

Court of Common Pleas of Philadelphia County
 Trial Division
Civil Cover Sheet

For Prothonotary Use Only (Docket Number)
JULY 2013
000866
 E-Filing Number: 1307008008

PLAINTIFF'S NAME ELLA CEDERBERG-EBAUGH	DEFENDANT'S NAME ETHICON WOMEN'S HEALTH AND UROLOGY, A DIV. OF ETHICON, INC.
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PLAINTIFF'S ADDRESS 215 CONEWAGO CREEK ROAD MANCHESTER PA 17345	DEFENDANT'S ADDRESS P.O. BOX 151 ROUTE 22 WEST SOMERVILLE NJ 08876
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PLAINTIFF'S NAME MARVIN EBAUGH	DEFENDANT'S NAME ETHICON, INC.
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PLAINTIFF'S ADDRESS 215 CONEWAGO CREEK ROAD MANCHESTER PA 17345	DEFENDANT'S ADDRESS ROUTE 22 WEST SOMERVILLE NJ 08876
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PLAINTIFF'S NAME	DEFENDANT'S NAME GYNECARE
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PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS ROUTE 22 WEST SOMERVILLE NJ 08876
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TOTAL NUMBER OF PLAINTIFFS 2	TOTAL NUMBER OF DEFENDANTS 8	COMMENCEMENT OF ACTION <input checked="" type="checkbox"/> Complaint <input type="checkbox"/> Petition Action <input type="checkbox"/> Notice of Appeal <input type="checkbox"/> Writ of Summons <input type="checkbox"/> Transfer From Other Jurisdictions
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AMOUNT IN CONTROVERSY <input type="checkbox"/> \$50,000.00 or less <input checked="" type="checkbox"/> More than \$50,000.00	COURT PROGRAMS <input type="checkbox"/> Arbitration <input type="checkbox"/> Mass Tort <input type="checkbox"/> Commerce <input type="checkbox"/> Settlement <input checked="" type="checkbox"/> Jury <input type="checkbox"/> Savings Action <input type="checkbox"/> Minor Court Appeal <input type="checkbox"/> Minors <input type="checkbox"/> Non-Jury <input type="checkbox"/> Petition <input type="checkbox"/> Statutory Appeals <input type="checkbox"/> W/D/Survival <input type="checkbox"/> Other: _____
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CASE TYPE AND CODE
 2P - PRODUCT LIABILITY

STATUTORY BASIS FOR CAUSE OF ACTION

RELATED PENDING CASES (LIST BY CASE CAPTION AND DOCKET NUMBER)	FILED PRO PROTHY JUL 03 2013 J. OSTROWSKI	IS CASE SUBJECT TO COORDINATION ORDER? YES NO
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TO THE PROTHONOTARY:
 Kindly enter my appearance on behalf of Plaintiff/Petitioner/Appellant: ELLA CEDERBERG-EBAUGH , MARVIN EBAUGH
 Papers may be served at the address set forth below.

NAME OF PLAINTIFF'S/PETITIONER'S/APPELLANT'S ATTORNEY LEE B. BALEFSKY	ADDRESS KLINE & SPECTER 1525 LOCUST ST. 19TH FLOOR PHILADELPHIA PA 19102
PHONE NUMBER (215) 772-0420	FAX NUMBER (215) 735-0960

SUPREME COURT IDENTIFICATION NO. 25321	E-MAIL ADDRESS lee.balefsky@klinespecter.com
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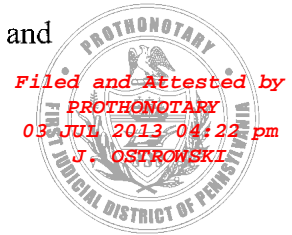
SIGNATURE OF FILING ATTORNEY OR PARTY <i>LEE BALEFSKY</i>	DATE SUBMITTED Wednesday, July 03, 2013, 04:22 pm
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COMPLETE LIST OF DEFENDANTS:

1. PRODESCO, INC.
700 WEST PARK AVENUE
PERKASIE PA 18944
2. SECANT MEDICAL, LLC
700 WEST PARK AVENUE
PERKASIE PA 18944
3. SECANT MEDICAL, INC.
700 WEST PARK AVENUE
PERKASIE PA 18944
4. SECANT MEDICAL
700 WEST PARK AVENUE
PERKASIE PA 18944
5. JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK NJ 08893
6. GYNECARE
ROUTE 22 WEST
SOMERVILLE NJ 08876
7. ETHICON, INC.
ROUTE 22 WEST
SOMERVILLE NJ 08876
8. ETHICON WOMEN'S HEALTH AND UROLOGY, A DIV. OF ETHICON, INC.
P.O. BOX 151 ROUTE 22 WEST
SOMERVILLE NJ 08876

KLINE & SPECTER, P.C.
By: Thomas R. Kline, Esquire/28895
By: Lee B. Balefsky, Esquire/25321
By: Michelle L. Tiger, Esquire/43872
1525 Locust Street
Philadelphia, PA 19102
(215) 772-1000

Attorneys for Plaintiff
Ella Cederberg - Ebaugh and
Marvin Ebaugh



ELLA CEDERBERG-EBAUGH and
MARVIN EBAUGH
215 Conewago Creek Road
Manchester, Pennsylvania 17345
PLAINTIFFS

v.

ETHICON WOMEN'S HEALTH
AND UROLOGY, a Division of
ETHICON, INC.
P.O. Box 151, Route 22 West
Somerville, NJ 08876

and

ETHICON, INC
Route 22 West
Somerville, NJ 08876

and

GYNECARE
Route 22 West
Somerville, NJ 08876

and

JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New Brunswick, NJ 08893

and

SECANT MEDICAL
700 West Park Avenue
Perkasie, PA 18944

and

SECANT MEDICAL, INC
700 West Park Avenue
Perkasie, PA 18944

and

SECANT MEDICAL, LLC
700 West Park Avenue
Perkasie, PA 18944

and

PRODESCO, INC.
700 West Park Avenue
Perkasie, PA 18944

DEFENDANTS

**PHILADELPHIA COUNTY
COURT OF COMMON PLEAS
TRIAL DIVISION - CIVIL**

JURY TRIAL DEMANDED

**ASSESSMENT OF DAMAGES
HEARING IS REQUIRED**

CIVIL ACTION COMPLAINT - NOTICE TO PLEAD

"NOTICE"

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER. IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

Philadelphia Bar Association
LAWYER REFERRAL & INFO.
One Reading Center
Phila., PA 19107
(215) 238-1701

"AVISO"

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas dispuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparencia escrita en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademias, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades o otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE. SI NO TIENE ABOGADO, VAYA EN PERSONA O LLAME PER TELEFONO A LA OFICINA QUE SE ENCUENTRA ESCRITA ABAJO. ESTA OFICINA PUEDE PROVEER DE USTED INFORMACION SOBRE EMPLEAR A UN ABOGADO. SI USTED NO TIENE SUFICIENTE DINERO PARA EMPLEAR UN ABOGADO, ESTA OFICINA PUEDE PODER PROVEER DE USTED LA INFORMACION SOBRE LAS AGENCIAS QUE PUEDEN OFRECER SERVICIOS LEGAL A LAS PERSONAS ELEGIBLES EN UN HONORARIO REDUCIDO O NINGUN HONORARIO.

Asociacion de Licenciados
de Filadelfia
Servicio de Referencia e Informacion
One Reading Center
Phila., PA 19107
(215) 238-1701

COMPLAINT AND JURY DEMAND NEGLIGENCE AND PRODUCTS LIABILITY

Plaintiffs, ELLA CEDERBERG-EBAUGH and MARVIN EBAUGH by and through their attorneys, Thomas R. Kline, Esquire, Lee B. Balefsky, Esquire, and Michelle L. Tiger, Esquire, of Kline & Specter, P.C., file this Complaint against Ethicon Women's Health and Urology, a Division of Ethicon, Inc., Ethicon, Inc., Gynecare, Johnson & Johnson, Secant Medical, Inc., Secant Medical, LLC, Secant Medical and Prodesco, Inc., both jointly and severally, the companies that designed, manufactured and/or marketed the medical devices inserted in Plaintiff ELLA CEDERBERG-EBAUGH. Accordingly, Plaintiff alleges the following:

I. PARTIES

1. Plaintiff, ELLA CEDERBERG-EBAUGH, is an adult citizen and resident of the State of Pennsylvania, who resides at 215 Conewago Creek Road, Manchester, Pennsylvania.

2. Plaintiff, MARVIN EBAUGH, is an adult citizen and resident of the State of Pennsylvania, who also resides at 215 Conewago Creek Road, Manchester, Pennsylvania.

3. Defendant, Ethicon Women's Health and Urology, is a division of Ethicon, Inc., located in Somerville, New Jersey.

4. Defendant, Ethicon, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson, located in Somerville, New Jersey.

5. Defendant, Gynecare, is a division of Ethicon, Inc., located in Somerville, New Jersey.

6. Defendant, Johnson & Johnson, is a corporation, and according to its website, the world's largest and most diverse medical devices and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. (collectively, Defendants Ethicon, Inc., Ethicon Women's Health and Urology of Ethicon, Inc., Gynecare and Johnson & Johnson are hereinafter referred to as the, "J&J Defendants").

7. Defendant Secant Medical, Inc. is a corporation located in Perkasio, Pennsylvania, which at all times material to this matter did business under the fictitious name, Secant Medical and/or as a division, subsidiary, agent, representative of, and/or successor in interest to, and/or jointly with Defendants Prodesco, Inc., Secant Medical, LLC and/or Secant Medical.

8. Defendant Secant Medical, LLC. is a corporation located in Perkasio, Pennsylvania, which at all times material to this matter did business under the fictitious name, Secant Medical and/or as a division, subsidiary, agent, representative of, and/or successor in interest to, and/or jointly with Defendants Prodesco, Inc., Secant Medical, Inc, and/or Secant Medical.

9. Defendant Secant Medical is a corporation located in Perkasio, Pennsylvania, which at all times material to this matter did business as a division, subsidiary, agent, representative of, and/or successor in interest to, and/or jointly with Defendants Secant Medical, Inc., Secant, Medical, LLC and/or Prodesco, Inc. (collectively, Secant Medical, Inc., Secant Medical, LLC, Secant Medical and Prodesco, Inc. are hereinafter referred to as the, "Secant Medical Defendants").

10. Defendant Prodesco, Inc. is a corporation located in Perkasio, Pennsylvania, which at all times material to this matter did business under the fictitious name, Secant Medical and/or as a division, subsidiary, agent, representative of, and/or successor in interest to, and/or jointly with defendants Secant Medical, Secant Medical, Inc. and/or Secant Medical, LLC. Collectively, Secant Medical, Secant Medical, Inc., Secant Medical, LLC, and Prodesco, Inc. are hereafter referred to as "Secant Medical Defendants.")

II. JURISDICTION AND VENUE

11. Plaintiff incorporates by reference all of the above paragraphs.

12. Jurisdiction and venue are proper in this Honorable Court as Defendants all have sufficient contacts with the Commonwealth of Pennsylvania, including the City of Philadelphia, through their substantial and purposeful transactions of business there, including but not limited

to their receipt of substantial compensation, revenues and/or profits from sales of the subject medical devices, synthetic mesh systems.

III. DEFENDANTS' PELVIC MESH PRODUCTS

13. In or about October, 2002, Defendants began to manufacture, market and sell a product known as Gynemesh, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references to Gynemesh include all variations of or names used for Gynemesh, including but not limited to Gynemesh PS.

14. Gynemesh was derived from a product known as Prolene Mesh, which was used in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. Prolene Mesh was derived from Defendants' Prolene mesh hernia product, and was and is utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references to Prolene Mesh include all variations of Prolene Mesh, including but not limited to Prolene Soft Mesh.

15. On or about January 1, 2005, without seeking FDA clearance, the Defendants began to market and sell a product known as the Prolift System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The ProliftSystem was and is offered as an anterior, posterior, or total repair system, and all references to the Prolift and/or Prolift System include by reference all variations.

16. On or about May, 2008, the Defendants began to market and sell a product known as Prolift+M System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift+M System was and is offered

as an anterior, posterior, or total repair system, and all references to the Prolift+M and/or Prolift +M System include by reference all variations.

17. On or about March 2010, Defendants began to market and sell a product known as Prosima System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prosima was and is offered as an anterior, posterior, or total repair system, and all references to Prosima include by reference all variations.

18. The Defendants market and sell a product known as TVT, for the treatment of stress urinary incontinence in females. The TVT has been and is offered in multiple and significant variations including, but not limited to, the TVT, TVT-Obturator (TVT-O), TVTSECUR (TVT-S), TVT Exact and TVT Abbrevio. All references to TVT include by reference all variations.

19. As stated above, the products known as Prolene Mesh, Gynemesh, Prolift, Prosima, Prolift+M, and TVT, as well as any as yet unidentified pelvic mesh products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation, are collectively referenced herein as Defendants' "Pelvic Mesh Products" or the "Products."

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

21. The Defendants did so knowing and intending that the Pelvic Mesh Products and/or the Mesh Components would be implanted, surgically into women.

IV. FACTUAL BACKGROUND

22. On or about May 31, 2007, Plaintiff ELLA CEDERBERG-EBAUGH was implanted with one or more of the Defendant Johnson & Johnson's Pelvic Mesh Products and/or Secant Medical Defendants' Mesh Components, a surgical pelvic repair mesh packaged as

Gynecare TVT Secur™, during a surgical procedure conducted upon her by her surgeon Paul Douglass, MD at Apple Hill Surgical Center in York, Pennsylvania.

23. On or about July 12, 2007, Plaintiff ELLA CEDERBERG-EBAUGH underwent corrective surgery to revise and/or remove one or more of the Defendant Johnson & Johnson's Pelvic Mesh Products and/or Secant Medical Mesh Component, during a second surgical procedure. At that time, Plaintiff was implanted with one or more of the Defendant Johnson & Johnson's Pelvic Mesh Products and/or Secant Medical Defendants' Mesh Components, a surgical pelvic repair mesh packaged as Gynecare TVT, during a surgical procedure conducted upon her by her surgeon Paul Douglass, MD at Apple Hill Surgical Center in York, Pennsylvania.

24. On or about June 14, 2011, Plaintiff ELLA CEDERBERG-EBAUGH underwent corrective surgery to revise and/or remove one or more of the Defendant Johnson & Johnson's Pelvic Mesh Products and/or Secant Medical Defendants' Mesh Components, during a third surgical procedure conducted upon her by her surgeon Howard A. Mirsky, MD at York Hospital in York, Pennsylvania.

25. On or about March 14, 2012, Plaintiff ELLA CEDERBERG-EBAUGH underwent corrective surgery to revise and/or remove one or more of the Defendant Johnson & Johnson's Pelvic Mesh Products and/or Secant Medical Defendants' Mesh Components during a fourth surgical procedure conducted upon her by her surgeon Dr. Toby Chai at University of Maryland Medical Center in Baltimore, Maryland.

26. The Secant Medical Defendants manufactured and sold the Mesh Components of the J&J Pelvic Mesh Products, specifically the Pelvic Mesh Products identified in the foregoing paragraphs and implanted in Plaintiff's body.

27. The Defendants' Pelvic Mesh Products and/or the Mesh Components were implanted in the Plaintiff ELLA CEDERBERG-EBAUGH to treat her stress pelvic floor prolapse and/or stress urinary incontinence, the uses for which the J&J Defendants and the Secant Medical Defendants manufactured, marketed, and/or sold them.

28. As a result of having the Pelvic Mesh Products and/or the Mesh Components implanted in her, Plaintiff ELLA CEDERBERG-EBAUGH has sustained permanent injury, undergone corrective surgery, and has experienced, and will continue to experience, significant mental and physical pain and suffering, financial or economic loss, including, but not limited to, obligations for medical services and expenses.

29. At all times relevant to this matter, the Defendants have marketed their Pelvic Mesh Products and/or the Mesh Components to the medical community and/or the medical device manufacturers and to patients and consumers 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 and 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.

30. The Defendants have marketed and sold their Pelvic Mesh Products and/or the Mesh Components to medical device manufacturers, 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 direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or include the provision of valuable consideration and benefits to health care providers. The

Defendants also utilized documents, brochures, websites, and/or telephone information lines, offering exaggerated and misleading expectations as to the safety and utility of the products.

31. Contrary to the J&J Defendants' representations and marketing to the medical community and to the patients themselves, their Pelvic Mesh Products which included Mesh Components manufactured by the Secant Medical Defendants have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff ELLA CEDERBERG-EBAUGH. In a study published based on a multi-center randomized controlled trial in August, 2010 in the Journal of the American College of Obstetricians and Gynecologists, it was concluded that there is a high (15.6%) vaginal mesh erosion (exposure of the mesh outside of the surgery site) rate with the Prolift, one of the Pelvic Mesh Products, "with no difference in overall objective and subjective cure rates. This study questions the value of additive synthetic polypropylene mesh for vaginal prolapse repairs."

32. The J&J Defendants in particular have consistently underreported and withheld information about the propensity of their Pelvic Mesh Products and/or the Mesh Components manufactured by the Secant Medical Defendants to fail and to cause injury and complications, and have misrepresented the efficacy and safety of their Pelvic Mesh Products and/or the Mesh Components manufactured by the Secant Medical Defendants, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

33. The J&J Defendants have known, continue to know and at all times had reason to know that their disclosures to the FDA were and are incomplete and misleading; and that their

Pelvic Mesh Products and/or the Mesh Components were and are causing numerous patients severe injuries and complications like those suffered by Plaintiff ELLA CEDERBERG-EBAUGH. The J&J 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 J&J Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that their Pelvic Mesh Products and/or the Mesh Components were and are safe and effective, leading to the prescribing and implantation of the Pelvic Mesh Products and/or the Mesh Components manufactured by the Secant Medical Defendants into the Plaintiff.

34. The J&J Defendants and/or the Secant Medical Defendants, individually and/or jointly failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products and/or the Mesh Components.

35. Knowing the significant risk that the Pelvic Mesh Products and/or the Mesh Components would fail and/or imperil the health and welfare of the women in which they were implanted, Defendants failed to design the Pelvic Mesh Products and/or the Mesh Components for, and to establish a safe, effective procedure for, the removal of the Pelvic Mesh Products and/or the Mesh Components, rendering it impossible to safely or easily remove the Pelvic Mesh Products and/or the Mesh Components.

36. Feasible and suitable alternative designs and products, as compared to the Defendants' Pelvic Mesh Products and/or the Mesh Components, as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and other similar conditions, have existed at all times relevant.

37. The Pelvic Mesh Products and/or the Mesh Components were at all times utilized and implanted in a manner foreseeable to the Defendants.

38. The J&J Defendants have at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Pelvic Mesh Products and/or the Mesh Components, and thus increase the sales of the Pelvic Mesh Product and/or its Mesh Components, and also leading to the dissemination of inadequate and misleading information to doctors and patients, including Plaintiff ELLA CEDERBERG-EBAUGH.

39. The Pelvic Mesh Products and/or the Mesh Components implanted into Plaintiff ELLA CEDERBERG-EBAUGH were in the same or substantially similar condition as they were when they left the possession of Defendants, and in the condition directed by and expected by the Defendants.

40. The injuries, conditions, and complications suffered by Plaintiff ELLA CEDERBERG-EBAUGH due to the Pelvic Mesh Products and/or the Mesh Components include but are not limited to mesh erosion, mesh exposure, mesh contraction, infection, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, pelvic floor damage, pelvic pain, and/or recurrent urinary incontinence.

41. Despite knowledge of these catastrophic injuries, conditions, and complications caused by the Pelvic Mesh Products and/or the Mesh Components, the J&J Defendants manufactured, marketed, and sold the Pelvic Mesh Products and/or the Mesh Components and the Secant Medical Defendants manufactured, prepared and sold their Mesh Components, while failing to adequately warn, label, instruct, and disseminate information with regard to the Pelvic

Mesh Products and/or the Mesh Components, both prior to and after the marketing and sale of the Pelvic Mesh Product and/or its Mesh Components.

42. On or about January 3, 2012, the FDA ordered the Defendants to conduct randomized, controlled clinical testing of the Pelvic Mesh Products and/or the Mesh Components or be ordered to cease their manufacture, marketing and sale.

43. On or about June 5, 2012, the J&J Defendants announced that they were withdrawing some or all of the Pelvic Mesh Products and/or the Mesh Components from the market and, as a result, would not be conducting the randomized, controlled clinical testing ordered by the FDA.

44. As of the date of the filing of this Complaint, neither the J&J Defendants nor the Secant Defendants have ever begun or completed any of the randomized, controlled clinical testing ordered by the FDA.

COUNT I
STRICT LIABILITY DEFECTIVE MANUFACTURE AND DESIGN
PLAINTIFF v. ALL DEFENDANTS

45. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

46. The Pelvic Mesh Products and/or the Mesh Components were defectively and improperly manufactured, rendering them defective and unreasonably dangerous and hazardous to Plaintiff ELLA CEDERBERG-EBAUGH.

47. The Pelvic Mesh Products and/or the Mesh Components are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

48. The Pelvic Mesh Products and/or the Mesh Components create risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Pelvic Mesh Products and/or the Mesh Components.

49. Defendants have intentionally and recklessly designed, manufactured, marketed, labeled, sold, and/or distributed the Pelvic Mesh Products and/or the Mesh Components with wanton and willful disregard for the rights and health of the Plaintiffs and others, and with malice, placing their economic interests above the health and safety of the Plaintiff ELLA CEDERBERG-EBAUGH and others.

50. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and/or distribution of the Pelvic Mesh Products and/or the Mesh Components, Plaintiff ELLA CEDERBERG-EBAUGH has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiffs ELLA CEDERBERG-EBAUGH and MARVIN EBAUGH demand judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT II
STRICT LIABILITY – FAILURE TO WARN
PLAINTIFF v. ALL DEFENDANTS

51. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein.

52. The Defendants failed to properly and adequately warn and instruct the Plaintiff ELLA CEDERBERG-EBAUGH or her physicians as to the proper candidates for, and the safest and most effective methods of implantation and use of, the Pelvic Mesh Products and/or the Mesh Components.

53. The Defendants failed to properly and adequately warn and instruct the Plaintiff ELLA CEDERBERG-EBAUGH or her physicians as to the risks and benefits of the Pelvic Mesh Products and/or the Mesh Components.

54. The Defendants failed to properly and adequately warn and instruct the Plaintiff ELLA CEDERBERG-EBAUGH and her health care providers with regard to the inadequate research and testing of the Pelvic Mesh Products and/or the Mesh Components, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products and/or the Mesh Components.

55. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Pelvic Mesh Products and/or the Mesh Components, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff ELLA CEDERBERG-EBAUGH.

56. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the Pelvic Mesh Products and/or the Mesh Components, Plaintiff ELLA CEDERBERG-EBAUGH has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiffs ELLA CEDERBERG-EBAUGH and MARVIN EBAUGH demand judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT III
NEGLIGENCE
PLAINTIFF v. ALL DEFENDANTS

57. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely herein.

58. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Pelvic Mesh Products and/or the Mesh Components.

59. Defendants breached their duty of care to the Plaintiff ELLA CEDERBERG-EBAUGH and her physicians, in the manufacture, design, labeling, warnings, instructions, sale, marketing, and distribution of the Pelvic Mesh Products and/or the Mesh Components.

60. The J&J Defendants had a duty to exercise reasonable and ordinary care in the recruitment and training of physicians and surgeons to implant the Pelvic Mesh Products and/or the Mesh Components.

61. The J&J Defendants breached their duty of care to Plaintiff ELLA CEDERBERG-EBAUGH in the recruitment and training of physicians and surgeons to implant the Pelvic Mesh Products and/or the Mesh Components manufactured by the Secant Medical Defendants.

62. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Products and/or the Mesh Components

and/or of the J&J Defendants' recruitment and training of physicians and surgeons to implant the Pelvic Mesh Products and/or the Mesh Components manufactured by the Secant Medical Defendants, Plaintiff ELLA CEDERBERG-EBAUGH has been injured catastrophically and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiffs ELLA CEDERBERG-EBAUGH and MARVIN EBAUGH demand judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IV
COMMON LAW FRAUD
PLAINTIFF v. ALL DEFENDANTS

63. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

64. The Defendants falsely and fraudulently have represented and continue to represent to medical device manufacturers, the medical and healthcare community, Plaintiff ELLA CEDERBERG-EBAUGH and her physicians, the FDA, and/or the public that the Pelvic Mesh Products and/or the Mesh Components had been appropriately tested and were found to be safe and effective.

65. The representations made by the Defendants were, in fact, false. When the Defendants made their representations, they knew and/or had reason to know that those representations were false, and they willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the Pelvic Mesh Products and/or the Mesh Component.

66. These representations were made by the Defendants with the intent of defrauding and deceiving medical device manufacturers, the medical community, Plaintiff, and the public, and also inducing the medical community, Plaintiff ELLA CEDERBERG-EBAUGH, Plaintiff's physicians, and/or the public, to recommend, prescribe, dispense, and purchase the Pelvic Mesh Products and/or the Mesh Components for use as a means of treatment for stress urinary incontinence and/or prolapse, all of which evidenced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff ELLA CEDERBERG-EBAUGH.

67. In representations to Plaintiff ELLA CEDERBERG-EBAUGH and/or to her healthcare providers, the Defendants fraudulently concealed and intentionally omitted the following material information:

- a) That the Pelvic Mesh Products and/or the Mesh Components were not as safe as other products and procedures available to treat incontinence and/or prolapse;
- b) That the risk of adverse events with the Pelvic Mesh Products and/or the Mesh Components was higher than with other products and procedures available to treat incontinence and/or prolapse;
- c) The Pelvic Mesh Products and/or the Mesh Components were not adequately tested;
- d) That the limited clinical testing revealed the Pelvic Mesh Products and/or the Mesh Components 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 Defendants deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers and either ignored, concealed and/or misrepresented those findings;
- f) That Defendants were aware of dangers in the Pelvic Mesh Products and/or the Mesh Components 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 Products and/or the Mesh Components were defective, and that they caused dangerous and 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 needed to be monitored more regularly than usual while implanted with the Pelvic Mesh Products and/or the Mesh Components and, if the products needed to be removed, that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly;
- i) That the Pelvic Mesh Products and/or the Mesh Components were manufactured negligently;
- j) That the Pelvic Mesh Products and/or the Mesh Components were manufactured defectively; and
- k) That the Pelvic Mesh Products and/or the Mesh Components were designed negligently and designed defectively.

68. The Defendants were under a duty to disclose to Plaintiff ELLA CEDERBERG-EBAUGH and her physicians, the defective nature of the Pelvic Mesh Products and/or the Mesh Components, including, but not limited to, the heightened risks of erosion, exposure, failure and permanent injury.

69. The Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Pelvic Mesh Products and/or the Mesh Components, such as Plaintiff ELLA CEDERBERG-EBAUGH.

70. The Defendants' concealment and omissions of material facts concerning the safety of the Pelvic Mesh Products and/or the Mesh Components were made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff ELLA CEDERBERG-EBAUGH, Plaintiff's physicians, surgeons and healthcare providers and to induce them to purchase, prescribe, and/or dispense the Pelvic Mesh Product and/or its Mesh Components; and/or to mislead them into reliance upon and cause them to use the Pelvic Mesh Products and/or the Mesh Components.

71. At the time these representations were made by the Defendants, and at the time Plaintiff ELLA CEDERBERG-EBAUGH and/or her physicians, used the Pelvic Mesh Product and/or its Mesh Components, Plaintiff ELLA CEDERBERG-EBAUGH and/or her physicians were unaware of the falsehood of these representations, and reasonably believed them to be true.

72. The Defendants knew and had reason to know that the Pelvic Mesh Products and/or the Mesh Components could and would cause severe and grievous personal injury to the users of the products, and that the products were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

73. In reliance upon these false representations, Plaintiff ELLA CEDERBERG-EBAUGH and her physicians were induced to, and did use the Pelvic Mesh Products and/or the Mesh Components, thereby causing severe and permanent personal injuries and damages to Plaintiff ELLA CEDERBERG-EBAUGH. The Defendants knew or had reason to know that the Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind the Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the Pelvic Mesh Products and/or the Mesh Components, as described in detail herein.

74. Plaintiff ELLA CEDERBERG-EBAUGH and her physicians reasonably relied on facts provided by the Defendants which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of the Pelvic Mesh Products and/or the Mesh Components.

75. Having knowledge based upon the J&J Defendants' research and testing, or lack thereof, the J&J Defendants blatantly and intentionally distributed false information, including but not limited to assurances to Plaintiff ELLA CEDERBERG-EBAUGH, the public, and Plaintiff's healthcare providers and physicians, that the Pelvic Mesh Products and/or the Mesh Components were safe for use as a means of providing relief from stress urinary incontinence and/or pelvic organ prolapse and were 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, these Defendants intentionally omitted, concealed and suppressed the dissemination of certain results of testing and research to healthcare professionals, Plaintiff ELLA CEDERBERG-EBAUGH, her physicians, and the public at large.

76. The Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, medical device manufacturers, Plaintiff ELLA CEDERBERG-EBAUGH, her physicians, and the FDA.

77. The information distributed to the public, the medical community, the medical device manufacturers, the FDA, Plaintiff ELLA CEDERBERG-EBAUGH and her physicians by the Defendants included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, professional literature, reports, press releases, advertising campaigns, television commercials, print advertisements, and/or other commercial media, and contained

material representations which were false and misleading, as well as omissions and concealments of the truth about the dangers of the use of the Pelvic Mesh Products and/or the Mesh Components.

78. These representations, and others made by the 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.

79. The Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Pelvic Mesh Products and/or the Mesh Components to Plaintiff, her physicians and the public at large, for the purpose of influencing the sales of products known to be dangerous and defective, and/or not as safe as other alternatives.

80. At the time the representations were made, Plaintiff ELLA CEDERBERG-EBAUGH 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 Pelvic Mesh Products and/or the Mesh Components.

81. Plaintiff ELLA CEDERBERG-EBAUGH did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff ELLA CEDERBERG-EBAUGH discover the false representations of the Defendants, nor would Plaintiff ELLA CEDERBERG-EBAUGH with reasonable diligence have discovered the true facts about the Defendant's misrepresentations at the time when the Pelvic Mesh Product and/or its Mesh Component was implanted surgically into her.

82. Had Plaintiff ELLA CEDERBERG-EBAUGH known the true facts about the dangers and serious health and/or safety risks of the Pelvic Mesh Products and/or the Mesh

Components, Plaintiff ELLA CEDERBERG-EBAUGH would not have purchased, used, or relied on Defendants' representations and omissions concerning the Pelvic Mesh Products and/or the Mesh Components.

83. The Defendants' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiff ELLA CEDERBERG-EBAUGH.

84. As a proximate result of the Defendants' conduct Plaintiff ELLA CEDERBERG-EBAUGH has been injured catastrophically and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiffs ELLA CEDERBERG-EBAUGH and MARVIN EBAUGH demand judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT V
NEGLIGENT MISREPRESENTATION
PLAINTIFF v. ALL DEFENDANTS

85. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

86. The Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, medical device manufacturers, Plaintiff ELLA CEDERBERG-EBAUGH, her healthcare providers and the public, that the Pelvic Mesh Products and/or the Mesh Components had been tested and found to be safe and effective for the treatment of stress urinary incontinence and pelvic organ prolapse.

87. Those representations made by the Defendants were, in fact, false.

88. The Defendants failed to exercise ordinary care in making representations concerning the Pelvic Mesh Products and/or the Mesh Components while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because the Defendants negligently misrepresented the Pelvic Mesh Products and/or the Mesh Components' high risk of unreasonable and dangerous adverse side effects.

89. The Defendants breached their duty in representing that the Pelvic Mesh Products and/or the Mesh Components have no serious side effects different from older generations of similar products and/or procedures to Plaintiff ELLA CEDERBERG-EBAUGH, her physicians, and the medical and healthcare community.

90. As a foreseeable, direct and proximate result of the negligent misrepresentation of the Defendants as set forth herein, the Defendants knew, and had reason to know, that the Pelvic Mesh Products and/or the Mesh Components had been insufficiently tested, or had not been tested at all, that the products lacked adequate and accurate warnings, that they created a high risk, and/or higher than acceptable risk, and/or higher than reported risk and that they represented a risk of adverse side effects, including, erosion, pain and suffering, surgery to remove the products, and other severe and personal injuries, which are permanent and lasting in nature.

91. As a proximate result of the Defendants' conduct, Plaintiff ELLA CEDERBERG-EBAUGH has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiffs ELLA CEDERBERG-EBAUGH and MARVIN EBAUGH demand judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such

other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VI
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS
PLAINTIFF v. ALL DEFENDANTS

92. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

93. The Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Pelvic Mesh Products and/or the Mesh Components to Plaintiff ELLA CEDERBERG-EBAUGH and her physicians, carelessly and negligently concealing the harmful effects of the Pelvic Mesh Products and/or the Mesh Components from Plaintiffs and their physicians, and carelessly and negligently misrepresenting the quality, safety and efficacy of the products.

94. Plaintiff ELLA CEDERBERG-EBAUGH was directly impacted by the Defendants' carelessness and negligence, in that she has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase and utilize the Pelvic Mesh Products and/or the Mesh Components sold and distributed by the Defendants.

95. As a proximate result of the Defendants' conduct, Plaintiff ELLA CEDERBERG-EBAUGH has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiffs ELLA CEDERBERG-EBAUGH and MARVIN EBAUGH demand judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VII
BREACH OF EXPRESS WARRANTY
PLAINTIFF v. ALL DEFENDANTS

96. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

97. At all relevant and material times, the Defendants manufactured, distributed, advertised, promoted, and sold the Pelvic Mesh Products and/or the Mesh Components.

98. At all relevant times, the Defendants intended that the Pelvic Mesh Products and/or the Mesh Components be used in the manner that Plaintiff ELLA CEDERBERG-EBAUGH used them and they expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other treatments for pelvic organ prolapse and/or stress urinary incontinence, and that they were adequately tested and fit for their intended use.

99. At all relevant times, the Defendants were aware that consumers, including Plaintiff ELLA CEDERBERG-EBAUGH, would use the Pelvic Mesh Product; which is to say that Plaintiff ELLA CEDERBERG-EBAUGH was a foreseeable user of the Pelvic Mesh Products and/or the Mesh Components.

100. Plaintiff ELLA CEDERBERG-EBAUGH and/ or her implanting physicians were at all relevant times in privity with the Defendants.

101. The Pelvic Mesh Products and/or the Mesh Components were expected to reach and did in fact reach its ultimate consumer, including Plaintiff ELLA CEDERBERG-EBAUGH and her implanting physicians, without substantial change in the condition in which it was manufactured and sold by the Defendants.

102. The Defendants breached various express warranties with respect to the Pelvic Mesh Product including the following particulars:

- a) The Defendants represented to Plaintiff ELLA CEDERBERG-EBAUGH and her physicians and healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Pelvic Mesh Products and their Mesh Components were safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Pelvic Mesh Products and/or the Mesh Components;
- b.) The Defendants represented to Plaintiff ELLA CEDERBERG-EBAUGH and her physicians and healthcare providers that the Pelvic Mesh Products and/or the Mesh Components were as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the Pelvic Mesh Products and/or the Mesh Components were not safer than alternatives available on the market; and
- c) The Defendants represented to Plaintiff ELLA CEDERBERG-EBAUGH and her physicians and healthcare providers that the Pelvic Mesh Products and/or the Mesh Components were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the products.

103. In reliance upon the Defendants' express warranties, Plaintiff ELLA CEDERBERG-EBAUGH was implanted with the Pelvic Mesh Products and/or the Mesh Components as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by the Defendants.

104. At the time of making such express warranties, the Defendants knew or should have known that the Pelvic Mesh Products and/or the Mesh Components do not conform to these

express representations because the Pelvic Mesh Products and/or the Mesh Components were not safe and had numerous serious side effects, many of which the Defendants did not accurately warn about, thus making the Pelvic Mesh Products and/or the Mesh Components unreasonably unsafe for their intended purpose.

105. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff ELLA CEDERBERG-EBAUGH and her physicians, relied upon the representations and warranties of the Defendants in connection with the use, recommendation, description, and/or dispensing of the Pelvic Mesh Products and/or the Mesh Components.

106. The Defendants breached their express warranties to Plaintiff ELLA CEDERBERG-EBAUGH in that the Pelvic Mesh Products and/or the Mesh Components were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

107. The Defendants' breach constituted violations of common law principles and 13 Pa. Stat. Ann. § 2313, *et seq.*

108. As a proximate result of the Defendants' conduct, Plaintiff ELLA CEDERBERG-EBAUGH has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiffs ELLA CEDERBERG-EBAUGH and MARVIN EBAUGH demand judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VIII

BREACH OF IMPLIED WARRANTY
PLAINTIFF v. ALL DEFENDANTS

109. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

110. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Pelvic Mesh Products and/or the Mesh Components.

111. At all relevant times, Defendants intended that the Pelvic Mesh Products and/or the Mesh Components to be implanted for the purposes and in the manner that Plaintiff ELLA CEDERBERG-EBAUGH or her physicians or surgeons used them and the Defendants impliedly warranted each Pelvic Mesh Product and/or its Mesh Component to be of merchantable quality, safe and fit for such use, and to have been adequately tested.

112. Defendants were aware that consumers, including Plaintiff ELLA CEDERBERG-EBAUGH or her physicians and surgeons would implant the Pelvic Mesh Product and/or its Mesh Component in the manner directed by the instructions for use and that Plaintiff ELLA CEDERBERG-EBAUGH was the foreseeable user of the Pelvic Mesh Products and/or the Mesh Components.

113. Plaintiff ELLA CEDERBERG-EBAUGH and/or her physicians and surgeons were at all relevant times in privity with Defendants.

114. The Defendants' Pelvic Mesh Products and/or the Mesh Components were expected to reach and did in fact reach consumers, including Plaintiff ELLA CEDERBERG-EBAUGH and/or her physicians and surgeons, without substantial change in the condition in which they manufactured and sold by Defendants.

115. Defendants breached various implied warranties with respect to the Pelvic Mesh Products and/or the Mesh Components, including the following particulars:

- a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, medical literature, and regulatory submissions that the Pelvic Mesh Products and/or the Mesh Components were safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Pelvic Mesh Products and/or the Mesh Components;
- b) Defendants represented that the Pelvic Mesh Products and/or the Mesh Components were safe, and/or safer than other alternative devices or procedures and fraudulently concealed information, which demonstrated that the Pelvic Mesh Products and/or the Mesh Components were not as safe or safer than alternatives available on the market; and
- c) Defendants represented that the Pelvic Mesh Products and/or the Mesh Components were more efficacious than other alternative treatments and fraudulently concealed information, regarding the true efficacy of the Pelvic Mesh Products and/or the Mesh Components.

116. In reliance upon Defendants' implied warranties, Plaintiff ELLA CEDERBERG-EBAUGH and/or her implanting physicians and surgeons used the Pelvic Mesh Products and/or the Mesh Components as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

117. Defendants breached their implied warranties to Plaintiff ELLA CEDERBERG-EBAUGH and/or her implanting physicians and surgeons in that the Pelvic Mesh Products and/or the Mesh Components were not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of common law principles and the following statutory provision: 13 Pa. Stat. Ann. §§ 2314 *et seq.*

118. As a proximate result of the Defendants' conduct, Plaintiff ELLA CEDERBERG-EBAUGH has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiffs ELLA CEDERBERG-EBAUGH and MARVIN EBAUGH demand judgment against the Defendants, jointly and severally, for compensatory damages, for

punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IX
VIOLATION OF CONSUMER PROTECTION LAWS
PLAINTIFF v. ALL DEFENDANTS

119. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

120. Plaintiff ELLA CEDERBERG-EBAUGH purchased and used the Pelvic Mesh Product and/or its Mesh Component primarily for personal use and thereby suffered ascertainable losses as a result of the Defendants' actions in violation of the consumer protection laws.

121. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff ELLA CEDERBERG-EBAUGH and her physicians would not have purchased and/or paid for the Defendants' Pelvic Mesh Products and/or the Mesh Components, and would not have incurred related medical costs and injury.

122. The Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff ELLA CEDERBERG-EBAUGH for the Pelvic Mesh Products and/or the Mesh Components, that were implanted into her, and that would not have been paid for had the Defendants not engaged in unfair and deceptive conduct.

123. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

- a) Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

- b) Advertising goods or services with the intent not to sell them as advertised; and,
- c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

124. Plaintiff ELLA CEDERBERG-EBAUGH was injured by the cumulative and indivisible nature of the Defendants' conduct. The cumulative effect of the Defendants' conduct directed at patients, physicians and consumers, including the Plaintiff ELLA CEDERBERG-EBAUGH and her physicians, was to create demand for and sell the Pelvic Mesh Products and/or the Mesh Components. Each aspect of the Defendants' conduct combined to artificially create sales of the Pelvic Mesh Products and/or the Mesh Components.

125. The Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Pelvic Mesh Products and/or the Mesh Components.

126. Had the Defendants not engaged in the deceptive conduct described above, Plaintiff ELLA CEDERBERG-EBAUGH would not have purchased and/or paid for the Pelvic Mesh Product and/or its Mesh Components, and would not have incurred related medical costs.

127. The Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff ELLA CEDERBERG-EBAUGH and her physicians, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes, including but not limited to 73 Pa. Stat. §§ 201-1 *et seq.*

128. The Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, including but not limited to of 73 Pa. Stat. §§ 201-1 *et seq.*

129. The Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, the Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

130. The Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Pelvic Mesh Products and/or the Mesh Components were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials and product labeling.

131. The actions and omissions of the Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

132. The Defendants had actual knowledge of the defective and dangerous condition of the Pelvic Mesh Products and/or the Mesh Components and failed to take any action to cure such defective and dangerous conditions.

133. Plaintiff ELLA CEDERBERG-EBAUGH and her implanting physicians and surgeons relied upon the Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform.

134. The Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constitute unfair and deceptive acts and practices.

135. By reason of the unlawful acts engaged in by the Defendants, and as a direct and proximate result thereof, Plaintiff ELLA CEDERBERG-EBAUGH has suffered ascertainable losses and damages.

136. As a direct and proximate result of the Defendants' violations of the state's consumer protection laws, Plaintiff ELLA CEDERBERG-EBAUGH has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs ELLA CEDERBERG-EBAUGH and MARVIN EBAUGH demand judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT X
GROSS NEGLIGENCE
PLAINTIFF v. ALL DEFENDANTS

137. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

138. The wrongs done by the Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff ELLA CEDERBERG-EBAUGH, for which the law would allow, and which Plaintiff ELLA CEDERBERG-EBAUGH will seek at the appropriate time under governing law for the

imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiff ELLA CEDERBERG-EBAUGH; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representations that were false, with Defendants, knowing that they was false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff ELLA CEDERBERG-EBAUGH.

139. Plaintiff ELLA CEDERBERG-EBAUGH and her physicians relied on the representations of Defendants and suffered injury as a proximate result of this reliance.

140. Plaintiff ELLA CEDERBERG-EBAUGH therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

141. Plaintiff ELLA CEDERBERG-EBAUGH also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff ELLA CEDERBERG-EBAUGH. In that regard, Plaintiff ELLA CEDERBERG-EBAUGH will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiffs ELLA CEDERBERG-EBAUGH and MARVIN EBAUGH demand judgment against the Defendants, jointly and severally, for compensatory

damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XI
LOSS OF CONSORTIUM
PLAINTIFFS v. ALL DEFENDANTS

142. Plaintiffs reallege each and every allegation of this Complaint as if each were set forth fully and completely herein.

143. At all relevant times hereto, Plaintiff (Insert name) and Plaintiff MARVIN EBAUGH were lawfully married.

144. For the reasons set forth herein, Plaintiff MARVIN EBAUGH has necessarily paid and has become liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

145. For the reasons set forth herein, Plaintiff MARVIN EBAUGH has suffered and will continue to suffer the loss of his spouse's support, companionship, services, society, love and affection.

146. Plaintiff MARVIN EBAUGH alleges that his marital relationship with Plaintiff (Insert name) was impaired and deprecated, and the marital association between husband and wife has been altered.

147. Plaintiff MARVIN EBAUGH has suffered great emotional pain and mental anguish and will in the future suffer great emotional pain and mental anguish as a proximate result of Defendants' misconduct.

148. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs (Insert name) and MARVIN EBAUGH have sustained and will continue to sustain severe emotional distress, economic losses and other damages, for which they are entitled to compensatory damages.

149. Defendants are liable to Plaintiff MARVIN EBAUGH jointly and severally for all general and special relief, to which he is entitled by law.

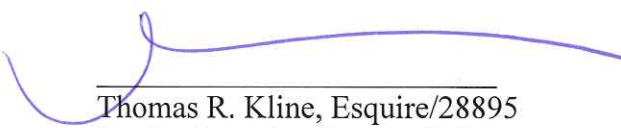
WHEREFORE, Plaintiff (Insert name) and MARVIN EBAUGH demand judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Respectfully submitted,

KLINE & SPECTER
A Professional Corporation



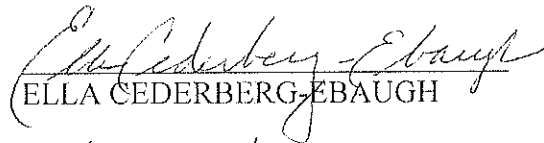
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ELLA CEDERBERG-EBAUGH and
MARVIN EBAUGH

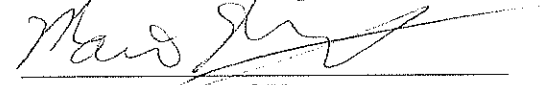
VERIFICATION

We, ELLA CEDERBERG-EBAUGH and MARVIN EBAUGH, being duly sworn according to law, depose and state:

1. We are the plaintiffs in this action;
2. We verify that the statements made in the foregoing Complaint are true and correct to the best of our knowledge or information and belief; and
3. We understand that the statements made in said Complaint are subject to the penalties of 18 Pa.C.S. Section 4904 relating to unsworn falsification to authorities.



ELLA CEDERBERG-EBAUGH



MARVIN EBAUGH

DATED: 7-1-13