

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

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

**CASE MANAGEMENT ORDER ON CERTAIN ASPECTS OF
BELLWETHER PROCESS**

The Court ORDERS as follows:

1. **Number of Cases:** The initial pool from which the first bellwether case(s) selected to be tried on or after March 4, 2024, will include 10 cases (hereinafter referred to as the “BELLWETHER POOL”).
2. **Eligibility for the BELLWETHER POOL:** The cases that are eligible for the BELLWETHER POOL must meet all of the following criteria:
 - a. the plaintiff must have been placed with a Paragard IUD and allege breakage upon removal;
 - b. the plaintiff must have a substantially complete Plaintiff Fact Sheet (including completed Authorizations) as defined in the Amended Case Management Order Regarding Plaintiff Fact Sheets and PFS Document Production (Doc. No. 385) dated on or before December 1, 2022.

- c. the plaintiff must not have any deficiencies that would give rise to an Order to Show Cause process, as set forth in [Doc. No. 385](#), as of December 1, 2022.

On or before February 24, 2023, the parties jointly will provide a list of cases (by plaintiff name and case number) to the Court that meet the criteria in Section 2(a)-(c) above (the “JOINT LIST”).

3. **Information Provided Prior To Case Selection**

- a. On or before February 27, 2023, Plaintiffs may identify 15 cases from the JOINT LIST from which their initial pool of potential bellwether cases may be selected.
- b. On or before March 13, 2023, the Defendants must provide the following information for the 15 cases identified by the Plaintiffs under subsection (a) above:
 - i. Any “complaint file”¹ in the possession of any Defendant for the Plaintiffs identified in subsection (a) above;

¹ By agreement of the parties, the term “complaint file” as used herein includes, if available:

Product Quality Complaint Files or inquiries are/were maintained in the following databases in the ordinary course of business: TrackWise NA, TrackWise Harmony, and TrackWise; in some instances, documents may be kept in paper form for the time period where one of these databases was not in place. Defendants will produce the Product Quality Complaint Files for Paragard (linked to search terms & review), including but not limited to, documents received, the initiating documents, the investigation conducted, the result of the investigation, and any other source documents and materials referenced in each Product Quality Complaint File (including attachments to emails).

Adverse Event documents or inquiries are maintained in the following databases in the ordinary course of business: Argus, IRMS, ARISg, PHIT, and Delta. Defendants will produce from the databases, if

ii. Yes/No responses to the following questions:

1. From and after 5 years prior to the placement of Plaintiff's Paragard, do you have (or have you had) a consulting agreement related to Paragard 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?; and
2. From and after 5 years prior to the placement of Plaintiff's Paragard, did you provide any type of remuneration , 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)?

4. **Method of Case Selection:**

- a. On or before March 17, 2023, the Plaintiffs collectively shall select three cases from the JOINT LIST for inclusion in the potential BELLWETHER POOL, the Defendants collectively shall select three cases from the JOINT LIST for inclusion in the potential

available, the Adverse Event documents for Paragard (linked to search terms & review), including, but not limited to documents of reports of adverse events received by Defendants; the initiating documents; any follow-up information; the investigation conducted and results thereof, if any; any report made to the FDA that is contained in an individual's adverse event documents contained in the databases, if applicable; and other source documents and materials therein, if any (including attachments to emails).

BELLWETHER POOL, and the Court shall select six cases randomly from the JOINT LIST, using a randomizer tool.

- b. If any case is selected by a party pick and randomly by the Court, the party pick will remain in the potential BELLWETHER POOL, and another random case will be selected by the Court.

5. **Challenges to Cases**

- a. On or before March 31, 2023, the parties may identify any of those randomly-selected cases that do not constitute a representative sampling of cases in this proceeding or present unique or idiosyncratic facts or law that would weigh against bellwether selection, and, therefore, should be removed from the potential BELLWETHER POOL. Plaintiffs shall also identify any cases that were randomly selected or selected by Defendants in which the Plaintiff declines to waive *Lexecon* pursuant to the provisions of Section 11 below.
- b. If the parties mutually agree that a case should be removed from the potential BELLWETHER POOL, then that case will be removed from the potential BELLWETHER POOL, and a replacement case from the JOINT LIST will be randomly selected as soon as possible by the Court using a randomizer tool.

- c. If the parties do not agree that a case should be removed from the potential BELLWETHER POOL, then the party who believes the case should be removed from the potential BELLWETHER POOL shall include such case(s) as an agenda item(s) for discussion at the April 10, 2023 MDL Status Conference, and the parties shall include in the agenda a brief paragraph of each of their respective positions. The parties will provide a joint proposed agenda to Ms. Poley on April 6, 2023, and may present their respective positions at the April 10, 2023 MDL Status Conference, or on such other date as determined by the Court.
- d. If a case is removed from the potential BELLWETHER POOL by the Court, a replacement case from the JOINT LIST will be randomly selected as soon as possible by the Court using a randomizer tool. The parties will have the same opportunity to consider whether that case will remain in the potential BELLWETHER POOL, and the process provided above in Section 5 (a) - (c) above will apply.
- e. The process provided in Section 5 will continue until 12 cases are generated for potential inclusion in BELLWETHER POOL.
- f. No later than three (3) days after the 12 cases (Section 5(e)) are generated, the Plaintiffs collectively and the Defendants collectively

shall each strike one case from the pool of 12 cases generated pursuant to Section 5(e), resulting in 10 BELLWETHER POOL cases. The parties shall notify Ms. Poley of their respective strike simultaneously at 4:00 p.m. ET.

6. **Number and General Description of Case-Specific Fact Witnesses:**

Upon finalization of the BELLWETHER POOL Cases, the following depositions may occur in each of the cases in the initial pool:

1. Plaintiff and, if applicable, Plaintiff's spouse;
2. Plaintiff's placing healthcare provider(s);
3. Plaintiff's removing healthcare provider(s);
4. One additional fact witness to plaintiff's claim for injuries, said witness as agreed to by the parties (if applicable); and
5. One sales representative (if applicable).

The Court recognizes that there may be more than one placing healthcare provider and/or removing healthcare provider, or more than one applicable sales representative. The parties will meet and confer in an attempt to agree upon whether more than one deposition each of placing and/or removing healthcare providers and/or whether more than one sales representative deposition should be taken, and any unresolved disputes may be brought to

the Court by way of simultaneously provided two-page, single-spaced letter briefs.

The Court also recognizes that there may be more than one additional fact witness to plaintiff's claim for injuries. The parties will meet and confer in an attempt to agree upon whether more than one deposition of additional fact witnesses to plaintiff's claim for injuries should be taken as part of the bellwether selection process, and any unresolved disputes may be brought to the Court by way of simultaneously provided two-page, single-spaced letter briefs.

7. **Number of Cases to Prepare for the First Bellwether Trial:** The BELLWETHER POOL shall be narrowed from 10 cases to 3 cases for the first bellwether trial(s) (hereinafter referred to as the "TRIAL ELIGIBLE POOL").
 - a. On or before August 4, 2023, the parties will meet and confer to make alternate strikes of the BELLWETHER POOL cases until six cases remain. Defendants collectively will make strikes 1 and 3, and Plaintiffs collectively will make strikes 2 and 4.
 - b. On or before August 7, 2023, the parties will meet and confer to make alternate picks from the six cases remaining. The Defendants will make pick 1, and the Plaintiffs will make pick 2.

- c. On or before August 11, 2023, the parties will provide a two page position paper to the Court concerning which 1 of the remaining 4 cases should be selected by the Court for inclusion in the TRIAL ELIGIBLE POOL. The Court shall select one of the remaining four cases for inclusion in the TRIAL ELIGIBLE POOL.
- d. The Court recognizes additional discovery may be needed for the three cases selected through this process. In the event that additional discovery is needed for these cases, the parties will meet and confer in an attempt to agree to the additional discovery needed. Any unresolved disputes may be brought to the Court by way of a concurrent submission of a two-page, single-spaced letter brief by August 2, 2023.
8. General and case-specific expert reports (and expert depositions) will be done only for the three cases selected as TRIAL ELIGIBLE CASES.
9. The August 18, 2023 through December 22, 2023 deadlines in the Initial Scheduling Order ([Doc. 372](#)) apply only to the three TRIAL ELIGIBLE CASES.
10. **Trial Selection:**

The Court will select which of the cases is the TRIAL PICK CASE (i.e., the first to go to trial on or after March 4, 2024), and which case is the BACK-UP case, in the event the first case does not proceed to trial.

11. **The Waiver of *Lexecon* in the TRIAL PICK CASE and the BACK-UP CASE:**

The Parties will agree to waive *Lexecon* and thereby submit to the jurisdiction of the Court to try the TRIAL PICK CASE, or, if necessary, the BACK-UP case in the Northern District of Georgia.

If the Court decides that a second bellwether trial is necessary, the Parties agree to waive *Lexecon* in a second trial case. That case would come from the remaining TRIAL ELIGIBLE CASES.

IT IS SO ORDERED this 22nd day of February, 2023.



LEIGH MARTIN MAY
UNITED STATES DISTRICT JUDGE