

**FILED**

SEP 15 2011

~~Carol E. Higbee, P.J. Cv.~~

In re PELVIC MESH LITIGATION/  
GYNECARE,

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION, ATLANTIC COUNTY

CIVIL ACTION

Case No. 291 CT  
Master Case 6341-10

Hon. Carol E. Higbee, P.J. Cv.

**CASE MANAGEMENT ORDER NO. 5  
(PFS/ ETHICON DEFENDANTS' DFS  
ENABLING ORDER)**

**THIS MATTER** having come before the Court on July 21, 2011, and counsel for Plaintiffs and counsel for Ethicon, Inc. and Johnson & Johnson ("Defendants") having been present and for good cause shown,

IT IS ON THIS 15 day of Sept, 2011,

**ORDERED** as follows,

1. For all cases filed as of the date of this Order (with the exception of cases in which plaintiffs have been deposed), Plaintiffs shall provide completed Plaintiff Fact Sheets ("PFS," annexed hereto as Exhibit 1) based on the number of cases being handled by the plaintiffs' counsel, as follows:

- a. 10 or fewer cases = 45 days
- b. 20 or fewer cases = 60 days
- c. 30 or fewer cases = 75 days
- d. Greater than 30 cases = 90 days

2. Plaintiffs and their counsel shall make a good faith effort to serve the completed PFS on a rolling basis to avoid unnecessary burden on Defendants that would result if all PFS statements are served upon Defendants on the same or last day of the periods set forth in Paragraph 1, above.

3. Defendants shall produce completed Defendants' Fact Sheets ("DFS", annexed hereto as Exhibit 2) in response to materially completed corresponding PFS's referenced in Paragraph 1, above, within 60 days of receipt.

4. For all cases filed after the date of this Order, Plaintiffs shall provide a completed PFS, no later than 45 days after the date of filing their complaint, and Defendants shall served a completed DFS within 45 days of service of the completed PFS.

5. For the plaintiffs who have been deposed, Defendants shall serve DFS forms within 60 days after the entry of this Order. Defendants have requested completed PFS forms for these plaintiffs and the parties will meet and confer with regard to the extent to which truncated Plaintiff Fact Sheets will be provided.

6. The parties met and conferred and understand that the timing of service of the PFS and the scope of certain of the information that may need to be gathered to complete the corresponding DFS may vary significantly. The parties have represented that they shall grant reasonable requests for extensions as needed, on a case-by-case basis.

7. Service of all PFS and DFS shall be made via email and hardcopy to the attorney(s) designated by Defendants, the designated Plaintiffs' Liaison Counsel, and the lead plaintiffs counsel of record for the individual case, respectively.

Associated document productions shall be made simultaneously consistent with the format agreed to by the parties. Defendants' liaison counsel and Plaintiffs' liaison counsel shall jointly maintain a list/log tracking service dates for PFS and DFS forms.

8. Production of Defendants' Fact Sheets shall not be delayed due to technical deficiencies in a PFS (e.g., missing telephone number, economic information to be supplied), but Plaintiffs understand that certain information must be supplied by Plaintiffs in the PFS in order for Defendants to provide a substantive response and Plaintiffs agree that missing information, whether substantive or "technical," must be supplied within a reasonable time period after service of the deficient PFS.

9. Liaison Plaintiffs' counsel (on behalf of all Plaintiffs' counsel) hereby consent to the disclosure of the individual names and law firm names of all counsel representing Plaintiffs in this litigation, in unredacted form, in adverse event reports that Defendants produce to Plaintiffs as part of the DFS response process. Plaintiffs' counsel (both liaison and non-liaison counsel) acknowledge and agree that no additional consent forms are necessary to authorize this disclosure. This paragraph shall be binding upon all counsel for Plaintiffs in pending and future-filed cases in this litigation. In the event that the reporting party of an adverse event is an attorney who does not represent a Plaintiff in this litigation, and the appropriate authorization cannot be obtained from that reporting attorney, then the adverse event report will be produced with only the name and identifying information of that reporting attorney redacted. Plaintiffs reserve the right to move at a later date for an unredacted copy of the adverse event report.

10. Case Management Order No. 3, entered and filed on June 1, 2011, is hereby amended as follows:

a. The following language is hereby added at the end of Paragraph 3:

“The parties further agree that if Defendants contest service, they shall raise that in the Short Form Answer or that defense shall be waived.”

b. A revised Master Short Form Complaint (annexed hereto as Exhibit 3) hereby replaces the Master Short Form Complaint previously served in this matter on June 2, 2011. The Master Short Form Complaint dated June 2, 2011 shall be removed from the Court’s website. The revised Master Short Form Complaint shall be posted on the Court’s website at: <http://www/judiciary.state.nj.us/masstort/forms/index.htm>. All individual complaints filed after the date of entry of this Order shall utilize the revised Master Short Form Complaint. The remaining provisions of Case Management Order No. 3 remain in full force and effect.

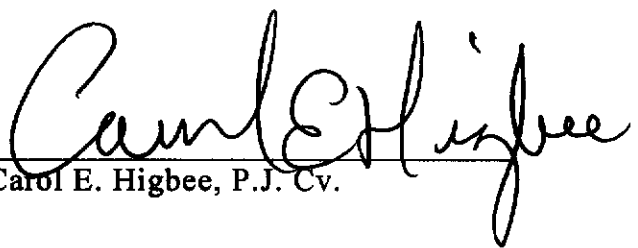
  
\_\_\_\_\_  
Carol E. Higbee, P.J. Cv.

Exhibit A

IN RE: PELVIC MESH/GYNECARE  
LITIGATION

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION: ATLANTIC COUNTY

CASE NO. 291 CT  
MASTER CASE 6341-10

### **PLAINTIFF FACT SHEET**

Please provide the following information for each individual on whose behalf a claim is being made. Please answer every question to the best of your knowledge. In completing this Fact Sheet, you are under oath and must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details requested, please provide as much information as you can. You must supplement your responses within a reasonable time if you learn that they are incomplete or incorrect in any material respect. If you are completing the Fact Sheet for someone who has died or who cannot complete the Fact Sheet him/herself, please answer as completely as you can for that person.

The Fact Sheet shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order. A completed Fact Sheet shall be considered interrogatory answers pursuant to Rule 4:18 of the New Jersey Rules of Civil Procedure and as responses to requests for production pursuant to Rule 4:18 of the New Jersey Rules of Civil Procedure. The questions and requests for production contained in the Fact Sheet are non-objectionable and shall be answered without objection.

In filling out this form, please use the following definitions:

"Healthcare provider" means any doctor, physician, surgeon, pharmacist, hospital, clinic, center, physician's office, infirmary, medical or diagnostic laboratory, or other facility that provides medical care or advice, and any pharmacy, x-ray department, radiology department, laboratory, physical therapist or physical therapy department, rehabilitation specialist, chiropractor, or other persons or entities involved in the diagnosis, care and/or treatment of you.

"You" or "Your" refer to the person who received a pelvic mesh product manufactured by Ethicon, Inc. and who is identified in Question I. 1 (d) below.

"Gynecare Mesh Product(s)" refers to any pelvic mesh product manufactured by Ethicon, Inc. that was implanted in you.

To the extent that the form does not provide enough space to complete your responses or answers, please attach additional sheets as necessary.

**I. BACKGROUND INFORMATION**

1. Please state:

a. Case caption: \_\_\_\_\_

b. Docket number: \_\_\_\_\_

c. Court in which case was originally filed: \_\_\_\_\_

d. Full name of the person who received the Gynecare Mesh Product, including maiden name:

\_\_\_\_\_

e. Full name and address of the person completing this form, if different from the person listed in 1 (a) above, and the relationship of the person completing this form to the person listed in 1 (a) above:

\_\_\_\_\_

\_\_\_\_\_

f. If completing this form in a representative capacity, please state whether you were appointed by a court, which court appointed you, and the date of your appointment: \_\_\_\_\_

\_\_\_\_\_

g. If you represent a decedent's estate, please state the date of the decedent's death:

\_\_\_\_\_

h. The name and address of the attorney representing you in this case: \_\_\_\_\_

\_\_\_\_\_

2. Your Social Security Number: \_\_\_\_\_

3. Your date and place of birth: \_\_\_\_\_

4. Your current residence address: \_\_\_\_\_

\_\_\_\_\_

5. Identify all individuals who currently live or have lived with you at your current address, their relationship to you, and the dates of residence. \_\_\_\_\_

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6. If you have lived at your current address for less than 10 years, provide each of your prior residence addresses from 2000 to the present:

Prior Address	Dates You Lived At This Address	People Who Lived With You At This Address/ Relationship To You

7. Have you ever been married? Yes \_\_\_ No \_\_\_

If Yes provide the names and addresses of each spouse and the inclusive dates of your marriage to each person. \_\_\_\_\_

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8. Do you have children? Yes \_\_\_ No \_\_\_

If Yes, please provide the following information with respect to each child:



9. Have you had any pregnancies other than those that resulted in the births of your children identified above?

Yes \_\_\_ No \_\_\_ If Yes, provide the date and the outcome of each pregnancy:

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10. Identify all secondary and post-secondary schools you attended, starting with high school and please provide the following information with respect to each:



11. Please provide the following information for your employment history over the past 10 years:

12. Have you ever served in any branch of the military? Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes, please provide the following information:

a. Branch and dates of service;; dates of your service, rank upon discharge and the type of discharge you received: \_\_\_\_\_  
\_\_\_\_\_

b. Were you discharged from the military at any time for any reason relating to your medical, physical, or psychiatric condition? Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes, state what that condition was: \_\_\_\_\_

13. To the best of your knowledge, as an adult, have you been convicted of, or plead guilty to, a felony and/or crime of fraud or dishonesty? Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes, please set forth where, when and the felony and/or crime:  
\_\_\_\_\_  
\_\_\_\_\_

## **II. CLAIM INFORMATION**

1) Do you claim to have been implanted with a pelvic mesh product manufactured by Ethicon, Inc. (hereafter referred to in these questions as the "Gynecare Mesh Product(s)")? Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes:

a) Identify the Gynecare Mesh Product(s) that were implanted in you and provide the product code and lot number specific to that product, if known:  
\_\_\_\_\_

b) Please give the date that the Gynecare Mesh Product(s) was implanted in you:  
\_\_\_\_\_

2) Please identify the type of surgery that you received:

- a) TVT: \_\_\_\_\_
- b) TVT-O: \_\_\_\_\_
- c) TVT-Secur: \_\_\_\_\_
- d) Prolift Total: \_\_\_\_\_
- e) Prolift Anterior: \_\_\_\_\_
- f) Prolift Posterior: \_\_\_\_\_
- g) TVT Exact

- h) TVT Abbrevio
- i) Prolift + M Total: \_\_\_\_\_
- j) Prolift + M Anterior: \_\_\_\_\_
- k) Prolift + M Posterior: \_\_\_\_\_
- l) Prosima
- m) Other: \_\_\_\_\_

3) Identify to the best of your knowledge the medical condition(s) and symptoms you were experiencing, that led to the implantation of the Gynecare Mesh Product(s): \_\_\_\_\_

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4) a) Give the name and address of the doctor who implanted the Gynecare Mesh Product(s):

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b) Are you currently being treated by the surgeon identified above?

Yes \_\_\_\_\_ No \_\_\_\_\_

If No, what was the date of your last visit or consultation with the surgeon?

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5) To the best of your knowledge, were there any concurrent surgical procedures performed during the surgery in which the Gynecare Mesh Products were utilized? If so please identify the concurrent procedure(s) and the doctor(s) who performed them:

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6) Give the name and address of the hospital or other healthcare facility where the Gynecare Mesh Product(s) was implanted: \_\_\_\_\_

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7) Prior to implantation, did you receive any **written or verbal** information or instructions regarding the Gynecare Mesh Product(s), including any risks or complications that might be associated with the use of the product(s)? Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes:

a) Provide the date you received the information or instructions: \_\_\_\_\_

b) Identify by name and address the person(s) who provided the information or instructions: \_\_\_\_\_

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c) If you have copies of the written information or instructions you received, please attach copies to your response.

8) To the best of your knowledge, was the Gynecare Mesh Product(s) that was implanted in you ever removed, in whole or in part?

Yes \_\_\_\_\_ No \_\_\_\_\_ I Don't Know \_\_\_\_\_

If Yes:

a) On what date, where and by whom (doctor) was the Gynecare Mesh Product(s), or any portion of it, removed? \_\_\_\_\_

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b) Explain why you consented to have the Gynecare Mesh Product(s), or any portion of it, removed? \_\_\_\_\_

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c) To the best of your knowledge, does any medical treater, physician or anybody else on your behalf have possession of any portion of the Gynecare Mesh Product(s) that was previously implanted in you and removed?

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9) To the best of your knowledge, if all or part of the Gynecare Mesh Product(s) remain implanted in you:

Has any doctor recommended removal of the Gynecare Mesh Product(s)?

Yes \_\_\_\_ No \_\_\_\_

If Yes, Identify by name and address the doctor who recommended removal and state your understanding of why the doctor recommended removal:

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10) Do you claim that you suffered bodily injuries as a result of the Gynecare Mesh Product(s)?

Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes:

a) Describe the bodily injuries, conditions and/or symptoms that you claim resulted from the Gynecare Mesh Product(s)?

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b) When is the first time you experienced bodily injuries, conditions and/or symptoms you have listed above that you now relate to the Gynecare Mesh Product(s)?

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- c) For each bodily injury, condition and/or symptom you now claim to have experienced relating to the Gynecare Mesh Product(s), please state approximately when you first saw a health care provider for each of those bodily injuries, name of provider and diagnosis, if any, provided:

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- d) Are you currently experiencing symptoms that you relate to your claimed bodily injuries?

Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes, please describe your current symptoms in detail

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- e) Are you currently seeing, or have you ever seen a doctor or healthcare provider for any of the bodily injuries, conditions and/or symptoms listed above?

Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes, please list all doctors you have seen for treatment of any of the bodily injuries you have listed above.

Name of Doctor		

f) Were you hospitalized at any time for the bodily injuries, conditions and/or symptoms you listed above?

Yes \_\_\_\_\_ No \_\_\_\_\_ If Yes, please provide the following:

Hospitalization Details		

11) To the best of your knowledge, have you been diagnosed with the following:

- a) Vaginal Prolapse: Yes \_\_\_\_\_ No \_\_\_\_\_
- b) Uterine Prolapse: Yes \_\_\_\_\_ No \_\_\_\_\_
- c) Rectocele: Yes \_\_\_\_\_ No \_\_\_\_\_
- d) Cystocele: Yes \_\_\_\_\_ No \_\_\_\_\_
- d) Enterocele: Yes \_\_\_\_\_ No \_\_\_\_\_
- e) Urinary incontinence: Yes \_\_\_\_\_ No \_\_\_\_\_
- f) Fecal Incontinence: Yes \_\_\_\_\_ No \_\_\_\_\_
- g) Urethral Hypermobility: Yes \_\_\_\_\_ No \_\_\_\_\_
- h) Interstitial Cystitis: Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes, to (a)-(h) above identify the doctor who communicated the diagnosis, the date of the diagnosis, and the course of treatment recommended:

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12) Are you making a claim for lost wages or lost earning capacity?

Yes \_\_\_\_\_ No \_\_\_\_\_ If Yes, please answer the following:

a) State the annual gross income you derived from your employment for each year, beginning five years prior to your surgery until the present:

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13) Are you making a claim for lost out-of-pocket expenses?

Yes \_\_\_\_\_ No \_\_\_\_\_ If Yes, please identify and itemize all out-of-pocket expenses you have incurred: \_\_\_\_\_

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14) Are you claiming mental and/or emotional damages?

Yes \_\_\_\_\_ No \_\_\_\_\_ If Yes, what mental and/or emotional damages do you claim and what do you attribute them to?

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If you are claiming mental and/or emotional damages, provide the following information for each provider (including but not limited to primary care physicians, psychiatrist, psychologists, therapists, and/or counselors) from whom you have sought treatment for your psychological, psychiatric or emotional conditions at any time:

Name	Address	Condition treated	Dates treated	Medications Prescribed




15) Has anyone filed a loss of consortium claim in connection with your lawsuit regarding the Gynecare Mesh Product(s)?

Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes: Identify by name and address the person who filed the loss of consortium claim, and state the relationship of that person to you.: \_\_\_\_\_

\_\_\_\_\_

16) Have you or anyone acting on your behalf, other than your attorneys, had any communication, oral or written, with any of the defendants or their representatives?

Yes \_\_\_\_\_ No \_\_\_\_\_ I Don't Know \_\_\_\_\_

If Yes, set forth the date of the communication, the method of communication, the name of the person with whom you communicated, and the substance of the communication between you and any defendants or their representatives:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**III. MEDICAL BACKGROUND**

1) Provide your current age: \_\_\_\_\_ Height \_\_\_\_\_ Weight \_\_\_\_\_

2) At the time you received the Gynecare Mesh Product(s), please state:

Your age \_\_\_\_\_ Your approximate weight \_\_\_\_\_

3) In chronological order, list any and all surgeries or hospitalizations you had **BEFORE** implantation of the Gynecare Mesh Product(s) for treatment of a gynecological, urological, abdominal and/or colo-rectal condition, excluding child births. Identify by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and provide the approximate date(s) for each:

	Date(s)	Healthcare Provider (Name and Street Address)

**[Attach additional sheets as necessary to provide the same information for any and all surgeries leading up to implantation of the Gynecare Mesh Product(s)]**

4) In chronological order, list any and all surgeries or hospitalizations you had **AFTER** the implantation of the Gynecare Mesh Product(s) for treatment of a gynecological, urological, abdominal, colo-rectal and/or mesh-related condition, excluding child births. Identifying by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and provide the approximate date(s) for each:

	Date(s)	Healthcare Provider (Name and Street Address)

	Name of	Doctor or Healthcare Provider Involved (including address)

- 5) To the extent not already provided in the charts above, provide the name, address, and telephone number of any internal or family doctor, surgeon or hospital from which you have received medical advice and/or treatment for the past 10 years:

		Approximate Date/Year of Visit

- 6) To the best of your knowledge, have you ever been diagnosed by a doctor or another health care provider with any of the following:

	Yes	No
Bleeding or clotting disorders		
Cancer		
Chronic obstructive pulmonary disease/COPD/chronic lung disease/Chronic coughing		
Complications related to childbirth		
Crohn's Disease, Irritable Bowel Syndrome, Ulcerative Colitis, Chronic Diarrhea or disease of the gut, intestines, or bowel		
Connective Tissue Disorder		
Diabetes		
Diverticulitis		
Fistula		
Hernia		
Malnutrition		
Obesity		
Pelvic Tumors or Fibroids		
Peripheral vascular disease or peripheral arterial disease		
Psychological/Mental/Emotional Conditions		
Recurrent constipation		

- 7) For each condition for which you answered Yes in the previous chart, or otherwise identified above, please provide the information requested below (attach additional sheets as needed):

Condition	Onset	Duration	Attending Physician	Current Status of Condition

- 8) Have you experienced menopause? Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes, at what age did it begin? \_\_\_\_\_

- 9) Have you undergone vaginal estrogen therapy, hormone therapy, or systemic estrogen replacement therapy (ERT)? Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes,

- a) Were you receiving vaginal estrogen therapy, hormone therapy, or systemic estrogen replacement therapy at the time of your implantation surgery?

Yes \_\_\_\_\_ No \_\_\_\_\_

- b) Please provide the type of therapy you received, date(s) of the therapy, and the name and address of the healthcare provider providing the therapy.

\_\_\_\_\_  
\_\_\_\_\_

- 10) Have you received a hysterectomy? If so please state the doctors' name, city and state and date.

\_\_\_\_\_  
\_\_\_\_\_

- 11) Do you now or have you ever smoked tobacco products? Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes:

- a) Provide the dates you smoked?

\_\_\_\_\_

- b) How much do/did you smoke?

\_\_\_\_\_

- 12) Other than the implantation of the Gynecare Mesh Product(s) that are the subject of your lawsuit, have you had implanted inside of your body any other medical product of any kind, whether a mesh product or other device? Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes, please provide the following information:

- a) Product Name: \_\_\_\_\_

- b) Date of Procedure Placing it and name and address of Doctor who placed it:

\_\_\_\_\_

- c) Condition sought to be treated through placement of the device :

\_\_\_\_\_

- d) Any complications you encountered with the medical product or procedure :

\_\_\_\_\_

- e) Does that product remain implanted inside of you today? Yes \_\_\_\_\_ No \_\_\_\_\_

- 13) List each prescription medication you have taken for more than 3 months at a time, within the last 3 years prior to the implantation of the Gynecare Mesh Product until the present, giving the name and address of the pharmacy where you received/filled the medication, the reason you took the medication, and the approximate dates of use.

			APPROXIMATE DATES OF USE

**IV. INSURANCE INFORMATION**

- 1) Provide the following information, to the best of your knowledge, for any past or present medical insurance coverage within the last 10 years:

		Type of Coverage	Date of Coverage

- 2) Are you receiving Medicare benefits due to age, disability, conditions or any other reason or basis?

Yes \_\_\_\_\_ No \_\_\_\_\_

The date on which you first began receiving such benefits: \_\_\_\_\_

*[Please note: if you are not currently a Medicare-eligible beneficiary, but become eligible for Medicare during the pendency of this lawsuit, you must supplement your response at that time. This information is necessary for all parties to comply with Medicare regulations. See 42 U.S.C. 1395y(b)(8), also known as Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 and 42 U.S.C. 1395y(b)(2) also known as the Medicare Secondary Payer Act.]*

- 3) Has Medicare or Medicaid, provided medical coverage to you or paid medical bills on your behalf in the last (10) years?

Yes \_\_\_\_\_ No \_\_\_\_\_ If Yes, please specify the following:

a) Medicare/Medicaid: \_\_\_\_\_

b) Address: \_\_\_\_\_

c) Dates of Service: \_\_\_\_\_

*[Please note: if you are not currently a Medicare-eligible beneficiary, but become eligible for Medicare during the pendency of this lawsuit, you must supplement your response at that time. This information is necessary for all parties to comply with Medicare regulations. See 42 U.S.C.*

*1395y(b)(8), also known as Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 and 42 U.S.C. 1395y(b)(2) also known as the Medicare Secondary Payer Act.]*

4) Have you ever been denied life insurance for reasons relating to your health?

Yes \_\_\_\_\_ No \_\_\_\_\_ If Yes, please state when the denial occurred, the name of the life insurance company, and the company's reason for denial: \_\_\_\_\_

\_\_\_\_\_

5) Have you personally paid or incurred any medical expenses that are related to any condition that you claim or believe was caused by a Gynecare Mesh Product and for which you seek recovery in the action you have filed?

Yes \_\_\_\_\_ No \_\_\_\_\_

If "Yes," state the total amount of such expenses at this time: \$ \_\_\_\_\_

6) Has your insurer, or any other entity or person, paid or incurred any medical expenses that are related to any condition that you claim or believe was caused by your use of a Gynecare Mesh Product and for which you seek recovery in the action you have filed?

Yes \_\_\_\_\_ No \_\_\_\_\_

If "Yes," state the total amount of such expenses at this time: \$ \_\_\_\_\_

#### **V. PRIOR CLAIM INFORMATION**

1) Have you filed a lawsuit or made a claim in the last 10 years, other than in the present suit relating to any bodily injury?

Yes \_\_\_\_\_ No \_\_\_\_\_ If Yes, please specify the following:

a) Court in which suit/claim filed or made: \_\_\_\_\_

b) Case/Claim Number: \_\_\_\_\_

c) Nature of Claim/Injury: \_\_\_\_\_

2) Have you applied for workers' compensation (WC), Social Security disability (SSI or SSD) benefits, or other state or federal disability benefits within the past 10 years?

Yes \_\_\_\_\_ No \_\_\_\_\_ If Yes, please specify the following:

a) Date (or year) of application: \_\_\_\_\_



- b) Type of benefits sought \_\_\_\_\_
- c) Agency/Insurer from which you sought the benefits: \_\_\_\_\_
- d) The nature of the claimed injury/disability: \_\_\_\_\_
- e) Whether the claim was accepted or denied: \_\_\_\_\_

3) Have you ever filed for bankruptcy?

Yes \_\_\_\_\_ No \_\_\_\_\_ If Yes, please specify the following:

- a) Court in which petition was filed: \_\_\_\_\_
- b) Case/claim number: \_\_\_\_\_
- c) Resolution of case: \_\_\_\_\_

**VI. FACT WITNESSES**

1) Please identify all persons who you believe possess information concerning your injury(ies) and current medical conditions, other than your healthcare providers, and please state their name address and his/her/their relationship to you:


**VII. ELECTRONICALLY STORED INFORMATION**

For the three years prior to implantation of the Gynecare Mesh Product(s) to present, please identify any websites that you own, maintain, use for social networking, instant messaging, tweeting, blogging, or otherwise posting messages on-line including MySpace and Facebook where you have posted anything with regard to your lawsuit, claims or the Gynecare Mesh Product(s), aside from communications with your attorneys, and provide the name or identity used by you in connection with those websites or postings.

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**VIII. AUTHORIZATIONS**

Provide ONE (1) SIGNED ORIGINAL copy of each of the records authorization forms attached as Ex. A, leaving blank the name to whom the release is directed, authorizing Ethicon, Inc. and/or its attorneys or agents to obtain those records identified in the authorizations, and send those executed authorizations immediately to:

**The Marker Group, Inc.**  
13105 Northwest Freeway  
Suite 300  
Houston, TX 77040

713.460.9070 *main*  
713.934.2586 *fax*

## **IX. DOCUMENTS**

State whether you have any of the following documents in your possession, custody, and/or control. If you do, please provide a true and correct copy of any such documents, with this completed Fact Sheet.

- a) If you were appointed by a court to represent the plaintiff in this lawsuit, produce any documents demonstrating your appointment as such.
- i. Not Applicable \_\_\_\_\_
  - ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- b) If you represent the estate of a deceased person in this lawsuit, produce a copy of the decedent's death certificate and autopsy report (if applicable).
- i. Not Applicable \_\_\_\_\_
  - ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- c) Produce any communications in your possession (sent or received) concerning the Gynecare Mesh Product(s), including e-mails, letters, blog entries and newsletters. Social media websites, including but not limited to Facebook, MySpace, Twitter, Friendster, are not included within this request and will be addressed later.
- i. Not Applicable \_\_\_\_\_
  - ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- d) Produce all documents or records in your possession relating to the bodily injuries, conditions and/or symptoms identified in your responses to questions II. (3), (3)(a), (10) and (11) of this Fact Sheet.
- i. Not Applicable \_\_\_\_\_
  - ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- e) Produce all documents or records in your possession relating to the surgeries, conditions and/or injuries identified in your responses to questions III. (3), (4) and (6) of this Fact Sheet.
- i. Not Applicable \_\_\_\_\_
  - ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_

- f) If you are advancing a claim for emotional or psychological injuries, produce all documents or records in your possession which refer or relate to any psychological, psychiatric, counseling, mental health treatment that you have received in the last 10 years.
- i. Not Applicable
  - ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- g) Produce all documents or records in your possession relating to the prescriptions identified in your response to question III. (13) of this Fact Sheet.
- i. Not Applicable \_\_\_\_\_
  - ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- h) Produce documents, including notes, diary or journal entries, and sufficient photographs, DVDs, videos, or other media to show: (1) the conditions which led to the surgery in which you received a Gynecare Mesh Product, or (2) the injuries or conditions for which you claim relief in this lawsuit. This request is limited to the time period beginning three years prior to your surgery until the present.
- i. Not Applicable \_\_\_\_\_
  - ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- i) Produce any Gynecare Mesh Product packaging, labeling, advertising, patient brochures, or any other Gynecare Mesh Product -related items in your possession.
- i. Not Applicable \_\_\_\_\_
  - ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- j) Produce all documents concerning any communication between you and the Food and Drug Administration (FDA) or between you and any employee or agent of the Defendants, regarding the Gynecare Mesh Product(s) at issue.
- i. Not Applicable \_\_\_\_\_
  - ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_

- k) Produce all documentation in your possession of correspondence or communication between Ethicon, Inc., Johnson & Johnson (or any of its related companies or divisions) and any of your doctors, healthcare providers, and/or you relating to the Gynecare Mesh Product(s).
- i. Not Applicable \_\_\_\_\_
- ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- l) Produce any and all documentation in your possession of any instructions or warnings you received prior to implantation of any Gynecare Mesh Product(s) concerning the risks and/or benefits of your surgery, including but not limited to any risks and/or benefits associated with the Gynecare Mesh Product(s).
- i. Not Applicable \_\_\_\_\_
- ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- m) Produce any and all documents reflecting the product code and lot number of the Gynecare Mesh Product(s) you received.
- i. Not Applicable \_\_\_\_\_
- ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- n) If you claim lost wages or lost earning capacity, copies of your federal and state tax returns for the 5 years prior to your surgery until the present.
- i. Not Applicable \_\_\_\_\_
- ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- o) Produce any and all statements by any party or any other person with knowledge relevant to this lawsuit, including their agents, servants, employees, officers or directors, regarding the Plaintiff and her condition, excluding work product.
- i. Not Applicable \_\_\_\_\_
- ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- p) Produce any and all documents regarding monies expended or expenses incurred for hospitals, doctors, nurses, x-rays, medicines and other health care related to the injuries and/or conditions you allege in this action.

- i. Not Applicable \_\_\_\_\_
  - ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- q) Produce any and all documents which itemize any and all other losses or expenses not otherwise set forth, incurred as a result of your injury and/or condition which forms the basis of this action.
- i. Not Applicable \_\_\_\_\_
  - ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- r) Produce any and all documents which identify money which you have received as a result of your injury and/or condition which forms the basis of this lawsuit.
- i. Not Applicable \_\_\_\_\_
  - ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_
- s) Produce any and all settlement agreements, releases and forms of payment relating to any other legal proceeding related to your claims and alleged injuries.
- i. Not Applicable \_\_\_\_\_
  - ii. The documents are attached \_\_\_\_\_ [OR] I have no documents \_\_\_\_\_

**SWORN DECLARATION**

Plaintiff, \_\_\_\_\_, deposes and states as follows:

I certify under penalty of perjury that all of the information provided in this Fact Sheet is true and correct to the best of my knowledge, information and belief; I have supplied all the documents requested in Section IX of this Fact Sheet to the extent that such documents are in my possession, custody, or control; and I have supplied the records authorizations requested in Section VIII of this Fact Sheet.

Dated: \_\_\_\_\_

\_\_\_\_\_  
Signature

**EXHIBIT A**



**AUTHORIZATION AND CONSENT  
TO RELEASE RECORDS AND PROTECTED HEALTH INFORMATION  
(Excluding psychotherapy notes)**

Name of Individual:  
Social Security Number:  
Date of Birth:

Provider Name: \_\_\_\_\_

TO:           All physicians, hospitals, clinics and institutions, pharmacists and other healthcare providers

                  The Veteran's Administration and all Veteran's Administration hospitals, clinics, physicians and employees

                  The Social Security Administration

                  The Internal Revenue Service

                  Open Records, Administrative Specialist, Department of Workers' Claims

                  All employers or other persons, firms, corporations, schools and other educational institutions

The undersigned individual hereby authorizes each entity included in any of the above categories to disclose and furnish to **Butler, Snow, O'Mara, Stevens & Cannada, PLLC, P. O. Box 6010, Ridgeland, MS 39158; Riker, Danzig, Scherer, Hyland & Perretti LLP, Headquarters Plaza, One Speedwell Avenue, P.O. Box 1981, Morristown, New Jersey 07962-1981; and The Marker Group, Inc., 13105 Northwest Freeway, Suite 300, Houston, Texas 77040;** and their authorized representatives, true and correct copies of all records, reports, files, documents, correspondence, memoranda and all other information related to the physical and mental health of the undersigned individual, regardless of the form of such information, including, without limitation, all notes of physicians, nurses, psychologists, counselors, dentists and other persons who have provided or who are providing health care to the undersigned individual, all radiology, pathology (including HIV test results, genetic testing information, and alcohol and drug abuse treatment) and other diagnostic test and laboratory results, records and reports, all prescription records, all surgical procedure records and reports, all dental records, all histories and summaries, all forms and other information related to admission of the undersigned to or discharge of the undersigned from a clinic, hospital or other health care facility, all surgical procedure and other consent forms, all bills, invoices, claim forms, records and other payment information, including payment by Medicaid/Medicare and other public assistance programs, insurance companies and by other persons. Notwithstanding the broad scope of the above disclosure request, the undersigned does not authorize the disclosure of "psychotherapy notes" as such term is defined by the Health Insurance Portability and Accountability Act, 45 CFR §164.501.

The undersigned also authorizes the disclosure of all records, reports, files, documents, correspondence, memoranda and all other information related to employment of the undersigned, including attendance reports, performance reports, W-2 and W-4 forms, medical reports and/or any and all other records relating to my past and present employment, and all educational records, including all courses taken, degrees obtained, and attendance records.

Further, to the extent such records currently exist and are in the Provider's possession, employment records, workers' compensation records, disability records, social security records, and insurance records, including Medicare/Medicaid and other public assistance claims applications, statements, eligibility material, claims or claim disputes, resolutions and payments, medical records provided as evidence of services provided, and any other documents or things pertaining to services furnished under Title XVII of the Social Security Act or other forms of public assistance (federal, state, local, or other). This listing is not meant to be exclusive.

The above list of types of records and other information to be disclosed is intended to be illustrative and not exhaustive. This authorization does not authorize ex parte communication concerning same.

- This authorization provides for the disclosure of the above-named patient's protected health information for purposes of the following litigation matter: \_\_\_\_\_ v. *Ethicon Women's Health and Urology, et al.*
- The undersigned individual is hereby notified and acknowledges that any health care provider or health plan disclosing the above requested information may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs this authorization.
- The undersigned individual is hereby notified and acknowledges that he or she may revoke this authorization by providing written notice either to **Butler, Snow, O'Mara, Stevens & Cannada, PLLC, Attention: Michael Brown, Butler Snow Privacy Officer, P.O. Box 6010, Ridgeland, Mississippi, 3915**, or **Riker, Danzig, Scherer, Hyland & Perretti LLP, attention: Maha Kabbash, Headquarters Plaza, One Speedwell Avenue, P.O. Box 1981, Morristown, New Jersey 07962-1981** and/or to one or more entities listed in the above categories, except to the extent that any such entity has taken action in reliance on this authorization.
- The undersigned is hereby notified and acknowledges he or she is aware of the potential that protected health information disclosed and furnished to the recipient pursuant to this authorization is subject to re-disclosure by the recipient for the purposes of this litigation in a manner that will not be protected by the Standards for the Privacy of Individually Identifiable Health Information contained in the HIPAA regulations (45 CFR §§164.500-164.534).
- The undersigned is hereby notified that he/she is aware that any and all protected health information disclosed and furnished to Butler, Snow, O'Mara, Stevens & Cannada, PLLC; Riker, Danzig, Scherer, Hyland & Perretti LLP; and/or The Marker Group, Inc., pursuant to this authorization will be shared with any and all co-defendants in the matter of \_\_\_\_\_ v. *Ethicon Women's Health and Urology, et al* and is subject to re-disclosure by the recipient for the purposes of this litigation in a manner that will not be protected by the Standards for the Privacy of Individually Identifiable Health Information contained in the HIPAA regulations (45 CFR §§164.500-164.534).

- I understand that information disclosed under this authorization could relate to, and I hereby authorize the disclosure of, information regarding treatment and testing for drug or alcohol abuse, Acquired Immunodeficiency Syndrome (AIDS), Human Immunodeficiency Virus (HIV), sexually transmitted diseases, Sickle Cell Anemia, Tuberculosis and Genetic testing and counseling.
- I further understand that, pursuant to applicable state law, I may have a right to receive a copy of this authorization as provided in 45 CFR 164.524.
- A photocopy of this authorization shall be considered as effective and valid as the original, and this authorization will remain in effect until the later of: (i) the date of settlement or final disposition of \_\_\_\_\_ v. Ethicon Women's Health and Urology, et al. or (ii) five (5) years after the date of signature of the undersigned below.

I have carefully read and understand the above and do hereby expressly and voluntarily authorize the disclosure of all of my above information to Butler, Snow, O'Mara, Stevens & Cannada, PLLC, P. O. Box 6010, Ridgeland, MS 39158; Riker, Danzig, Scherer, Hyland & Perretti LLP, Headquarters Plaza, One Speedwell Avenue, P.O. Box 1981, Morristown, New Jersey 07962-1981; The Marker Group, Inc., 13105 Northwest Freeway, Suite 300, Houston, Texas 77040; and/or and their authorized representatives, by any entities included in the categories listed above.

Date: \_\_\_\_\_

\_\_\_\_\_  
Signature of Individual or Individual's Representative

Individual's Name and Address:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Printed Name of Individual's Representative (If applicable)

\_\_\_\_\_  
Relationship of Representative to Individual (If applicable)

\_\_\_\_\_  
Description of Representative's authority to act for Individual (If applicable)

This authorization is designed to be in compliance with the Health Insurance Portability and Accountability Act, and the regulations promulgated thereunder, 45 CFR Parts 160 and 164 (collectively, "HIPAA").

**AUTHORIZATION AND CONSENT  
TO RELEASE PSYCHOTHERAPY NOTES**

Name of Individual:  
Social Security Number:  
Date of Birth:

Provider Name: \_\_\_\_\_

TO: All physicians, hospitals, clinics and institutions, pharmacists and other healthcare providers  
The Veteran's Administration and all Veteran's Administration hospitals, clinics, physicians and employees

The Social Security Administration

The Internal Revenue Service

Open Records, Administrative Specialist, Department of Workers' Claims

All employers or other persons, firms, corporations, schools and other educational institutions

The undersigned individual hereby authorizes each entity included in any of the above categories to furnish and disclose to **Butler, Snow, O'Mara, Stevens & Cannada, PLLC, P. O. Box 6010, Ridgeland, MS 39158; Riker, Danzig, Scherer, Hyland & Perretti LLP, Headquarters Plaza, One Speedwell Avenue, P.O. Box 1981, Morristown, New Jersey 07962-1981; and The Marker Group, Inc., 13105 Northwest Freeway, Suite 300, Houston, Texas 77040;** and their authorized representatives, with true and correct copies of all "psychotherapy notes", as such term is defined by the Health Insurance Portability and Accountability Act, 45 CFR §164.501. Under HIPAA, the term "psychotherapy notes" means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint or family counseling session and that are separated from the rest of the individual's record. This authorization does not authorize ex parte communication concerning same.

- This authorization provides for the disclosure of the above-named patient's protected health information for purposes of the following litigation matter: \_\_\_\_\_ v. *Ethicon Women's Health and Urology, et al.*
- The undersigned individual is hereby notified and acknowledges that any health care provider or health plan disclosing the above requested information may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs this authorization.
- The undersigned individual is hereby notified and acknowledges that he or she may revoke this authorization by providing written notice to either **Butler, Snow, O'Mara, Stevens & Cannada, PLLC, Attention: Michael Brown, Butler Snow Privacy Officer, P.O. Box 6010, Ridgeland, Mississippi, 3915,** and/or **Riker, Danzig, Scherer, Hyland & Perretti LLP, attention Maha Kabbash, Headquarters Plaza, One Speedwell Avenue, P.O. Box 1981, Morristown, New**

Jersey 07962-1981, and/or to one or more entities listed in the above categories, except to the extent that any such entity has taken action in reliance on this authorization.

- The undersigned is hereby notified and acknowledges that he or she is aware of the potential that protected health information disclosed and furnished to the recipient pursuant to this authorization is subject to re-disclosure by the recipient for the purposes of this litigation in a manner that will not be protected by the Standards for the Privacy of Individually Identifiable Health Information contained in the HIPAA regulations (45 CFR §§164.500-164.534).
- The undersigned is hereby notified that he/she is aware that any and all protected health information disclosed and furnished to Butler, Snow, O'Mara, Stevens & Cannada, PLLC , Riker, Danzig, Scherer, Hyland & Perretti LLP, and/or The Marker Group, Inc. pursuant to this authorization will be shared with any and all co-defendants in the matter of \_\_\_\_\_  
\_\_\_\_\_ v. *Ethicon Women's Health and Urology, et al.* and is subject to re-disclosure by the recipient for the purposes of this litigation in a manner that will not be protected by the Standards for the Privacy of Individually Identifiable Health Information contained in the HIPAA regulations (45 CFR §§164.500-164.534).
- A photocopy of this authorization shall be considered as effective and valid as the original, and this authorization will remain in effect until the later of: (i) the date of settlement or final disposition of \_\_\_\_\_ v. *Ethicon Women's Health and Urology, et al.* or (ii) five (5) years after the date of signature of the undersigned below.

I have carefully read and understand the above and do hereby expressly and voluntarily authorize the disclosure of all of my above information to Butler, Snow, O'Mara, Stevens & Cannada, PLLC, P. O. Box 6010, Ridgeland, MS 39158, Riker, Danzig, Scherer, Hyland & Perretti LLP, Headquarters Plaza, One Speedwell Avenue, P.O. Box 1981, Morristown, New Jersey 07962-1981, and The Marker Group, Inc., 13105 Northwest Freeway, Suite 300, Houston, Texas 77040 and their authorized representatives, by any entities included in the categories listed above.

Date: \_\_\_\_\_

\_\_\_\_\_  
Signature of Individual or Individual's Representative

Individual's Name and Address:

\_\_\_\_\_  
Printed Name of Individual's Representative (If applicable)

\_\_\_\_\_  
Relationship of Representative to Individual (If applicable)

\_\_\_\_\_  
Description of Representative's authority to act for Individual (If applicable)

This authorization is designed to be in compliance with the Health Insurance Portability and Accountability Act, and the regulations promulgated thereunder, 45 CFR Parts 160 and 164 (collectively, "HIPAA").



## Medicare

Beneficiary Services: 1-800-MEDICARE (1-800-633-4227)  
TTY/TDD: 1-877-486-2048

This form is used to advise Medicare of the person or persons you have chosen to have access to your personal health information.

**Where to Return Your Completed Authorization Forms:**

After you complete and sign the authorization form, return it to the address below:

**Medicare BCC, Written Authorization Dept.  
PO Box 1270  
Lawrence, KS 66044**

**For New York Medicare Beneficiaries ONLY**

The New York State Public Health Law protects information that reasonably could identify someone as having HIV symptoms or infection, and information regarding a person's contacts. Because of New York's laws protecting the privacy of information related to alcohol and drug abuse, mental health treatment, and HIV, there are special instructions for how you, as a New York resident, should complete this form.

- For question 2A, check the box for *Limited Information*, even if you want to authorize Medicare to release any and all of your personal health information.
- Then proceed to question 2B.

**Medicare BCC, Written Authorization Dept.  
PO Box 1270  
Lawrence, KS 66044**

**Instructions for Completing Section 2B of the Authorization Form:**

*Please select one of the following options.*

- **Option 1** To include all information, in the space provided, write: "all information, including information about alcohol and drug abuse, mental health treatment, and HIV". Proceed with the rest of the form.
- **Option 2** To exclude the information listed above, write "Exclude information about alcohol and drug abuse, mental health treatment and HIV" in the space provided. *You may also check any of the remaining boxes and include any additional limitations in the space provided.* For example, you could write "payment information". Then proceed with the rest of the form.

If you have any questions or need additional assistance, please feel free to call us at 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Sincerely,

**1-800-MEDICARE**  
Customer Service Representative

Encl.

**Information to Help You Fill Out the  
"1-800-MEDICARE Authorization to Disclose Personal Health Information" Form**

By law, Medicare must have your written permission (an "authorization") to use or give out your personal medical information for any purpose that isn't set out in the privacy notice contained in the Medicare & You handbook. You may take back ("revoke") your written permission at any time, except if Medicare has already acted based on your permission.

If you want 1-800-MEDICARE to give your personal health information to someone other than you, you need to let Medicare know in writing.

If you are requesting personal health information for a deceased beneficiary, please include a copy of the legal documentation which indicates your authority to make a request for information. (For example: Executor/Executrix papers, next of kin attested by court documents with a court stamp and a judge's signature, a Letter of Testamentary or Administration with a court stamp and judge's signature, or personal representative papers with a court stamp and judge's signature.) Also, please explain your relationship to the beneficiary.

Please use this step by step instruction sheet when completing your "1-800-MEDICARE Authorization to Disclose Personal Health Information" Form. Be sure to complete all sections of the form to ensure timely processing.

**1. Print the name of the person with Medicare.**

Print the Medicare number exactly as it is shown on the red, white, and blue Medicare card, including any letters (for example, 123456789A).

Print the birthday in month, day, and year (mm/dd/yyyy) of the person with Medicare.

- 2. This section tells Medicare what personal health information to give out. Please check a box in 2a to indicate how much information Medicare can disclose. If you only want Medicare to give out limited information (for example, Medicare eligibility), also check the box(es) in 2b that apply to the type of information you want Medicare to give out.**
- 3. This section tells Medicare when to start and/or when to stop giving out your personal health information. Check the box that applies and fill in dates, if necessary.**
- 4. Medicare will give your personal health information to the person(s) or organization(s) you fill in here. You may fill in more than one person or organization. If you designate an organization, you must also identify one or more individuals in that organization to whom Medicare may disclose your personal health information.**
-



5. The person with Medicare or personal representative must sign their name, fill in the date, and provide the phone number and address of the person with Medicare.

If you are a personal representative of the person with Medicare, check the box, provide your address and phone number, and attach a copy of the paperwork that shows you can act for that person (for example, Power of Attorney).

6. Send your completed, signed authorization to Medicare at the address shown here on your authorization form.
7. If you change your mind and don't want Medicare to give out your personal health information, write to the address shown under number six on the authorization form and tell Medicare. Your letter will revoke your authorization and Medicare will no longer give out your personal health information (except for the personal health information Medicare has already given out based on your permission).

You should make a copy of your signed authorization for your records before mailing it to Medicare.

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**1-800-MEDICARE Authorization to Disclose Personal Health Information**

Use this form if you want 1-800-MEDICARE to give your personal health information to someone other than you.

1. **Print Name** \_\_\_\_\_ **Medicare Number** \_\_\_\_\_ **Date of Birth** \_\_\_\_\_  
(First and last name of the person with Medicare) (Exactly as shown on the Medicare Card) (mm/dd/yyyy)

2. Medicare will only disclose the personal health information you want disclosed.

2A: Check only one box below to tell Medicare the specific personal health information you want disclosed:

Limited Information (go to question 2b)

Any Information (go to question 3)

2B: Complete only if you selected "limited information". Check all that apply:

Information about your Medicare eligibility

Information about your Medicare claims

Information about plan enrollment (e.g. drug or MA Plan)

Information about premium payments

Other Specific Information (please write below; for example, payment information)

3. Check only one box below indicating how long Medicare can use this authorization to disclose your personal health information (subject to applicable law—for example, your State may limit how long Medicare may give out your personal health information):

~~Disclose my personal health information indefinitely.~~

Disclose my personal health information for a specified period only  
beginning: (mm/dd/yyyy) \_\_\_\_\_ and ending: (mm/dd/yyyy) \_\_\_\_\_

**4. Fill in the name and address of the person(s) or organization(s) to whom you want Medicare to disclose your personal health information. Please provide the specific name of the person(s) for any organization you list below:**

1. Name:

Address: Butler, Snow, O'Meara, Steves & Cannada, PLLC, and Riker, Danzig, Scherer, Hyland & Perretti LLP, Headquarters Plaza, and The Market Group, Inc., and their authorized representatives, all c/o The Market Group, 135105 Northwest Freeway, Suite 300 Houston, Texas 77040

2. Name: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

3. Name: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

5.

**I authorize 1-800-MEDICARE to disclose my personal health information listed above to the person(s) or organization(s) I have named on this form. I understand that my personal health information may be re-disclosed by the person(s) or organization(s) and may no longer be protected by law.**

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Telephone Number

\_\_\_\_\_  
Date (mm/dd/yyyy)

Print the address of the person with Medicare (Street Address, City, State, and ZIP)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Check here if you are signing as a personal representative and complete below. Please attach the appropriate documentation (for example, Power of Attorney). This only applies if someone other than the person with Medicare signed above.

Print the Personal Representative's Address (Street Address, City, State, and ZIP)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Telephone Number of Personal Representative: \_\_\_\_\_

Personal Representative's Relationship to the Beneficiary: \_\_\_\_\_

**6. Send the completed, signed authorization to:**

**Medicare BCC, Written Authorization Dept.  
PO Box 1270  
Lawrence, KS 66044**

**7. Note:**

**You have the right to take back ("revoke") your authorization at any time, in writing, except to the extent that Medicare has already acted based on your permission. If you would like to revoke your authorization, send a written request to the address shown above.**

**Your authorization or refusal to authorize disclosure of your personal health information will have no effect on your enrollment, eligibility for benefits, or the amount Medicare pays for the health services you receive.**

**According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0930. The time required to complete this information collection is estimated to average 15 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.**

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**Social Security Administration  
Consent for Release of Information**

Form Approved  
OMB No. 0980-0566

**Instructions for Using this Form**

Complete this form only if you want us to give information or records about you, a minor, or a legally incompetent adult, to an individual or group (for example, a doctor or an insurance company). If you are the natural or adoptive parent or legal guardian, acting on behalf of a minor, you may complete this form to release only the minor's non-medical records. If you are requesting information for a purpose not directly related to the administration of any program under the Social Security Act, a fee may be charged.

**NOTE:** Do not use this form to:

- Request us to release the medical records of a minor. Instead, contact your local office by calling 1-800-772-1213 (TTY-1-800-325-0778), or
- Request information about your earnings or employment history. Instead, complete form SSA-7050-F4 at any Social Security office or online at [www.ssa.gov/online/ssa-7050.pdf](http://www.ssa.gov/online/ssa-7050.pdf).

**How to Complete this Form**

We will not honor this form unless all required fields are completed. An asterisk (\*) indicates a required field. Also, we will not honor blanket requests for "all records" or the "entire file." You must specify the information you are requesting and you must sign and date this form.

- Fill in your name, date of birth, and social security number or the name, date of birth, and social security number of the person to whom the information applies.
- Fill in the name and address of the individual (or organization) to whom you want us to release your information.
- Indicate the reason you are requesting us to disclose the information.
- Check the box(es) next to the type(s) of information you want us to release including the date ranges, if applicable.
- You, the parent or legal guardian acting on behalf of a minor, or the legal guardian of a legally incompetent adult, must sign and date this form and provide a daytime phone number where you can be reached.
- If you are not the person whose information is requested, state your relationship to that person. We may require proof of relationship.

**PRIVACY ACT STATEMENT**

Section 205(a) of the Social Security Act, as amended, authorizes us to collect the information requested on this form. The information you provide will be used to respond to your request for SSA records information or process your request when we release your records to a third party. You do not have to provide the requested information. Your response is voluntary; however, we cannot honor your request to release information or records about you to another person or organization without your consent.

We rarely use the information provided on this form for any purpose other than to respond to requests for SSA records information. However, in accordance with 5 U.S.C. § 552a(b) of the Privacy Act, we may disclose the information provided on this form in accordance with approved routine uses, which include but are not limited to the following: 1. To enable an agency or third party to assist Social Security in establishing rights to Social Security benefits and/or coverage; 2. To make determinations for eligibility in similar health and income maintenance programs at the Federal, State, and local level; 3. To comply with Federal laws requiring the disclosure of the information from our records; and, 4. To facilitate statistical research, audit, or investigative activities necessary to assure the integrity of SSA programs.

We may also use the information you provide when we match records by computer. Computer matching programs compare our records with those of other Federal, State, or local government agencies. Information from these matching programs can be used to establish or verify a person's eligibility for Federally-funded or administered benefit programs and for repayment of payments or delinquent debts under these programs.

Additional information regarding this form, routine uses of information, and other Social Security programs are available from our Internet website at [www.socialsecurity.gov](http://www.socialsecurity.gov) or at your local Social Security office.

**PAPERWORK REDUCTION ACT STATEMENT**

This information collection meets the requirements of 44 U.S.C. § 3507, as amended by section 2 of the Paperwork Reduction Act of 1995. You do not need to answer these questions unless we display a valid Office of Management and Budget control number. We estimate that it will take about 3 minutes to read the instructions, gather the facts, and answer the questions. **SEND OR BRING THE COMPLETED FORM TO YOUR LOCAL SOCIAL SECURITY OFFICE.** You can find your local Social Security office through SSA's website at [www.socialsecurity.gov](http://www.socialsecurity.gov). Offices are also listed under U.S. Government agencies in your telephone directory or you may call 1-800-772-1213 (TTY 1-800-325-0778). You may send comments on our time estimate above to: SSA, 6401 Security Blvd., Baltimore, MD 21235-6401. Send *only* comments relating to our time estimate to this address, not the completed form.



**AUTHORIZATION AND CONSENT  
TO RELEASE ADVERSE EVENT REPORTS**

I, \_\_\_\_\_, hereby authorize and consent to the release of any and all Adverse Event reports relating to my medical conditions and care at issue, and with my name unredacted, including but not limited to FDA MedWatch Reports and manufacturer-generated Issue Reports, to my counsel of record, as indicated below:

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

\_\_\_\_\_  
Signature of Individual or Representative

Date: \_\_\_\_\_

\_\_\_\_\_  
Printed Name of Representative and Relationship of Representative to Individual (if applicable)

\_\_\_\_\_  
Description of Representative's Authority (if applicable)

This Authorization and Consent is designed to be in compliance with regulations promulgated under 21 C.F.R. § 20.63.

Exhibit B



**In re PELVIC MESH / GYNECARE  
LITIGATION,**

**SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION, ATLANTIC COUNTY**

**CIVIL ACTION**

**Case No. 291 CT  
Master Case 6341-10**

**Hon. Carol E. Higbee, P.J. Cv.**

**DEFENDANTS' FACT SHEET**

**Plaintiff:** \_\_\_\_\_  
Name of Plaintiff

**Individual Case Docket No.** \_\_\_\_\_

For each case, the Gynecare defendants must complete this Fact Sheet. Each response must either provide the substantive information requested (and documents, as applicable), or in the event the substantive information requested cannot be provided, the response must provide a detailed explanation as to why the information cannot be provided, including the efforts made to obtain the requested information. This Fact Sheet shall be served in accordance with Case Management Order No. 5 setting forth the procedures for completion and exchange of this document.<sup>1</sup>

**I. CASE INFORMATION**

This defendant fact sheet pertains to the following case:  
Case Name:

**II. CONTACTS WITH TREATING AND EVALUATING PHYSICIANS**

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

As to each physician identified by Plaintiffs in response to the PFS who treated and/or evaluated plaintiff for pelvic organ prolapse, stress or urinary incontinence, and/or associated conditions that led to or resulted from the use of the Product(s), with whom the defendants were affiliated, consulted or otherwise had contact outside the context of sales representative contacts, set forth the following information:

**1. Identify the physician.**

<sup>1</sup> All references to Product(s), the device, surgical device, or implant includes each of the Ethicon polypropylene pelvic mesh products at issue in these matters, including but not limited to the Prolift, Prolift +M, Gynemesh, Prolene mesh, and TVT (all variations).

2. Identity and title of each of defendants' 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 drug or device samples, provided to the physician by any agent of any named defendant, including amounts, dates, and purpose.
6. For any device manufactured by any named defendant, 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 nature of the contact with and 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 any named defendant's products.
8. Set forth the number of procedures performed by the physician, to either implant or remove any of the products, products used, and the results of those procedures, to the extent known to defendants.
9. Set forth any contact between the defendants and the physician with regard to the plaintiff.
10. Set forth all information provided by the physician to the defendants with regard to the safety, use, or efficacy of the Product(s).

**B. SALES REPRESENTATIVE CONTACTS**

As to each sales representative who had any contact with an identified physician who implanted the identified device(s) or who performed any mesh revision or removal procedure on the plaintiff beginning five (5) years prior to the implantation surgery date, set forth the following:

1. Identity of physician.
2. Identity and last known address and telephone number of sales representative.
3. The work history and current relationship, if any, between the specified defendant(s) and the sales representative.
4. Identity of the sales representative's supervisor(s) during his/her employment for the response period.
5. The product(s) that the sales representative marketed, sampled, provided to, or otherwise presented to or discussed with the physician.
6. Identify all sales and marketing literature or other information utilized or referenced by the sales representative with regard to the product(s).
7. Set forth the details of all training and instruction provided to the sales representative with regard to the sale and marketing of the defendants' product(s).
8. Set forth all information provided by the sales representative to the physician with regard to the safety, use, or efficacy of the defendants' products.
9. Set forth all information provided by the physician to the sales representative with regard to the safety, use, or efficacy of the defendants' product(s).
10. Set forth all information provided by the physician to the sales representative, with regard to the plaintiff.
11. Set forth the date, and location of each operation or procedure performed on the plaintiff, which was attended at all by the sales representative; or whether the sales representative was present at the identified facility on the date of implantation.

12. State whether the sales representative 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 defendants' possession or control or which have been reviewed or analyzed by defendants, 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 number.

B. Identify any direct or indirect contact, either written or oral, between the plaintiff and any employee or representative of the defendants, including but not limited to pre-operative inquiries, and post-operative complaints.

C. Set forth the date, and location of each operation or procedure performed on the plaintiff, which was attended at all by any employee, agent, or contractor of any defendant, and identify the name and position of each person who attended.

D. 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.

E. Identify all written information with regard to the defendants' product(s) that were used to implant and/or implanted into the plaintiff, which were provided to the plaintiff and/or her physician, before the implantation of the defendants' product(s).

F. Identify all written information with regard to the defendants' product(s) that were used to implant and/or implanted into the plaintiff that were available to be provided but were not provided to the plaintiff and/or her physician.

G. Identify all marketing and advertising information that was publicly available or disseminated with regard to the defendants' product(s) that were used to implant and/or implanted into the plaintiff, on and before the date of implantation.

H. Set forth any information or knowledge defendants have with respect to research studies conducted on or that include information related to plaintiff's implant(s) or associated lot number(s).

I. If you contend that any person, entity, condition, or product, other than the defendants and their product(s), is a cause of the plaintiff's injuries, ("Alternate Cause") set forth:

- i) Identify the Alternate Cause with specificity.
- ii) Set forth the date and mechanism of alternate causation.

IV. MANUFACTURING INFORMATION

- A. Set forth the lot number(s) for the device(s) implanted into the plaintiff, as identified by Plaintiff in the PFS.
- B. Provide the Device History Record (a.k.a. Batch Record) for the lot. [The Batch Record will address both the finished goods and the component pieces and include a report detailing any nonconformities to the product specifications, if any.]

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. Identify and attach all records, documents, and information that refers or relates to the plaintiff in defendants' possession or control, to the extent not identified and attached in response to a prior question.
- C. Identify and attach any documents to or from plaintiff's physicians with regard to plaintiff and/or the product(s), to the extent not identified and attached in response to a prior question.
- D. Identify and attach any research or patient studies that were conducted using any lot number associated with any product used to implant and/or that was implanted into the plaintiff.

**ETHICON CERTIFICATION**

I hereby certify that I am an agent of Ethicon, Inc. authorized for the purposes of the matters *In Re Pelvic Mesh/ Gynecare Litigation- CT 291*, Atlantic County, New Jersey, to certify regarding the accompanying Response of Ethicon, Inc. and its Gynecare Division to Defendants' Fact Sheet that the matters stated therein are not within my personal knowledge, but the facts stated therein have been assembled by authorized employees and counsel for Ethicon, Inc. and I am informed that the facts stated therein are true. I hereby certify, in my authorized capacity as an agent for Ethicon, Inc., that the responses to the aforementioned Defendants' Fact Sheet are true and complete to the best of Ethicon, Inc.'s knowledge.

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Title:  
Ethicon, Inc.

**JOHNSON & JOHNSON CERTIFICATION**

I hereby certify that I am an agent of Johnson & Johnson authorized for the purposes of the matters *In Re Pelvic Mesh/ Gynecare Litigation- CT 291*, Atlantic County, New Jersey, to certify regarding the accompanying Response of Johnson & Johnson to Defendants' Fact Sheet that the matters stated therein are not within my personal knowledge, but the facts stated therein have been assembled by authorized employees and counsel for Ethicon, Inc. and I am informed that the facts stated therein are true. The facts stated therein were not obtained from Johnson & Johnson's files. I hereby certify, in my authorized capacity as an agent for Johnson & Johnson, that the responses to the aforementioned Defendants' Fact Sheet as compiled by Ethicon, Inc. are true and complete to the best of Johnson & Johnson's knowledge.

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Title:  
Johnson & Johnson