**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

IN RE: AMERICAN MEDICAL SYSTEMS, INC.,
PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No. 2325

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THIS DOCUMENT RELATES TO ALL CASES

**PRETRIAL ORDER # 49**
(Defendant's Fact Sheet)

The parties have agreed to and submitted for entry, the attached Defendant's Fact Sheet ("DFS"). It is **ORDERED** that defendant must submit a completed DFS pursuant to PTO # 37 for each case in the Discovery Pool on or before **March 18, 2013**, to the plaintiffs electronically at:

Jade Brennan at jbrennan@motleyrice.com

If defendant fails to comply with the DFS obligations under this order, including failure to timely submit a DFS or failure to submit a substantially complete DFS, defendant may, for good cause shown, be subject to sanctions to be determined by the court, upon motion of the plaintiffs. The court expects the parties to meet and confer before such a motion is filed, and will adjudicate such motions on an expedited basis.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2325 and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:13-cv-04151. In cases subsequently filed in this district, a copy of the most recent pretrial order will be

provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

ENTER: March 11, 2013

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

IN RE: AMERICAN MEDICAL SYSTEMS, INC.
PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION

MDL NO. 2325

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THIS DOCUMENT RELATES TO
CIVIL ACTION NO: _____

# DEFENDANT'S FACT SHEET

For each case, American Medical Systems, Inc. ("AMS") must complete this Fact Sheet. Except as otherwise set forth in any Order, this Fact Sheet must be completed and served on plaintiffs' counsel in the first 30 discovery pool cases by March 18, 2013.

## I. CASE INFORMATION

This defendant fact sheet pertains to the following case:

Case Name:

## II. CONTACTS WITH TREATING AND EVALUATING PHYSICIANS

Plaintiff has identified each physician who treated and/or evaluated plaintiff for pelvic organ prolapse, stress or urinary incontinence, and/or associated conditions that led to the use of Defendant's women's pelvic mesh products. As to each such physician, provide the following information:

### A. CONSULTATION AND OTHER NON-SALES REPRESENTATIVE CONTACTS

As to each identified physician with whom the Defendant was affiliated, consulted or otherwise had contact outside the context of sales representative contacts, set forth the following:

1. Identify the physician.

2. Identity and title of each of Defendant's employees who had such contact with the physician.

3. Dates of contact/affiliation with physician.

4. Nature of the contact/affiliation with physician.

5. Set forth any monetary and/or non-monetary benefits, including but not limited to money, travel, and device samples, provided to the physician by any agent of Defendant, including amounts, dates, and purpose.

6. With respect to the AMS women's pelvic mesh products, set forth any training provided to or by the physician; including but not limited to date, location, physician's role, cost for attending such training, and subject matter.

7. List any written agreements, contracts, letters, memoranda, or other documents setting forth the terms or nature of any contact or affiliation with the physician; this includes but is not limited to any agreements to research or otherwise study Defendant's products.

8. For each facility where the physicians were associated, set forth the number and type of AMS women's pelvic mesh products purchased from you.

9. Set forth any contact between the Defendant and the physician with regard to the plaintiff, this includes but is not limited to any information or knowledge Defendant has with respect to research studies conducted on or that include information related to plaintiff's implant or associated lot and reference number.

10. Set forth all information provided by the physician to the Defendant with regard to the safety, use, or efficacy of the Defendant's product(s).

B. SALES REPRESENTATIVE CONTACTS

As to each sales representative who had any contact with an identified physician to discuss AMS women's pelvic mesh products, set forth the following:

1. Identity of physician.

2. Identity and last known address and telephone number of sales representative.

3. The work history, with you, and current relationship, if any, between Defendant and the sales representative.

4. Identity of the sales representative's supervisor(s) during his/her employment.

5. Identify all district and/or regional sales managers who were responsible for the management of the sales representatives identified in your response to Number 2 above, and their current relationship, if any, with American Medical Systems.

6. Set forth all information provided by the physician to the sales representative, with regard to the plaintiff.

7. Set forth the date and location of each operation or procedure performed on the plaintiff, which was attended at all by the sales representative.

8. State whether the sales representative, while employed by you, has ever been investigated, reprimanded, and/or otherwise penalized by any person, entity, or government agency for his/her sales or marketing practices, and if so set forth the details thereof.

III. INFORMATION REGARDING THE PLAINTIFF

A. Identify all data, information, objects, and reports in Defendant's possession or control or which have been reviewed or analyzed by Defendant, with regard to the plaintiff's medical condition; this also includes but is not limited to any study or research that includes plaintiff's specific implant or associated lot and reference number. Attorney-work product is specifically excluded from this request.

B. Identify any direct or indirect contact, either written or oral, between the plaintiff and any employee or representative of Defendant, including but not limited to pre-operative inquiries, and post-operative complaints. This request specifically includes, but is not limited to, calls to the AMS Consumer Affairs Group.

C. Identify all Med Watch Adverse Event Reports and/or any other documents submitted to the FDA or any other government agency with regard to the plaintiff.

D. If you have any evidence or records indicating or demonstrating the possibility that any person, entity, condition, or product, other than the Defendant and its product(s), is a cause of the plaintiff's injuries, ("Alternate Cause") set forth:

1. Identify the Alternate Cause with specificity.

2. Set forth the date and mechanism of alternate causation.

IV. MANUFACTURING INFORMATION

To the extent Plaintiff has identified in her Complaint or in medical records provided with the Plaintiff Profile Form the lot and reference number(s) for the AMS women's pelvic mesh product(s) implanted into the Plaintiff ("implanted device") and/or the device(s) used to implant AMS's women's pelvic mesh product(s) ("implanting device"), please identify the following:

A. Identify the location and date of manufacture for each implanted device's lot and reference number and/or each implanting device's lot and reference number.

B. Identify the date of shipping and sale, and the person or entity purchasing, each of plaintiff's implanted and/or implanting device(s).

C. Identify all manufacturing facilities and associated lot and reference number(s) of plaintiff's implanted device(s), including but not limited to all trocars and any other surgical devices or means of implantation included or sold with plaintiff's implant(s).

V. DOCUMENTS

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.

A. Identify and attach complete documentation of all information set forth in I through IV above; except, you may identify but not serve copies of medical records that were provided to defendants by plaintiff's counsel.

B. Aside from any privileged materials, identify and attach all records, documents, and information that refer or relate to the plaintiff in defendants' possession or control, to the extent not identified and attached in response to a prior question.

C. Produce a true and complete copy of the device history record for the Plaintiff's lot and reference number(s).

D. Produce a true and complete copy of the complaint file relating to the Plaintiff.

E. All call notes, detail notes, call summaries, entries made by sales representatives into Salesforce.com, hard copy documents, emails, and/or notes or records or summaries of calls, contacts and/or communications of any kind regarding each implanting or treating physician during the relevant time period.

**VERIFICATION**

_____, being first duly sworn upon his oath, deposes and says:

That I am an authorized agent of American Medical Systems, Inc. and that I verify the Defendant's Response to Plaintiff_____'s Defendant's Fact Sheet addressed to American Medical Systems, Inc. in In Re American Medical Systems, Inc. Pelvic Mesh Repair Systems Products Liability Litigation, MDL No. 2325 (S.D. W. Va.), and that the matters stated therein are not the personal knowledge of deponent; that the facts stated therein have been assembled by authorized employees and counsel of American Medical Systems, Inc. and deponent is informed that the facts stated therein are true. I hereby certify, in my authorized capacity as an agent for American Medical Systems, Inc., that the responses to the aforementioned Defendant's Fact Sheet are true and complete to the best of American Medical Systems, Inc.'s knowledge.

_____

Title:
American Medical Systems, Inc.

SUBSCRIBED and SWORN to before me this ____ day of , 20___.

_____

Notary Public

My Commission expires:

_____