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# Exhibit A.3

#### 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:	

# PROCTER & GAMBLE DEFENDANT FACT SHEET

The Procter & Gamble Company and The Procter & Gamble Manufacturing Company (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, unless otherwise agreed, 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 Procter & Gamble Company and/or The Procter & Gamble Manufacturing Company, to the extent named as defendant(s) in the case to which responses to this DFS are provided.

"PLAINTIFF" shall mean the plaintiff to whom this DFS applies.

"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), PRILOSEC OTC to 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 PLAINTIFF for the injury alleged to have been caused by PRILOSEC OTC.

"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 with regard to PRILOSEC OTC, unless otherwise indicated in this DFS.

As used herein, "KEY OPINION LEADER" or "THOUGHT LEADER" shall mean and refer to healthcare providers hired by, consulted with, or retained by DEFENDANT(S) to, amongst other things, consult, give lectures, respond to media inquiries, write articles or abstracts, sign their names as authors to articles or abstracts written by others, sit on advisory boards, or make presentations on their behalf at regulatory meetings or hearings.

"PRILOSEC OTC SAMPLES" means any medication or unit of PRILOSEC OTC not intended to be sold, which is given to promote the sale of PRILOSEC OTC.

"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 PRILOSEC OTC to physicians or other healthcare providers; distributing PRILOSEC OTC SAMPLES to physicians or other healthcare providers; or promoting disease state awareness for the medical condition(s) YOU promoted PRILOSEC OTC to treat, if any.

"MEDICAL SCIENCE LIAISON" means any person presently or formerly engaged or employed by YOU for the purpose of direct field communication with the PRESCRIBING or PRIMARY TREATING HEALTH CARE PROVIDERS about medical and science information about PRILOSEC OTC. "CALL NOTES" means entries in YOUR call notes database(s) reflecting contacts with PLAINTIFF'S PRESCRIBING HEALTHCARE PROVIDERS about PRILOSEC OTC.

"PRESCRIBING DATA" means any prescriber-level data currently purchased or licensed by DEFENDANT(S) (*e.g.*, IMS data) that details or summarizes the PRILOSEC OTC prescribing habits and/or history of PLAINTIFF'S PRESCRIBING HEALTHCARE PROVIDER(S) of PRILOSEC OTC.

Subject to the above provisions and definitions, "RELEVANT TIME PERIOD" shall mean from the date DEFENDANTS' SALES REPRESENTATIVES first began detailing PRILOSEC OTC 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 PROVIDER(S)

A. For each PRESCRIBING HEALTHCARE PROVIDER identified in PLAINTIFF'S PFS Section III.B. as having prescribed PRILOSEC OTC to the PLAINTIFF:

Identify by name YOUR SALES REPRESENTATIVE(S) and MEDICAL SCIENCE LIAISON(S), if any, who called on or detailed PLAINTIFF'S PRESCRIBING HEALTHCARE PROVIDER(S) regarding PRILOSEC OTC during the RELEVANT TIME PERIOD, and identify (or provide documents listing) the dates on which the SALES REPRESENTATIVE or MEDICAL SCIENCE LIAISON had such 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

A searchable report or reports that contain(s) the same fields of information may be provided in lieu of completing the above chart.

- B. For each SALES REPRESENTATIVE and MEDICAL SCIENCE LIAISON identified in this DFS, please produce:
  - 1. His/her CALL NOTES for each contact with the PRESCRIBING HEALTHCARE PROVIDER about PRILOSEC OTC. To the extent reasonably available, call notes must be produced in a format that the SALES REPRESENTATIVES are familiar with and would recognize at their deposition.
  - 2. PRESCRIBING DATA currently licensed by DEFENDANT(S) for each of PLAINTIFF'S PRESCRIBING HEALTHCARE PROVIDERS regarding PRILOSEC OTC, subject to the execution of IMS's confidentiality agreement.<sup>1</sup>
- C. Have DEFENDANT(S) or their SALES REPRESENTATIVE(S) ever provided any PRILOSEC OTC 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 (adding rows if needed):

Prescribing Healthcare Provider	Amount and Dosage	Date(s) Provided	Sales Representative or Department Who Provided the PRILOSEC OTC SAMPLE

A searchable report that contains the same fields of information may be provided in lieu of completing the above chart.

<sup>&</sup>lt;sup>1</sup> On the date this DFS was agreed to, DEFENDANTS licensed/purchased PRESCRIBING DATA from a third party. DEFENDANTS are under no obligation to continue to license or purchase PRESCRIBING DATA from the third party solely for purposes of responding to a DFS. Thus, if DEFENDANTS stop licensing or purchasing PRESCRIBING DATA from the third party, DEFENDANTS shall have no obligation to respond to this question as part of the DFS process except for any historical data they may have retained.

D. Physician Information Requests:

If, during the RELEVANT TIME PERIOD, YOU 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 PRILOSEC OTC 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 PRILOSEC OTC 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 PLAINTIFF'S PFS Sections III.B., and first named in V.D. and V.E., please answer the following:

A. With regard to PRILOSEC OTC, Vicks over-the-counter drug products, or Pepto-Bismol, has the HEALTHCARE PROVIDER had a CONSULTING RELATIONSHIP with YOU or had a financial relationship with or has been provided REMUNERATION by YOU?

\_YES \_\_NO.

If YES, 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

A searchable report or reports that contain(s) the same fields of information, if available, may be provided in lieu of completing the above chart.

B. If the response to part III(A) above is "Yes," then please identify and produce any and all consulting agreements/contracts and/or retainer agreements/contracts entered into by DEFENDANT(S) with the HEALTHCARE PROVIDERS identified in PLAINTIFF'S 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 PLAINTIFF'S PFS involved in any clinical trial sponsored by DEFENDANTS related to Prilosec OTC?

\_\_\_\_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 PLAINTIFF'S 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 PRILOSEC OTC?

\_\_\_\_Yes \_\_\_\_No

If yes, and to the extent such information is available in the NON-CUSTODIAL DOCUMENT SOURCE, please state as to each such PRESCRIBING HEALTHCARE PROVIDER, if known:

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

A searchable report or reports that contain(s) the same fields of information, if available, may be provided in lieu of completing the above chart.

# V. ADVERTISING PRACTICES

Was PLAINTIFF registered with any program owned, operated, or controlled by DEFENDANTS whereby PLAINTIFF received electronic communications concerning PRILOSEC OTC?

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'S injury as alleged in PLAINTIFF'S complaint and/or PFS, or PLAINTIFF'S alleged use of PRILOSEC OTC?

Yes No No

If YOU have been contacted by any person or entity concerning PLAINTIFF (other than PLAINTIFF'S counsel) for a reason other than reporting an adverse event, please state the name of the person(s) who contacted YOU and the name and address of the person(s) who responded to the contact on YOUR behalf.

B. Other than in connection with any adverse event report, have YOU initiated contact with PLAINTIFF'S PRESCRIBING or PRIMARY TREATING HEALTHCARE PROVIDERS concerning PLAINTIFF'S injuries as alleged in PLAINTIFF'S complaint and/or PFS?

Yes	No
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C. Have YOU been contacted by anyone regarding the alleged side effect or alleged adverse event experienced PLAINTIFF while on PRILOSEC OTC, excluding contact/reporting by counsel for PLAINTIFF and/or submission in connection with this litigation?

Yes No

If yes, please identify and produce any documents related to such contact, and a copy of any summary report from YOUR adverse event database.

- D. Please identify and produce all DOCUMENTS created by YOU before the filing of PLAINTIFF'S lawsuit which reflect any communication between any person and YOU concerning PLAINTIFF'S use of PRILOSEC OTC.
- E. Please produce a copy of any MedWatch form, other than DOCUMENTS initiated in the course of litigation, which refers or relates to PLAINTIFF. Any MedWatch form produced may be redacted in accordance with federal law.
- F. Please produce a copy of any pictures, videos, and/or other surveillance materials and/or documents that YOU have obtained, which refers or relates to PLAINTIFF.

# **CERTIFICATION**

The foregoing answers were prepared with the assistance of a number of individuals, including counsel, upon whose advice and information I relied. I declare under penalty of perjury subject to 28 U.S.C. 1746 that all of the information provided in this Defendant Fact Sheet is true and correct to the best of my knowledge.

Signature

Print Name

Date

#### PPI MDL: The Procter and Gamble Company and The Procter and Gamble Manufacturing Company (collectively, "P&G") DFS Deferral Agreement

In connection with the negotiation of the P&G-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.<sup>1</sup> 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 P&G have agreed the following information will be produced as part of P&G's general discovery production and not as part of the DFS:

- (a) An identification of advertisements/marketing/promotional materials, including television ads, print ads, and materials sales representatives had available to use during sales calls (collectively, "marketing piece(s)"), which identifies, to the extent such information exists and is reasonably available,<sup>2</sup> the following information:
  - i. for Prilosec OTC pieces: the name/description of the marketing piece, the document number, the "approved" date of the marketing piece, any expiration date (or date after which the piece was not used) 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 P&G). In the event that any of the above information is not available for any given marketing piece, P&G's counsel shall notify the PSC's representatives and the parties shall work in good faith to use best efforts to provide the information to permit a plaintiff to determine what marketing pieces likely were in use in his/her market area and during what time periods, by other reasonable and available means;

- (b) Materials that P&G provided to healthcare professionals who were retained as KEY OPINION LEADERS, THOUGHT LEADERS, or members of a speakers' bureau, if any, relating to PRILOSEC OTC or disease state awareness that are available in noncustodial sources (provided, however, that P&G also may produce such documents in certain custodial files);
- (c) Additional information about the manner in which P&G marketed Prilosec OTC and relationships between P&G and various types of retailers for Prilosec OTC; and

<sup>&</sup>lt;sup>1</sup> 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.

 $<sup>^{2}</sup>$  In the event that P&G identifies any materials that they claim are not reasonably available, P&G shall promptly notify the PSC. and the parties shall meet and confer about such materials.

(d) The custodial files for the "Sales Representatives" (or other title used at various times) for Prilosec OTC who interact with the "big box stores" or large chain pharmacies (provided, however, that the precise number of such custodial files of such employees that P&G produces will be discussed as part of the global production of custodial files and will be subject to any limits on the number of files either agreed to or imposed by the Court).

The PSC and P&G 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 P&G 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.

- (a) Custodial files for sales representatives and medical science liaisons ("MSL" or any other acronym or title used at various times), if any, who called on or detailed 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 may 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 any consulting arrangement with a plaintiff's prescribing or treating physicians which may be located in sales representative custodial files;
- (d) 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
- (e) 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.)

Gina M. Saelinger (on behalf of The Procter and Gamble Company and The Procter and Gamble Manufacturing Company)