

KLINE & SPECTER, P.C.
BY: THOMAS R. KLINE, ESQUIRE
KILA B. BALDWIN, ESQUIRE
Attorney I.D. Nos. 28895/94430
1525 Locust Street
Philadelphia, PA 19102
(215) 772-1000
Attorneys for Plaintiff

SHARON BELTZ,
Plaintiff
v.
ETHICON WOMEN'S HEALTH AND
UROLOGY, A DIVISION OF ETHICON,
INC., et al.,
Defendants

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY
June Term 2013
No. 003835

**PLAINTIFFS' MOTION *IN LIMINE* TO PRECLUDE EVIDENCE OF ALLEGED
ATTRIBUTES OF THE TVT-O**

TYPE OF LITIGATION: Mass Tort Program, Pelvic Mesh Litigation

OPPOSING COUNSEL:

Andrew P. Reeve, Esquire
Kenneth A. Murphy, Esquire
Melissa A. Merk, Esquire
Molly E. Flynn, Esquire
DRINKER BIDDLE & REATH
One Logan Square, Suite 2000
Philadelphia, PA 19103

Julie A. Callsen, Esquire
Tucker Ellis LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213

Tracy Van Steenburgh, Esquire
Nilan Johnson Lewis PA
120 S. Sixth Street, Suite 400
Minneapolis, MN 55402

Nils B. Snell, Esquire
Butler Snow
500 Office Center Drive, Suite 400
Fort Washington, PA 19034

Christy Jones, Esquire
Ashley Stubbs Nader, Esquire
Jordan N. Walker, Esquire
Paul S. Rosenblatt, Esquire
Ridgeland, MS 39157

Maha M. Kabbash, Esquire
Riker Danzig
Headquarters Plaza
Suite 1400 One Speedwell Avenue
Morristown, NJ 07962

Phillip J. Combs, Esquire
Thomas Combs & Spann PLLC
300 Summers Street, Suite 1380
Charleston, WV 25301

*Attorneys for Defendants Ethicon, Inc.
and Johnson & Johnson*

Kathleen Gallagher, Esquire
Beck Redden
1221 McKinney Street, Suite 4500
Houston, TX 77010

*Attorneys for Defendants Ethicon, Inc.
and Johnson & Johnson*

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ORDER

AND NOW, this _____ day of _____, 2017, it is hereby Ordered and Decreed that Plaintiffs' Motion *in Limine* to Preclude Evidence or Argument of the Alleged Attributes of the TVT-O is GRANTED and Defendants are precluded from offering any evidence or argument of the alleged safety and/or efficacy of the TVT-O at trial. Defense counsel shall advise their experts of this Order.

BY THE COURT:

J.

KLINE & SPECTER, P.C.

By: Thomas R. Kline, Esquire/Attorney I.D. No. 28895

Kila B. Baldwin, Esquire/Attorney I.D. No. 94430

1525 Locust Street, 19th Floor

Philadelphia, PA 19102

215-772-1000

Attorneys for Plaintiffs

SHARON BELTZ

Plaintiff

v.

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**PLAINTIFF'S MOTION *IN LIMINE* TO PRECLUDE EVIDENCE OF THE ALLEGED
ATTRIBUTES OF THE TVT-O**

1. On June 28, 2017, Plaintiff Sharon Beltz filed suit in this matter, alleging, *inter alia*, the Prolift and TVT-O implants she had implanted in September of 2006 for her pelvic organ prolapse and stress urinary incontinence, respectively, were defective. See complaint, attached hereto as Exhibit "A".

2. On April 25, 2017, Plaintiff's counsel represented to defense counsel that Plaintiff was dropping her claims related to the TVT-O. See email attached hereto as Exhibit "B".

3. Thereafter, on May 4, 2017, the parties put a stipulation on the record that Plaintiff Sharon Beltz was not proceeding with her claims related to the TVT-O, and would not make any claim that her current urinary and/or incontinence issues are being caused by the Prolift:

MR. KLINE: Your Honor, plaintiffs have decided to voluntarily dismiss Walter Beltz' claim. So we are not pursuing the loss of consortium claim, and Plaintiff Sharon Beltz have voluntarily agreed to dismiss all claims related to the transvaginal operator tape, the TVTO. So that would leave in the case related to the Prolift product strict liability design defect, failure to

adequately warn and misrepresentation claims. I believe there was fraudulent and negligent misrepresentation claims and we're still seeking both compensatory and punitive damages claims still in the case. And I've spoken to defense counsel and I'll represent -- and he can correct me if I'm wrong -- that we have reached an agreement that defendants will not -- the parties will not enter into evidence the fact that these claims were brought at all.

See Trial Transcript dated May 4, 2017 at pp. 3-4, attached hereto as Exhibit "C".

4. Thus, Plaintiff's remaining claims are design defect as to the Prolift, failure to adequately warn of the risks of the Prolift, and negligent and/or fraudulent misrepresentations as to the attributes of the Prolift, in addition to claims for punitive damages.

5. Plaintiff is not alleging that any of her current urinary and/or incontinence issues were caused by the Prolift.

6. Pursuant to this agreement, Plaintiff withdrew the designated testimony of her expert urogynecologist, Dr. Rosenzweig, which related specifically to the defects in the TVT-O. See expert report of Dr. Bruce Rosenzweig, attached hereto as Exhibit "D". Further, Plaintiff withdrew the designated testimony of Dr. Uwe Klinge, biomaterial researcher, related to the TVT-O, as well as all designated testimony of Ethicon/Johnson & Johnson witnesses related to the TVT-O. See expert report of Dr. Klinge, attached hereto as Exhibit "E".

7. On May 8, 2017, the Court struck testimony designated by the parties from the deposition of Dr. Heather Van Raalte referring or relating to the TVT-O and Sharon Beltz' underlying urinary issues, as they were no longer at issue in the case.

8. On May 9, 2017, defense counsel represented that Defendants intended to introduce evidence of the safety and efficacy of the TVT-O as part of the defense of the Prolift product. See Trial Transcript dated May 9, 2017. (Counsel has not yet received this transcript and will provide transcript upon receipt.)

9. Obviously, certain background information about Mrs. Beltz is relevant to the jury's overall assessment of her health, and the jury has heard Mrs. Beltz had some urinary issues prior to her implant, had a TVT-O implanted, and has some urinary issues currently.

10. However, at this stage of the trial, any defense of the Prolift by introducing evidence about the safety and efficacy of the TVT-O is not relevant to this case, and will serve only to waste time and confuse the jury.

11. Rule 403 of the Pennsylvania Rules of Evidence states that "[t]he Court may exclude relevant evidence if its probative value is outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, wasting time, or needlessly presenting cumulative evidence."

12. As this Court has recognized on multiple occasions, the TVT-O is out of this case. See May 4, 2017 Trial Transcript at pp. 3-5 and May 5, 2017 Trial Transcript at pp. 13-17, 18-25, attached hereto as Exhibits "C" and "F", respectively.

13. Introduction of the alleged safety and efficacy of the TVT-O has absolutely nothing to do with the questions the jury will ultimately have to decide here, namely, whether the Prolift was defective, whether its warnings were adequate, and whether material misrepresentations were made about the Prolift's attributes. See Exhibit "A".

14. The TVT-O, or trans-vaginal tape implanted through a woman's obturator space, is a device designed for the treatment of stress urinary incontinence. It is not indicated for the treatment of pelvic organ prolapse. See Exhibit "D" at p. 10. This is undisputed.

15. The Prolift is a device designed for the treatment of pelvic organ prolapse. It is not indicated for the treatment of stress urinary incontinence. See report of Dr. Daniel Elliott at p. 8, attached hereto as Exhibit "G". This is not disputed.

16. The devices are very different in shape and size. See diagrams attached hereto as Exhibit “H”.

17. The mesh in Prolift is Gynemesh PS. The mesh in TVT-O is Prolene polypropylene. See 8/24/15 expert report of Dr. Uwe Klinge, at p. 2, attached hereto as Exhibit “E”.

18. Any introduction of the alleged attributes of the TVT-O will only confuse the jury as to which product is at issue in this case, which of Mrs. Beltz’ current health conditions are at issue, and what damages Mrs. Beltz is seeking compensation for.

19. Further, if defense counsel is permitted to back-door evidence at this late stage of the game, in violation of the stipulation that the TVT-O is out of the case, it will waste time and force the jurors to then hear (1) Plaintiff’s expert testimony about the defects in the TVT-O, (2) Plaintiff’s designated testimony of Ethicon/Johnson & Johnson’s witnesses about the TVT-O, and (3) the problems that that TVT-O has created for Mrs. Beltz, which the jury is not being asked to compensate her for.

20. Defense counsel also represented that when Defendants introduce evidence about the alleged attributes of the TVT-O, Defendants intend to violate this Court’s MIL rulings precluding the FDA from the case. See Orders attached hereto as Exhibit “I”. Defendants intend to offer evidence about how the TVT was substantially similar to the Prolift, which is how the Prolift gained 510(k) clearance. See report of Peggy Pence, Ph.D. at p. 38, attached hereto as Exhibit “J”. This necessitates Plaintiff calling her regulatory expert, Peggy Pence, to testify at trial as well.

21. Further, Defense counsel represented Defendants would also be violating a stipulation that Defendants would not introduce any statements by AUGS or SUFU at trial, two

medical societies who issued opinion papers about TVT products. See Trial Transcript dated May 4, 2017 at pp.13-14.

22. This Court cannot allow Defendants to introduce irrelevant evidence that will waste time, confuse the jury, violate Orders previously issued on motions *in limine*, prejudice Plaintiffs, and violate stipulations and/or agreements made by the parties.


WHEREFORE, for all of the foregoing reasons, Plaintiffs respectfully request this Court grant Plaintiff's Motion to Preclude Evidence or Argument of the Alleged Attributes of the TVT-O.

Respectfully submitted,

KLINE & SPECTER, P.C.

Dated: 5/10/17

BY:



Thomas R. Kline, Esquire/28895
Kila B. Baldwin, Esquire/ 94430
1525 Locust Street, 19th Floor
Philadelphia, PA 19102
(215) 772-1000
Attorneys for Plaintiffs

VERIFICATION

I, KILA B. BALDWIN, ESQUIRE, attorney for plaintiffs in the within action, hereby verify that I am authorized to make this verification on behalf of plaintiffs and that the statements made in the foregoing Plaintiffs' Motion *in Limine* to Preclude Evidence or Argument of the Alleged Attributes of the TVT-O are true and correct to the best of my knowledge, information and belief. I understand that false statements therein are made subject to the penalties of 18 PA. CONS. STAT. ANN. § 4904 relating to unsworn falsification to authorities.



KILA B. BALDWIN, ESQUIRE

Dated:

5/10/17

CERTIFICATE OF SERVICE

I hereby certify that on the date indicated below, a copy of the foregoing Plaintiffs' Motion *in Limine* to Preclude Evidence or Argument of the Alleged Attributes of the TVT-O was served via electronic filing to the following counsel:

Andrew P. Reeve, Esquire
Kenneth A. Murphy, Esquire
Melissa A. Merk, Esquire
Molly E. Flynn, Esquire
DRINKER BIDDLE & REATH
One Logan Square, Suite 2000
Philadelphia, PA 19103

Julie A. Callsen, Esquire
Tucker Ellis LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213

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500 Office Center Drive, Suite 400
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Riker Danzig
Headquarters Plaza
Suite 1400 One Speedwell Avenue
Morristown, NJ 07962

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300 Summers Street, Suite 1380
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