

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION**

IN RE: DEPUY ORTHOPAEDICS, INC.)	
PINNACLE HIP IMPLANT PRODUCT)	MDL No. 2244
LIABILITY LITIGATION)	
)	3:11-MD-2244-K
_____)	
)	CASE MANAGEMENT
This Document Relates to All Cases:)	ORDER No. 11
_____)	
)	

**AGREED CASE MANAGEMENT ORDER NO. 11
DEFENDANTS' FACT SHEET**

Pursuant to agreement of counsel in this MDL, this Order shall apply to all actions currently pending in MDL No. 2244, all future actions transferred to MDL No. 2244, and all future actions direct-filed in MDL No. 2244 (collectively, "Actions").

1. In addition to the materials previously produced to Plaintiffs in the MDL production (the "General Production"), Defendants will provide a Defendants' Fact Sheet ("DFS") (attached as Exhibit A) in response to each Pinnacle Plaintiff Profile Form ("PPF") provided by each plaintiff in this MDL ("Plaintiff") to Defendants.

2. Subject to the Protective Order governing this MDL and applicable statutes and regulations, the Court hereby authorizes the Plaintiffs' Executive Committee ("PEC"), as well as any duly authorized agents or designees of the PEC, to review any and all PPFs, responsive DFSs and referenced documents, and Plaintiff-

specific medical records, information, and documents to be used exclusively in connection with the preparation of these Actions.

3. Defendants have represented that they have created a Defendants' Fact Sheet Database (the "DFS Database") that includes some of the documents that are responsive to the DFS, as well as other information that will assist Plaintiff in identifying the previously produced documents within the General Production that are responsive to the DFS. Defendants have represented that Plaintiffs will be provided with login information when they receive a DFS.

4. The timing of the service of the DFS will correspond to the groups of cases identified in Section 2 of Case Management Order No. 10 dated April 6, 2018 ("PPF Order"). The DFS will be provided in response to each PPF received pursuant to Section 2.a. ("PPF Group 1"), Section 2.b. ("PPF Group 2"), Section 2.c. ("PPF Group 3"), and Section 2.d. ("PPF Group 4"), within 30, 60, 90, and 120 days, respectively, of the date specified in the applicable section of the PPF Order.

5. A DFS that identifies how to access the materials described below (which shall be produced in the time frames identified below) shall be served in response to each PPF:

(a) Device History Records ("DHRs") (DFS Section A.2.) – Defendants will populate the DFS Database with the DHRs for the Pinnacle cup(s), liner(s), and head(s) implanted in Plaintiffs to the extent that the lot numbers for those components are identified in the PPFs. The DFS Database will be

searchable by component lot number. Defendants will make reasonable efforts to populate the DFS Database with DHRs on a rolling basis (prioritizing cases that have been selected for trial workup, hereinafter “Trial Group Cases”) to be completed according to the following schedule:

PPF Group 1: October 12, 2018

PPF Group 2: November 30, 2018

PPF Group 3: February 8, 2019

PPF Group 4: March 29, 2019

(b) Complaint Files (DFS Sections A.3. & E.1.) – The DFS Database will contain information to permit Plaintiffs to identify their complaint files. Defendants will make reasonable efforts to identify the complaint file(s) for each Plaintiff using information from the PPFs, as necessary, including, but not limited to, Plaintiff name, address, date of birth, date(s) of surgery, surgeon(s), component lot numbers, component catalog numbers, and other product information. Defendants will make reasonable efforts to populate the DFS Database with Bates numbers of complaint files on a rolling basis (prioritizing Trial Group Cases) to be completed according to the following schedule:

PPF Group 1: October 12, 2018

PPF Group 2: November 30, 2018

PPF Group 3: February 8, 2019

PPF Group 4: March 29, 2019

(i) The parties have indicated that 21 C.F.R § 20.63 pertains to certain information contained in adverse event reports possessed by Defendants. The Court has not reviewed Defendants' information and has not formed an opinion on the matter. In producing documents and information and responding to interrogatories in this MDL, it is Defendants' responsibility to make sure they are in compliance with § 20.63 as well as any other applicable statutes and regulations.

(ii) Subject to the Protective Order governing this MDL and applicable statutes and regulations, the Court notes that in addition to providing information necessary for Plaintiffs to identify their complaint files, in light of the requirements of 21 C.F.R. § 20.63, Defendants may restrict access to unredacted versions of complaint files for Plaintiffs to the PEC, subject to the following qualifications. Such unredacted copies will be provided with the understanding that the PEC will take appropriate steps to maintain the confidentiality of the unredacted complaint files, including, but not limited to, not disclosing at trial unredacted complaint files without express written authorization from the Plaintiff(s) whose complaint files are being disclosed. Pursuant to 21 C.F.R. § 20.63, Defendants will redact only the reporter field in the unredacted complaint files provided. Notwithstanding the foregoing, the PEC may provide the unredacted complaint files to their authorized

agents or designees who have a need to review them for purposes of these Actions and only for use in connection with the preparation of these Actions.

(c) Plaintiff Name Searches (DFS Section D.2.) – The DFS Database will identify the Bates numbers of documents in the General Production (including DePuy documents and documents produced from distributors) that “hit” on Plaintiff names, based on reasonable searches. Defendants will make reasonable efforts to populate the DFS Database with this information on a rolling basis (prioritizing Trial Group Cases) to be completed according to the following schedule:

PPF Group 1: October 12, 2018

PPF Group 2: November 30, 2018

PPF Group 3: February 8, 2019

PPF Group 4: March 29, 2019

(d) Distributors (DFS Sections B.2. & B.4.) – Defendants will include as an attachment to the DFS response the Bates number prefixes associated with each distributor that can be used to identify the distributor documents in the General Production that have been collected pursuant to agreement with Plaintiffs’ counsel. In addition, for the Trial Group Cases, Defendants will make reasonable efforts to populate the DFS Database with the Device Experience Reports (“DERs”) pertaining to each Plaintiff within the Trial

Group Cases within 90 days of selection of such cases. The PEC also may identify up to 10 distributors for which Defendants will make reasonable efforts to locate and provide in the General Production all DERs associated with DePuy hip devices (To aid the PEC in selecting these distributors, Defendants will make reasonable efforts to provide the PEC, within 60 days of the entry of this Order, supplemental information regarding the previous territory names and/or distributors associated with geographic distribution regions. Upon receipt of such supplemental information, the PEC will have 30 days to select up to 10 distributors.). Defendants will provide such DERs on a rolling basis for the selected distributors according to the following schedule: 3 distributors by December 21, 2018; 3 distributors by June 28, 2019; and 4 distributors by December 20, 2019.

(e) Identification of Sales Representatives (DFS Sections B.1. & B.3.) – For each Plaintiff whose PPF indicates a revision surgery, Defendants will make reasonable efforts to identify the sales representatives who were present at the Plaintiff’s implantation and explantation surgeries (“Operative Representatives”). Defendants will make reasonable efforts to identify the Operative Representatives on a rolling basis (prioritizing Trial Group Cases) to be completed according to the following schedule:

PPF Group 1: December 21, 2018

PPF Group 2: April 30, 2019

PPF Group 3: August 31, 2019

PPF Group 4: December 20, 2019

Additionally, Defendants will include with the complaint file information described in Subsection 5(b) above the name(s) of sales representatives, if any, identified on the list of sales representatives provided to Plaintiffs on August 11, 2017 (and any subsequent supplements to that list) that are identified in the complaint files for each Plaintiff.

(f) Sales Representatives Document Production (DFS Section B.3.) – Defendants will include as an attachment to the DFS the Bates number prefixes associated with each of the sales representative productions that have been made prior to the date of this Order that can be used to identify such documents in the General Production. In addition, Defendants will conduct reasonable searches and supplement the General Production with documents for up to a total of 180 sales representatives annually through 2021, including the Operative Representatives for the Trial Group Cases (which shall be prioritized) and the additional sales representatives (“Additional Representatives”) selected by the PEC (By way of example, if there are 120 Operative Representatives in a group of Trial Group Cases, Defendants will conduct reasonable searches to produce documents for those 120 Operative Representatives and the PEC may select 60 Additional Representatives for which Defendants will similarly conduct reasonable searches to produce

documents.). To aid the PEC in selecting the Additional Representatives, Defendants will make reasonable efforts to provide to the PEC by July 13, 2018, a spreadsheet, compiled from the information contained in the PPFs submitted in PPF Group 1, the following information for each surgical facility: the address(es) of the implant and revision surgery facility(ies), the date(s) of surgery(ies), surgeon(s), and the sales representative(s) associated with each facility for the relevant time period. Within 30 days after receipt of such spreadsheet, the PEC will select the Additional Representatives. Defendants will conduct reasonable searches to produce documents from such Operative Representatives and Additional Representatives on a rolling basis (prioritizing Trial Group Cases) for the up to a total of 180 representatives by December 14, 2018.

6. Defendants will update the spreadsheet described in Subsection 5(f) above to include the individuals from PPF Group 2 by January 18, 2019. The parties will meet and confer on February 15, 2019, and no later than the end of February each subsequent year, to determine the process and schedule for selection of the 180 sales representatives for which Defendants will produce documents annually, taking into account the schedule for selection of additional Trial Group Cases.

7. The parties may agree to extensions of the above time limits. Consideration should be given to requests for extensions where a large volume of material is due on or near the same date(s). If the parties cannot agree on reasonable

extensions of time, such party may apply to the Court for such relief upon a showing of good cause.

SO ORDERED.

Signed April 6th, 2018.



ED KINKEADE
UNITED STATES DISTRICT JUDGE