JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

MARGARET VICTORIA CAMAC

(b) County of Residence of First Listed Plaintiff Fulton, Georgia
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Aylstock, Witkin, Kreis & Overholtz, PLLC
17 E. Main St., Ste. 200, Pensacola, FL 32503. Phone: (850)

DEFENDANTS

ENDO PHARMACEUTICALS; et al.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

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- ☐ 151 Medicare Act
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- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
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- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

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PERSONAL INJURY
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- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
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- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
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- ☒ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
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- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
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- ☐ 446 Amer. w/Disabilities - Other
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- ☐ 510 Motions to Vacate Sentence

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- ☐ 620 Other Food & Drug
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- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
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- ☐ 690 Other

LABOR
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- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
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- ☐ 791 Empl. Ret. Inc. Security Act

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- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
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- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
28 USC 1332

Brief description of cause:
Personal Injury - Product Liability

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
04/01/2013

SIGNATURE OF ATTORNEY OF RECORD
/s/ James D. Barger

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA
PHILADELPHIA DIVISION

MARGARET VICTORIA CAMAC, Plaintiff, v. COOK GROUP, INC.; COOK INCORPORATED; COOK BIOTECH, INC; COOK UROLOGICAL INCORPORATED; COOK MEDICAL INC., ENDO PHARMACEUTICALS; AMERICAN MEDICAL SYSTEMS, INC.;, Defendants.	CIVIL ACTION: _____

COMPLAINT AND JURY DEMAND

COMES NOW MARGARET VICTORIA CAMAC as Plaintiff herein and hereby files this Complaint, showing the Court as follows:

PARTIES, JURISDICTION AND VENUE

1. Plaintiff is a citizen of Atlanta, Georgia.

2. Defendant Cook Group, Inc. is a corporation organized under the laws of Indiana, with a principal place of business at 750 N. Daniels Way, Bloomington, Indiana 47404-9120. Cook Group Incorporated was allegedly founded to help manage financial, legal and regulatory issues that emerged as the COOK companies expanded in the United States and abroad. http://www.cookmedical.com/profile.do?id=profile_cookgroup All acts and omissions of Cook Group, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments

and/or ownership. At all times material hereto, Cook Group, Inc. did business in Pennsylvania.

3. Defendant Cook Incorporated is a corporation organized under the laws of Indiana, with a principal place of business at 750 Daniels Way, P.O. Box 489, Bloomington, Indiana 47402. Cook Incorporated is allegedly also on the forefront of developing next generation technologies that advance combination drug/device and biologic/device design concepts. http://www.cookmedical.com/profile.do?id=profile_cookinc All acts and omissions of Cook Incorporated, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership. At all times material hereto, Cook Incorporated, Inc. did business in Pennsylvania.

4. Defendant Cook Biotech, Inc. is a corporation organized under the laws of Indiana, with a principal place of business at 1425 Innovation Place, West Lafayette, Indiana 47906. Cook Biotech was allegedly created to develop and manufacture biomaterials from natural tissue sources for use in medical products. The company purports to conduct research, development and manufacturing operations in a state-of-the-art facility. Cook Biotech operates its own processing and production line where natural tissues are transformed into acellular biomaterials. In cooperation with university researchers, Cook Biotech has developed a line of products that can remodel native tissues using a biomaterial made from porcine small intestinal submucosa (SIS). Several FDA-cleared products using this technology to dress wounds or to surgically repair soft tissues are currently available from COOK and its distributors. Numerous potential medical applications for products made from SIS and other natural tissues are under development. http://www.cookmedical.com/profile.do?id=profile_biotech All acts and

omissions of Cook Group, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership. At all times material hereto, Cook Biotech, Inc. did business in Pennsylvania.

5. Defendant Cook Urological Incorporated is a corporation organized under the laws of Indiana, with a principal place of business at 1100 West Morgan Street, P.O. Box 227, Spencer, IN 47460 Cook Urological is the global sales and marketing headquarters for the Urological and Women's Health strategic business units. Cook Urological was allegedly established to provide professionals in urologic healthcare with minimally invasive diagnostic and therapeutic technology. The company is recognized worldwide for innovation in stone management, diagnostic and therapeutic products for the urinary system, and biomaterials for the treatment of stress urinary incontinence. http://www.cookmedical.com/profile.do?id=profile_uro All acts and omissions of Cook Urological Incorporated as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership. At all times material hereto, Cook Group, Inc. did business in Pennsylvania.

6. Defendant Cook Medical, Inc. is a corporation organized under the laws of Indiana, with a principal place of business at 1025 W. Acuff Road, Bloomington, Indiana 47402-4195. Cook Medical Incorporated was allegedly established to offer a synchronized service for the efficient purchase and distribution of all Cook medical devices. With particular focus on lowering supply chain costs, the company coordinates price file access, purchase orders, ship points and accounts payable. http://www.cookmedical.com/profile.do?id=profile_cmi All acts and omissions of Cook Medical, Inc. as described herein were done by its agents, servants,

employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership. At all times material hereto, Cook Medical, Inc. did business in Pennsylvania.

7. Upon information and belief, the Cook Defendants individually or collectively make, use, offer for sale, sell in the United States, and/or import into the United States products used to treat pelvic organ prolapse and stress urinary incontinence including the Surgisis Biodesign system or line of pelvic products and related delivery devices.

8. Upon information and belief, Defendant Cook Group, Inc. is the parent company for all other named Defendants and did the following through its subsidiaries named herein: designed; secured clearance for sale; manufactured; labeled; marketed; distributed; sold; benefited financially from the sale; and placed into the stream of commerce the products implanted in Plaintiffs. Defendants, as such, are individually, jointly and severally liable to Plaintiffs.

9. Upon information and belief, and upon review of Defendants own combined website, Plaintiffs assert that the following Defendants' participated in placing the product implanted in Plaintiff into the stream of commerce causing her injuries: Cook Group, Inc. is the parent and nerve center of the Cook operations which, through its subsidiaries designed, tested, sought regulatory clearance, marketed, advertised, labeled, distributed and sold the subject medical device; Defendant Cook Incorporated participated in the development of the subject medical device; Defendant Cook Biotech, Inc. developed, with the aid of other co-Defendants, manufactured, sought regulatory clearance, marketed, advertised, labeled, distributed and sold the subject medical device; Defendant Cook Urological Incorporated with the aid of other co-Defendants, manufactured, sought regulatory clearance, marketed, advertised, labeled,

distributed and sold biomaterials for the treatment of stress urinary incontinence including the subject medical device; and Defendant Cook Medical, Inc. were the central and key agent in the distribution of Plaintiff's medical device.

10. Defendants COOK GROUP, INC., COOK INCORPORATED, COOK BIOTECH, IN., COOK UROLOGICAL INCORPORATED and COOK MEDICAL INC. share many of the same officers, directors and operations; and maintain ownership in the assets and/or liabilities relating to the design, manufacture, marketing, distribution and sale of the medical device line at issue in this litigation and shall be referenced collectively hereinafter as "Cook Defendants".

11. Defendant Endo Pharmaceuticals ("Endo") is a Pennsylvania corporation, with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317.

12. Defendant American Medical Systems ("AMS") is a Delaware corporation, with its principal place of business at 10700 Bren Road West, Minnetonka, Minnesota

13. Defendants Endo Pharmaceuticals and American Medical Systems share many of the same officers, directors and operations; and maintain ownership in the assets and/or liabilities relating to the design, manufacture, marketing, distribution and sale of the medical device line at issue in this litigation and shall be referenced collectively hereinafter as "Ethicon Defendants".

14. Defendants, when referenced collectively, shall hereinafter referred to as "Defendants".

15. Damages sought in this matter are in excess of $75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

16. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

17. Venue is proper in this District as the ENDO defendant is incorporated in Pennsylvania and are citizens with their principal place of business in this District and have assumed all liabilities and assets relating to the sale, implantation and ultimate injury caused by the medical device at issue in the instant suit.

18. Defendants conducted substantial business in Pennsylvania and in this District, distributes Pelvic Mesh Products in this District, receives substantial compensation and profits from sales of Pelvic Mesh Products in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District.

19. Defendants conducted business in the State of Pennsylvania through sales representatives conducting business in the State of Pennsylvania and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promotion and/or selling, either directly or indirectly, and/or through third parties or related entities, Pelvic Mesh Products; thus, there exists a sufficient nexus between Defendant forum contacts and the Plaintiff's claims to justify assertion of jurisdiction in Pennsylvania.

20. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of Pennsylvania such that requiring an appearance does not offend traditional notices of fair play and substantial justice.

FACTUAL BACKGROUND

Stress-Urinary Incontinence and Pelvic Organ Prolapse

21. Defendants promote their medical devices as devices intended to treat stress urinary incontinence and/or pelvic organ prolapse.

22. Stress urinary incontinence ("SUI") is the involuntary loss of urine during movement that puts pressure on the bladder, such as laughing, coughing, or sneezing, or during aerobic or strenuous exercise. Although incontinence is suffered by men and women, it is more common in women and can be caused by menopause or by physical changes that occur to the body during pregnancy or childbirth.

23. Childbirth, for example, can injure the pelvic floor muscles and ligaments that help support a woman's bladder. If these structures weaken, the bladder can move downward, pushing slightly out of the bottom of the pelvis toward the vagina. The movement of the bladder, or other pelvic organs, such as the urethra, cervix or rectum, is known as pelvic organ prolapse ("POP"). A prolapsed bladder can prevent the muscles that ordinarily force the urethra shut from squeezing as tightly as they should, resulting in an involuntary loss of urine.

24. Stress urinary incontinence can be embarrassing and uncomfortable. Pelvic organ prolapse is also uncomfortable and can interfere with urinary and defecatory functions, many daily activities, and sex.

25. Both SUI and POP are, in most cases, treatable. A woman who elects to have her SUI or POP surgically treated has several options. SUI, for example, can be corrected through traditional abdominal surgery using sutures to attach the urethra to a ligament in the pelvis (known as the "Burch procedure"). SUI can also be surgically addressed using synthetic materials such as suprapubic mid-urethral "slings" placed under the urethra to provide support

Similarly, POP can be corrected through traditional procedures via abdominal or transvaginal surgery. POP can also be surgically addressed using biologic, composite, or synthetic materials.

26. The surgical mesh products manufactured by Defendants are considered Class II medical devices.

27. Under the 510(k) process, a manufacturer must provide a premarket notification that allows the FDA to determine whether the device is substantially equivalent to a "predicate device." A predicate device is one that the FDA has placed into one of three classification categories and "cleared" for marketing.

28. Unlike Class III medical devices, such as an artificial heart or an Automated External Defibrillator, Class II devices do not require "approval" by the FDA. Whereas Class III devices cannot be sold until the manufacturer demonstrates to the FDA, through adequate and well-controlled clinical trials, that the proposed device is safe and effective, there is no such requirement for Class II devices. The "premarket notification" process -- for Class II devices – is not focused on whether the device is safe and effective, but rather is concerned with whether the proposed device is substantially equivalent to an existing predicate device that was already cleared for marketing by the FDA.

29. Defendants were aware, or should have been aware, of the dangers inherent in its transvaginal mesh products generally, notwithstanding the fact that these products were "cleared" for sale by the FDA.

Background on Cook Defendants Products

30. In or about 1999, Defendants began to market and sell products for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

31. Specifically, Cook Group, Incorporated, by and through its subsidiary, Cook Biotech, Inc., sought and secured 510K clearance on the following medical devices indicated and/or sold for the repair or restoration of stress urinary incontinence: Surgisis Biodesign Urethral Sling on September 23, 1999 and Surgisis Biodesign Tension-Free Urethral Sling on April 9, 2002. Cook Biotech, Inc. sought and secured 510K clearance on the following medical devices indicated and/or sold for the repair or restoration of pelvic floor repair: Surgisis Biodesign Anterior Pelvic Floor Graft; Surgisis Biodesign Posterior Pelvic Floor Graft; and Surgisis Biodesign Vaginal Erosion Repair Graft on September 23, 1999.

32. Defendants' products were derived largely from hernia mesh products, and were and are utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

33. Defendants' Pelvic Mesh Products were designed, patented, manufactured, labeled, marketed, and sold and distributed by the Defendants, at all times relevant herein.

34. Defendants' make the following assertions regarding their products:

> Surgisis Biodesign is not a new- graft or mesh, but a whole new category in the evolution of tissue repair. A breakthrough technology, it incorporates the best attributes of a biologic graft—**resistant to infection and complete remodeling**—with the added benefits of moderate price, ease of use and widespread availability. Surgisis Biodesign offers you a new level of assurance and, most important, contributes to an improved quality of life for your patient. http://www.cookmedical.com/bioNew/bio_overview.html.

35. Defendants' further assert the following about their Biodesign products: "And unlike synthetic mesh, **nothing is left permanently in the body to cause problems down the road**." http://www.cookbiodesign.com/for-patients/conditions/fistula/faqs.

36. On August 20, 2011, Defendants issued a communication to the FDA in advance of the September 2011 Advisory Committee Hearings regarding the investigation into the risks

associated with mesh for stress urinary incontinence and pelvic floor repair and/or pelvic floor prolapse. In its communication, Defendants assert regarding its non-cross linked biologic matrix that: "**[a]ny inflammation is localized in regions where small remnants of the synthetic suture used to affix the graft remain.**"

37. Contrary to Defendants assertions that its products are resistant to infection; result in complete remodeling, are limited in inflammatory response to area where synthetic sutures are/were utilized during surgery and will not cause any problem down the road, the following non-inclusive literature suggests otherwise:

A. In November of 2005, results from a study were published in the International Journal of Obstetrics & Gynecology relating to the comparison of the host response, architectural integration and tensile strength of polypropylene to porcine small intestine submucosa-derived implants including Defendants SIS products. Implants from the SIS group showed a short term increase in thickness in the first 14 days. **Formation of adhesions was significantly more extensive in the SIS group at 90 days. Tensile strength increased over time in both groups but was significantly lower in the SIS group. Implants in the SIS group showed inflammatory response.**

Konstantinovic ML., Lagae P., Zheng F., Verbeken EK., De Ridder D., Deprest JA. (2005). Comparison of host response to polypropylene and non-cross-linked porcine small intestine serosal-derived collagen implants in a rat model. *BJOG: An International Journal of Obstetrics & Gynecology*, 112(11),1554-1560.

B. In October of 2008, results from a study were published in the Archives of Gastroenterology relating to the comparison of the repair of induced abdominal wall defects with Defendants' Surgisis mesh and Covidien, Inc.'s Parietex. Both meshes induced skin erosions. There were peritoneal adhesions to the surface of both types of meshes after 30 and 60 days. **Meshes' shrinking correspond to 1/3 of the original size and Parietex caused less inflammatory process at the histologic evaluation.**

Baroncello JB., Czeczko NG., Malafaia O., Ribas-Filho JM., Nassif PA., Dietz AU. (2008). [The repair of abdominal defects in rabbits with Parietex and Surgisis meshes abdominal wall]. *Arquivos de Gastroenterologia*, 45(4), 323-9.

C. In November of 2008, results from a study were published in Urology relating to reports of intense local inflammatory reactions in patients undergoing pubovaginal sling or tape using a small intestinal submucosa graft. **After implantation of 16 standard pubovaginal sling or tension-free tape procedures for stress urinary incontinence, using the Cook 4-ply Stratasis or 8-ply Stratasis-TF system, 5 (31.3%) had intense suprapubic pain after surgery. One patient had induration of the mons pubis that required surgical drainage. One patient had vaginal inflammation, with expulsion of graft material. Other patients had intense rectus sheath inflammation, as confirmed on computed tomography. This study confirmed previous case reports of inflammatory complications of small intestinal submucosa leading to that institution's cessation of use of Defendants' products.**

John TT., Aggarwal N., Singla AK., Santucci RA. (2008). Intense inflammatory reaction with porcine small intestine submucosa pubovaginal sling or tape for stress urinary incontinence. *Urology,* 72(5), 1036-9.

D. In January of 2009, results from a study were published in the Journal of Biomedical Materials Research Part B relating to the evaluation of Defendants' Surgisis Gold to other materials including C.R. Bard, Inc.'s Permacol; Ethicon's Prolene mesh and Life Cell's Alloderm in the context of human mesothelial cells. **The results of the study indicate that Surgisis Gold was inferior in aiding in the growth and fibrinolytic activity of human mesothelial cells than other products.**

Wilshaw SP., Burke D., Fisher J., Ingham E. (2009). Investigation of the antiadhesive properties of human mesothelial cells cultured in vitro on implantable surgical materials. *Journal of Biomedical Materials Research Part D: Applied Biomaterials,* 88(1), 49-60.

E. In October of 2011, results from a study were published in the Archives of Gastroenterology relating to the comparison of different biologic materials regarding relative implant integration, shrinkage, and foreign body reaction. Relating to **Defendants' Surgisis, the integration of its product was insufficient and could detached easily from the underlying tissue; the penetration of fibroblasts and vessels was limited; foreign body reaction was pronounced, leading to persistent granulomatous inflammation; and shrinkage was excessive in comparison to all other products. Other products yielded sufficient anti-adhesion and elicited no foreign body reaction.**

Petter-Puchner AH., Fortelny RH., Silic K, Brand J., Gruber-Blum S., Redl H. (2011). Biologic hernia implants in experimental intraperitoneal onlay mesh plasty repair: the impact of proprietary collagen processing methods and fibrin sealant application on tissue integration. *Surg Endosc,* 25(10), 3245-52.

F. In February of 2012, results from a study were published in Hernia relating to the comparison of different biologic meshes including Defendants' Surgisis Gold regarding the relative performance and efficacy as between two non-crosslinked meshes and two crosslinked prostheses. **Major complications seen with Defendants' product included: that it appeared to be wrinkled and folded by excessive shrinkage, eliciting severe adhesions and a pronounced local inflammation, characterized by foreign body giant cells. The multilayer design was preserved but disintegrated by transversal movement of layers against each other.**

de Castro Brás LE., Shurey, S., Sibbons, PD. (2012). Evaluation of crosslinked and non-crosslinked biologic prostheses for abdominal hernia repair. *Hernia,* 16(1), 77-89.

G. In September of 2012, results from a study were published in Biomaterials relating to the clinical performance of biomaterials in the context of comparing leukocyte activation by commercially available biologic surgical materials and define the extent manufacturing variables influence down-stream response. The data demonstrated **Defendants' Surgisis Biodesign which was implanted in Plaintiff showed excessive leukocyte activation and was significantly more pro-inflammatory as compared to the other products analyzed. High degrees of leukocyte activation lead to poor material/patient compliance, accelerated degeneration and graft rejection.**

Bryan N., Ashwin H., Smart N., Bayon Y., Scarborough N., Hunt JA. (2012). The innate oxygen dependant immune pathway as a sensitive parameter to predict the performance of biological graft materials. *Biomaterials*, 33(27), 6380-92.

Background on Endo Pharmaceuticals

38. AMS developed technology to diagnose and treat conditions related to the pelvic health of both men and women. AMS manufactured, marketed, advertised, promoted and sold synthetic mesh systems worldwide including the system implanted in Plaintiff.

39. On April 11, 2011, in a press release issued announcing its agreement to acquire AMS, Dave Holveck, President and Chief Executive Officer of Endo, said: '

This acquisition is a great step in achieving Endo's core strategy. We are creating a company uniquely positioned to respond to the changing healthcare environment and the competitive, rapidly consolidating industry landscape. Through the acquisition of AMS,

> we will gain scale in devices and services, and will be positioned as a leading provider of healthcare solutions in the field of pelvic health, with a full spectrum of product offerings ranging from pharmaceuticals to medical devices.

40. Under the terms of the merger agreement, which was approved by the Boards of Directors of both companies, Endo acquire 100 percent of the shares of AMS for $30.00 per share or a total cash consideration of $2.9 billion in cash, which includes the assumption and repayment of $312 million of AMS debt.

41. On June 17, 2011, Endo completed the acquisition of AMS for approximately $2.4 billion in aggregate consideration, including $2.3 billion in cash paid for equity, $71.6 million related to existing AMS stock-based compensation awards and certain other amounts, at which time AMS became a wholly-owned subsidiary of ENDO. AMS's shares were purchased at a price of $30.00 per share. The acquisition has been accounted for as a business combination (in accordance with ASC 805 Business Combinations) and, as such, the AMS assets acquired and liabilities assumed have been recorded at their respective fair values. The determination of fair value for the identifiable tangible and intangible assets acquired and liabilities assumed requires extensive use of accounting estimates and judgments.

42. On June 20, 2011, Endo issued another press release in which it announced the completion of its acquisition of AMS. Endo announced that on April 11, 2011, it entered into a definitive agreement to acquire AMS, a leading provider of world-class devices and therapies for male and female pelvic health, for approximately $2.9 billion in cash.

43. On August 9, 2011, the Associated Press reported that Endo advised that its medical device and service revenue totaled $76.3 million, of which $26.8 million came from American Medical Systems.

44. On the same day, Endo issued another press release stating in pertinent part:

> Our devices and services sales were $76.3 million for the second quarter and demonstrate our increased diversification. Revenues from our device and services segment include $26.8 million from our recent acquisition of American Medical Systems, (AMS), which furthers Endo's evolution from a product-driven company to a healthcare solutions provider. We believe that AMS strengthens Endo's core urology franchise, diversifies revenue and improves gross margin.

45. In reporting the completion of the acquisition of AMS, ENDO provided an Unaudited Pro Forma Condensed Combined Financial Statement which makes clear that Endo purchased all of AMS's liabilities including all that may be related to products liability claims. The following representation in pertinent part was made regarding the accounting of ENDO's acquisition of AMS's product liability related liabilities:

> Reflects (1) an adjustment to remove AMS's $4.4 million product liability reserve. In accordance with ASC 805, the fair value of the pre-acquisition contingency related to product liability cannot be reasonably estimated or determined.

46. Endo acknowledges its exposure to liability in this very litigation, stating in its Form 8-K that it filed with the SEC that "[s]urgical mesh was the subject of a public health notification in 2009. Following the completion of the AMS Acquisition, we will be subject to liabilities arising out of these cases."

47. Discussing its acquisition of AMS, Endo purports in its Form 10-Q it filed with the SEC to assume $1,105,694,000 in "total liabilities."

48. In the same filing, Endo again acknowledges litigation arising from AMS vaginal mesh products, adding that "we may be subject to liabilities arising out of these cases, and will be responsible for the cost of managing these cases. We intend to contest all of these cases vigorously."

Plaintiff's Medical History and Experience

49. Plaintiff Margaret Victoria Camac was implanted with the Surgisis Biodesign Tension-Free Urethral Sling, the Stratasis Tension-Free Urethral Sling and the In-Fast Sling ("Products") during surgery performed at Emory University Hospital in Snellville, Georgia.

50. The Products were implanted in Plaintiff to treat her pelvic organ prolapse and/or stress urinary incontinence, the use for which the Products were designed, marketed and sold.

51. As a result of having the Products implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone and will undergo corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

52. Plaintiff in the exercise of due diligence, could not have reasonably discovered the cause of her injuries including but not limited to the defective design and/or manufacturing of the products implanted inside of her until recently.

Factual Allegations Common to All Counts

53. Defendants' pelvic mesh products incorporate a monofilament polypropylene mesh intended for the treatment of pelvic organ prolapsed and/or stress urinary incontinence. Despite claims that this material is inert, the emerging scientific evidence suggests that this material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendants' pelvic mesh products containing this material. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Moreover, the mesh migrates within the surrounding tissues causing irreparable damage to the tissue including nerve endings residing

within the tissues. Damaged nerve endings do not regenerate and lead to debilitating neuromas suffered by patients such as Plaintiff.

54. Defendants' pelvic mesh products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ prolapse or stress urinary incontinence, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing pelvic mesh products.

55. The Defendants have marketed and sold its pelvic mesh products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable cash and non-cash benefits to health care providers. Also utilized are documents, brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of the products.

56. Contrary to the Defendants' representations and marketing to the medical community and to the patients themselves, the Defendants' Medical Devices have high failure, injury, and complication rates, fails to perform as intended, requires frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making it defective under the law. The Defendants have consistently underreported and withheld information about the propensity of its pelvic mesh products to fail and cause injury and complications, and has misrepresented

the efficacy and safety of its products and, through various means and media, actively and intentionally been misleading the FDA, the medical community, patients, and the public at large.

57. Defendants have known and continue to know that some of the predicate products for their Medical Devices had high failure and complication rates, resulting in the recall of some of these predicate devices; that there were and are differences between the Defendants' Medical Devices and some or all of the predicate products, rendering them unsuitable for designation as predicate products; that significant differences exist and existed between the Medical Devices and their predecessor and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and that the Medical Devices were and are causing numerous patients severe injuries and complications. The Defendants suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a result, the Defendants actively and intentionally misled and continues to mislead the public, including the medical community, health care providers and patients, into believing that the Medical Devices and the procedures for the implantation were and are safe and effective, leading to the prescription for and implantation of the Medical Devices into Plaintiff.

58. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Medical Devices.

59. Defendants failed to design and establish a safe, effective procedure for removal of their pelvic mesh products; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Medical Device.

60. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation have existed at all times relevant as compared to the Medical Devices.

61. The Medical Device(s) were at all times utilized and implanted in a manner foreseeable to the Defendants, as Defendants generated the instructions for use, created the procedure for implanting the device, and trained the implanting physicians.

62. The Defendants provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Medical Devices, and thus increased the sales of the Medical Devices, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

63. The Medical Device(s) implanted into Plaintiff were in the same or substantially similar condition as it was when it left the possession of Defendants, and in the condition directed by and expected by the Defendants.

64. Plaintiff and her physicians foreseeably used and implanted Defendants' Medical Device(s), and did not misuse, or alter the Medical Device(s) in an unforeseeable manner.

65. The injuries, conditions, and complications suffered by women who have been implanted with Defendants' pelvic mesh products, include without limitation: mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, the recurrent prolapse of organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other

medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

66. The medical and scientific literature studying the effects of polypropylene pelvic mesh, like Defendants' pelvic mesh products, have examined each of these injuries, conditions, and complications and determined that they are, in fact, casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

67. Defendants misrepresented to the medical and healthcare community, Plaintiff, the FDA, and the public at large that the pelvic mesh products had been tested and were found to be safe and effective for the purposes of treating incontinence and/or prolapse.

68. These representations were made by Defendants with the intent of inducing Plaintiff, the medical community, and the public to recommend, prescribe, dispense, and purchase the Medical Device for use as a means of treatment for stress urinary incontinence and/or pelvic organ prolapse, all of which evinced an indifference to the health, safety, and welfare of Plaintiff.

69. Defendants acted unreasonably in failing to undertake its duties to properly know the qualities of their products and in representations to Plaintiff and/or to Plaintiff's healthcare providers, and concealed and intentionally omitted the following material information:

a. That the Medical Device was not as safe as other products and procedures available to treat incontinence and/or prolapse;

b. That the risk of adverse events with the Medical Device was higher than with other products and procedures available to treat incontinence and/or prolapse;

c. That the risk of adverse events with the Medical Device was not adequately tested and were known by Defendants;

d. That the limited clinical testing revealed the Medical Device had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

e. That Defendats failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;

f. That Defendants were aware of dangers in its pelvic mesh products, including the pelvic mesh systems, in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

g. That the pelvic mesh systems were dangerous and caused adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

h. That patients frequently would need revisionary surgery due to changes in the structure of the Medical Device that would cause it to be become loose, or shift position within the body.

i. That patients needed to be monitored more regularly than usual while using the Medical Device and that in the event the product needed to be removed that the procedure to remove them had a very high failure rate and/or needed to be performed repeatedly.

70. Defendants were under a duty to disclose to Plaintiff and her physicians the defective nature of the Medical Device, including, but not limited to, the heightened risks of erosion, failure and permanent injury.

71. Defendants had sole access to material facts concerning the defective nature of the Medical Device and its propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Medical Device.

72. Defendants' concealment and omissions of material facts concerning the safety of its pelvic mesh products were made to cause Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the Medical Device; and/or to mislead Plaintiff into reliance and cause Plaintiff to use the Medical Device.

73. At the time these representations were made by Defendants, and at the time Plaintiff used the Medical Device, she was unaware of the falsehood of these representations, and reasonably believed them to be true.

74. Defendants knew and had reason to know that the Medical Device could and would cause severe and grievous personal injury to their users, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

75. In reliance upon these false representations, Plaintiff was induced to, and did, use the Medical Device thereby sustaining severe and permanent personal injuries and damages.

76. Defendants knew or had reason to know that Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the Medical Device, as described in detail herein.

77. As a result of Defendants' research and testing or lack thereof, it distributed false information, including but not limited to assuring Plaintiff, the public, and Plaintiff's healthcare providers and physicians that the Medical Device was safe for use as a means of providing relief

from stress urinary incontinence and/or prolapse and was as safe or safer than other products and/or procedures available and on the market. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiff, and the public at large.

78. Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, Plaintiff's healthcare providers, and the FDA.

79. The information distributed to the public, the medical community, the FDA, and Plaintiff by Defendants included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Medical Device.

80. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the Medical Device specifically that it did not have dangerous and/or serious adverse health safety concerns, and that it was as safe as other means of treating stress urinary incontinence and/or prolapse.

81. Defendants intentionally failed to inform the public, including Plaintiff, of the high failure rate, including erosion, the difficulty of removing the Medical Device, and the risk of permanent injury.

82. Defendants chose to over-promote the safety, efficacy and benefits of the Medical Device instead.

83. Defendants' intent and purpose in making these misrepresentations was to deceive the public, the medical community, and Plaintiff; to gain the confidence of the public, the

medical community, and Plaintiff; to falsely assure them of the quality and fitness for use of the Medical Device; and induce Plaintiff, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Medical Device.

84. Defendants made claims and representations in documents it submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the Medical Device did not present serious health risks.

85. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

86. These representations, and others made by Defendants, were made with the intention of deceiving Plaintiff, Plaintiff's healthcare professionals, and other members of the healthcare community, and were made in order to induce Plaintiff, and her healthcare professionals, to rely on misrepresentations, and caused Plaintiff to purchase, rely, use, and request the Medical Device and her healthcare professionals to dispense, recommend, or prescribe the Medical Device.

87. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Medical Device to the public at large, for the purpose of influencing the sales of product known to be dangerous and defective, and/or not as safe as other alternatives.

88. Defendants utilized direct-to-consumer advertising to market, promote, and advertise the Medical Device.

89. At the time the representations were made, Plaintiff and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use

of the Medical Device. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts or Defendants' misrepresentations.

90. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of the Defendants' Medical Device(s), she would not have purchased, used, or relied on Defendants' Medical Device.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

91. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

92. Defendants had a duty to individuals, including Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Products.

93. Defendants were negligent in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Products.

94. As a direct and proximate result of Defendants' negligence, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages and other damages.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

95. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

96. The Products implanted in Plaintiff were not reasonably safe for their intended use and were defective as a matter of law with respect to their design.

97. As a direct and proximate result of the Products' aforementioned defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages and other damages.

98. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT III: STRICT LIABILITY - MANUFACTURING DEFECT

99. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

100. The Products implanted in Plaintiff were not reasonably safe for their intended use and were defective as a matter of law with respect to their manufacture.

101. As a direct and proximate result of the Products' aforementioned defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages and other damages.

102. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

103. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

104. The Products implanted in Plaintiff were not reasonably safe for their intended use and were defective as a matter of law due to their lack of appropriate and necessary warnings.

105. As a direct and proximate result of the Products' aforementioned defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages and other damages.

106. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT V: BREACH OF EXPRESS WARRANTY

107. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

108. Defendants made assurances to the general public, hospitals and health care professionals that the Products were safe and reasonably fit for their intended purpose.

109. Plaintiff and/or her health care providers chose the Products based upon Defendants' warranties and representations regarding the safety and fitness of the Products.

110. Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the Products were safe, merchantable and reasonably fit for their intended purpose.

111. Defendants breached these express warranties because the Products implanted in Plaintiff were unreasonably dangerous and defective and not as Defendants had represented.

112. Defendants' breach of their express warranties resulted in the implantation of unreasonably dangerous and defective products in Plaintiff's body, placing said Plaintiff's health and safety in jeopardy.

113. As a direct and proximate result of Defendants' breach of the aforementioned express warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages and other damages.

COUNT VI: BREACH OF IMPLIED WARRANTY

114. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

115. Defendants impliedly warranted that the Products were merchantable and were fit for the ordinary purpose for which they were intended.

116. When the Products were implanted in Plaintiff to treat her pelvic organ prolapse and stress urinary incontinence, they were being used for the ordinary purposes for which they were intended.

117. Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranty of merchantability in consenting to have the Products implanted in her.

118. Defendants breached these implied warranties of merchantability because the Products implanted in Plaintiff were neither merchantable nor suited for the intended uses as warranted.

119. Defendants' breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective Products in Plaintiff body, placing her health and safety in jeopardy.

120. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages and other damages.

COUNT VII: PUNITIVE DAMAGES

121. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

122. Defendants knew or should have known that the Products were defective and presented unreasonable risks of harm to Plaintiff.

123. Defendants' conduct as described in this Complaint, for which Plaintiff is entitled to recover compensatory damages, manifested a conscious indifference to, and/or flagrant disregard of, the safety of those persons who might foreseeably have been harmed by the Products, including Plaintiff, justifying the imposition of punitive damages.

WHEREFORE, Plaintiff demands a trial by jury, judgment against Defendants, jointly and severally, for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, and any other relief, monetary or equitable, to which they are entitled.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Dated: April 1, 2013.

BY: _____

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ATTORNEYS FOR PLAINTIFF

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

MARGARET VICTORIA CAMAC	:	CIVIL ACTION
v.	:	
ENDO PHARMACEUTICALS; et al.	:	NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ☑

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

4/1/2013	/s/ James D. Barger	Plaintiff
Date	**Attorney-at-law**	**Attorney for**
850-202-1010	850-916-7449	jbarger@awkolaw.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: MARGARET VICTORIA CAMAC

Address of Defendant: Endo Pharmaceuticals (100 Endo Blvd., Chadds, PA 19317); AMS (10700 Bren Rd., W. Minnetonka, MN 55343); Cook Defendants (P.O. Box 4195, Bloomington, IN 47402)

Place of Accident, Incident or Transaction: Emory Medical Center (Snellville, Georgia)

(*Use Reverse Side For Additional Space*)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☑ No☐

Does this case involve multidistrict litigation possibilities? Yes☑ No☐

RELATED CASE, IF ANY:

Case Number: _____ Judge _____ Date Terminated: _____

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?
   Yes☐ No☑
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?
   Yes☑ No☐
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes☐ No☑
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?
   Yes☐ No☑

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases*:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases
    (Please specify) _____

B. *Diversity Jurisdiction Cases*:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☑ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases
   (Please specify) _____

ARBITRATION CERTIFICATION

(*Check Appropriate Category*)

I, James D. Barger, counsel of record do hereby certify:

☐ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: 4/1/2013 /s/ James D. Barger 310056

Attorney-at-Law Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: _____ /s/ James D. Barger 310056

Attorney-at-Law Attorney I.D.#

CIV. 609 (5/2012)