UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE:

MIRENA IUD PRODUCTS LIABILITY LITIGATION

This Document Relates To All Actions

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ORDER NO. 8
(Defendant Fact Sheet)

13-MD-2434 (CS)
13-MC-2434 (CS)

Seibel, J.

I. Defense Fact Sheet and Responsive Documents

1. The parties have agreed upon a Defense Fact Sheet ("DFS"), which is attached to this Order as Exhibit 1.

2. The DFS includes document requests. Defendant Bayer Healthcare Pharmaceuticals, Inc. ("Defendant") shall produce to Plaintiff a completed DFS and documents responsive to the DFS ("Responsive Documents") pursuant to the terms of this order. "Defendant" in the context of this document shall be defined pursuant to the Agreed Order Regarding Proper Party-Defendant, (No. 13-MC-2434, Doc. 22), and any future amendments thereto.

3. The DFS is a convenient form of propounding interrogatories and requests for production of documents. The completed DFS shall be considered interrogatory answers pursuant to Fed. R. Civ. P. 33 and as responses to requests for production pursuant to Fed. R. Civ. P. 34 and will be governed by the standards applicable to written discovery under Fed. R. Civ. P. 26 through 37. The questions and requests for production contained in these Fact Sheets are non-objectionable and shall be answered without objection. As set forth below in section III, each DFS that is completed must be substantially complete. This section does not prohibit Defendant from withholding or redacting information pursuant to the Preservation and Production Protocol (to be entered). In the event that a dispute arises concerning the

completeness or adequacy of Defendant's response to any request contained in the DFS, this section shall not prohibit Defendant from asserting that its response is adequate.

4. Nothing in the DFS shall be deemed to limit the scope of inquiry at depositions and admissibility of evidence at trial. The scope of inquiry at depositions shall remain governed by the Federal Rules of Civil Procedure. The admissibility of information in responses to the DFS shall be governed by the Federal Rules and no objections are waived by virtue of any DFS response.

II. Schedule of Production of DFSs

5. Defendant must serve upon each Plaintiff a completed DFS including Responsive Documents within 60 days of receipt of service of a substantially complete Plaintiff Fact Sheet ("PFS") as defined in Order No. 7 (Plaintiff Fact Sheet), (No. 13-MC-2434, Doc. 29), that identifies the physician/treater/clinic by name and full address that implanted Plaintiff's Mirena IUD and which also identifies the physician/treater/clinic by name and full address that treated Plaintiff for her Mirena IUD related injury.

6. Service of the DFS shall be either in hard copy or in an electronic format via email or on CD or USB flash drive via first class mail to Plaintiff and to Plaintiffs' Steering Committee at mirenamdldfs@yourlawyer.com.

III. DFS Must Be Substantially Complete In All Respects

7. Defendant is required to provide Plaintiff with a DFS that is substantially complete in all respects. Substantially complete in all respects requires that Defendant:

a) Answer all applicable questions in the DFS ;

b) Include a signed Declaration (found at the back of the DFS); and

c) Produce the documents requested in the DFS, to the extent such documents are in Defendant's possession, custody or control.

IV. Non-compliance with DFS Requirements

8. If a Plaintiff in a particular case has not received a DFS that is substantially complete within 30 days following the due date set forth herein, Plaintiff will send a Notice of Overdue Discovery to Defendant's counsel identifying the discovery overdue. If Plaintiff has not received a completed DFS within 30 days after serving Defendant with a 30-day notice, Plaintiff may move the Court for an Order compelling Defendant to complete the DFS at issue. While the DFS is deficient, no further discovery of Plaintiff is permitted and no action can be taken against a Plaintiff, *e.g.*, no motion to dismiss may be filed.

SO ORDERED.

Dated: August 15, 2013
White Plains, New York

Cathy Seibel

CATHY SEIBEL, U.S.D.J.

EXHIBIT 1

MIRENA®

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE:

13-MD-2434 (CS)(LMS)

MIRENA IUD PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

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MIRENA DEFENDANT'S FACT SHEET

For each case, the Defendant Bayer Healthcare Pharmaceuticals Inc. ("Defendant") must complete this Defendant's Fact Sheet ("DFS") and identify or provide documents and/or data relating to each Plaintiff responsive to the questions set forth below to the best of Defendant's knowledge. "Defendant" in the context of this document shall be defined pursuant to the Agreed Order Regarding Proper Party Defendant and any future amendments thereto.

In completing this DFS, you are under oath and must provide information that is true and correct to the best of your knowledge at the time you complete this DFS. If you cannot recall all of the details requested, please provide as much information as you can. The DFS must be supplemented or revised upon receiving any information making any answer incorrect or incomplete.

You may attach as many documents (as defined below) as necessary to fully answer these questions.

As used herein, the term "Documents" shall include, information stored, maintained or available to Defendant, including without limitation, any written, printed, typed, photostatic, photographed, recorded, computer generated, computer-stored, or otherwise maintained or reproduced communication or representation, any data compilation in any form, whether comprised of letters, words, numbers, pictures, sounds, bytes, emails, electronic signals or impulses, electronic data, active files, deleted files, file fragments, or any combination thereof including, without limitation, all memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, projections, estimates, working papers, accounts, analytical records, reports and/or summaries of investigations, opinions or reports of consultants or experts not retained for purposes of litigation, opinions or reports of accountants,

other reports, trade letters, press releases, comparisons, books, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, forecasts, drawings, diagrams, instructions, minutes of meetings or communications of any type, including inter- and intra-office communications, questionnaires, surveys, charts, graphs, photographs, films, discs, data cells, drums, printouts, all other compiled data which can be obtained, documents maintained on, stored in or generated on any electronic transfer or storage system, any primary versions, drafts or revisions of any of the foregoing, and shall include all non-identical copies and drafts of any of the foregoing now in the possession, custody or control of Defendant. Defendant is not required to identify or produce any pleading filed in litigation relating to Mirena® ("Mirena") or medical records produced in Plaintiff's individual case.

As used herein, the terms "you," "your" or "yours" means Defendant and any officers, agents, employees, representatives or others acting on its behalf.

As used herein, the phrase "provided" means sold, distributed, shipped, delivered or otherwise placed into the stream of commerce.

As used herein, the term "communication" and/or "correspondence" shall mean and refer to any oral, written, spoken or electronic transmission of information, including, without limitation, meetings, discussions, conversations, telephone calls, memoranda, letters, e-mails, voice recordings, postings, instructions, conferences, or seminars or any other exchange of information between Defendant or between you and any other person or entity.

Nothing in this DFS shall be construed contrary to the requirements of the Preservation Order, or any other Order, in this action.

As used herein, the phrase "Specified Health Care Provider(s)" means each of Plaintiff's medical providers who prescribed and/or inserted Plaintiff's Mirena(s) as identified with particularity in the Plaintiff Fact Sheet ("PFS").

As used herein, the phrase "Promotional Items" means any and all promotion items, marketing devices, freebies, merchandise, handouts, meals, or any other items related to Mirena including but not limited to physical items marked with the Mirena trademark such as anatomical models, notepads, post-it-notes, pens, flashlights, other day-to-day office supplies of any type, models for patient demonstration, diagnostic tools and aids, medical assessment and dosage calculators, pharmacy and pharmacist tools, patient compliance tools, custom medical calculators and software, branded apparel (such as but not limited to shirts, hats, etc), leather portfolios, prescription pads, picture frames, letter openers, clipboards, water bottles, coffee mugs/cups, pocket/pen lights, key chains, badge-holders, bags, travel accessories, other "freebies" provided to Implanting/Prescribing Health Care Providers (this list is not meant to be exhaustive). "Promotional Items" shall mean and include any and all cross-promotional materials related to Mirena jointly with other products or advertising campaigns.

As used herein, the term "identify" or "identity" with respect to persons, means to give, to the extent known, the person's full name, and as to former employees or third–parties, their present or last known address.

As used herein, the term "person" means natural person, as well as corporate and/or governmental entity.

As used herein, the terms "relating to," "relate to," "referring to," "refer to," "reflecting," "reflect," "concerning," or "concern" shall mean evidencing, regarding, concerning, discussing, embodying, describing, summarizing, containing, constituting, showing, mentioning, reflecting, pertaining to, dealing with, relating to, referring to in any way or manner, or in any way logically or factually, connecting with the matter described in that paragraph of these demands, including documents attached to or used in the preparation of or concerning the preparation of the documents.

Unless otherwise indicated, the "relevant period" for the information sought is January 1, 2000 to the present.

This Defendant Fact Sheet does not prohibit Defendant from withholding or redacting information pursuant to the Preservation and Production Protocol.

If a claim of privilege is made, a privilege log shall be provided to Plaintiffs' counsel pursuant to the requisite section(s) of the Preservation and Production Protocol agreed to and entered in this MDL litigation.

I. CASE INFORMATION

This DFS pertains to the following case:

Case caption:_____

Civil Action No.: _____

Court in which action was originally filed:_____

Date that this DFS was completed:_____

Name and address of all persons who provided information responsive to the questions posed in this DFS:

A: _____
(Name)

_____
(Address)

_____
(Phone Number)

B: _____
(Name)

_____
(Address)

_____
(Phone Number)

II. CONTACTS WITH HEALTH CARE PROVIDERS

For each Specified Health Care Provider identified in the PFS, please state the following:

A. **Dear Doctor Letters:**

1. Please identify and provide information below for each "Dear Doctor" or "Dear Heath Care Provider" letter that you contend was actually sent to the Plaintiff's Specified Health Care Provider concerning Mirena from 2000 through the date of removal.

Sender (Name and Address)	Letter or Document Date	Recipient (Name and Address)	Bates Number of Supporting Documentation

B. **Physician's Information Request**

1. If any of the Specified Health Care Provider(s) identified in the PFS has ever contacted Defendant about Mirena, provide the following from 2000 through the date of removal:

Name and Address of Person Making Contact	Date	Name and Address of Recipient	Response Sent (Y/N)	Type of Contact (PIR, call, etc.)

2. For each contact in which a response was sent as indicated by a "Yes" above, please identify the following:

Original Contact Date	Format of Response (Letter or Otherwise)	Date Response Sent	Response Sender (Name and Address)	Response Recipient (Name and Address)	Bates Number of Supporting Documentation

C. **Sales Representative Contacts**

1. For each Specified Health Care Provider identified in the PFS, please produce or identify all contacts and communications between the Implanting/Prescribing Health Care Provider and Defendant's Sales Representatives that relate to Mirena from 2000 through the date of removal.

Name of Plaintiff's Specified Health Care Provider	Name and, if no longer employed by defendant, last known address and telephone number of Defendant's Sales Representative	Current employment status of Sales Representative	Date Range of Contacts

2. For each Sales Representative or detail person that had contact with each Specified Health Care Provider(s) listed in the PFS regarding Mirena from 2000 through the date of removal please provide the following information:

Plaintiff's Specified Health Care Provider	**Name of Sales Rep / Detail Person**	**Territory (ies) Covered**	**Date of Hire / Date Last Employed**	**Supervising District Manager(s) and, if no longer employed by defendant, last known address and telephone number**	**Supervising Field Sales Director current (or last known) and, if no longer employed by defendant, last known address and telephone number**

3. For each Specified Health Care Provider, please state whether Defendant or its representatives ever provided him/her Mirena samples. If the answer is "yes," please state from 2000 through the date of removal:

(a) The number of samples provided;

(b) The dates that they were shipped and/or provided;

(c) The lot numbers for the samples provided on each date identified;

(d) The identity of the person or persons who provided the samples;

(e) The identity of the person or persons who received the samples;

4. For each Specified Health Care Provider, please state whether Defendant or its representatives provided him/her with "Promotional Items" from 2000 through the date of removal (if available, a physical sample of each Promotional Item will be produced to Plaintiffs' Lead Counsel). If the answer is "yes," please provide:

   (a) A description of each Promotional Item provided;

   (b) The dates that each type of Promotional Item was delivered, shipped and/ or provided;

   (c) The total quantity of each such Promotional Item that was delivered, shipped and/or provided;

   (d) The identity of the person or persons who provided the Promotional Item;

   (e) The identity of the person or persons who received the Promotional Item and their title or job description; and

   (f) The fair market value of each such Promotional Item.

5. For each Specified Health Care Provider, please produce any data or documents that identify whether Defendant's sales representatives provided him/her with any type of documentation (including published studies or journal articles) relating in any way to the safety, efficacy, benefits, risks or on- or off-label use of Mirena from 2000 through the date of removal, including, to the extent available:

   (a) A description of each document provided;

   (b) The dates that the document was mailed and/or provided;

   (c) The identity of the person or persons who provided the documentation;

   (d) The identity of the person or persons to whom the documentation was provided; and

   (e) A copy of any cover letters sent to Plaintiff's Implanting/Prescribing Physician with the material.

6. For each Specified Health Care Provider, please state the number of non-Mirena sales calls made by Defendant's women's healthcare sales representatives during each year within the three years prior to Plaintiff's Mirena insertion.

7. Please identify the person or persons who provided information responsive to Section II or any of its subparts.

_____

_____

III. CONSULTING WITH PLAINTIFF'S IMPLANTING/PRESCRIBING HEALTH CARE PROVIDER

A. If you have retained any of the Specified Health Care Provider(s) listed in the PFS as a Mirena "thought leader," "Key Opinion Leader," a member of a "speaker's bureau," a "clinical investigator," a "consultant," or in any other capacity, from 2000 through the date of removal please provide the following information:

Name of Plaintiff's Specified Health Care Provider consulted or retained by Defendant	**Date(s) he or she was consulted or retained**	**Records of documents related to the consultation/retention role provided to the Specified Health Care Provider by Defendant**

B. For each Specified Health Care Provider identified in the PFS (regardless of whether included in Section III(A) above or not), please state how much money you have paid to them from 2000 through the date of removal, whether for expenses, honoraria, fees, or any other payment, for each calendar year, and produce the 1099s or, if unavailable, other documents or data sufficient to evidence such payments.

C. For each of the Implanting/Prescribing Health Care Providers identified in Section III(B) above, please identify or provide all documentation detailing the services for which the Specified Health Care Provider was paid from 2000 through the date of removal including but not limited to consulting agreements and contracts.

D. For each Specified Health Care Provider(s) identified in the PFS, please state whether they attended any Defendant-sponsored luncheons, dinners, CME, conferences or events ("Programs") relating to Mirena from 2000 through the date of removal. If your answer is "Yes," please state:

Identity of the Specified Health Care Provider	**Title, location and date of the Program attended**	**Topic of the Program**	**All speakers at the Program**	**Please provide or identify the agenda/brochure for the Program**

E. Please identify the person or persons who provided information responsive to Section III or any of its subparts, giving their name and, address, and telephone number indicating whether said person is currently an employee of Defendants and/or any of its subsidiaries and the dates of employment.

_____

_____

F. If available, please identify the person or persons or entity or entities that authored, maintained, and/or disseminated, the documents responsive to Section III.A, giving their name, address, telephone number indicating whether said person is currently an employee of Defendants and/or any of its subsidiaries or contractors or vendor and the dates of employment.

_____

_____

IV. PLAINTIFF'S SPECIFIED HEALTH CARE PROVIDER'S IMPLANTING/PRESCRIBING PRACTICES

For each Specified Health Care Provider identified in the PFS please state and produce the following:

A. Do you have or have you had access to any database or information which purports to track the dispensing/prescribing practices of any Implanting/Prescribing Health Care Providers listed in the PFS with respect to Mirena from 2000 through the date of removal.

_____Yes _____No

If your answer is "yes", please produce or identify the database or document that captures that information and the name of the department, division, contractor, vendor or other entity that authored or maintained the database or document that capture the information:

_____

_____

B. Please identify the person or persons who provided information responsive to Section IV or any of its subparts.

_____

_____

V. PLAINTIFF'S MEDICAL CONDITION

A. Other than in connection with any adverse event report, have you initiated contact with any of Plaintiff's physicians concerning Plaintiff's injuries?

_____Yes _____No

B. Other than in connection with any adverse event report, have you been contacted by Plaintiff, any of her physicians, or anyone on behalf of Plaintiff concerning Plaintiff (other than counsel for Plaintiff)?

_____Yes _____No

C. If your answer to A or B above is "Yes", please state the name, address and telephone number of these individuals:

Name	**Address**	**Phone**

D. Please produce any non-privileged documents that reflect any communication between Plaintiff, any of her physicians, or anyone on behalf of Plaintiff (other than counsel for Plaintiff) and you concerning Plaintiff.

E. Please produce a copy of any MedWatch form and any other adverse event reporting document, form, line item listing or other such information whether internal or not, that refers or relates to Plaintiff, including back-up documentation concerning Plaintiff and any evaluation or investigation you did concerning the Plaintiff.

F. If you cannot identify or provide a Med Watch form or other adverse event reporting documentation for plaintiff, please provide an explanation.

G. Please identify the person or persons who provided information responsive to Section V or any of its subparts.

_____

_____

VI. ADVERTISING

A. Aside from national advertising (i.e., advertising buys that were not directed in any way to specific regions), did you advertise Mirena in the Media Market in which Plaintiff resided at, or within three (3) years preceding the time she had the Mirena implanted?

_____Yes _____No

If your answer is "Yes," please provide the following information:

Identity of the Advertisement	**Nature of media (print or television)**	**Identify the media outlet**	**Dates that advertisements ran**

Please provide or identify true and accurate copies of any advertisement identified above.

B. Aside from national advertising, did you advertise Mirena in the Media Market of any of the Implanting/Prescribing Health Care Providers' office locations listed on the PFS at, or within three (3) years of, the time that Plaintiff's Mirena was implanted?

_____Yes _____No

If your answer is "Yes," please provide the following information:

Identity of the Advertisement	**Nature of media (print or television)**	**Identify the media outlet**	**Dates that advertisements ran; Prescriber/Dispenser on PFS within 100 miles**

Please provide or identify true and accurate copies of any advertisement identified above.

C. Was the Plaintiff registered with any program owned, operated or controlled by Defendant whereby Plaintiff received electronic communications concerning Mirena?

_____Yes _____No

If your answer is "Yes", identify or produce documents describing such program and reflecting any communications with the Plaintiff.

_____

VIII. DOCUMENTS

To the extent you have not already done so, please produce a copy of all documents and things in your possession, custody and control that fall into the categories listed below:

1. Any document sent to or received from any of Plaintiff's Specified Health Care Provider(s) relating to Mirena, subject to the limitations and exceptions described in this DFS.

2. Any document reflecting any actual communication between you and Plaintiff's Specified Health Care Provider(s) concerning the topics identified in Section II.B, subject to the limitations and exceptions described in this DFS.

3. Any documents reflecting any contacts or actual communications between you and any of Plaintiff's Specified Health Care Provider(s) regarding Mirena, subject to the limitations and exceptions described in this DFS.

4. Any document which reflects or purports to describe the Implanting/Prescribing practices of any of Plaintiff's Implanting/Prescribing Health Care Providers relating to Mirena, subject to the approval or agreement of the owner of the prescribing data to release the data.

5. Any and all documentation relating to your retention and/or compensation of any of Plaintiff's Specified Health Care Provider(s) as a Mirena "key opinion leader," "thought leader," member of a "speaker's bureau," "clinical investigator," or "consultant."

6. Any and all documents requested or referred to in Sections I-VII, above.

DECLARATION

I am authorized to make this Declaration on behalf of Defendant. The information provided in the foregoing Defendant Fact Sheet has been compiled by employees and legal counsel for Defendant. Although I do not have personal knowledge of all of the information set forth therein, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, understanding, and belief formed after due diligence and reasonable inquiry.

_____	_____	_____
Signature	Print Name	Date