

Exhibit A.4

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: PROTON PUMP INHIBITOR (PPI) PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2789
	:	Civil Action No. 1:17-MD-2789
	:	
	:	JUDGE CLAIRE C. CECCHI
	:	
	:	

THIS DOCUMENT RELATES TO:

CASE NAME: _____

CASE NO: _____

TAKEDA DEFENDANT FACT SHEET

The Takeda DEFENDANT(S) (hereafter “DEFENDANTS”) must complete and serve this Defendant Fact Sheet (“DFS”) pursuant to the terms in CMO 22. DEFENDANT(S) shall provide the answers and responses herein and produce responsive DOCUMENTS pursuant to the Protective Order (D.I. 23) and the Order Regarding Format of Production of Hardcopy Documents and Electronically Stored Information (D.I. 73). The answers and responses herein are based on information reasonably available and known to DEFENDANT(S) as of the date of completion of this DFS. DEFENDANT(S) reserve the right to supplement these answers and responses in accordance with the Federal Rules of Civil Procedure and CMO 22.

DEFINITIONS & INSTRUCTIONS

“YOU,” “YOUR,” or “YOURS” means the DEFENDANT(S) responding to this DFS.

“DEFENDANT(S)” means the entity(ies) named as defendant(s) in the case to which responses to this DFS are provided.

“PRESCRIBING HEALTHCARE PROVIDER” means any physician or other individual healthcare provider identified by full name and address in PFS Section III.B. who prescribed, and/or dispensed (if PPI SAMPLE use alleged by Plaintiff), the responding DEFENDANT’S PPI drug to the Plaintiff.

“PRIMARY TREATING HEALTHCARE PROVIDER” means the first named physician(s) or other individual healthcare provider(s) identified by full name and address in PFS Section V.D. and PFS Section V.E. who primarily diagnosed and treated the Plaintiff for the injury alleged to have been caused by DEFENDANT’S PPI drug.

“REMUNERATION” means anything of monetary value greater than \$50 in cash or in kind, but specifically excludes SAMPLES, discounts and rebates, in-kind items for charity care, educational materials intended for patients, medical devices loaned for clinical trials, and warranty services.

“DOCUMENT” shall, consistent with Federal Rule of Civil Procedure 34(a)(1)(A), mean 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 form which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form,” that are reasonably accessible and centrally located in NON-CUSTODIAL DOCUMENT SOURCES identified by YOU. Unless otherwise agreed, hard copy archives will not be searched.

“CONSULTING RELATIONSHIP” means a PRESCRIBING or PRIMARY TREATING HEALTH CARE PROVIDER’S SERVICE, if any, to DEFENDANT as a key opinion leader, thought leader, member of a speaker's bureau, clinical investigator, or consultant to DEFENDANT.

As used herein, “KEY OPINION LEADER” or “THOUGHT LEADER” shall mean and refer to physicians, often academic researchers, who are believed by DEFENDANTS to be effective at transmitting messages to their peers and others in the medical community. This term shall mean and refer to any doctors or medical professionals hired by, consulted with, or retained by DEFENDANTS to, amongst other things, consult, give lectures, respond to media inquiries, conduct clinical trials, write articles or abstracts, sign their names as authors to articles or abstracts written by others, sit on advisory boards and make presentations on their behalf at regulatory meetings or hearings.

“PPI SAMPLES” means any medication or unit of a PPI drug not intended to be sold, which is given to promote the PPI drug's sales.

“SALES REPRESENTATIVE” means any person presently or formerly engaged or employed by YOU whose job duties include calling on physicians or other healthcare professionals, healthcare facilities, hospitals, and/or physician practice groups for the purpose of promoting PPIs manufactured or licensed by YOU to physicians or other healthcare providers; distributing PPI SAMPLES to physicians or other healthcare providers; or promoting disease state awareness for the medical conditions YOU promoted YOUR PPIs to treat. “SALES REPRESENTATIVE” also includes those who occupy positions titled “Professional Sales Representative,” “Sales Professional,” “Specialty Sales Representative,” “Senior Sales Representative,” “Senior Health Care Representative,” “Professional Representative,” “Health Care Representative,” “Institutional” or “Managed Care” sales representative, “Medical Service Representative,” and “Medical Sales Representative” or any other titles used by DEFENDANTS and any of their divisions to describe a role fitting the above job description.

“MEDICAL SCIENCE LIAISON” means any person presently or formerly engaged or employed by YOU for the purpose of direct field communication with PRESCRIBING or PRIMARY TREATING HEALTH CARE PROVIDERS about medical and science information related to YOUR PPI drugs.

“CALL NOTES” means entries in YOUR call notes database(s) reflecting contacts with PRESCRIBING HEALTHCARE PROVIDERS related to PPI drugs.

“PRESCRIBING DATA” means any prescriber-level data available to DEFENDANT (*e.g.*, IMS data) that details or summarizes the PPI drug prescribing habits and/or history of the plaintiff’s prescribing healthcare providers identified in Section III.B. of the corresponding Plaintiff Fact Sheet (“PFS”).

“RELEVANT TIME PERIOD” shall mean from the date DEFENDANTS’ SALES REPRESENTATIVES first began detailing its PPI products to Plaintiff’s PRESCRIBING HEALTHCARE PROVIDERS to the first day of the month in which the PFS is served.

I. CASE INFORMATION

This DFS pertains to the following case:

Case caption: _____

Civil Action No.: _____

Date this DFS was completed: _____

Date this DFS was supplemented: _____

II. COMMUNICATIONS AND CONTACTS WITH PLAINTIFF’S PRESCRIBING HEALTHCARE PROVIDERS

A. For each PRESCRIBING HEALTHCARE PROVIDER identified in PFS Section III.B.:

Identify by name YOUR SALES REPRESENTATIVES and MEDICAL SCIENCE LIAISONS who called on or came in contact with Plaintiff’s PRESCRIBING HEALTHCARE PROVIDER(S) regarding DEFENDANT(S)’ PPIs during the RELEVANT TIME PERIOD, and identify (or provide documents listing) the dates on which the SALES REPRESENTATIVE or MEDICAL SCIENCE LIAISON had contact with the PRESCRIBING HEALTHCARE PROVIDER (adding rows below as needed).

Name of Prescribing Healthcare Provider	Name of Sales Representative or Medical Science Liaison	Title	Current or Former Employee	Dates of Contact with Prescribing Healthcare Provider

B. For each SALES REPRESENTATIVE and MEDICAL SCIENCE LIAISON identified in this DFS, please produce:

1. His/her complete CALL NOTES for each contact with the PRESCRIBING HEALTHCARE PROVIDER that relates to DEFENDANT(S)' PPI products. Call notes must be produced in a format that the sales representatives are familiar with and will recognize at their deposition.
2. Any and all PRESCRIBING DATA available to DEFENDANTS for each of Plaintiff's PRESCRIBING HEALTHCARE PROVIDERS regarding DEFENDANTS' PPIs, subject to the execution of IMS's confidentiality agreement.

C. Have DEFENDANT(S) or their SALES REPRESENTATIVES ever provided any PPI SAMPLES to Plaintiff's PRESCRIBING HEALTHCARE PROVIDER(S) identified in Section III.B. of the PFS?

Yes _____ No _____

If the answer is "Yes," please provide the following information related to PPI SAMPLES (adding rows if needed):

Prescribing Healthcare Provider	Brand	Amount and Dosage	Date(s) Provided	Sales Representative or Department Who Provided

D. Physician Information Requests:

If, during the RELEVANT TIME PERIOD, YOU ever received from the PRESCRIBING or PRIMARY TREATING HEALTHCARE PROVIDER(S) (identified by Plaintiff in III.B. and first named in V.D. and first named in V.E.) a request for information regarding PPIs that is captured in a database, please provide as an attachment to this DFS in native excel format, the (a) name and address of the requestor (*i.e.*, the physician who called/wrote to DEFENDANT(S)); (b) the date of the inquiry, (c) the format of the inquiry, (d) the date of the response, if any, (e) the method of response (*i.e.*, fax, letter), if any, and (f) the address to which the response was sent (*i.e.*, fax number, mailing address); and produce the DOCUMENT(S) reflecting that written inquiry and any DOCUMENT sent in response, if available.

E. Dear Doctor Letters:

Please identify any “Dear Doctor,” “Dear Health Care Provider,” “Dear Colleague,” or any other letter sent by YOU to the PRESCRIBING HEALTHCARE PROVIDER(S) identified by Plaintiff in III.B. of the PFS concerning YOUR PPI drugs during the RELEVANT TIME PERIOD. For each letter or DOCUMENT identified, please identify the name of the individual who sent the letter or DOCUMENT; the date the letter or DOCUMENT was sent; the name of the recipient of the letter or DOCUMENT; and produce the DOCUMENT (adding rows if needed).

Sender (Name and Address)	Letter or Document Date	Recipient (Name and Address)

III. CONSULTING RELATIONSHIP WITH PLAINTIFF’S PRESCRIBING OR PRIMARY TREATING HEALTHCARE PROVIDER(S)

For each PRESCRIBING or PRIMARY TREATING HEALTHCARE PROVIDER identified in PFS Sections III.B., and first named in V.D. and V.E., please answer the following:

- A. If the HEALTHCARE PROVIDER has had a CONSULTING RELATIONSHIP with YOU in any capacity, or had a financial relationship with or has been provided REMUNERATION by YOU, please state the following for each (adding rows if needed):

Prescribing or Primary Treating Healthcare	Date(s) Consulted, Retained, or Compensated	Nature of Affiliation	Compensation, Reimbursement, and/or Remuneration	Total Number of Payments

- B. Please identify and produce any and all consulting agreements/contracts and/or retainer agreements/contracts entered into by DEFENDANTS with the HEALTHCARE PROVIDERS identified in PFS Sections III.B., and first named in V.D. and V.E. unless the contract requires prior notice to the HEALTHCARE PROVIDER before production.

IV. PLAINTIFF’S PRESCRIBING HEALTHCARE PROVIDER’S PRACTICES

A. Was the PRESCRIBING HEALTHCARE PROVIDER(S) identified in Sections III.B. of the PFS involved in any clinical trial sponsored by DEFENDANTS related to Prevacid or Dexilant?

_____ Yes _____ No

B. If yes, identify the clinical trial number(s) in which the PRESCRIBING HEALTHCARE PROVIDER was involved:

C. For each PRESCRIBING HEALTHCARE PROVIDER identified in Sections III.B. of the PFS, please state whether he/she attended any educational or promotional event, conference, lecture, luncheon, dinner or other meeting sponsored or co-sponsored by YOU regarding PPIs?

_____ Yes _____ No

If yes, please state as to each such PRESCRIBING HEALTHCARE PROVIDER, if known:

Prescribing Healthcare Provider	Title, Location, and Date of Program	Program topic	Speaker(s)

V. ADVERTISING PRACTICES

Was the Plaintiff registered with any program owned, operated, or controlled by DEFENDANTS whereby Plaintiff received electronic communications concerning DEFENDANTS' PPI products?

Yes _____ No _____

VI. PLAINTIFF'S MEDICAL CONDITION

A. Have YOU been contacted by Plaintiff, or anyone acting on behalf of Plaintiff (other than Plaintiff's counsel), concerning Plaintiff?

Yes _____ No _____

PPI MDL: Takeda DFS Deferral Agreement

In connection with the negotiation of the Takeda-specific Defense Fact Sheet for the Proton Pump Inhibitor Products Liability Litigation (No. II), Case No. 2:17-md-02789-CCC-MF, the parties have agreed that certain items that the PSC has requested will be provided either (a) as part of general discovery and be available to all plaintiffs or (b) for any case that gets selected to be worked up for further case-specific discovery as part of a bellwether or “early” discovery process.¹ The production of these materials outside of the DFS was part of the give-and-take by both sides in order to reach agreement on the terms of the DFS.

The PSC and Takeda have agreed the following information will be produced as part of Takeda’s general discovery production and not as part of the DFS:

- (a) An identification of advertisements/marketing/promotional materials, including but not limited to television ads, print ads, and materials sales representatives had available to use during sales calls (collectively, “marketing piece(s)”), which identifies, to the extent it exists, the following information:
 - i. for Prevacid and Dexilant marketing pieces: the name/description of the marketing piece (which may identify the region/market/target of the marketing piece), the document number, the “approved” date of first use and expiration date, and corresponding beginning Bates number.

This information will be produced in a native Excel spreadsheet (where maintained in that format in the ordinary course of business by Takeda) so that it can be searched and sorted as needed by the PSC. In the event that any of these items are not available for any given marketing piece, Takeda’s counsel shall notify the PSC’s representatives and the parties shall work in good faith to provide the necessary information to permit each plaintiff to know what marketing pieces were in use in his/her market area and during what time periods, by other available means.

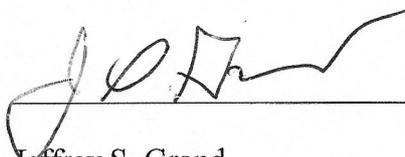
- (b) Materials that Takeda provided to healthcare professionals on its speaker bureau (or the functional equivalent) relating to PPIs or disease state awareness that are available in non-custodial sources (provided, however, that Takeda also may produce documents relating to its speaker bureau in certain custodial files).

The PSC and Takeda have agreed the following information will be produced for any case that gets selected to be worked up for further case-specific discovery as part of a bellwether or early discovery case and will not be produced for every case as part of the DFS. The Parties recognize that the process for selection of bellwether or early discovery cases has not yet been determined, including details like the number of cases or amount of case-specific discovery to be done (*e.g.*, core discovery vs. full trial work-up). To the extent, if any, that Takeda believes the volume of this production is too burdensome, the parties agree that they will meet and confer and if necessary, promptly bring any disagreements to the Court.

¹ The parties agree that the agreements made in connection with this document and the accompanying DFS are based on facts that are specific to this litigation.

- (a) Custodial files for sales representatives and medical science liaisons (“MSL” or any other acronym or title used at various times) who called on or spoke with the plaintiff’s prescribing physicians and the treating physicians identified in the DFS during the relevant time (as those terms are defined in the DFS), which will include information such as any emails that may have been sent between a doctor and a sales representative or MSL;
- (b) The names and employment status of managers for sales representatives and MSLs, as well as their custodial files. With regard to the production of custodial files for the managerial employees, the parties shall continue to confer concerning at which point in the bellwether or early discovery/trial pool process the custodial files will be produced.;
- (c) Additional information about physician consultants, which may be located in sales representative custodial files, and the production of any consulting contracts that were not produced because the contract requires notice to the physician prior to production (see DFS § III (B)) and reasonably available additional payment information; and
- (d) The DFS will be updated upon a case’s selection as a bellwether or early trial case.

Dated: July 27, 2018



Jeffrey S. Grand
(on behalf of the Plaintiffs’ Steering Comm.)



Sherry A. Knutson
(on behalf of the Takeda Defendants)