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ELLA EBAUGH and MARVIN EBAUGH vs. ETHICON WOMEN'S HEALTH AND UROLOGY, A DIV. OF ETHICON, INC., et al	COURT OF COMMON PLEAS PHILADELPHIA COUNTY JULY TERM, 2013 NO. 000866

PLAINTIFFS' PRETRIAL MEMORANDUM

I. CONCISE SUMMARY OF THE NATURE OF THE CASE

Ella Ebaugh is a 52 year old woman living in Manchester, Pennsylvania with her husband of 4 years, Marvin Ebaugh, and her youngest son, Jacob, age 16. Mrs. Ebaugh also has three adult children who no longer live at home. Mrs. Ebaugh was previously employed as a warehouse clerk for Friendly's.

In 2005, Dr. Paul Douglass, Mrs. Ebaugh's gynecologist, diagnosed her with mixed urinary incontinence. Primarily she had stress urinary incontinence, which is the involuntary leakage of urine when a woman coughs, sneezes, or jumps. She also had some episodes of urgency, meaning she had times when she had to hurry to get the bathroom out of fear of wetting herself.

Dr. Douglass implanted Mrs. Ebaugh with a TVT-SECUR ("TVT-S") on May 31, 2007 to treat her stress urinary incontinence. The TVT-S was a product sold by Gynecare, a division of Ethicon, which is a Johnson & Johnson company. Ethicon and Johnson & Johnson are the Defendants in this case. The TVT-S is made of polypropylene, or prolene, mesh cut into a short strip that resembles a piece of tape. The TVT-S is designed to be implanted through the vagina in the tissue below the mid-urethra. The urethra is the tube that carries urine from the bladder outside of the body. In theory, by supporting the urethra, the TVT-S was supposed to help a woman's stress urinary incontinence.

Within one week of her TVT-S being implanted, Mrs. Ebaugh has a conversation with someone at Dr. Douglass' office about the fact that the TVT-S was providing no relief for her stress urinary incontinence. Dr. Douglass saw Mrs. Ebaugh following that call, and on July 12, 2007, Mrs. Ebaugh had a second Ethicon/Johnson & Johnson implant for the treatment of her stress urinary incontinence, the TVT. The TVT, short for trans-vaginal tape, is a markedly longer strip of prolene mesh that is also inserted through the vagina to support the mid-urethra.

Sadly, not only did the TVT-S and TVT fail to cure Mrs. Ebaugh's stress urinary incontinence, but these defective devices have also caused multiple other problems which cannot be cured. More specifically, due to the defective nature of the mesh, which is discussed further *infra*, Mrs. Ebaugh's TVT devices eroded through her urethra on 3 separate occasions, necessitating 3 revision surgeries on June 14, 2011, March 9, 2012, and March 1, 2016. In addition to these revision surgeries, Mrs. Ebaugh has been forced to undergo countless cystoscopies, where a tube is inserted in her urethra to examine her urethra and bladder, and has also been forced to undergo a myriad of imaging studies in an attempt to diagnose and treat her urinary problems.

Today Mrs. Ebaugh has intrinsic sphincter deficiency, meaning she loses the entire contents of her bladder without warning, destrusor instability causing severe stress urinary incontinence, partial bladder obstruction, recurrent urinary tract infections, massive scarring of the mid and distal urethra, dyspareunia (pain with sex), pelvic, abdominal, and flank pain, and the sequela of expected problems related to these conditions.

Mrs. Ebaugh filed her lawsuit on July 3, 2013. When she got her implants, she was warned of the generic risks of the products, including the risk of erosion and the risk that the devices would not work. However, her implanting physician, Dr. Douglass, understood these risks were rare, and had not seen them with his patients. When she experienced her first erosion, Mrs. Ebaugh understood from her physicians it was a risk of the procedure. In fact, Dr. Clyde Strang and Dr. Howard Mirsky, urologists who saw her for her erosion, never suggested to her the mesh was defective, and she felt relief from her symptoms after her first revision surgery. It wasn't until after her second revision surgery on March 9, 2012 that Mrs. Ebaugh saw a television commercial regarding the defective nature of mesh that she put together that the defective nature of the mesh was causing her problems. Prior to that, even the specialist from the University of Maryland who performed her second revision surgery, Dr. Toby Chai, had not suggested the mesh was defective. After seeing this television commercial she sought an attorney and timely filed her lawsuit.

Dr. Michael Margolis is a urogynecologist in private practice in the San Francisco bay area who examined Mrs. Ebaugh in 2016 after doing a thorough review of all of her medical records. Dr. Margolis will testify the TVT and TVT-S mesh implants are the source of Mrs. Ebaugh's aforementioned problems, and she will suffer from them for the rest of her life.

Moreover, she is at risk for erosions and other complications, as there is no way to safely remove all of the mesh from the TVT-S and TVT after implantation.

All of Mrs. Ebaugh's problems which are directly attributable the TVT-S and TVT are problems that Ethicon knew about when it was developing these products. Ethicon acted recklessly and irresponsibly by ignoring the defective and dangerous nature of the TVT-S and TVT, and placing them on the market for permanent implantation in women. The risks of the TVT and TVT-S are not rare, transient, or easily treatable, as Ethicon falsely misrepresented to physicians, but common, life-long, and severe.

A detailed outline of the reckless behavior of Ethicon with regard to the TVT-S and TVT follows, and will be presented to the jury through the testimony of plaintiffs' experts and the designated video deposition testimony of Ethicon's employees who played crucial roles in the development and marketing of these products.

TVT

TVT was Ethicon's first product that used polypropylene mesh for vaginal insertion for pelvic floor disorders in women. It was invented by Professor Ulf Ulmsten, a Swedish surgeon who was partial owner of a company called Medscand. Prolene mesh has been used since the 1970's to repair abdominal hernias, and is made by knitting together strands of prolene sutures, which have been around for decades.

The Defendants purchased Professor Ulmsten's device, which would become the TVT, for over $24 million dollars. They also paid Professor Ulmsten over $4,000,000 separately from this purchase price. Because Professor Ulmsten was an owner of Medscand, he also got a portion of the sale price. In total, Professor Ulmsten earned over $7,000,000 from the Defendants before his death in 2012.

As part of the purchase of the TVT device, Johnson & Johnson and Ethicon agreed to make certain milestone payments conditioned on the results of studies performed by Professor Ulmsten. However, Defendants never reviewed or analyzed any of Professor Ulmsten's underlying data, and relied blindly on his published summaries of the data. By doing so, Defendants never questioned whether the data was skewed because of Professor Ulmsten's known vested interest in producing favorable results about the performance of the TVT and never verified the data. Even more outrageous, Professor Ulmsten hand-picked the select group of surgeons who participated in the multicenter study that his milestone payments depended on. Defendants to this day rely on Professor Ulmsten's data as proof of the safe and efficacious nature of its family of TVT products, completely ignoring the obvious problems with it.

The TVT was first marketed in the United States in 1998 and is still on the market. Despite Defendants' touting the thousands of studies done on the product, the fact remains there are no long term clinical trials with safety as the primary endpoint. The vast majority of studies have been performed with grant money from the Defendants and/or written by individuals who are on the Ethicon/Johnson & Johnson payroll. The publicly available literature does not adequately reveal the defective nature of these products.

Testimony from Defendants' employees makes it clear that the TVT is defective. First, the prolene mesh used in the TVT has pores that are too small, a condition known as microporous. The size of the pores is critical to the body's reaction to the mesh. Larger pores ("macroporous mesh") allow tissue to grow through the pores, thus allowing the mesh to retain its elasticity. This is essential because the mesh is being implanted between the vagina and bladder just under the urethra, all structures that are designed to expand and contract with normal expected human movement such as intercourse and bladder filling. When the pores are too small, or deform under

tension of implantation, scar tissue grows over the pores, rather than through them, encapsulating the mesh. This process is called bridging fibrosis and scar plating. Scars themselves are rigid, and can contract around the mesh, reducing its surface area, causing the mesh to become contracted, rigid, and hard. Hard, inflexible foreign bodies surrounded by scar tissue causes pain with bladder filling because the bladder can't expand, pain with sex because the vagina can't expand, and pain in the pelvic region.

Second, the prolene mesh degrades after implantation in the body. This leads to the release of toxic compounds in the tissue surrounding the mesh, leading to inflammation, infection, or worse. There is testing that shows that the polypropylene used in the mesh is cytotoxic for human tissue, meaning it can cause cell death.

Third, prolene mesh causes a chronic inflammatory reaction in the body. Despite warnings to physicians about a transient foreign body reaction, Defendants knew that the body's reaction to mesh placed vaginally would be chronic, and would never go away. Clinically, that means excess scar formation, chronic foreign body reaction, and problems with infections. In Ella Ebaugh's case, she's had a history of recurrent urinary tract infections that have become antibiotic resistant because of the numerous attempts to treat them.

Fourth, the hard rigid mesh can erode through the tissue plane where it was implanted, into surrounding organs where it is not meant to be. In Ella Ebaugh's case, the mesh has eroded through her urethra on 3 separate occasions. The third time it eroded was after Dr. Toby Chai attempted to remove all of her mesh from her body. Because the mesh can never be safely removed, this is a lifelong problem for women with these implants.

Fifth, the mesh can lose its shape and characteristics in the human body, causing to rope, curl, or otherwise become disfigured. This increases the risk of erosion into unwanted areas of the body, and may cause further inflammatory reaction.

Sixth, the mesh, when machine cut, can experience particle loss, meaning particles can literally break off in the body and migrate to unwanted areas. In Ella Ebaugh's case, Dr. Toby Chai saw mesh on her bladder during cystoscopy that was unexplained. Machine cut mesh also can have sharp edges that can cut into surrounding tissue, a risk Ethicon was well aware of when it started marketing an alternative product, laser cut mesh.

TVT-S

The TVT-S was launched in the United States in September of 2006. The TVT-S was developed by Ethicon and Johnson & Johnson not for medical reasons, but solely to protect Defendants' market share in the stress urinary incontinence medical device injury. Defendants came up with a concept, ran limited cadaver labs and testing on sheep, and then launched the product without any clinical testing on humans. Instead, Defendants relied on the unreliable Ulmsten data to prove the mesh was safe and effective. Defendants, companies worth billions of dollars, cancelled their commitment to do a randomized clinical trial shortly after launch due to "budget constraints".

Almost immediately after the TVT-S was launched, Ethicon began receiving worldwide reports of complications. Throughout 2007, reports of high failure rates flooded in from Germany, South Africa, Australia, and Canada. Surgeons were retrained and improvement was not always seen. Additional training materials were developed, including a Key Technical Points and Critical Steps guide. Despite these steps, surgeons complained, and problems were still reported. A review

of the data from studies eventually done in the United States showed the TVT was not meeting the predetermined endpoints for efficacy.

By June of 2008, a quality hold was put on the TVT-S in Australia, meaning it was not sold there any longer. One of the studies sponsored by Ethicon was stopped prematurely due to safety concerns.

Despite awareness of these considerable problems, Ethicon continued to push the TVT-S through physician marketing and professional education. Defendants promoted the TVT-S as a less invasive, less complicated procedure. Dr. Douglass, Ella Ebaugh's implanting physician, told her when she wanted surgery to wait a few months so she could get the TVT-S, as he had heard it was going to be released and was unknowingly, the victim of false advertising about its benefits.

The TVT-S carried an array of problems including insertion difficulties, releasing difficulties, fixation tips failing to stay in place, bladder perforation, excessive bleeding, tensioning failures, a not-well-defined "cookbook," longer than anticipated learning curve, and lack of the appropriate training. In October 2007, the company assessed the "Lessons Learned" from the TVT-S debacle in an internal presentation, among which were "considered not carrying out a first human trial and launching a product at the same time (the learnings from a first human trial should be gathered, digested, and the device/training adjusted accordingly before launch)" and "do not underestimate the learning curve."

Although the Defendants very quickly became aware that the TVT-S was not a simple procedure and involved a significant surgeon learning curve, the company continued to market the product to doctors and patients as simple and less invasive. They continued to push the TVT-S in an effort to win back sales from the competition. As a result, sales of the TVT-S managed to reach $21.47 million in its first year. The TVT-S was pulled from the market in 2012.

II. BASIS OF LIABILITY & CAUSATION

Plaintiffs served expert reports setting forth liability and causation as follows:

A. Dr. Bruce Rosenzweig

Dr. Rosenzweig is a urogynecologist who received his medical degree from the University of Michigan. He completed a pelvic surgery fellowship at the State University of New York-Syracuse and a urogynecology fellowship at UCLA, after which he joined the faculty at the University of Illinois-Chicago. Dr. Rosenzweig is also an assistant professor of obstetrics and gynecology at Rush University Medical Center. *See* Dr. Rosenzweig's expert reports dated June 9, 2014 at p. 1, August 24, 2015 at p. 2, and January 22, 2016 at p. 1, attached as Exhibits "A", "B", and "C", respectively, and Curriculum Vitae, attached as Exhibit A to each report.

Dr. Rosenzweig has performed more than 1,000 surgeries on the pelvic floor, and he conservatively estimates that this number includes 200 surgeries to remove synthetic mesh products, including Defendants' TVT devices, because of complications. *Id.* Dr. Rosenzweig's expertise relating to stress urinary incontinence and pelvic mesh products is well recognized. He has published numerous articles and given numerous lectures on topics such as pelvic organ prolapse and urinary incontinence. In fact, his experience and reputation are such that Dr. Rosenzweig was invited by Ethicon to attend both its Gynecare Prolift Training Seminar and its TVT Obturator Seminar in Belgium. *Id.*

Dr. Rosenzweig's report dated August 24, 2015 regarding the TVT, a copy of which is attached hereto as Exhibit "B", states, in pertinent part, as follows:

> Ethicon has marketed and sold the TVT despite the fact that it is contains numerous characteristics that make it unsuitable for implantation in a woman's

vagina. These characteristics include the following: (1) degradation of the mesh; (2) chronic foreign body reaction; (3) fraying, sharp edges and particle loss; (4) Infections and Bio-films; (5) roping and curling of the mesh; (6) loss of pore size with tension; (7) fibrotic bridging leading to scar plate formation and mesh encapsulation; and (8) shrinkage/contraction of the encapsulated mesh.

Not only does Ethicon sell a product which should never be put in the vagina, it failed to inform physicians and their patients about numerous risks associated with the product despite the fact that these risks were known before the product was launched. Ethicon has removed the ability of physicians to appropriately inform their patients of the risks and benefits of the TVT and made it impossible for women to consent to the procedure. In addition, despite having knowledge to the contrary, Ethicon never informed physicians and their patients that the TVT could be toxic to their bodies. Finally, while keeping this information from women, Ethicon marketed its product with promotional pieces that did not disclose key conflict of interest information or the true complication rates of its products.

As a result of these failures as fully set forth in this report, the TVT has caused and will continue to cause a multitude of injuries in women, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, nerve injury, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others.

All opinions I have are to a reasonable degree of medical certainty. I understand discovery is still ongoing in this case and I reserve my right to amend my opinions if further information is provided in any form including, but not limited to, corporate documents, depositions and expert reports of both Plaintiff and Defense experts. I have also reviewed the opinions of Dr. Uwe Klinge, Dr. Muhl, Dr. Vladimir Iakovlev and Dr. Elliott and incorporate those opinions herein.

See Id. at pp. 3-5, 99-101.

Dr. Rosenzweig also issued a report dated January 22, 2016 regarding the TVT-S, a copy of which is attached hereto as Exhibit "C". His report states, in pertinent part, as follows:

Ethicon marketed and sold the TVT -S despite the fact that it had numerous characteristics making it unsuitable and not reasonably safe for implantation in a woman's vagina. Among other noted herein, these characteristics include the following: (1) excessive rigidity; (2) degradation of

the mesh; (3) chronic foreign body reaction; (4) infections and bio-films; (5) fibrotic bridging leading to scar plate formation and mesh encapsulation; and (6) shrinkage/contraction of the encapsulated mesh. Regardless of skill level, there were numerous known risks by Ethicon that were undisclosed in the TVT -S' IFU. Not only did Ethicon sell a product which should never be put in the vagina, it failed to inform physicians and their patients about numerous risks associated with the product despite the fact that these risks were known before the product was launched. The IFU warnings that were provided were wholly inadequate and, coupled with the device's various defects, demonstrate the TVT-S was unreasonably dangerous as sold. Ethicon has removed the ability of physicians to appropriately inform their patients of the risks and benefits of the TVT-S and made it impossible for women to consent to the procedure. In addition, despite having knowledge to the contrary, Ethicon never informed physicians and their patients that the TVT -S was associated with cancer and could be toxic to their bodies. Finally, while keeping this information from women, Ethicon marketed its product with promotional pieces that did not disclose key conflict of interest information or the true complication rates of its products.

As a result of these failures, the TVT -S has caused and will continue to cause a multitude of injuries in women, including the potential for multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, nerve injury, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others.

See Id. at pp. 2-4, 78-79. *See also* Dr. Rosenzweig's report dated January 15, 2016 and reports dated May 22, 2017, attached hereto as Exhibit "D", "E", and "F", respectively.

B. Daniel S. Elliott, M.D.

Dr. Elliott is an associate professor of urology at the Mayo Clinic College of Medicine in Rochester, Minnesota and is also a consultant with the Department of Urology at the Mayo Clinic. He is double board certified in Urology and Female Pelvic Medicine and Reconstructive Surgery. He received his medical degree from Loma Linda University, and completed his residency at the Mayo Clinic College of Medicine. He completed a fellowship in neurourology, urodynamics, and voiding dysfunction at the Baylor College of Medicine. He has published 60 peer reviewed articles, 14 book chapters, and 32 abstracts, in addition to having numerous journal

responsibilities, winning a myriad of professional awards, and winning several research grants. *See* Dr. Elliott's C.V., attached as Exhibit A to his January 25, 2016 report. Dr. Elliott issued a report dated January 25, 2016, a copy of which is attached hereto as Exhibit "G".

Dr. Elliott's report states, in pertinent part, as follows:

> In sum, I concur with the results of Ethicon's (unpublished) summary of first-year data on the TVT-S, which showed that nearly a third of women experienced "major" complications: "As long as complications occur at the rate seen in this study . . . the single-incision procedure cannot be recommended as a first line treatment for [SUI]."108 As explained throughout this report, the TVT-S is a defective device sold with faulty instructions, which never should have been brought to market. As a result of the TVT-S, many women have experienced severe complications that are in many cases irreversible.

See id. at pp.5, 43.

C. <u>Prof. Dr. Med. Uwe Klinge</u>

Dr. Klinge is an abdominal hernia surgeon who has focused on surgical research in the areas of biomaterial science including tissue engineering, material characteristics, and design of preclinical models for surgical mesh and histopathology since 1993. He is the author or co-author of over 200 peer reviewed publications, has contributed to or authored more than 50 book chapters, and has been an invited lecturer at over 160 speaking engagements. In 1994, Dr. Klinge began working with Dr. Bernd Klosterhalfen to establish a way to analyze soft tissue reactions in order to determine the differences materials implanted in the body, and to see the extent of inflammation, foreign body reaction, and fibrosis a biomaterial would have on soft tissue, and how that would affect complications. He has been awarded numerous grants, including grants from Ethicon to examine mesh. *See* Dr. Klinge's C.V. attached to his report dated October 13, 2013, attached hereto as Exhibit "H". Dr. Klinge's report states, in pertinent part, as follows:

> Prior to launching their first surgical mesh for gynecological repair, TVT for sale in the U.S., and according to their own documents, Ethicon was aware of the most important design requirements for a safe pelvic floor mesh product.

According to their documents, Ethicon also knew why these design requirements were so important in terms of patient safety. However, as is also stated in their documents, Ethicon was aware of the challenges and uncertainties of designing a safe mesh for the pelvic floor; that the design of their pelvic floor meshes, including TVT, did not meet all their claimed optimal design requirements; and, that as a result, this led to patient complaints and complications.

Ethicon has a long history of manufacturing surgical meshes that are intended to be permanently implanted by doctors in patients' bodies. They likewise have a long history of reported complications with their prosthetic meshes. With their experience from complications associated with some of the poor design characteristics in hernia meshes, Ethicon knew that poor design leads to poor outcome.

Through my team's collaborative efforts with Ethicon in the late 1990's and early 2000's, Ethicon learned that the development of an optimal surgical mesh design for any application has to consider first, the polymer; second, the biomechanics (physiological requirements) as to strength, elasticity and structural stability; and third, the structure of the device in terms of geometric design, knitting characteristics, fiber size and pore size. Ethicon knew that the result of these design considerations and choices would influence the tissue reaction, primarily the intensity of the inflammatory and fibrotic response, thereby directly affecting the biocompatibility of the device and thus the clinical outcome.

However, despite this knowledge, Ethicon failed to appropriately design and test TVT to determine if these unintended and adverse events would occur when implanting it permanently into a woman's pelvic tissues resulting in significant morbidity to women around the world.

Ethicon has stated repeatedly in its documents that it had a very poor understanding of the biomechanics of the pelvic floor, which apparently continues to this day. As such, they were not able to establish reliable parameters for the design of the device. Furthermore, despite Ethicon's apparent knowledge of the significant amount of mesh shrinkage experienced by patients in whom the TVT is implanted, the potential causes of mesh shrinkage, as well the resultant patient complications that could occur as a result of this shrinkage, they did no testing nor made any design changes to TVT in order to reduce the occurrence of this known and serious complication. Failure by Ethicon to act as a reasonable manufacturer and to properly study and/or make the necessary design changes to avoid this and the other safety hazards mentioned in this report was improper, irresponsible and threatened patient safety.

See id. at pp. 88-89.

Dr. Klinge also issued a report dated August 24, 2015, a copy of which is attached hereto as Exhibit "I". Dr. Klinge's August 24, 2015 report states, in pertinent part, as follows:

The Prolene mesh in TVT undergoes a Chronic FBR

After implantation of the TVT mesh, there is a chronic (permanent) foreign body reaction in a woman's pelvic tissue whereby the woman's body will react to the polypropylene indefinitely, creating a chronic inflammatory response that leads to scarring around the mesh fibers. Claims by Ethicon in its TVT Instructions for Use (IFU) that "a transient foreign body response may occur" and in its TVT marketing brochures that there is "[n]o foreign body reaction after PROLENE mesh implantation" are inconsistent, false and misleading, and Ethicon knew or should have been known to them to be untrue at the time the company employees, wrote these documents and certainly prior to the launch of TVT in 1998.

The weight (surface area) of the Prolene mesh in TVT unnecessarily increases the risk of patient injury versus lighter weight mesh design.

The greater the surface area of a medical implant, the greater the foreign body reaction and the inflammatory response. Ethicon had critical mesh design information regarding the negative consequences in the human tissue of heavy weight, small pore meshes beginning as early as 1998. The heavy weight Prolene mesh (105-110 g/m2) in Ethicon's TVT products is many times stronger than it needs to be for its intended purpose of treating stress urinary incontinence and thus, it is "overengineered" and leaves much more polymer material in a woman's delicate and sensitive pelvic tissues than is necessary. Any pelvic mesh designed with this much excess surface area and weight unreasonably and unnecessarily increases the risk of injury to the patient and is a less safe design than lighter weight mesh as it causes an unnecessarily increased FBR and inflammatory response.

The distance between the fibers of the Prolene mesh in TVT unnecessarily increases the risk of patient injury versus mesh design with a larger distance between the fibers.

The smaller the distance between the fibers of a mesh implant, the greater the risk of scar tissue forming in the pores ("bridging fibrosis" or "fibrotic bridging:). As early as 1998, and certainly by the early 2000's, Ethicon had critical design information that the risk of bridging fibrosis is increased by polypropylene surgical mesh with a distance between the fibers of less than 1mm in all directions, which in turn increases the risk of a rigid scar plate forming throughout the mesh, leading to integration of the entire mesh in scar tissue. Any pelvic mesh designed with pores this small unreasonably and unnecessarily increases the risk of injury to the patient and is a less safe design than mesh with a greater distance between the fibers. The pore size of the Prolene mesh in Ethicon's TVT products is, according to Ethicon, less than 1mm.

Ethicon's failure to implement new, critical mesh design changes (lighter weight, greater 3 distance between the fibers) in TVT before the launch of TVT-R in 1998 was unreasonable; it unnecessarily compromised patient safety; and it has led to patient complications like chronic inflammatory reaction, excessive scarring through and around the mesh, nerve entrapment, chronic pain, dyspareunia, erosions, erosions and the necessity of reoperation in an attempt to correct these problems. The Prolene mesh in Ethicon's TVT products is unsuitable for use as a permanent implant for treatment of a woman's stress urinary incontinence. Ethicon did not act as a reasonable manufacturer in choosing to use the "Old Construction 6 mil" Prolene mesh in its TVT products.

The Prolene mesh in TVT undergoes pore deformation under minimal stress.

A knitted surgical mesh device like the TVT that is permanently implanted in human tissue must be designed in such a manner that the pores of the mesh do not collapse and deform upon the expected forces of implantation as well as the expected in vivo forces. Under minimal strain, the TVT mesh pores deform and collapse thereby increasing the risk of injury to patients in which it is implanted and is a less safe design than products that better withstand these conditions and do not display these poor outcomes. Permanent deformation and pore collapse of the TVT mesh leads to fibrotic bridging, scar plate formation, excessive scarring through and around the mesh and a host of tissue complications that can lead to chronic pain, recurrence, erosions, dyspareunia and need for reoperation, to name a few, making it unnecessarily unsafe for its intended purpose of being permanently implanted in a woman's pelvic tissue.

The Prolene mesh in TVT contracts/shrinks.

The Prolene mesh in Ethicon's TVT products contracts or shrinks 30-50% after implantation. This shrinkage was known in the medical device community prior to the launch of TVT in 1998. TVT mesh shrinkage, caused by fibrosis leads to nerve entrapment, chronic pelvic pain, erosions, organ dysfunction, recurrence and the need for reoperation to remove some or all of the contracted mesh and excessive scar tissue, thereby making TVT unsuitable for its intended use as a permanent pelvic implant to treat stress urinary incontinence in women.

The Mechanical Cut Prolene Mesh in the TVT products deforms, frays, loses particles, curls and ropes increasing the risk of complications to the patients.

The TVT mesh is a knitted textile design without a border and therefore, as tension is placed on the mesh, its frayed, unbordered edges shed particles of polypropylene before, during and after the surgery. As tension is placed on the mesh, it also curls and ropes causing increased scarring between the fibers. The release of particles into the surrounding tissue with its increase of surface area and the curled roped mesh all lead to an increased inflammatory response, chronic foreign body reaction, erosions, chronic pelvic pain, failure of the implant,

chronic sexual dysfunction and dyspareunia, organ damage, urinary dysfunction, inability to remove the device and the need for surgical intervention.

There are safer alternative pelvic mesh design characteristics than those of TVT.

There are alterative design characteristics of pelvic floor meshes that would be safer in a woman's pelvic tissues as a treatment for incontinence than some of the design characteristics of the Prolene mesh in TVT. The Old Construction TVT MCM Prolene mesh was created in the 1970's, years before Ethicon developed meshes for both henna repair and pelvic floor repair using safer mesh design. For example, by the late 1990's and early 2000's, the technology of surgical meshes had evolved to produce meshes that were lighter weight, had greater distance between the fibers, had better stability under stress, had laser cut edges and had a different polymer material. Ethicon began marketing lighter weight meshes with longer distance between the fibers as early as 1998 and continued to advance this technology in its hernia and certain pelvic floor repair mesh products through 2002. It had designed meshes with a different polymer (PVDF) by at least 2002 and meshes that were laser cut by 1998, including TVT laser cut samples. Ethicon knew in 1999 that the TVT with the laser cut mesh had a marked reduction in the amount of loose ends falling off compared to mechanically cut mesh, and is less difficult to deform, facilitating correct placement of the mesh. However, Ethicon has continued to market its 1970's technology Old Construction Prolene mesh in its original TVT-R up to the present date.

Based upon the opinions above, I am able to conclude, to a reasonable degree of medical and scientific certainty, that the Prolene mesh used in Ethicon's TVT products is designed in such a way that it does in fact unnecessarily cause a greater inflammatory response and greater foreign body reaction in women's pelvic tissues leading to harmful complications in some patients. I am also able to conclude that these materials were inadequately tested and studied before being sold to treat incontinent e and that as a result of all of these factors, set forth more fully in this report, the TVT device is not adequately designed to be safely implanted in a woman's pelvis for the rest of her life.

See id. at pp. 2-5. *See also* report dated November 16, 2015, a copy of which is attached hereto as Exhibit "J".

D. Dr. Michael T. Margolis

Dr. Margolis is also double board certified as in Obstetrics and Gynecology and Female Pelvic Medicine and Reconstructive Surgery. He received his medical degree from the University of Kansas Medical Center and performed his residency at the Department of Obstetrics and Gynecology of the University of Kansas Medical Center. Dr. Margolis did a fellowship in pelvic surgery at the Emory University Hospital System. Today, Dr. Margolis is in private practice and is also an Assistant Clinical Professor in the Department of Obstetrics & Gynecology at the David Geffen School of Medicine at UCLA. *See* Dr. Margolis' C.V., attached hereto as Exhibit "K".

Dr. Margolis examined Mrs. Ebaugh on August 1, 2016 and issued a report on January 6, 2017. *See* Dr. Margolis' report, attached as Exhibit "L". Dr. Margolis' report states, in pertinent part, as follows:

> This patient has numerous complications including recurrent urinary tract infections, partial bladder outlet obstruction, multiple erosions, urgency and detrusor instability, dyspareunia, pelvic/abdominal/lower flank pain as well as profoundly worsened stress urinary incontinence. All of these problems are caused by her TVT and TVT -S mesh implants, and she will suffer from them for the rest of her life with limited options to mitigate her suffering.
>
> I have reviewed the reports of Dr. Uwe Kling and Dr. Bruce Rosensweig regarding the characteristics of the TVT and TVT-S, and the prolene mesh they are made of, and agree with their opinions about these defective products.
>
> The defects of the TVT and TVT-S include the following:
> - tendency to rope, curl, fray, and have particle loss
> - chronic mesh inflammation
> - chronic infections
> - mesh contraction
> - severe and permanent scarring
> - scar plating and fibrotic bridging
> - mesh erosions, exposures, and obstructions
> - chronic pain and dyspareunia
>
> Additionally, the patient's TVT was made of machine cut mesh, which is known to have an increased risk of particle loss and degradation, as well as changes to the nature of mesh.

The TVT and TVT -S lacked adequate warnings to physicians about all of these risks.

The defective characteristics of the TVT and TVT-S are causing all of Ms. Ebaugh's complications. Because there is no way to safely remove the TVT or TVT -S in their entirety after implantation, Ms. Ebaugh is at risk for all of these complications for the remainder of her life.

Although Ms. Ebaugh had urinary tract infections prior to her implants and some voiding hesitancy, the problems were not nearly as severe as they are now. The problematic obstruction and recurrent urinary tract infections are clearly the result of not only the sling obstructing the urethra, but also the erosion of the foreign body into the bladder. The foreign body erosion has contaminated the bladder and seeded it with bacteria making urinary tract infections far more likely to occur. With most of the mesh removed, the urinary tract infection frequency has diminished, but she will continue to have recurrent urinary tract infections nonetheless, hopefully just less frequently. She will need to be on antibiotics for the rest of her life, and unfortunately will have to deal with the problems associated with chronic use of antibiotics, including increased frequency of yeast infections and disorientation, which she has already experienced. She can take vitamin C and cranberries to help reduce UTI frequency, and can also try to void more frequently, which might help mitigate the UTI frequency.

As for the erosions, there is no evidence of an erosion on physical exam now after 3 explant surgeries. However, it is without doubt that some mesh remains in her body, as no physician can remove all parts of a TVT or TVT -S after implantation without a horribly morbid procedure, which was not done here. Ms. Ebaugh is at risk for erosions and the sequellae for the remainder of her life.

Regarding her urgency and detrusor instability, which are much more severe than pre-implant, these are the result of the sling and the damage to the urethra caused by the sling. She might see some improvement with different anticholinergic medicines. Furthermore, intravesical Botox injections might be of some value. Finally, InterStim might be considered for refractory urgency if everything else fails. However, it is unlikely any of these treatment options can cure her urgency and detrusor instability, and she will suffer from these problems for the remainder of her life.

As for her persistent and worsened stress urinary incontinence, she has limited choices for treatment of this. One could consider a Burch procedure, but it would be a technically challenging procedure and would potentially increase her risks of bladder injury, especially given the pronounced scarring around the urethra and bladder that already exists. Other options for treatment of stress incontinence include a periurethral collagen-type injection which though temporary might be of some value for her.

> Finally as for the dyspareunia and pelvic/abdominal pain, it has improved some. She will always have some degree of dyspareunia as well as the other complications she has suffered already and I advised her that she will probably need to develop coping mechanisms to deal with the sequelae of the sling. There are no good surgical options for her.

See id. at pp. 6-8.

Dr. Margolis saw Mrs. Ebaugh again October 11, 2016, and performed a cystoscopy so he could visualize her urethra and performed urodynamic testing. *See* Dr. report dated October 11, 206 attached as Exhibit "M". Dr. Margolis' report states, in pertinent part, as follows:

> This patient has urodynamically-proven detrusor instability, urodynamically-proven intrinsic sphincter deficiency, scarring of the corpus of the bladder as well as marked and pronounced scarring and distortion of the mid and distal urethra, a polyp in the urethra and fixation of the mid urethra from substantial scarring. These urodynamic and cystoscopic findings confirm her history of extensive damage to the urethra as well as damage to the bladder from her slings. I continue to hold all of the opinions expressed in my first report, as well as this report, to a reasonable degree of professional medical certainty.

See id. at pp. 1-2.

E. <u>Dr. Vladimir Iakovlev</u>

Dr. Iakovlev is the Director of Cytopathology at the Department of Laboratory Medicine at St. Michael's Hospital in Toronto, Canada. Dr. Iakovlev has reviewed over 170 cases involving transvaginal mesh in connection with his work as a pathologist at St. Michael's Hospital. In addition, Dr. Iakovlev has reviewed mesh samples provided to him in litigation, including the pathology specimens from Mrs. Ebaugh's March 1, 2016, revision surgery. *See* Dr. Iakovlev's December 24, 2016, expert report, attached as Exhibit "N", at pp. 1-2, 119-146, and Curriculum Vitae, attached hereto as Exhibit "O".

Dr. Iakovlev's report states, in pertinent part, as follows:

> Based on the pathological findings described above; my review of the clinical records of Ms. Ebaugh; my knowledge, training and experience in medicine and

pathology; my review of the scientific literature and my own research work in the field of implantable mesh, it is my opinion to a reasonable degree of medical certainty, that the mesh and the mesh related pathological processes caused recurrent mesh erosion into the urethra and the bladder and the associated symptoms for Ms. Ebaugh. It is further my opinion to a reasonable degree of medical certainty that the residual parts of the mesh that were not removed during the excisions either remained in the bladder or the urethral wall or continued and continue to pose a significant risk for mesh erosion into the bladder and/or the urethra for Ms. Ebaugh.

***

Based on my review of the clinical records of Ms. Ebaugh; my knowledge, training and experience in medicine and pathology; my review of the scientific literature and my own research work in the field of implantable mesh, it is my opinion to a reasonable degree of medical certainty, that the mesh the mesh related pathological processes caused mesh-related (de novo) urinary symptoms for Ms. Ebaugh. It is further my opinion to a reasonable degree of medical certainty that the residual parts of the mesh that were not removed during the excisions, as well as the scarring and tissues damage caused by the mesh and the excision surgeries continued and continue to pose a risk for mesh related urinary symptoms for Ms. Ebaugh.

***

Based on my knowledge and experience, my review of the published literature and my own research in the field of implantable meshes, my review of the clinical records of Ms. Ebaugh and examination of the specimen described above; it is my opinion to a reasonable degree of medical certainty that the mesh and the associated tissue changes caused mesh-related symptoms of pain and dyspareunia for Ms. Ebaugh. It is further my opinion to a reasonable degree of medical certainty that the residual parts of the mesh that were not removed during the excisions, as well as the scarring and tissue damage caused by the mesh and the excision surgeries continued and continue to pose a risk for vaginal/pelvic pain and dyspareunia for Ms. Ebaugh.

***

Based on the pathological findings described above; my knowledge, training and experience; my review of the scientific literature, Ethicon internal documents and my own research work in the field of implantable devices, it is my opinion that polypropylene of the mesh device degraded while in the body of Ms. Ebaugh. It is my opinion to a reasonable degree of medical certainty that degradation of polypropylene contributed to the development of mesh related complications.

See Id at pp. 145-147. *See also* supplemental report dated June 28, 2017, attached hereto as Exhibit "P".

III. DAMAGES

Mrs. Ebaugh, only 52 years old, has had 2 implant surgeries because her initial TVT-S implant failed, and has had 3 urethral erosions necessitating 3 revision surgeries to remove the mesh from her urethra. She has urinary symptoms that are much more severe than what she experienced before her implant, including frequency, urgency, nocturia, and stress urinary incontinence, likely due to her intrinsic sphincter deficiency, detrusor instability, extensive scarring of her urethra, and partial bladder outlet obstruction. She now suffers from pain with sex, daily pelvic and abdominal pain, and flank pain. She is also at risk for future erosion, as it is impossible to remove all of the mesh. Mrs. Ebaugh has had a long struggle with depression that has only worsened because of these injuries.

Plaintiff's actuarial science expert, David Hopkins, estimates economic loss for Mrs. Ebaugh to be $694,541 - $1,351.822. *See* November 30, 2016 report at pp. 8-9, and C.V. of David Hopkins, attached hereto as Exhibit "Q".

Mr. Ebaugh has a loss of consortium claim and Plaintiffs also have a claim for punitive damages.

IV. WITNESSES

Pursuant to the Case Management Order, Plaintiffs are submitting their full Witness List to the Court, attached hereto as Exhibit "R".

V. EXHIBITS

Pursuant to the Case Management Order, Plaintiffs are submitting their full Exhibit List to the Court, attached hereto as Exhibit "S".

VI. STIPULATIONS DESIRED

Plaintiffs request a stipulation as to the authenticity of all medical records produced.

VII. CURRENT DEMAND/CURRENT OFFER

None to date.

VIII. ESTIMATED TRIAL TIME

It is estimated that the trial of this matter will take four (4) weeks.

Respectfully submitted,

KLINE & SPECTER, P.C.

Dated: 6/7/17 BY: _____

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CERTIFICATE OF SERVICE

I hereby certify that on the date indicated below, a copy of the foregoing Plaintiffs' Pretrial Memorandum was served via electronic mail to the following counsel:

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