

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

IN RE DEPUY ORTHOPAEDICS, INC.	§	
PINNACLE HIP IMPLANT	§	MDL Docket No.
PRODUCTS LIABILITY LITIGATION	§	3:11-MD-2244-K
	§	
This Document Relates To All Cases	§	Honorable Ed Kinkeade

CASE MANAGEMENT ORDER NO. 12
(Administrative Order)

The Court hereby issues this Order requiring the following groups of litigants to respond to and produce specified information regarding their claims as follows:

A. Existing Plaintiffs: All Plaintiffs with claims that were filed in, transferred to, or removed to this MDL proceeding, and which are pending as of the date of entry of this order, who allege any injury resulting from any Pinnacle prosthesis, whether metal-on-metal or non-metal-on-metal, and whether revised or unrevised, shall be considered “Existing Plaintiffs” for purposes of this Order, and shall be subject to its requirements as set forth below.

B. New Plaintiffs: All Plaintiffs with claims that are filed in, transferred to, or removed to this MDL proceeding after the date of entry of this order, who allege any injury resulting from the implant of any Pinnacle prosthesis, whether metal-on-metal or non-metal-on-metal, and whether revised or unrevised, shall be considered

“New Plaintiffs” for purposes of this Order, and shall be subject to its requirements as set forth below.

I. COMMENCEMENT OF NOTICE AND DISCOVERY OBLIGATIONS

All obligations of Existing Plaintiffs under this Order are stayed until November 8, 2019, absent agreement of the parties or subsequent Court Order.

As to New Plaintiffs, after their case is docketed in this Court (whether through direct filing, removal, or transfer), counsel for Defendants shall serve upon counsel for New Plaintiff(s) by email (or if a New Plaintiff is proceeding *pro se*, the New Plaintiff shall be served by regular mail) a copy of this Order. Counsel for Defendants will transmit the Order by email with Delivery Receipt functionality to counsel for New Plaintiff(s). The Delivery Receipt will be deemed the operative delivery or transmittal date for the purposes of this Order. All obligations of New Plaintiffs are effective immediately upon the transmittal of this Order by Defendants to counsel for New Plaintiff (or the New Plaintiff if proceeding *pro se*), absent agreement of the parties or subsequent Court Order.

Persons who represent themselves *pro se* in this proceeding shall comply fully with all obligations required of counsel by this Order. References to obligations of “counsel for an Existing Plaintiff or New Plaintiff” as used herein shall apply equally to any Existing Plaintiffs or New Plaintiffs representing themselves *pro se* in this proceeding.

II. PRESERVATION NOTICE REQUIREMENT

A. Within forty-five (45) days of the transmittal of this Order by Defendants to a New Plaintiff, or within thirty (30) days of the lifting of the stay as it applies to an Existing Plaintiff, counsel for an Existing Plaintiff or New Plaintiff shall notify the following individuals or entities, by registered mail, that they may have records relevant to the claim of the Existing Plaintiff or New Plaintiff in this MDL Proceeding (“Claim”), and that any records or physical evidence (including explanted devices, tissue blocks, or pathology slides) relating to the Existing Plaintiff or New Plaintiff must be preserved, pending collection by the Existing Plaintiff or New Plaintiff or person(s) acting on behalf of the Existing Plaintiff or New Plaintiff (“Notice” or “Notices”):

1. Each doctor or healthcare provider (including, but not limited to, family/primary care physicians, orthopedic surgeons, physical therapists, chiropractors, nurse/nurse practitioners, and practitioners of the healing arts) Plaintiff has seen for medical care and treatment for any condition, including, but not limited to, any condition related to Plaintiff’s affected hip(s), for the period five (5) years before Plaintiff’s first hip surgery to the present;
2. Each hospital, clinic, surgery center, healthcare facility, physical therapy or rehabilitation center where Plaintiff has received medical treatment (in-patient, out-patient, emergency room visit, or telephonic/virtual consultation) for any condition, including, but not limited to, any condition related to Plaintiff’s affected hip, for the period five (5) years before Plaintiff’s first hip surgery to the present;
3. Each hospital or other facility that may have physical evidence (including explanted devices, tissue blocks, or pathology slides) related to any revision of the Plaintiff’s Pinnacle prosthesis;

4. Each facility at which radiographs (x-rays, ultrasounds, MRIs, CT scans) were taken of Plaintiff's hips, pelvis, or legs for the period five (5) years before Plaintiff's first hip surgery to the present;
5. Each laboratory at which Plaintiff's blood was tested for blood levels of any metals, including cobalt and chromium, for the period five (5) years before Plaintiff's first hip surgery to the present; and
6. Any pharmacy (physical or virtual) where Plaintiff has had a prescription filled in the period five (5) years before Plaintiff's first hip surgery to the present.

B. Within fifty (50) days of the transmittal of this Order by Defendants to a New Plaintiff, or within thirty-five (35) days of the lifting of the stay as it applies to Existing Plaintiffs, counsel for an Existing Plaintiff or New Plaintiff shall serve a statement listing the names and addresses of all individuals or entities to which Notices were sent, along with copies of the Notices and a representation that the Notices were sent as required by this Order. Service shall be made in accordance with the service procedures set forth in Exhibit A to this Order.

C. For any deficiencies, the parties shall follow the Notice and Show Cause procedures set forth in Section V.A.

D. Defendants may elect, but are not required, to waive the foregoing Notice requirement for any Plaintiff who has already submitted records for Defendants' resolution consideration.

III. DISCOVERY REQUIREMENTS

A. All Plaintiffs who claim to have suffered or experienced an injury related to the implant of a Pinnacle hip replacement prosthesis, including revision of the prosthesis, or any other injury as a result of the implant of a Pinnacle hip replacement

prosthesis must produce all of the information described in this Section to Defendants, unless the Plaintiff has already done so, whether pursuant to prior discovery obligations and/or for resolution considerations. In the event that the parties dispute whether Plaintiff(s) prior productions satisfy their obligations under this Order, Plaintiff(s) will be required to produce the required discovery information pursuant to their obligations under this Order.

B. The following information must be produced to Defendants by Existing Plaintiffs and New Plaintiffs pursuant to this Section:

1. Operative report(s) for implant surgery of the Pinnacle implant(s) and product identification for Pinnacle implant(s) at issue. Existing Plaintiffs shall produce these records within forty-five (45) days of the lifting of the stay, as set forth in Section I, above, and New Plaintiffs shall produce these records within sixty (60) days of the transmission of this Order by Defendants.
2. If any death is claimed to have resulted from the Pinnacle implant, a copy of the death certificate, if one exists, and autopsy report, if one was performed. Existing Plaintiffs shall produce any such certificate and/or report within forty-five (45) days of the lifting of the stay, as set forth in Section I, above, and New Plaintiffs shall produce any such certificate and/or report within sixty (60) days of the transmission of this Order by Defendants.
3. A completed New or Supplemental Plaintiff Fact Sheet (“PFS”), including all verifications and authorizations, in the form and manner set forth in Exhibit A to Case Management Order (“CMO”) No. 5. Service of the PFS shall be made pursuant to the service protocol set forth in CMO No. 5. Existing Plaintiffs shall produce a New or, if already produced, Supplemental PFS within forty-five (45) days of the lifting of the stay, as set forth in Section I, above. New Plaintiffs shall produce a New PFS within sixty (60) days of the transmission of this Order by Defendants.

4. All medical records relating to the Plaintiff from all healthcare providers identified in Section II of Plaintiff's PFS for the period starting five (5) years before Plaintiffs' first hip surgery to the present. Existing Plaintiffs shall produce these records within forty-five (45) days of the lifting of the stay, as set forth in Section I, above, and New Plaintiffs shall produce these records within sixty (60) days of the transmission of this Order by Defendants.
5. A New or Supplemental completed, signed Plaintiff Profile Form ("PPF") in the form and manner set forth in Exhibit A to Case CMO No. 10. Service of the PPF shall be made pursuant to the service protocol set forth in CMO No. 10. Existing Plaintiffs shall produce a New or, if already produced, Supplemental PPF within forty-five (45) days of the lifting of the stay, as set forth in Section I, above. New Plaintiffs shall produce a New PPF within sixty (60) days of the transmission of this Order by Defendants.
6. A sworn, notarized affidavit signed by the Plaintiff: (i) attesting that records have been collected from all healthcare facilities where Plaintiff underwent an operative procedure involving the Pinnacle hip replacement prosthesis, including but not limited to, index and revision procedures; (ii) attesting that all records described in subparagraph (B)(1) and (4) above have been collected; and (iii) attesting that all records collected pursuant to subparagraphs (B)(1), (2) and (4) of this Section have been produced pursuant to this Order, and (iv) stating whether any physical evidence (including explanted devices, tissue blocks or pathology slides) related to any revision of the Plaintiff's Pinnacle prosthesis exists, and if so identifying who has custody of the evidence. If any of the documents described in paragraphs (B) (1), (2) and (4) of this Section do not exist, the Plaintiff shall state that fact in his or her affidavit and the reason, if known, why they do not exist and provide a "No Records Statement" from the healthcare provider and/or facility. Existing Plaintiffs shall produce this affidavit to Defendants within forty-five (45) days of the lifting of the stay, as set forth in Section I, above, and New Plaintiffs shall produce this affidavit within sixty (60) days of the transmission of this Order by Defendants.

C. With the exception of the PFS and PPF, Plaintiffs shall serve all items set forth above in accordance with the service procedures outlined in Exhibit A to this Order.

D. For any deficiencies, the parties shall follow the Notice and Show Cause procedures set forth in Section V.A. With respect to the PFS and PPF obligations set forth in Section III.B.3 and III.B.5, the Notice and Show Cause procedures set forth in Sections V.A herein hereby supersede and replace the procedures for non-compliant PFS and PPF set forth in CMO Nos. 5 and 10, respectively.

E. Defendants' obligation to produce Defense Fact Sheets ("DFS") is hereby stayed pending further order of the Court.

IV. EXPERT REPORT REQUIREMENTS

A. Plaintiffs shall provide the following expert reports:

1. If a Plaintiff is claiming injury due to a design defect in that Plaintiff's Pinnacle hip replacement prosthesis, Plaintiff must provide a Rule 26(a)(2) case-specific report from a qualified expert or experts: (i) identifying with particularity each design defect alleged to exist in that Plaintiff's specific implant, (ii) identifying how the design should have been different, (iii) stating to a reasonable degree of medical certainty that the identified design defect caused injury to the Plaintiff, and (iv) identifying that injury. Existing Plaintiffs shall produce a copy of this case-specific expert report within seventy-five (75) days of the lifting of the stay, as set forth in Section I, above. New Plaintiffs shall produce a copy of this case-specific expert report within one hundred twenty (120) days of the transmission of this Order by Defendants.
2. If a Plaintiff is claiming injury due to a manufacturing defect in that Plaintiff's Pinnacle hip replacement prosthesis, Plaintiff must provide a Rule 26(a)(2) case-specific report from a qualified expert or experts attesting (i) identifying with particularity each manufacturing defect alleged to exist in the specific device implanted that Plaintiff, (ii)

identifying the specific facts that show a manufacturing defect existed in the Plaintiff's implant (e.g., what design specification was not met and the basis for claiming the Plaintiff's particular component(s) did not meet that specification), (iii) stating to a reasonable degree of medical certainty that the identified manufacturing defect caused injury to the Plaintiff, and (iv) identifying that injury. Existing Plaintiffs shall produce a copy of this case-specific expert report within seventy-five (75) days of the lifting of the stay, as set forth in Section I, above. New Plaintiffs shall produce a copy of this case-specific expert report within one hundred twenty (120) days of the transmission of this Order by Defendants.

3. If a Plaintiff is claiming injury due to a marketing/warning defect in that Plaintiff's Pinnacle hip-replacement prosthesis, plaintiff must provide a Rule 26(a)(2) case-specific report from a qualified expert or experts: (i) identifying with particularity each warning or marketing defect alleged to exist with respect to Plaintiff's specific implant, (ii) identifying the specific facts showing the warning or marketing was inadequate or incomplete, (iii) stating what warning or information should have been given and to whom it should have been given, and (iv) stating how the warning or marketing defect impacted the particular Plaintiff or the particular Plaintiff's implanting surgeon and caused the Plaintiff's alleged injuries. Existing Plaintiffs shall produce a copy of this case-specific expert report within seventy-five (75) days of the lifting of the stay, as set forth in Section I, above. New Plaintiffs shall produce a copy of this case-specific expert report within one hundred twenty (120) days of the transmission of this Order by Defendants

B. Plaintiffs shall serve all items set forth above in accordance with the service procedures outlined in Exhibit A to this Order.

C. For any deficiencies, the parties shall follow the Notice and Show Cause procedures set forth in Sections V.A.

V. NOTICE AND PENALTIES FOR VIOLATIONS OF THIS ORDER

A. Plaintiffs who fail to fully comply with the requirements of this Order shall be given notice by e-mail (except for individuals representing themselves *pro se*,

who shall receive notice by regular mail) from Defendants' Lead Counsel or their designees, and shall be provided thirty (30) additional days from the date of notice to cure such deficiency (the "Cure Period"). No other extensions will be granted, except upon application to the Court for good cause shown. If a Plaintiff fails to cure the deficiency within the Cure Period, Defendants' Lead Counsel shall identify all such deficient Plaintiffs to the Court and/or the Special Master on a monthly basis. Any Plaintiff so identified shall be required to show cause why the claim should not be dismissed with prejudice for failure to prosecute. The Plaintiff shall thereupon have thirty (30) days to cure the deficiencies or respond to the request to Show Cause (the "Deficiency Period"). Any failure to respond within the Deficiency Period shall lead to the dismissal of Plaintiff's claims with prejudice, except upon further motion and for good cause shown. Determination of good cause shown following lapse of the Deficiency Period shall be made at the Court's discretion.

B. A Plaintiff may be prohibited from seeking to introduce into evidence at trial, or in any opposition to summary judgement or pre- or post-trial motions, any document, information or evidence concerning a Plaintiff's treatment or operative history, symptoms, condition, injuries, or damages if a Notice was not sent as directed in Section II.

C. A Plaintiff may be prohibited from seeking to introduce into evidence at trial, or in any opposition to summary judgement or pre- or post-trial motions, any

document, information or expert opinion that is required to be produced in Sections III and IV but is not provided, subject to determination by the Court at a later date.

SO ORDERED.

Signed September 11th, 2019.

A handwritten signature in cursive script that reads "Ed Kinkeade".

ED KINKEADE
UNITED STATES DISTRICT JUDGE

CASE MANAGEMENT ORDER NO. 12: SERVICE & SUBMISSION INSTRUCTIONS

Note: The following submission instructions do not apply to service of new or supplemental Plaintiff Fact Sheets and Plaintiff Profile Forms, as required by Sections III.B.3 and III.B.5 of this Order. As indicated in Sections III.B.3 and III.B.5, service of the Plaintiff Fact Sheet and Plaintiff Profile Forms shall be made according to the procedures outlined in Case Management Orders No. 5 and 10.

These submission instructions apply to all documents and records required to be submitted pursuant to Sections II.B, III.B and IV.A of Case Management Order No. 12, except the Plaintiff Fact Sheet and Plaintiff Profile Forms as noted above. Plaintiffs shall produce to Defendant any such records, documents or reports by uploading them to a secure file share site in the manner and format explained below.

I. File Share Access

Plaintiff's counsel (or Plaintiff, if proceeding *pro se*) shall send a request to PinnacleClaims@btlaw.com with the following information: The Plaintiff's name, the injury/injuries claimed by the Plaintiff, the name of Plaintiff's counsel, the names and email address of any/all team members who require access to the file transfer site. To the extent a firm represents multiple Plaintiffs subject to the Order, Plaintiffs' counsel may include the foregoing information for each Plaintiff in one email to PinnacleClaims@btlaw.com.

Following receipt of the request, counsel for DePuy will send Plaintiff's counsel an email invitation from PinnacleClaims@btlaw.com containing a link to the site and a temporary password. Once accessed, Plaintiff's counsel will see a folder with the name of his/her firm and a subfolder for Plaintiff's claimed injury type. Each firm will only have access to its own folder. It is important that records for each Plaintiff be foldered correctly to avoid delay in review and/or unnecessary deficiency notices.

For each Plaintiff, Plaintiff's counsel shall name the top folder with the name of the claimant in the format: Last Name, First Name, Case Number (*i.e.* Doe, Jane, 11-md-2244) and shall place all records, documents and reports within that folder.

Note: In the event Plaintiff's counsel already has requested and received File Share Access from Defendants, no additional request is required.

II. Records Format

A. Operative Reports and Medical Records

All pharmacy and medical records shall be produced to Defendants as searchable PDFs with each facility or provider record produced as a separate PDF. No individual

PDF produced shall exceed 100 MB (100,000 KB). In the event that PDFs larger than 100 MB are produced, Plaintiff's counsel will be advised of the issue and will be required to resubmit a new version of the file that is under 100 MB.

PDFs shall be named using the following format: sequential numbering, Plaintiff's Last Name, Plaintiff's First Name, and the name of the facility or provider that produced the records. For example, the second PDF produced by Plaintiff Jane Doe from Memorial Hospital shall be named "2 Doe, Jane_Memorial Hospital."

Each PDF also must be Bates-numbered in the following format: a combination of an alpha prefix containing plaintiff's initials and the initials of the facility or provider name along with a 4-digit number and be numerically sequential within a given PDF. For example, for claimant Jane Doe's records from Memorial Hospital use JD_MH_0001. Please be sure to begin Bates numbering on the first page of the PDF (even if that page is the authorization form or slip sheet).

B. Expert Reports & Affidavits

Any expert report produced to Defendants shall be named using the following format: the words "Report of" followed by the name of the expert, Plaintiff's Last Name, and Plaintiff's First Name. For example, a report from expert Frank Smith produced by Plaintiff Jane Doe should be named "Report of Frank Smith_Doe, Jane."

The affidavit required by Section III.B.6 of Case Management Order No. 12 shall be named "Affidavit of [Plaintiff Name]."

III. Questions & Concerns

Questions or concerns regarding these instructions and/or access to the FTP site should be directed to PinnacleClaims@btlaw.com.