IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

MDL No. 2974
In Re: Paragard IUD Products Liability Litigation

DEFENDANT FACT SHEET

In completing this Defendant Fact Sheet ("DFS"), you are under oath and must complete and serve this DFS in accordance with the requirements set forth in Case Management Order No. _____.

The answers and responses herein are based on information reasonably available and known to Defendant as of the date of completion of this DFS. Defendants reserve the right to supplement these Answers and responses in accordance with the Federal Rules of Civil Procedure and CMO _____.

DEFINITIONS

1. "Paragard" shall mean the Paragard Intrauterine Copper Contraceptive ("IUD").

2. The terms "You" and "Your," or "Defendant" unless otherwise defined in a particular question, shall mean (a) Teva Women's Health, LLC ("TWH, LLC"), for those DFSs produced by TWH, LLC; and (b) CooperSurgical, Inc. ("CooperSurgical") for those DFSs produced by CooperSurgical.

3. The term "Health Care Provider" or "HCP" includes, but is not limited to, medical doctors, physicians, nurses, physician assistants, nurse practitioners, and midwives, who either placed Plaintiff's Paragard, attempted to remove, or removed Plaintiff's Paragard.

I. CASE INFORMATION

This DFS pertains to the following case:

1. Case Caption: _____

2. Docket No.: _____

3. Plaintiff: _____

4. Defendant Completing this DFS: _____

5. Do you contend that that Plaintiff failed to join all necessary and appropriate parties?

   Yes ☐ No ☐ Possibly ☐ Unknown at this time ☐

   If yes, please identify the parties you contend should be joined:

   _____

II. PRODUCT INFORMATION

1. If the Plaintiff has included a Lot Number for the Paragard placed in her in either (a) paragraph 13.a. of her Short Form Complaint; or (b) section III A. of her Plaintiff Fact Sheet, then state the date and location of manufacture for each Paragard Lot so identified by Plaintiff:

Lot Number	Date of Manufacture	Location of Manufacture

2. If the Plaintiff has included a Lot Number for the Paragard placed in her in either (a) paragraph 13.a. of her Short Form Complaint; or (b) section III A. of her Plaintiff Fact Sheet, then state the date on which that Lot was first shipped from the manufacturing facility:

Lot Number	Date Shipped

3. If the Plaintiff has included a Lot Number for the Paragard placed in her in either (a) paragraph 13.a. of her Short Form Complaint; or (b) section III A. of her Plaintiff Fact Sheet, then state the name(s) address(es)of the entity(ies) to whom that Lot was first shipped:

Lot Number	Name and Address of Entity Shipped to

4. If the Plaintiff has included a Lot Number for the Paragard placed in her in either (a) paragraph 13.a. of her Short Form Complaint; or (b) section III A. of her Plaintiff Fact Sheet, then state the name(s) address(es)of the person or entity to whom each Paragard was sold:

Lot Number	Name and Address of Purchaser

5. Do you claim that the Paragard(s) placed in Plaintiff were modified, altered or changed in any way from the condition in which they were sold?

Yes ☐ No ☐ Unknown at this time ☐

If yes, please describe the modification, alteration or change to each Paragard identified by Lot Number in (a) paragraph 13.a. of her Short Form Complaint; or (b) section III A. of her Plaintiff Fact Sheet:

Lot Number	Description of modification, alteration or change

III. REPORTING

1. Identify any MedWatch manufacturer report number pertaining to each Paragard implanted Plaintiff:

Lot Number	MedWatch Manufacturer Report Number

2. Identify any documents or reports submitted to the FDA or any other government agency about the Plaintiff, and/or the Plaintiff's specific Paragard IUD(s):

Lot Number	Report Title	Agency	Date

IV. CONTACT

1. From and after 5 years prior to the placement of Plaintiff's Paragard, do you have (or have you had) a consulting agreement with any of the Health Care Provider(s) ("HCP") who placed, attempted to remove, and/or removed Plaintiff's Paragard(s) that are identified by Plaintiff in either (1) paragraph 10 of her Short Form Complaint; or (2) sections III A. and III D. of her Plaintiff Fact Sheet

   Yes ☐ No ☐

   If yes, please provide the following information:

Name of Healthcare Provider	Date(s) of consulting agreement	Subject of consulting agreement	Amount set forth in consulting agreement

2. From and after 5 years prior to the placement of Plaintiff's Paragard, did you provide any type of remuneration[1], to any of the HCPs identified by Plaintiff in either (1) paragraph 10 of her Short Form Complaint; or (2) sections III A. and III D. of her Plaintiff Fact Sheet, who placed, attempted to remove, and/or removed Plaintiff's Paragard(s)?

Yes ☐ No ☐

If yes, please provide the following information:

Name of Healthcare Provider	**Date(s) of remuneration**	**Amount of remuneration**	**Reason for remuneration**

3. Have you ever provided to any of the HCPs identified by Plaintiff in either (1) paragraph 10 of her Short Form Complaint; or (2) sections III A. and III D. of her Plaintiff Fact Sheet, who placed, attempted to remove, and/or removed Plaintiff's Paragard(s), any information, in addition to the Paragard label[2] that accompanies the product, about the risks, benefits, instructions for use, side effects, warnings, and/or complications associated with Paragard?

Yes ☐ No ☐

If yes, provide the following information:

[1] Remuneration is defined as any and all financial compensation, including but not limited to monetary payments, consulting fees, speaker fees, honoraria, and/or stipends.

[2] Sometimes referred to as "Labeling – Package Insert," "Package Insert," "Prescribing Information," "Full Prescribing Information," "Labeling – Patient Package Insert," "Patient Package Insert," "Information for Patients," or "Patient Information," among others.
See https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process

Name of Healthcare Provider	Name of individual who had contact	Title	Current or Former employee	Date(s) information was provided

4. If Plaintiff checked the "yes" box in section III G. of her Plaintiff Fact Sheet, please respond to the following questions:

   a. Have You contacted Plaintiff about her Paragard?

      Yes ☐ No ☐

   b. If yes, please state the name of the person(s) who made that contact, the date of the contact, and the method of the contact(s):

      _____

5. Have You had contact, other than that provided in question 3, above (IV. 3) with any of HCPs identified by Plaintiff in either (a) paragraph 10 of her Short Form Complaint; or (b) sections III A. and III D. of her Plaintiff Fact Sheet, about her Paragard?

   Yes ☐ No ☐

   a. If yes, please state the name of the person(s) with whom You had contact, the date of contact(s), and the method of contact(s):

   _____

V. PLAINTIFF CLAIMS AND DAMAGES

1. Are you claiming that Plaintiff's damages, if any, were caused in whole or in part by Plaintiff's own negligence and/or fault?

Yes ☐ No ☐ Unknown at this time ☐

If yes, please describe the negligence and/or fault attributed to Plaintiff:

_____

_____

_____

_____

2. Are you claiming Plaintiff's damages, if any, were caused solely by or contributed to by the act and fault of third parties for whom Defendant is not liable or responsible?

Yes ☐ No ☐ Unknown at this time ☐

If yes, list the third parties believed to have caused or contributed to the damages alleged by Plaintiff:

_____

_____

3. Are you claiming Plaintiff failed to mitigate her damages?

Yes ☐ No ☐ Unknown at this time ☐

If yes, briefly describe the action or inaction of Plaintiff upon which the alleged failure is based:

_____

_____

4. Are you claiming the injuries alleged in the Complaint were caused or enhanced by pre-existing or unrelated medical, environmental, or psychiatric conditions, diseases or illnesses, by Plaintiff's own idiosyncratic reactions, and/or by operation of nature?

Yes ☐ No ☐ Unknown at this time ☐

If yes, list the pre-existing or unrelated medical, environmental, or psychiatric conditions, diseases or illnesses, or Plaintiff's own idiosyncratic reactions, and/or the operation of nature upon which that claim is based:

_____

_____

VI. DOCUMENTS

Please produce the following:

1. The Product Quality Complaint File relating to Plaintiff's claims.

☐ The documents are attached.
☐ See responsive documents previously produced at Bates Nos.
_____
_____

☐ No documents exist.

2. The sales invoice for each Paragard implanted in Plaintiff.

☐ The documents are attached.
☐ No documents exist.

3. The Paragard call activity, if any, for each sales representative, medical liaison, territory manager and/or district manager and Plaintiff's HCP identified in IV. 3 above.

☐ The documents are attached.
☐ No documents exist.

4. All documents or information constituting or containing data that tracks or purports to track the prescribing practices of any healthcare providers identified by Plaintiff who implanted, attempted to remove and/or removed Paragard.

☐ The documents are attached.
☐ No documents exist.

5. Any consulting agreement identified in response to IV.1 above.

☐ The documents are attached.
☐ No documents exist.

6. Any and all 1099s and/or other documents which memorialize the payments identified in IV.2 above.

☐ The documents are attached.
☐ No documents exist.

7. Any MedWatch Report for Plaintiff.

☐ The documents are attached.
☐ See responsive documents previously produced at Bates Nos.
_____
_____
☐ No documents exist.

8. Any Dear Doctor, Dear Healthcare Provider, Dear Colleague or similar type of letter or document sent by Defendants to any of Plaintiff's HCPs identified in Section III of the Plaintiff Fact Sheet regarding Paragard.

☐ The documents are attached.
☐ No documents exist.

9. Copies of any written contact between the Plaintiff and You, or anyone acting on Plaintiff's behalf (if known), and any employee or representative of yours, including any responses as identified in IV. 5. above.

☐ The documents are attached.
☐ See responsive documents previously produced at Bates Nos.
_____
_____

☐ No documents exist.

10. A copy of all communications identified in IV. 6, including initial correspondences and all replies from any party.

☐ The documents are attached.
☐ See responsive documents previously produced at Bates Nos.
_____
_____

☐ No documents exist.

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