

EXHIBIT A

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

IN RE: DEPUY ORTHOPAEDICS, INC.)	
PINNACLE HIP IMPLANT PRODUCT)	MDL Docket No. 2244
LIABILITY LITIGATION)	3:11-MD-2244-K
)	
<hr/>)	DEFENDANTS' FACT SHEET

DEFENDANTS' FACT SHEET

Instructions

Please provide the following information for plaintiff (or plaintiff's decedent) (hereinafter "Plaintiff") who was implanted with the Pinnacle Hip System or any components thereof (hereinafter "Device") that is the subject of Plaintiff's complaint in the above referenced action. In filling out any section or sub-section of this form, please submit additional sheets as necessary to provide complete information.

In completing this Defendants' Fact Sheet, the following definitions apply to all discovery requests and interrogatories:

- "Adverse Event Report" means a report relating to any "adverse event", as used in 21 C.F.R. § 803.50 *et seq.*, concerning the Pinnacle Hip System, including reports received by Defendants and reports submitted by Defendants to the FDA.
- "Communication" means any oral, written, spoken, or electronic transmission of information, including but not limited to, meetings, discussions, conversations, telephone calls, memoranda, letters, emails, text messages, postings, instructions, conferences, or seminars, or any other exchange of information between Defendants or between Defendants and any other person or entity.
- "Defendants," "You," or "Your" mean DEPUY ORTHOPAEDICS, INC., n/k/a Medical Device Business Services, Inc., JOHNSON & JOHNSON, and their successors and assigns.

- “Device History Record” means DePuy’s compilation of documents created for each lot of each component manufactured (i.e., cup, liner, and head) that tracks the lot from the time of manufacture through the point at which it is ready for sale.
- “Distributor” means the distributor of the Pinnacle Hip System or any components thereof at the time Plaintiff’s Device (or any component) was implanted and/or at the time Plaintiff’s Device (or any component) was explanted.
- “Documents” is coextensive with the meaning of the terms “documents,” “electronically stored information,” and “tangible things” as used in Federal Rule of Civil Procedure 34, and shall have the broadest possible meaning and interpretation ascribed to those terms under Rule 34 and the applicable Local Rules for the Northern District of Texas.
- “General Production” refers to DePuy’s document production in this MDL.
- “Health Care Provider” means all surgeons, identified in Question 2 of the Pinnacle Plaintiff Profile Form submitted by Plaintiff, who performed implantation or revision surgery to implant or explant Plaintiff’s Device.
- “Produce” means to identify where in the General Production the documents requested may be located, either by Bates Number or by some other identifier (e.g., Complaint file number or keywords which may yield the documents).
- “Pinnacle Hip System” means any cup, liner, or femoral head manufactured by DePuy that is intended to be used with the Pinnacle modular cup system.
- “Sales Representative” means the sales representative for the Pinnacle Hip System or components thereof present at the surgical facility at the time Plaintiff’s Device (or any component) was implanted and/or at the time Plaintiff’s Device (or any component) was explanted.

In completing this Defendants’ Fact Sheet, You are under oath and must provide information that is true and correct to the best of Your knowledge, information, and belief. If the response to any question is that You do not know the information requested, that response should be entered in the appropriate location(s).

In completing this Defendants’ Fact Sheet, please respond on the basis of information and/or documents that are reasonably available to each of the Defendants; the Distributor; the Sales Representative; and the Sales Representative’s

employer or company.

In completing this Defendants' Fact Sheet, the following rules of construction apply to all discovery requests and interrogatories: (1) The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope; and (2) the use of the singular form of any word includes the plural and vice versa.

Defendants' Response

Defendants DEPUY ORTHOPAEDICS, INC., n/k/a Medical Device Business Services, Inc. and JOHNSON & JOHNSON (collectively "Defendants") hereby submit the following Defendants' Fact Sheet responses and related Documents. Defendants object to these requests to the extent that they seek information protected from disclosure by the attorney-client privilege, the work product doctrine, the joint defense privilege, the common interest doctrine, and/or any other privilege recognized by law. Subject to this objection, Defendants respond as follows.

In connection with their response to this DFS, Defendants have created a Defendants' Fact Sheet Database (the "DFS Database"). The DFS Database includes some of the documents that are responsive to the Defendants' Fact Sheet, as well as other information that will assist Plaintiff in identifying the previously produced documents within the General Production that are responsive to the Defendants' Fact Sheet. Plaintiffs have been provided with login information with the email transmitting this Defendants' Fact Sheet.

A. DEVICE MANUFACTURE INFORMATION

1. The identity by name and address of the person or entity to whom the Device was sold.
2. Produce the Device History Record for the Device.
3. For each Device identified by Plaintiff in response to the Pinnacle Plaintiff Profile Form, please provide the following:
 - a. Produce a copy of the Plaintiff's complaint file(s), including medical records, if any, that were obtained or received as part of the complaint process in the ordinary course of business.
 - b. Please provide the complaint file number(s) that would permit Plaintiff to identify his/her complaint file, if any, in the General Production.

B. PRODUCT/MARKETING/SALES REPRESENTATIVE AND DISTRIBUTOR INFORMATION

1. Provide the name and business address of both the Sales Representative and his or her employer or company (if they differ).
2. Provide the name and address of the Distributor.
3. Produce documents that relate in a reasonably direct manner to the DePuy metal-on-metal hip systems from the Sales Representative and/or his or her employer or company identified in question B.1., above.

The Sales Representative Documents should include:

- a. Scheduling documents including operating room schedules, scheduling calendars, date books, and/or other documents that record the Sales Representative's schedule as it relates to the DePuy metal-on-metal hip systems;
- b. Call notes, field reports, operative or procedure summaries, and other documents provided to the Sales Representative, prepared by the Sales Representative, and/or prepared at the request of the Sales Representative identified in B.1.;
- c. Communications from the Distributor and/or Defendants to the Sales Representative identified in B.1. concerning the Pinnacle Hip System, metal on metal hip devices, including but not limited to marketing materials, medical device reports, metal on metal sales data, budgetary and sales information, surgeon, health care provider or orthopedic sales, implant, explant and other related data; and
- d. Training materials provided to the Sales Representative identified in B.1. concerning his or her position, job requirements, standards (whether J&J/DePuy internal or external) and/or regulations concerning the promotion, distribution, device sale and/or operating room procedures, and/or protocols, including reporting requirements and preservation requirements including adverse event reporting, medical device reports, and/or surgical or other reports concerning the Pinnacle Hip System and any components compatible to the Pinnacle Hip System, the failure of or any other problem(s) related to the Pinnacle Hip System and any compatible components, interaction and relations with surgeons, health care providers, Distributors, Defendants, health care office staff, key opinion leaders, thought leaders, consultants, orthopedic clinics, and/or hospitals.

4. Produce documents that relate in a reasonably direct manner to the DePuy metal-on-metal hip systems from the Distributor identified in question B.2., above.

The Distributor Documents should include:

- a. Call notes, field reports, operative or procedure summaries and any and all other Documents prepared by the Distributor or at the request of the Distributor identified in B.2.;
- b. Communications from the Sales Representative and/or Defendants to the Distributor identified in B.2. concerning the Pinnacle Hip System, metal on metal hip devices, including but not limited to marketing materials, medical device reports, metal on metal sales data, budgetary information, surgeon, health care provider or orthopedic sales, implants, explants, and other related data;
- c. Training materials provided to the Distributor identified in B.2. concerning their position, job requirements, standards (whether J&J/DePuy internal or external), and/or regulations concerning the promotion, distribution, device sale, and/or operating room procedure, including all reporting requirements and preservation requirements, adverse event reports, medical device reports, surgical and/or other reports concerning the Pinnacle Hip System, and any components compatible to the Pinnacle Hip System, the failure of or any other problem(s) related to the Pinnacle Hip System and any compatible components, interaction and relations with surgeons, health care providers, health care office staff, Sales Representatives, Defendants, key opinion leaders, thoughts leaders, consultants, orthopedic clinics, and hospitals; and
- d. Files pertaining to the Distributor identified in B.2. including but not limited to their metal on metal sales data, complaint data, training data and contract and related documentation between and among DePuy, J&J and the Distributor, and training requirements.

C. HEALTH CARE PROVIDER DATA

Produce data, communications, information, or materials concerning the number of DePuy hip devices implanted by Plaintiff's Health Care Provider, any and all sales data, including financial data, revision data, complaints, training and any other data, communications, or information compiled concerning Plaintiff's Health Care Provider and in the possession, custody, and control of Defendants, Distributors, and Sales Representatives (or their employers or companies).

D. COMMUNICATIONS AND RELATIONSHIPS WITH PLAINTIFF'S HEALTH CARE PROVIDERS AND PLAINTIFF

1. Produce Communications between the Defendants, the Sales Representative, the Sales Representative's employer or company, and/or the Distributor identified in section B above, and Plaintiff's Health Care Providers about the Pinnacle Hip System, including but not limited to Dear Health Care Provider letters, recall letters, telephone or email contacts, or meetings.
2. Produce Communications between and among Defendants, the Sales Representative, the Sales Representative's employer or company, and/or the Distributor identified in section B above and Plaintiff, Health Care Provider, surgeon, or other entity or individual to the extent not contained in the complaint file, if any.
3. Produce documents that relate in a reasonably direct manner to consulting agreements, if any, between Defendants and any of Plaintiff's Health Care Providers, including but not limited to all consulting relationships to provide advice on the design, study, testing, or use of hip replacement systems, or to consult as a thought leader, opinion leader, member of a speaker's bureau, or similar arrangement.
4. Produce documents that relate in a reasonably direct manner to relationships, if any, between Defendants and any of Plaintiff's Health Care Providers to conduct any pre-clinical, clinical, post-marketing surveillance, or other study or trial concerning any hip replacement systems including but not limited to any component of the Pinnacle Hip System, or that is compatible with the Pinnacle Hip System.
5. Produce documents that reflect financial compensation, things of value and promotional items provided by Defendants, the Sales Representative, the Sales Representative's employer or company, and/or the Distributor identified in section B above to Plaintiff's Health Care Providers. Please include all fees, expenses, honoraria, royalties, grants, gifts, travel (i.e., airfare, hotel etc.), and any other payments or things of value given.

E. ADVERSE EVENT REPORTS

1. Provide the identification number for any Medical Device Adverse Event Report relating to Plaintiff.

VERIFICATION

I am employed by DePuy Orthopaedics, Inc., one of the Defendants in this action. I am authorized by Defendants to make this verification on each corporation's behalf. The foregoing answers were prepared with the assistance of a number of individuals, including counsel for Defendants, upon whose advice and information I relied. I declare under penalty of perjury that all of the information as to the foregoing Defendants provided in this Defendants' Fact Sheet is true and correct to the best of my knowledge upon information and belief.

Date: _____

Signature _____

Printed Name: _____

Employer: _____

Title: _____