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

IN RE: PARAGARD IUD PRODUCTS LIABILITY LITIGATION	))))	MDL DOCKET NO. 2974 (1:20-md-02974-LMM) This Document Relates to All Cases

CASE MANAGEMENT ORDER REGARDING DEFENDANT FACT SHEETS AND DFS DOCUMENT PRODUCTION

The Court hereby issues this Case Management Order to govern the form, procedure, and schedule for the completion and service of Defendant Fact Sheets ("DFS"), and other documents referenced therein, and the process for addressing deficient and delinquent DFS. The form DFS is attached hereto as Exhibit A.

A. SCOPE

1. Cases to which this Order applies. This Order applies only to those cases in which a Plaintiff has served a PFS which is compliant with the requirements of Case Management Order Regarding Plaintiff Fact Sheets and PFS Document Production [Doc. 331, as amended [Doc. 385], and has served all documents responsive to the Document Requests in the PFS. If, and during all times, the Plaintiff is subject to Section I.D and/or Section I.E of the Amended Case Management Order Regarding Plaintiff Fact Sheets and PFS Document Production

[Doc. 385, and any amendments thereto], no DFS shall be due and the time period to respond to a DFS shall not begin to run.

2. Responding Defendants. In all cases in which one or more of the following defendants is/are named: Teva Pharmaceuticals USA, Inc.; Teva Women's Health, LLC ("TWH, LLC"); Teva Branded Pharmaceutical Products R&D, Inc., the DFS will be responded to only by TWH, LLC. In all cases in which one or more of the following defendants is named: The Cooper Companies, Inc.; CooperSurgical, Inc. ("CSI"), the DFS will be responded to only by CSI. If a defendant is not served, that defendant is not required to respond to a DFS.

B. DEADLINES AND SERVICE OF A DFS AND RELATED MATERIALS

1. Cases Currently Pending in MDL No. 2974. A DFS must be served on the Plaintiff's counsel of record the latter of (1) 120 days from the date of this Order; or (2) 120 days from the date the Plaintiff is in full compliance with Section A.1 above.

2. Cases Transferred by the JPML to MDL No. 2974 after the Entry of this Order. For any case that is transferred by the JPML to MDL No. 2974 after the Entry of this Order, a DFS must be served on the Plaintiff's counsel of record 90 days from the date the Plaintiff is in full compliance with Section A.1 above.

3. Cases Directly Filed in MDL No. 2974. For any case that was directly filed in MDL No. 2974 after the date of this Order, a DFS must be served on the Plaintiff's counsel of record 90 days from the date the Plaintiff is in full compliance with Section A.1 above.

4. Extensions of DFS Deadlines. For any Plaintiff who received an extension of time pursuant to the Case Management Order Regarding Plaintiff Fact Sheets and PFS Document Production [Doc. 331, as amended [Doc. 385, and any amendments thereto] Defendants automatically shall have the same extension of time to serve a DFS without the need to seek an extension from Plaintiff's counsel. In cases where the Plaintiff did not seek and receive an extension to serve a PFS, a Defendant may request one extension not to exceed thirty (30) days to serve a completed DFS, which Plaintiffs shall not unreasonably withhold. Such requests must be made in writing via email to Plaintiff's counsel of record before the expiration of the deadline.

5. Transmission of DFS and Other Documents to Plaintiffs. Defendants shall complete and serve their DFS and documents responsive to the requests for production of documents set forth therein to Plaintiff's counsel of record via email and upon the PSC at ParagardDFS@fibichlaw.com. Unless otherwise agreed, all documents shall be produced in accordance with the requirements as set

forth in the Case Management Order Regarding Production of Electronically Stored Information and Paper Documents ("ESI Protocol") [Doc. No. 128].

C. DFS GENERAL REQUIREMENTS AND EFFECT

1. DFS Form. As agreed to by the Parties and approved by the Court, the form DFS that shall be used in MDL No. 2974 and all Member Actions is appended to this Order as Exhibit A. The substance of Exhibit A may not be modified in any respect without the agreement of the Parties and approval of the Court; however, a Defendant may attach additional pages to respond to particular questions, if necessary and appropriate.

2. Items to be provided or produced. For cases in which a DFS is due in accordance with the terms of this Order, the Defendant shall provide or produce the following within the deadlines set forth above: (a) a DFS responding to all questions applicable to the Plaintiff therein; (b) a signed and dated Declaration Page; and (c) the requested documents, if any, in response to the document requests set forth in the DFS (to the extent not subject to privilege and/or work-product protections).

3. DFS that is complete. In responding to the DFS, TWH, LLC and/or CSI is required to provide a DFS that is complete. For a DFS to be complete, the responding Defendant must comply in full with Sections C.2(a)-(c) above.

4. Deficiencies. Those Defendants who serve a DFS, but who do not provide a complete DFS or who provide incomplete or deficient information, shall be governed by Section D below.

5. Delinquencies (i.e., No DFS Served). Defendants who do not serve a DFS by the deadline set forth in Section B above, including any granted extension, shall be governed by Section E below.

6. Defendants shall remain under a duty to supplement the information provided in the DFS pursuant to Fed. R. Civ. P. 26(e).

7. Each completed DFS, and the information contained therein, shall be verified, signed, and dated by a representative of the responding Defendant as if they were interrogatory responses under Rule 33 or a response to a Request for Admission under Rule 36. All responses in a DFS or amendment thereto are binding on the individual Defendant as if they were contained in answers to interrogatories under Rule 33 or a response to a Request for Admission under Rule 36 and can be used for any purpose and in any manner that answers to interrogatories or responses to a request for admission can be used pursuant to the Federal Rules of Civil Procedure, subject to the confidentiality provisions of Section F below. The requests for production in the DFS shall be treated as document requests under Rule 34.

8. The admissibility of information in the Defendant Fact Sheet is governed by the Federal Rules of Evidence, and objections to admissibility are not waived by virtue of the completion and service of a Defendant Fact Sheet.

D. DFS DEFICIENCY PROCESS

1. DFS Subject to Order to Show Cause Procedure for Incompleteness and/or Certain Deficiencies

a. If a Defendant fails to sign and date the Declaration page or if a Defendant fails to produce responsive documents or information as identified by the Defendant in the DFS, Plaintiff's counsel shall notify Defendant's counsel in writing via email of the alleged deficiency(ies), and inform such Defendant that it has an additional fifteen (15) days to correct the deficiency(ies). If the deficiency(ies) is not cured in full within the 15-day period, Plaintiff may include the case on a request to the Court for an Order to Show Cause.

b. The parties may agree that certain deficiencies need not be resolved until a later point. The failure to raise a deficiency(ies) does not waive or prejudice a Plaintiff's right to seek supplementation or provision of the information in response to a deficiency at a later time.

E. DFS DELINQUENCY PROCESS (i.e., NO DFS SERVED)

1. If a Defendant does not serve an executed DFS within the deadline set forth in Section B above, including any extensions, Plaintiff's counsel

of record shall send a "Notice of Delinquency" letter via email to that Defendant's counsel, and the Defendant shall have thirty (30) days from the date of the Notice of Delinquency letter to serve an executed, complete DFS.

2. If the Defendant does not serve an executed, complete DFS by the expiration of the thirty (30) day period provided for in Section E.1 above, Plaintiff may include the case on a request to the Court for an Order to Show Cause.

F. CONFIDENTIALITY

All information disclosed in a DFS, the DFS itself, and all documents produced pursuant to the DFS shall be deemed confidential and treated as "Confidential Information" as defined in the Agreed Protective Order [Doc. No. 36].

SO ORDERED this 23rd day of February, 2023

Leigh Martin May
United States District Judge

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