

**UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND**

IN RE SMITH & NEPHEW BIRMINGHAM
HIP RESURFACING (BHR) HIP IMPLANT
PRODUCTS LIABILITY LITIGATION

MDL No. 2775

Master Docket No. 1:17-md-2775

JUDGE CATHERINE C. BLAKE

**THIS DOCUMENT RELATES TO
THA TRACK CASES**

**[REDACTED] CASE MANAGEMENT ORDER NO. 12
Preliminary Disclosures and Plaintiff and Defendant Fact Sheets
for THA Track Cases**

The parties hereby submit this Stipulated Order regarding Preliminary Disclosures and the exchange of Plaintiff and Defendant Fact Sheets in THA Track cases.

I. Scope of this Order

This Order applies only to personal injury actions brought by any U.S. citizen or resident against Smith & Nephew, Inc. ("Smith & Nephew" or Defendant) by a Plaintiff implanted with a Birmingham Hip Resurfacing (BHR) cup with a modular femoral head, or an R3 acetabular shell and metal liner, as part of a total hip arthroplasty ("THA") construct or cases otherwise designated for the THA Track pursuant to Case Management Order No. 7, that (i) are currently pending in MDL No. 2775, or (ii) will be direct-filed in, removed to, or transferred to this Court and placed in the THA Track ("THA cases").

II. Plaintiff's Preliminary Disclosure

A. Each Plaintiff shall provide (1) product identification/chart stickers for each component implanted; (2) operative report(s) from implant surgery or surgeries; and (3) operative report(s) from revision surgery or surgeries (collectively, "Plaintiff Preliminary Disclosure") within the time period provided below. The Plaintiff Preliminary Disclosure shall

be submitted electronically to Plaintiffs' Lead Counsel by e-mail to: bhr@jonesward.com, and to Defendant's Lead Counsel by e-mail to: bhr-mdl-ppd@irwinllc.com.

B. Plaintiffs in THA cases pending in MDL 2775 pending as of the date of this Order shall serve the Plaintiff Preliminary Disclosure within thirty (30) days of the date of this Order.

C. Plaintiffs in matters filed in or transferred to MDL 2775 after the date of this Order shall serve the Plaintiff Preliminary Disclosure within thirty (30) days after the case is transferred to or filed in MDL 2775.

D. If any Plaintiff fails to materially comply with his or her obligations under this Order within the timelines established herein, Defendant's Lead Counsel or designee shall send a notice of deficiency (the "Deficiency Letter") to the Plaintiff's Counsel for the individual who allegedly failed to comply and copy Plaintiffs' Lead Counsel at: bhr@jonesward.com. The Deficiency Letter shall identify the alleged deficiency and state that the Plaintiff will have thirty (30) days to cure the alleged deficiency. If the alleged deficiency is not cured within that time (or within any extension of that time as agreed by the parties), Defendant may move for dismissal of Plaintiff's claims, including dismissal with prejudice upon an appropriate showing.

III. Defendant's Preliminary Disclosure

A. For matters pending in MDL 2775 as of the date of this Order, Defendant shall produce within sixty (60) days of this Order copies of MedWatch forms (Form FDA 3500A) submitted to the U.S. Food and Drug Administration for Plaintiffs who have timely-served Plaintiff Preliminary Disclosures. The Defendant's Preliminary Disclosure shall be submitted electronically to Plaintiffs' Lead Counsel by email to bhr@jonesward.com.

B. For matters filed in or transferred to MDL 2775 after the date of this Order, Defendant shall produce on a bi-monthly basis copies of MedWatch forms (Form FDA 3500A)

submitted to the U.S. Food and Drug Administration for Plaintiffs who have timely-served Plaintiff Preliminary Disclosures.

IV. Plaintiff Fact Sheets

A. Plaintiffs' Obligation to Complete and Serve a Plaintiff Fact Sheet. Each individual Plaintiff bound by this Order shall serve upon Defendant a completed Plaintiff Fact Sheet, in the form attached as Exhibit A as hereby approved by the Court, including a signed and dated verification, responsive documents and an executed authorization (collectively, the "PFS"), pursuant to the schedule ordered herein. Each completed PFS shall be submitted via the online MDL Centrality System designed and provided by BrownGreer PLC and accessible at www.mdlcentrality.com/ to complete and serve Plaintiff and Defendant Fact Sheets, as follows:

- (1) Each Plaintiff required to submit a PFS under CMO 12, shall, by counsel or as *pro se*, establish a secure online portal in the MDL Centrality online system and obtain authorized user names and secure login passwords to permit use of MDL Centrality by such counsel or Plaintiff. Except as set forth herein, Counsel for a Plaintiff or each *pro se* Plaintiff shall be permitted to view, search and download on MDL Centrality only those materials submitted by that Plaintiff and by Defendant relating to that Plaintiff, and not materials submitted by or relating to other Plaintiffs.
- (2) The Defendant shall establish a secure online portal with the MDL Centrality online system and obtain authorized user names and secure login passwords to permit use of MDL Centrality by Defendant's counsel.
- (3) The Plaintiffs' Steering Committee and Plaintiffs' attorney designees appointed by the Plaintiffs' Steering Committee, shall have access to and be able to view, search and download all materials submitted by all Plaintiffs and by Defendant.
- (4) Each Plaintiff and Defendant shall use the MDL Centrality online system to obtain, complete or upload data, and serve the appropriate Fact Sheet online (including the upload of PDFs or other documents, images, photographs and videos required by the Fact Sheets). Each Plaintiff and Defendant shall provide a signed verification with their Fact Sheets, which will be signed in hard copy, uploaded and served through MDL Centrality.
- (5) Each Plaintiff shall use the MDL Centrality online system to obtain, complete and serve online the record release Authorizations. Each Plaintiff shall sign each of

the required Authorizations, which will then be uploaded and served through MDL Centrality.

- (6) Service of a completed Fact Sheet, Authorizations, and supporting documentation shall be deemed to occur when the submitting party has performed each of the steps required by the MDL Centrality online system to execute the online submission of the materials, and the submitting party has received confirmation on screen that the materials have been successfully submitted.
- (7) If a party must amend a previously served Fact Sheet, all subsequent versions must be named accordingly ("First Amended Fact Sheet", "Second Amended Fact Sheet", etc.), and all iterations of a Party's Fact Sheet must remain available and accessible to all Parties to a case through trial, appeal (if any), or other resolution of the litigation.
- (8) By using MDL Centrality, each Plaintiff authorizes the disclosure of his or her medical records and other health information submitted as part of the PFS or DFS to BrownGreer PLC as the administrator of the MDL Centrality online system, the Court, Plaintiff Leadership and Defendants, and to the authorized agents, representatives and experts of the foregoing, for purposes of this litigation.
- (9) BrownGreer charges \$20 per PFS for the use of MDL Centrality online system as described above. The cost will be split between the parties, with each side paying \$10 for each submitted PFS. There is no charge for PFS amendments or the DFS, and no user or administrative fees.

B. Exception to Use of MDL Centrality For Good Cause Shown. For good cause shown, a Plaintiff may request submission of Fact Sheets by U.S. mail, email, or both. Requests should be made to:

Defendant's Lead Counsel Contact for PFS:
Jimmy Irwin
Irwin Fritchie Urquhart & Moore LLC
400 Poydras Street, Suite 2700
New Orleans, Louisiana 70130
Email: bhr-mdl-ppd@irwinllc.com

With a copy to Plaintiffs' Lead Counsel Contact for PFS:
Alex Davis
Jones Ward PLC
1205 E. Washington St., Suite 111
Louisville, Kentucky 40206
Email: bhr@jonesward.com

at least two weeks prior to the PFS due date. For purposes of this subparagraph, good cause requires a demonstration of undue hardship with the use of the MDL Centrality online system, including but not limited to being a *pro se* plaintiff without Internet access. If good cause is shown, requests and responses to requests for extensions, additional authorizations, and Deficiency Letter communication shall be made by U.S. mail or email in lieu of MDL Centrality.

C. Answers Binding under Federal Rules of Civil Procedure and Signed Under Penalty of Perjury. Each PFS verification shall be signed and dated by the Plaintiff or the proper Plaintiff Representative under penalty of perjury. All responses in a PFS are binding on each Plaintiff as if they were obtained in responses to interrogatories and responses to requests for production of documents under the Federal Rules of Civil Procedure, and will be governed by the standards applicable to written discovery under the Federal Rules of Civil Procedure. Nothing in this Order prohibits a Plaintiff from withholding or redacting information based on a recognized privilege. If information is withheld on the basis of privilege, Plaintiff shall provide Defendants with a privilege log in accordance with the Federal Rules of Civil Procedure, the Discovery Guidelines of this Court, and the Stipulated Order Regarding Discovery of Electronically Stored Information [D.E. 492].

D. Schedule for Service of PFS. Plaintiffs with THA cases pending in MDL 2775 as of the date of this Order are identified in Exhibit B. Plaintiffs in these THA cases shall serve a PFS within sixty (60) days of the date of this Order. Plaintiffs with THA cases filed in or transferred to MDL 2775 after the date of this Order should include a caption that identifies the case as a THA Track case pursuant to CMO 7, and shall serve a PFS within sixty (60) days after the case is transferred to or filed in MDL 2775. The applicable time to serve a PFS may be extended by agreement of the parties. Requests for extension should be made to Defendant's

Lead Counsel at the address above, and should clearly state the reason such an extension is requested. If the parties cannot agree on a reasonable extension of time, Plaintiffs may apply to the Court for such relief upon a showing of good cause.

E. PFS Must Be Substantially Complete. Every Plaintiff is required to submit a PFS that is substantially complete in all respects. “Substantially complete” requires that a Plaintiff:

1. Answer all applicable questions in the PFS. Plaintiff may answer questions in good faith by indicating “not applicable,” “I don’t know,” or “Unknown”;
2. Include a signed Verification (found at Section XIV of the PFS), which will be dated and signed in hard copy;
3. Provide an unaddressed, duly executed record release Authorization (Section XIII of the PFS); and
4. Produce the documents requested in the PFS, to the extent such documents are in Plaintiff’s possession, custody, or control.

F. PFS Supplement. Plaintiffs are required to supplement their PFS responses as required under the Federal Rules of Civil Procedure by submitting an amended PFS on MDL Centrality, accompanied by a verification dated and signed in hard copy. Moreover, any Plaintiff who has a BHR System component explanted subsequent to the service of his/her PFS must supplement the PFS with information about the explant procedure, including location of the explanted device and other applicable information, and supplement the production of responsive documents, if any, within thirty (30) days from the date of the procedure.

V. Defendant Fact Sheets

A. Defendant's Obligation to Complete and Serve a Defendant Fact Sheet. For each THA case in which a Plaintiff provides Defendant with a substantially complete PFS, Defendant shall complete and serve a Defendant Fact Sheet ("DFS"), in the form attached as Exhibit C and hereby approved by the Court, on the following schedule. Within one-hundred-twenty (120) days from the date of this Order, Defendant shall serve the corresponding DFS for each Plaintiff who serves a substantially complete PFS on or before sixty (60) days from the date of this Order, so long as no more than twenty-five (25) DFSs are due in a given calendar week. If more than twenty-five (25) DFSs are due in a given calendar week, Defendant will serve DFSs on a rolling basis with twenty-five (25) DFSs served each week. The completed DFS shall be served via the MDL Centrality online system. With regard to substantially complete PFSs served on Defendant's counsel more than sixty (60) days after the date of this Order, Defendant shall serve the corresponding DFS on or before sixty (60) days after the receipt of the substantially complete PFS, so long as no more than twenty-five (25) DFSs are due in a given calendar week, in which case Defendant will serve DFSs on a rolling basis with twenty-five (25) DFSs served each week. If information is withheld on the basis of privilege, Defendant shall provide Plaintiff with a privilege log in accordance with the Federal Rules of Civil Procedure, the Discovery Guidelines of this Court, and the Stipulated Order Regarding Discovery of Electronically Stored Information [D.E. 492]. If Defendant does not notify Plaintiff of a deficiency within 90 days of the date upon it has received all of the following: (1) the PFS, (2) a signed and dated verification, and (3) an unaddressed, duly executed authorization, or by such other time as agreed upon by the parties or determined by the Court, the PFS shall be deemed to be substantially complete.

B. Nothing in the DFS shall be deemed to limit the scope of inquiry at depositions or affect the admissibility of evidence at trial. The scope of inquiry at depositions and the admissibility of information in the DFS shall be governed by the Federal Rules, applicable Local Rules, and any applicable Court order, and no objections are waived by virtue of any DFS response.

C. Extensions of Time. The applicable time to serve a DFS may be extended by agreement of the parties. Requests for extension should be made to Plaintiffs' lead counsel at the address above. If the parties cannot agree on a reasonable extension of time, Defendant may apply to the Court for such relief upon a showing of good cause.

VI. Authorizations and Compliance

A. Authorizations For the Release of Records.

1. As set forth in Section II.D above, unaddressed, executed Authorizations for the Release of Records together with copies of such records, to the extent that those records or copies thereof are in the Plaintiff's possession, custody, or control, or reasonably available to Plaintiff, shall be provided with the PFS at the time the Plaintiff is required to serve a PFS pursuant to this Order. Defendant may use unaddressed authorizations to obtain its own set of medical records, but only for healthcare providers identified in a PFS or any medical records produced with the PFS, and for the time periods described in the PFS, if such time periods are identified.

2. In addition to the Authorizations described above, Plaintiff's individual representative counsel shall also maintain in their file unaddressed, executed Authorizations. If Defendant wishes to obtain medical records for a healthcare provider other than those identified in a PFS or in any medical records produced with the PFS, Defendant shall request additional authorizations from Plaintiffs' Lead Counsel at the address above. The request shall identify the

healthcare provider, address, and time period of the records to be requested. Within seven (7) days of the date of the request, Plaintiff's individual representative counsel shall respond by e-mail, either to provide the requested addressed, executed Authorization or respond with a written objection, clearly stating the basis for the objection. If Plaintiff's individual representative counsel does not respond in the allotted time by either providing the requested Authorization or objecting, Defendant may use the unaddressed, executed Authorization in Section IV.A.1 to obtain the records.

3. Undated Authorizations constitute permission for Defendant to date (and where applicable, re-date) Authorizations before sending to records custodians.

4. In the event that an institution or medical provider to whom any Authorization is presented refuses to provide records in response to that Authorization, Defendant shall notify Plaintiff's individual representative counsel. Should a particular form be required, Defendant will provide it to Plaintiff's individual representative counsel by e-mail or U.S. mail. The individual Plaintiff shall execute and return to Defendant's Lead Counsel within twenty-one (21) days whatever form is required by that institution or provider, using e-mail or U.S. mail. Further, to the extent an institution or medical provider fails to respond to a medical records request with the executed Authorization, Plaintiff's individual representatives counsel agrees to contact that institution or medical provider directly, or otherwise to provide reasonable assistance in obtaining the requested medical records.

5. Defendant's record copy service shall have the right to contact institutions or medical providers to follow up on medical record copying or production.

B. Non-Compliance with PFS Requirements. If any Plaintiff fails materially to comply with his or her obligations under this Order within the timelines established herein,

including the failure to serve a substantially complete PFS as defined in Section II.D herein, Defendant's Lead Counsel or designee shall send a notice of deficiency (the "Deficiency Letter") via the MDL Centrality online system to the Plaintiff's counsel for the individual who allegedly failed to comply and Plaintiffs' Lead Counsel. The Deficiency Letter shall identify the alleged material deficiency(ies) and state that the Plaintiff will have thirty (30) days to cure the alleged material deficiency(ies). If the alleged material deficiency(ies) is/are not cured within that time (or within any extension of that time as agreed by the parties), Defendant may move for dismissal of Plaintiff's claims, including dismissal with prejudice upon an appropriate showing.

C. Non-Compliance with DFS Requirements. If Defendant fails materially to comply with its obligations under this Order within the timelines established herein, Plaintiffs' Lead Counsel shall send notice of the material deficiency to Defendant's Lead Counsel using the MDL Centrality online system. The parties shall promptly meet and confer in an attempt to resolve the deficiency(ies). If the parties are unable to resolve the material deficiency(ies) after conferring, Plaintiffs' Lead Counsel may request a telephone conference with the Court or may include the dispute on the agenda for the next regularly-scheduled status conference after providing reasonable notice to Defendant.


D. No Impact on Privileges or Work Product Protection. The use of the MDL Centrality online system by any party shall not alter or otherwise waive or affect any attorney-client privilege or work product doctrine protection that would otherwise apply to a document or communication in the absence of the use of MDL Centrality. Any notations placed on materials, comments entered, or documents stored or uploaded to MDL Centrality by a user shall be considered to be the work product of such user unless and until the material is served on or purposefully disclosed to the opposing party through the use of the MDL Centrality online

system or otherwise. Pursuant to Rule 502(d) of the Federal Rules of Evidence, this Order with respect to privilege and work product doctrine protection applies to any other federal or state proceeding.

E. ECF Notifications. The Clerk of Court may execute the steps necessary to include BrownGreer as the MDL Centrality Administrator as an interested party for purposes of receiving emailed ECF notifications related to this matter.

F. MDL Centrality Administrator Contact Information. Questions regarding MDL Centrality online system setup, use, or technical issues should be directed to BrownGreer at smithnephew@browngreer.com.

IT IS SO ORDERED, this 4th day of Dec. 2018.



HON. CATHERINE C. BLAKE
UNITED STATES DISTRICT JUDGE