse event reporting data is attached hereto, a query of Merck's systems produced no data responsive to these requests prior to the lawsuit initiated by Plaintiff. If no data is attached hereto, a query of Merck's systems produced no data responsive to these requests.

2. MedWatch form which refers or relates to Plaintiff, as well as any underlying documentation including but not limited to evaluation or investigation Merck did concerning Plaintiff (e.g., the adverse event source file, medical records, and non-privileged investigative reports) which refer or relate to Plaintiff up and until filing of the Complaint in this lawsuit.

Merck states that if someone calls Merck on behalf of a patient, in the ordinary course of business, including making reports of adverse events, Merck does not require that the caller provide the name of the patient or any patient-identifying information. Therefore, only data associated with name fields that explicitly contain Plaintiff's name can be provided. Finally, adverse event reporting for clinical trials does not identify subjects by name because of blinding.

Merck further states that it does not require that the name of the person who initiated or received the contact be recorded in the ordinary course of business. Individuals at Merck who were contacted cannot always be uniquely identified in its systems such that an address and telephone number can be obtained. Data will be provided to the extent available through Merck systems.

Merck hereby responds to this portion of the MPF by providing the following information regarding Medwatch forms relating to Plaintiff, to the extent any such documentation exists. If no data is attached hereto, a query of Merck's systems produced no data responsive to these requests prior to the lawsuit initiated by Plaintiff.

RESPONSE

VI. THIRD PARTIES

- A. Identify each and every party whom you believe is a necessary and proper party to this litigation.

RESPONSE

VII. DOCUMENTS

To the extent you have not already done so, please produce a copy of all documents, electronic documents and things in your possession, custody and control from the categories listed below:

Any document which relates to or refers to Plaintiff.

Merck responds that it has already produced available data in response to the foregoing requests.

Any document sent to or received from any of the Prescribing Health Care Providers identified in the PPF concerning Propecia/Proscar during the Prescription Period.

Merck responds that it has already produced available data in response to the foregoing requests.

Any document sent to or received from the Plaintiff during the Prescription Period.

Merck responds that it has already produced available data in response to the foregoing requests.

Any document reflecting any actual communication between Defendant Merck and any of the Prescribing Health Care Providers identified in the PPF concerning Propecia/Proscar during the Prescription Period.

Merck responds that it has already produced available data in response to the foregoing requests.

Any document which reflects or purports to describe the Dispensing/Prescribing practices of any of the Prescribing Health Care Providers that Plaintiff identified in the PPF concerning Propecia/Proscar during the Prescription Period.

Merck responds that it has already produced available data in response to the foregoing requests.

Any and all documents requested or referred to in Sections I-VI, above and listed anywhere else in this MPF.

Merck responds that it has already produced available data in response to the foregoing requests.

CERTIFICATION

I declare under penalty of perjury, pursuant to 28 U.S.C. §. 1746, that the foregoing is true and correct to the best of my knowledge, understanding and belief, formed after due diligence and reasonable inquiry.

Signature	Print Name	Date
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