

NIGH GOLDENBERG RASO & VAUGHN

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH DEVICES LIABILITY LITIGATION Case No. 2:18-md-2846

CHIEF JUDGE EDMUND A. SARGUS, JR. Magistrate Judge Kimberly A. Jolson

This document relates to: ALL ACTIONS.

CASE MANAGEMENT ORDER NO. 16

Regarding Defendant Fact Sheets

This Court hereby issues the following Case Management Order to govern the form, procedure, and schedule for the completion and service of the Defendant Fact Sheets ("DFS") and other documents referenced therein.

I. Scope of this Order

This Order applies to all Plaintiffs, Defendants and their counsel in: (a) all actions selected as Bellwether Pool Cases pursuant to CMO 10 and CMO 15.

II. Defendant Fact Sheets

A. The DFS Form and Service

1. The Defendant Fact Sheet is attached as Exhibit A, which has been agreed to by the parties and approved by the Court.

2. In accordance with CMO 10, the DFS for the 12 Plaintiffs whose cases have been selected as Bellwether Pool Cases shall be due on or before April 25, 2019.

1

3. The completed DFS served upon the respective individual Plaintiff's counsel of record via the individual counsel's email. A copy of the DFS shall also be sent to the PEC's designee at bardmdldfs@fleming-law.com.

B. <u>Amendments</u>

Defendants shall remain under a continuing duty to supplement the information provided in the DFS.

C. DFS Deficiency Dispute Resolution

1. Phase I: Deficiency Letter

a. If Plaintiffs deem a DFS deficient, then Plaintiffs' counsel shall notify Defendants' attorney of record of the purported deficiencies via email and allow Defendants 14 days from the date of notification to correct the alleged deficiency. A courtesy copy of the email shall be sent to the PEC's designee at bardmdldfs@fleming-law.com.

b. Plaintiffs shall include sufficient detail regarding the alleged deficiency(ies).

2. <u>Phase II: Meet and Confer</u>

Should Defendants not respond to the deficiency letter within the time required, then Plaintiffs may request a meet and confer. Plaintiffs' counsel shall notify Defendants' attorney of record via email of the request to meet and confer and state that the meet and confer shall occur within 10 days. A courtesy copy of the email shall be sent to the PEC's designee at bardmdldfs@fleming-law.com. The parties' meet and confer period shall begin upon receipt of the email by Defendants' attorney of record and, absent agreement of the parties, shall be completed by the conclusion of the 7 days.

3. Phase III: Motion to Compel

2

Case: 2:18-md-02846-EAS-KAJ Doc #: 128 Filed: 04/01/19 Page: 3 of 10 PAGEID #: 1941

a. Following the meet and confer period, should Defendants: (i) fail to cure the stated deficiency(ies); (ii) fail to assert objections to same; (iii) fail to respond to or participate in the meet and confer process; or (iv) otherwise fail to provide responses, and absent agreement of the parties to further extend the meet and confer period, at any time following expiration of the 14 day meet and confer period, Plaintiffs may then file a Motion to Compel the allegedly deficient discovery information via ECF, with a courtesy copy sent via email to Defendants' attorney of record and to the PEC's designee at bardmdldfs@fleming-law.com.

b. Any motion to compel pursuant to this CMO need not be noticed for presentment as required by Local Rule 7.1.

c. Any response to such a motion shall be filed and served within 14 days following the date of service. Any reply, if necessary, shall be filed within 5 days following the date of service of the opposition.

d. Absent an Order from the Court granting a request by either or both parties for oral argument, the Court will rule on such motions without hearing argument.

D. Failure to Serve a DFS

1. Defendants may request one extension of 7 days to serve a completed DFS, which Plaintiffs shall not unreasonably withhold. Such requests must be made via email to Plaintiffs' counsel before the expiration of the deadline, with a courtesy copy sent to the PEC's designee at bardmdldfs@fleming-law.com.

2. <u>Phase I: Notice of Non-Compliance</u>

a. Should Defendants fail to serve a DFS within the time required in this CMO, Plaintiffs shall send a Notice of Non-Compliance letter via email to that Defendants' attorney of record, with a courtesy copy to the PEC's designee at bardmdldfs@fleming-law.com.

3

b. Following the receipt of the Notice of Non-Compliance, Defendants shall have 7 days to serve the DFS.

3. Phase II: Motion to Compel

a. Should Defendants fail to provide an executed DFS following the time period allowed above, Plaintiffs may then move the Court for a motion to compel via ECF, with a courtesy copy sent via email to Defendants' attorney of record and to the PEC's designee at bardmdldfs@fleming-law.com. No meet and confer shall be required for such a motion.

b. Any motion to compel pursuant to this CMO need not be noticed for presentment as required by Local Rule 7.1.

c. Any response to such a motion shall be filed and served within 7 days following the date of service. Any reply, if necessary, shall be filed within 5 days following the date of service of the opposition.

d. Absent an Order from the Court granting a request by either or both parties for oral argument, the Court will rule on such motions without hearing argument.

III. <u>Confidentiality</u>

All information disclosed in a DFS, the DFS itself, and all related documents (including health care information) produced pursuant to the DFS shall be deemed confidential and treated as "Confidential Information" under CMO 7.

IT IS SO ORDERED.

<u>4-1-2019</u> DATE

A. SARGUS, JR. CHIEF UNITED STATES DISTRICT JUDGE

KIMBERLY A. JOLSON UNITED STATES MAGISTRATE JUDGE

UNITED STATES DISTRICT COURT THE SOUTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

CHIEF JUDGE EDMUND A. SARGUS, JR. Magistrate Judge Kimberly A. Jolson

This document relates to: PLAINTIFF NAME

Civil Action No.____

DEFENDANT FACT SHEET

For each case selected as a Bellwether Case, Davol Inc. and C.R. Bard, Inc. ("Defendants") must complete this Defendant Fact Sheet. The timing of the Defendant Fact Sheet is subject to CMO No. 10 or a future Court Order. As used in this Defendant Fact Sheet, "Davol/Bard Hernia Mesh Device" refers to the medical device or devices identified in paragraph 8 of the Plaintiff's Short Form Complaint or, if no Short Form Complaint has been filed in the individual action, then "Davol/Bard Hernia Mesh Device" refers to the medical device or devices at issue in the Plaintiff's operative complaint ("Plaintiff's Complaint"). In completing this Defendant Fact Sheet, Defendants must answer every question and not leave any blanks throughout the Fact Sheet. A completed Fact Sheet shall be considered interrogatory responses pursuant to Federal Rules of Civil Procedure 33 and 34, and will be governed by the standards applicable to written discovery under Federal Rules of Civil Procedure 26 through 37.

I. SALES REPRESENTATIVE CONTACTS WITH TREATING PHYSICIANS

Plaintiff has identified in the Plaintiff Fact Sheet each physician who treated and/or evaluated plaintiff for hernia repair and/or associated conditions that led to the use of the Davol/Bard Hernia Mesh Device in the case ("Identified Physicians"). As set forth in more detail below, to the extent known or identifiable by electronic search, Defendants will provide the following information for each Identified Physician relating to contact with any sales representative employed by Defendants responsible for Davol/Bard Hernia Mesh Devices:

1. For each Identified Physician who is alleged to have implanted one or more of the Davol/Bard Hernia Mesh Devices identified in the Plaintiff's Complaint, identify the sales representative(s) responsible for one or more of the Davol/Bard Hernia Mesh Devices identified in Plaintiff's Complaint for the territory encompassing where this Identified Physician practiced according to the information in the Plaintiff Fact Sheet. The timeframe for this question is from (a) the later of the launch of the Davol/Bard Hernia Mesh Device(s) implanted by this Identified Physician or ten years before the date of implant of the Davol/Bard Hernia Mesh Device(s) implanted by this Identified Physician until (b) seven years after the date of implant of the Davol/Bard Hernia Mesh Device(s) implanted by this Identified Physician.

2. For each Identified Physician who is alleged to have removed some or all of one or more of the Davol/Bard Hernia Mesh Devices identified in Plaintiff's Complaint, identify the sales representative(s) responsible for one or more of the Davol/Bard Hernia Mesh Devices identified in the Plaintiff's Complaint for the territory encompassing where this Identified Physician practiced according to the information in the Plaintiff Fact Sheet. The timeframe for this question is from (a) two years before the date of removal by this Identified Physician of some or all of one or more of the Davol/Bard Hernia Mesh Device(s) and (b) two years after the date of removal by this Identified Physician of some or more of the Davol/Bard Hernia Mesh Device(s).

3. For each sales representative identified in subparts 1 and 2, identify the last known address and telephone number of the sales representative and the dates of employment of the sales representative with Davol or C.R. Bard.

4. For each sales representative identified in subparts 1 and 2, identify the sales representative's immediate supervisor (including, but not limited to, regional supervisor or district manager) at Davol or C.R. Bard for the applicable time period, including each supervisor's dates of employment with Davol or C.R. Bard and last known address and telephone number.

5. For each sales representative identified in subparts 1 and 2, Defendants shall search the electronically stored data already collected or reasonably accessible for each sales representative for references to each Identified Physician implicated by the responses to subparts 1 and 2. The searches shall be designed to capture from these sources records relating to contacts with the Identified Physicians concerning Davol/Bard Hernia Mesh Devices, including but not limited to marketing presentations to the Identified Physicians, promotional materials provided to the Identified Physicians, DHP letters provided to the Identified Physicians, trainings of the Identified Physicians, and surgeries attended by the sales representative. The timeframe for this question will correlate to the timeframes in subparts 1 and 2. As set forth in Section V below, Defendants will produce to each Plaintiff any documents identified through these searches.

6. For each sales representative identified in subparts 1 and 2 and each supervisor identified in subpart 4, Defendants shall search the electronically stored data already collected or reasonably accessible for each sales representative and supervisor for responsive documents according to the agreed-upon ESI protocol and search terms. The timeframe for this question will correlate to the timeframes in subparts 1 and 2. As set forth in Section V below, Defendants will produce to each Plaintiff any discoverable documents identified through these searches.

II. <u>AGREEMENTS WITH IMPLANTING FACILITY(IES)</u>

In the Plaintiff Fact Sheet, Plaintiff has identified each hospital, surgical center, or facility where each Davol/Bard Hernia Mesh Device(s) identified in the Plaintiff's Complaint was implanted ("Implanting Facility"). For each Implanting Facility, to the extent known or identifiable by electronic search, identify contacts and contracts as follows:

1. Identify by Bates range and/or produce all purchasing contracts governing Davol/Bard Hernia Mesh Devices between Defendants and each facility in effect at the time of implant of Defendants' Hernia Mesh Devices(s) identified in the Plaintiff's Complaint at each applicable Implanting Facility.

2. Identify by Bates range and/or produce all communications, documents, correspondence, or otherwise sent from Defendants to each Implanting Facility for a period of five years prior to the date of implantation of Defendants' Hernia Mesh Device(s) identified in the Plaintiff's Complaint at each applicable Implanting Facility to five years after implantation of such device.

III. <u>OTHER CONTACTS, CONTRACTS, AND AGREEMENTS WITH</u> <u>PHYSICIANS.</u>

As set forth in more detail below, to the extent known or identifiable by electronic search, Defendants will provide the following information for each Identified Physician (as defined in Section I above):

1. For any agreement(s) between Defendants and the Identified Physician(s), please provide the information below. It is understood that the search for this information will include the applicable database in effect from 2014 to present, as well as a search of the electronically stored data already collected or reasonably accessible for the time frame starting with the later of the launch of the Davol/Bard Hernia Mesh Device(s) identified in Plaintiff's Complaint or five years before the date of implant of the Davol/Bard Hernia Mesh Device(s).

Name of Identified Physician Retained by Davol and/or Bard (indicate which one or both)	Date(s) of Contract(s) or Agreement(s)	Nature of Agreement ("Key Opinion Leader," "Clinical Investigator," Preceptor, Etc.)
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2. For any monetary or non-monetary compensation or benefits including, but not limited to, money, travel, and compensation for meal(s), provided to the Identified Physician(s), please provide the information below. It is understood that the search for this information will include the applicable database in effect from 2014 to present, as well as a search of the electronically stored data already collected or reasonably accessible for the time frame starting with the later of the launch of the Davol/Bard Hernia Mesh Device(s) or five years before the date of implant of the Davol/Bard Hernia Mesh Device(s).

Name of Identified Physician	Date(s) of compensation	Amount of Compensation	Which Defendant (or Both) and Purpose of Compensation

3. For any training conducted by the Defendants or any representative thereof provided to or by the Identified Physician(s) for any Davol/Bard Hernia Mesh Device, please provide the information below. It is understood that the search for this information will include the applicable database in effect from 2008 to present, as well as search of the electronically stored data already collected or reasonably accessible for the time frame starting with the later of the launch of the Davol/Bard Hernia Mesh Device(s) or five years before the date of implant of the Davol/Bard Hernia Mesh Device(s).

Name of Identified Physician	Date(s) and Location(s) of training	Title or Topic of Program	Identity of Location of Related Written Materials for Program

Case: 2:18-md-02846-EAS-KAJ Doc #: 128 Filed: 04/01/19 Page: 9 of 10 PAGEID #: 1947

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IV. PLAINTIFF-SPECIFIC AND DEVICE MANUFACTURING INFORMATION

1. Based on the lot number information in the Plaintiff Fact Sheet, for each Davol/Bard Hernia Mesh Device(s) identified in Plaintiff's Complaint, identify the location and date of manufacture.

2. Identify by Bates range and/or produce the lot manufacturing and release records for the lots referenced in Question 1 above.

3. Identify by Bates range and/or produce the complaint file relating to Plaintiff's claims, including but not limited to all MedWatch Adverse Event Reports and/or any other documents submitted to the FDA or any other government agency with regard to Plaintiff.

4. Identify by Bates range and/or produce any documents relating to clinical research or clinical studies conducted by or on behalf of Defendants involving either (a) the implantation of devices with the same lot number(s) identified in the Plaintiff Fact Sheet or (b) in which Plaintiff was a known study participant.

V. <u>DOCUMENTS</u>

Please ensure that the production of documentation includes specific reference to the question to which the documentation is provided in response. Documentation is defined to include all forms of documents, including but not limited to paper, email, video, audio, spreadsheets, or otherwise. Documents previously produced by Defendants in connection with this MDL need not be re-produced, but Defendants may identify responsive documents by Bates number or other identifying information.

1. Produce complete documentation of all information set forth in I through IV above. For documents related to I above, Defendants are only required to search in electronically stored data collected for the Davol or C.R. Bard sales representative(s) responsible for one or more of the Davol/Bard Hernia Mesh Devices assigned to the territory where the Identified Physician(s) was practicing to the extent that sales representative's electronic data was collected in connection with this litigation or prior litigations.

2. Produce any documents in Defendants' possession or control that were provided to or received from Plaintiff's Identified Physicians with regard to Plaintiff and/or the Davol/Bard Hernia Mesh Device(s) implanted in Plaintiff, to the extent not identified and attached in response to a prior question.

Defendant Fact Sheet Certification

I am an authorized agent of Defendants and I hereby certify that the matters stated herein are not the personal knowledge of the undersigned; that the facts stated herein have been assembled by authorized employees and counsel to Defendants and undersigned is informed that the facts stated therein are true. I further certify in my capacity as an authorized agent of Defendants that the responses herein are true and complete to the best of Defendants' knowledge, and that based upon a diligent search and analysis of the information available to the Defendants and their counsel, and that the requested documentation has been provided.

Print Name

Title

Date: