

DOCKET NO.: CV-14-6025333-S : **COMPLEX DOCKET**
ROBIN SHERWOOD and
GREG HOELSCHER : **J.D. OF WATERBURY**
V. : **AT WATERBURY**
STAMFORD HEALTH SYSTEM, INC.
D/B/A STAMFORD HOSPITAL : **NOVEMBER 14, 2016**

REPLY MEMORANDUM OF LAW IN
SUPPORT OF MOTION FOR SUMMARY JUDGMENT

Defendant, Stamford Hospital, respectfully submits this Reply Memorandum of Law in support of its Motion for Summary Judgment. Stamford Hospital is entitled to summary judgment for the reasons set forth in its initial Memorandum of Law and for the reasons set forth below.

PRELIMINARY STATEMENT

In deciding this motion, the Court must answer the question whether a plaintiff can wait eight and a half years after her April, 2006 surgery to file this case against a known party, Stamford Hospital, when she knew about the injury and its cause as early as 2006 and no later than 2007. Under Connecticut law, the unambiguous answer to that question is and always has been “no.” Summary judgment is therefore required.

Plaintiffs’ objection is based on two main themes: (1) actionable harm did not accrue until 2014 when a lawyer informed Ms. Sherwood that she “had a case” against Stamford Hospital;¹ and (2) the statute of limitations is tolled by the continuing course of conduct or fraudulent concealment doctrine² because Stamford Hospital breached an alleged continuing

¹ This argument is only relevant to the CPLA claim.

² Plaintiffs appear to combine these two doctrines although no court has ever done so. She uses the term “fraudulent continuing course of conduct doctrine.” P. 10, Objection.

duty to warn Ms. Sherwood.³ Both arguments are unavailing because they have no basis in fact or Connecticut law. Plaintiffs' 'a lawyer needs to tell me I have a claim' argument would render statutes of limitations meaningless. As defendant also argued in its initial brief, there is no legal basis for this argument. The 'continuous fraud' tolling argument is equally flawed. Ms. Sherwood admitted that by 2007 and certainly 2008, she realized that the mesh implant was causing her injuries and all of her treating physicians told her that it needed to be removed. Tolling doctrines are irrelevant when a plaintiff already has actual knowledge of actionable harm.⁴ See Mountaindale Condo. Assn, Inc. v. Zappone, 59 Conn. App. 311, 319-322, 332 (2000) (fraudulent concealment and continuing course of conduct tolling doctrine are irrelevant when there is no genuine issue of material fact that plaintiff actually knew of actionable harm during statute of limitations period); Wojtkiewicz v. Middlesex Hosp., 141 Conn. App. 282, 287 (2013) (continuing course of conduct tolling doctrine does not apply when plaintiff has already discovered injury). Even plaintiffs' expert, Dr. Richard Bercik, a Yale urogynecologist and Ethicon Prolift Preceptor testified that he did not understand why the Prolift caused chronic pain in a small number of cases until 2009/2010 and that he did not, nor did Yale New Haven Hospital, send any of his former patients a letter about the problems with the Ethicon Prolift. Pp 45-47 (Bercik Depo.), Exhibit 1.

Because the plaintiff's arguments lack any factual or legal merit under Connecticut law, summary judgment is required.

³ Neither the CPLA nor Ms. Sherwood's expert, Dr. Bercik, provides that Stamford Hospital should have notified Ms. Sherwood in July, 2011 that the FDA had issued a "Safety Communication" saying that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare." Bercik Depo. at 45-47. In any case, more than five years post-surgery, the record reflects that Ms. Sherwood's physicians, including plaintiff's expert, Dr. Bercik, told her she had a problem with the mesh and recommended removal. Pp. 141-42, 143, 145, 147, 154-55, 160-61 (Sherwood Depo.), Exhibit 2.

⁴ In addition, there is no dispute that Ms. Sherwood did not continue to treat with Dr. Hines. P. 134 (Sherwood Depo.). She went other to medical providers instead. Id. at 141-161. There is no evidence and certainly not clear and convincing evidence that Stamford Hospital defrauded Ms. Sherwood.

ADDITIONAL FACTUAL BACKGROUND

After the Motion for Summary Judgment was filed, Stamford Hospital's counsel deposed Plaintiff's expert, Dr. Richard Bercik. Dr. Bercik is an assistant professor in the Department of Obstetrics and Gynecology and Reproductive Sciences at Yale-New Haven Medical School. P. 8 ("Bercik Depo."). He also has a similar appointment in the Department of Urology. Id. His position consists 100 percent of clinical work, with about 95 percent of his time involving direct patient care. Id. He has performed between 150 to 200 surgeries implanting Ethicon Prolift mesh in patients at Yale-New Haven Hospital. Id. at. 45. He continues to perform surgeries to this day implanting different pelvic mesh products in patients, including transvaginal mesh. Id. at 53.

Dr. Bercik's testimony reveals that there is no genuine issue of material fact that Stamford Hospital did not have a continuing duty to inform patients that had been implanted with the device about FDA alerts issued after the patients' surgery.

Q. Okay. Now when the FDA alert—strike that.

When the FDA one came out in 2008, the public health notification, up until that point in time, how many patients had you implanted Prolift in?

A. I'm not really sure because it wasn't the only device I was using at the time. . . You're talking about 2006/2007 until the end of 2008. I would guess probably 150 to 200, something like that.

Q. And that's consistent, I think, with what you said in the Farrell deposition.

Did you – when the FDA came out, did you go back and contact any of those patients to say, hey, we have new information you might want to be aware of?

A. We generally follow our patients – a routine following up, you know, we see them four or five times the first year and then

annually thereafter, so I didn't think it was necessary to necessarily call patients because we were continuing to see them.

Q. Right

A. And we had pretty good compliance from all our patients.

Q. And the same question, when you stopped using the Prolift, did you reach back to the patients in whom you had implanted Prolift and say, hey, look, we don't use this anymore or words to that effect because of complications and severity of pain, et cetera, et cetera?

A. No, we didn't reach back. We had prepared a letter to send out when it was removed from the market, but it wasn't 2008. We never sent that letter out. We had internal conversations with our internal legal department and they preferred we didn't, so we didn't. But we didn't do it with the 2008 alert.

* * *

Q. Okay. What could the notice have said to patients after 2008. I mean, is there even – you didn't think there was an obligation to do it is, basically, your testimony?

A. An obligation to?

Q. An obligation to reach back and send some communication out to your patients in whom the Prolift had been implanted after the 2008 bulleting?

A. Correct. We didn't feel we had to do that.

(Emphasis added) Pp. 45-47 (Bercik Depo.).

Dr. Bercik also testified that there was not a continuing duty to warn patients after the 2011 FDA alert. Exhibit 4. He stated that internal conversations regarding whether Yale-New Haven Hospital would continue use of the Prolift "intensified" after the 2011 alert, but he did not recognize the existence of any duty to warn patients of the alert that had already been implanted with the device. P. 84, (Bercik Depo.).

In addition, Dr. Bercik confirmed that he had no criticisms of Dr. Hines. Id. at 41. How could he? Dr. Bercik implanted the same mesh (the Prolift) during the same period (2005-2009) as Dr. Hines. Dr. Bercik stopped using the Prolift when his patient, Pamela Wicker, experienced chronic pain in about 2010. Id. at 21. Dr. Hines stopped using Prolift when he confirmed that Ms. Farrell, the plaintiff in *Farrell v. Johnson & Johnson*, had chronic pain, early in 2009. Pp. 47-49 (Hines Depo.), Exhibit 5.

Dr. Bercik also testified that hospitals stocked the Prolift and he did not believe Dr. Hines or Stamford Hospital had done anything wrong by implanting the device into Ms. Sherwood. Dr. Bercik testified:

Q. You are not critical of Dr. Hines or Stamford Hospital for stocking the Prolift in the 2005/2006, 2007/2008 timeframe I take it?

A. No.

Ms. Fusco: Objection to form.

The Witness: I'm not critical of Dr. Hines whatsoever and I'm certainly no expert in hospital process, so I don't have any opinion one way or the other.

By Mr. Stockman:

Q. Okay. Yale stocked it, correct?

A. Yes, they did.

* * *

Q. You attended society meetings and read the literature, presumably there were lots of hospitals stocking it in the 2005/'06/'07/'08 timeframe?

A. That would be my assumption, yes.

Q. And you have no basis to be critical of Stamford Hospital as we sit here today for stocking the Prolift?

A. Correct.

Id. at 49-50.

Dr. Bercik's testimony also offered factual support to the well-established principle that a surgery in which a device is implanted in a patient is provision of a service, not a sale of a product.

Q. Do you know of any hospital that sells the mesh directly to patients?

A. I'm not aware that medical devices are allowed to be sold to patients.

Id. at 55. Dr. Bercik also confirmed that the Ethicon Prolift did not come with a warranty. Id. at 86.

As explained further below, Plaintiff's own expert's testimony supports Stamford Hospital's argument that it is entitled to summary judgment for all of the reasons set forth in its initial Memorandum of Law.

ARGUMENT

I. Plaintiff's Interpretation Of Actionable Harm Is Incorrect So Plaintiff's CPLA Claim Is Barred By Applicable Statutes of Limitations⁵

As Stamford Hospital stated in its initial Memorandum of Law, actionable harm under § 52-577a(a) accrues when a plaintiff is aware or reasonably should have been aware of a possible causal nexus between her injuries and the offending product. See Peerless Ins. Co. v. Tucciarone, 48 Conn. App. 160, 167 (1998). Plaintiff, by her own admission, in 2006 and 2007 attributed the harm she was suffering to the recently implanted device. By 2008, all of her treating physicians instructed her to have the device removed. In fact, Ms. Sherwood, herself,

⁵ Plaintiff's non-CPLA claims are also barred by applicable statutes of limitations as set forth in Part II of the initial Memorandum of Law. For the sake of brevity, Stamford Hospital will not repeat that argument. It also should be noted that, additionally, Plaintiff's breach of warranty claims fail because Plaintiff's own expert testified that there were no applicable warranties for the device implanted in Plaintiff. Pp. 86-87 (Bercik Depo.).

contacted Ethicon seeking guidance on the removal of the device in 2008. See Exhibit 3 (Documents to be filed under seal). The weight of authority demonstrates that actionable harm accrued for the CPLA claim, at the absolute latest, when Plaintiff's doctors recommended that she have the device removed. See, e.g., Timothy v. Boston Scientific Corp. (In re Boston Sci. Corp.), No. 2:12-cv-05950; MDL No. 2326, 2015 U.S. Dist. LEXIS 38389, at *15 (S.D. W. Va. Mar. 26, 2015) (actionable harm occurred when doctor informed patient that pelvic mesh caused her injuries and needed to be repaired with subsequent surgery).⁶ In February, 2011, Plaintiff had the device removed pursuant to her doctors' recommendations.

Plaintiff adheres to the flawed interpretation that actionable harm did not accrue until 2014, when an attorney (Ms. Fusco or Mr. Leydon, apparently) told Ms. Sherwood that she had a cause of action. Plaintiff primarily bases this interpretation of actionable harm on a misreading of two cases, Tarnowsky v. Socci, 271 Conn. 284, 288 (2004) and Jackson v. Tohan, 113 Conn. App. 782 (2009). These cases are both inapplicable because they dealt with instances where the plaintiffs did not know the identity of their tortfeasor. In Jackson, a plaintiff was injured during a surgery conducted by two doctors, Shah and Tohan. Id. at 784. The plaintiff knew that Shah

⁶ Plaintiff also cites to a handful of decisions from the pending MDL cases, which are distinguishable from the present case. She relies on In re Boston Sci. Corp., No. 2:13-cv-15591, 2015 U.S. Dist. LEXIS 34024 (S.D. W. Va. Mar. 19, 2015) for the proposition that actionable harm can accrue after removal of the device. In re Boston Sci. Corp. involves a distinguishable and specific fact pattern. Unlike in the present case, the plaintiff, Ms. Foreman, decided on her own to have the mesh removed, without any recommendation from her doctor. Id. at *8-9. In the present case, there is no genuine issue of material fact that Plaintiff's doctors informed her not later than 2008 that there was a problem with the mesh and that it needed to be removed. See Robinson v. Boston Sci. Corp. (In re Boston Sci. Corp., Pelvic Repair Sys. Prods. Liab. Litig.), 2015 U.S. Dis. LEXIS 39988, at *15 (S.D. W. Va. March 30, 2015), aff'd, 647 Fed. Appx. 184 (4th Cir. 2016) (statute of limitations began running when plaintiff's doctor told her she should have pelvic mesh product removed).

She also relies on Sanchez v. Boston Scientific Corp., 2014 U.S. Dist. LEXIS 6216 (S.D. W. Va. Jan. 17, 2014), which likewise is distinguishable from the present case. In Sanchez, the plaintiff and her doctor both testified that her doctor never told her that her injuries were specifically caused by a problem with the mesh device. Id. at *22. The plaintiff's doctor testified that she had told the plaintiff all along that her symptoms were related to her body's natural rejection of the device, not a problem with the device. Id. at 24. Thus, the court concluded that there was a genuine issue of material fact as to when the plaintiff learned that her injuries had been caused by the mesh. There is no such issue of material fact in the present case. Ms. Sherwood's doctors told her, no later than March, 2008, not only that her injuries were caused by the mesh but also that the mesh needed to be removed. Dr. Bercik, her treater and expert, confirmed this fact. Pp. 62, 67-69 (Bercik Depo.).

would be performing the surgery but was never informed that Tohan would assist in the surgery. The court affirmed the trial court's denial of summary judgment on the action against Tohan on statute of limitations grounds because there was a question of material fact as to when the plaintiff learned of Tohan's identity as a tortfeasor. Id. at 789-90. The court stated that the plaintiff's incapacitation during the surgery prevented her from knowing his identity as a tortfeasor. Id. at 790. Thus, there was a genuine issue of material fact as to when actionable harm accrued.⁷ As Stamford Hospital has already explained, Tarnowksy is similarly distinguishable from the present case in that it involved a set of facts where the plaintiff had not been able to discover the identity of the tortfeasor. See Memorandum of Law at 16-17.

In the present case, plaintiff admitted that she knew, in 2006 and 2007, that her injuries were caused by problems with the Ethicon Prolift and that Dr. Hines surgically implanted the devices at Stamford Hospital. See Initial Memo at pp. ___. There is no genuine issue of material fact that she had knowledge of all elements of a product liability cause of action. Under Connecticut law, actionable harm accrued at that time. See Peerless Ins. Co. v. Tucciarone, 48 Conn. App. 160, 167 (1998).

Plaintiff's counsel mischaracterizes the language in Tarnowksy to *invent* the proposition that actionable harm does not accrue until an attorney tells a plaintiff whether or not she has a claim against a defendant. This would destroy the concept of a statute of limitations and leave it solely within the discretion of an attorney. It would disqualify counsel of record because they

⁷ The Plaintiff's assertion on page 19 of her Objection that the Appellate Court held that "the court improperly equated [plaintiff's] knowledge that 'something' had gone wrong during her first surgery with knowledge of actionable harm" is incorrect and mischaracterizes the language of the opinion. That sentence begins with the phrase "The plaintiff claims that the court improperly equated her knowledge that 'something' had gone wrong..." Id. at 787. It is clear that the sentence as a whole is a summary of the plaintiff's argument, not the Appellate Court's holding. The Appellate Court reversed the case on the grounds that there was a genuine issue of material fact as to when actionable harm accrued because the plaintiff's incapacitation during the surgery prevented her from discovering that Tohan participated in the surgery with Shah, who was the only doctor she had been told would perform the surgery.

would be material witnesses. Despite plaintiff's suggestion, none of the cases she cites stand for that extreme interpretation of when actionable harm accrues. As Stamford Hospital has already stated, the Appellate Court continues to hold that actionable harm is determined based on the *"plaintiff's knowledge of the facts rather than on the discovery of applicable legal theories."* Mollica v. Toohey, 134 Conn. App. 607, 613 (2012). Common sense and the law must prevail here.

II. The Continuing Course of Conduct and Fraudulent Concealment Tolling Doctrines Are Inapplicable To Both The CPLA And Non-CPLA Claims Because The Plaintiff Had Actual Knowledge of Actionable Harm

Plaintiff's argument that some combination of the continuing course of conduct and/or the fraudulent concealment doctrines tolled the statute of limitations fails for two reasons. First, plaintiff's own expert refutes her assertion that Stamford Hospital had a continuing duty to contact patients that had already been implanted with the Ethicon Prolift about the 2008 and 2011 FDA Safety Alerts and other studies that occurred after their surgeries. Plaintiff bases her argument regarding a continuing course of conduct or fraudulent concealment entirely on Stamford Hospital's violation of this alleged duty. Second, and more fundamental, plaintiff's reply memorandum fails to address the established principle that doctrines tolling the statute of limitations do not apply when a plaintiff has actual knowledge of actionable harm.

Much of Plaintiff's Objection to the Motion for Summary judgment is based on her conclusory allegations⁸ that Stamford Hospital violated an alleged duty to warn plaintiff of subsequent FDA safety updates regarding the pelvic mesh products. However, plaintiff's own expert refuted plaintiff's contention that a duty exists in these circumstances. Dr. Bercik has performed hundreds of surgeries implanting pelvic mesh products, including the Ethicon Prolift.

⁸ Plaintiff fails to supply expert testimony or law that a Hospital defrauds its former surgical patients when it fails to alert them of an FDA Safety Alert. The Ethicon Prolift was never recalled nor were physicians directed not to use it.

He testified that in his own practice, there was no duty to contact patients who had already been implanted with pelvic mesh products about the subsequent FDA safety alerts in 2008 and 2011. Because plaintiff's own expert refutes her assertion that Stamford Hospital had a duty to warn plaintiff regarding the 2011 FDA Safety Alert more than five years post surgery, there is no basis for her argument. There is no factual basis for Plaintiff's claim that Stamford Hospital had engaged in a continuing course of conduct or fraudulently concealed information that tolled the statute of limitations.

Putting aside Dr. Bercik's testimony, it is well-established that when a plaintiff has actual knowledge of actionable harm, tolling doctrines do not apply. See, e.g., Mountaindale Condo. Ass'n, Inc. v. Zappone, 59 Conn. App. 311, 319-322, 332 (determining fraudulent concealment and continuing course of conduct tolling doctrine is irrelevant when there is no genuine issue of material fact that plaintiff actually knew of actionable harm during statute of limitations period); see also, Wojtkiewicz v. Middlesex Hosp., 141 Conn. App. 282, 287 (2013) (continuing course of conduct tolling doctrine does not apply when plaintiff has already discovered injury).

Plaintiff asserts that actionable harm for all her claims did not accrue until 2014 due to Stamford Hospital's violation of an alleged duty to warn, which plaintiff argues is a continuing course of conduct that tolled the statute of limitations. Stamford Hospital addressed in depth in its initial brief that there is no genuine issue of material fact that Ms. Sherwood, in 2006 and 2007, or by 2008 at the latest, knew that she had been injured due to the Ethicon Prolift that were surgically implanted by Dr. Hines at Stamford Hospital. Tolling doctrines are inapplicable because Ms. Sherwood had actual knowledge of actionable harm.

III. The Hospital Is Not A Product Seller As A Matter Of Law

Stamford Hospital has addressed in depth the issue that a Hospital is not a product seller as a matter of law. Rather than repeat that argument, Stamford Hospital merely notes that the

cases plaintiff cites do not support the proposition that Stamford Hospital is a product seller in this case. See Plaintiff’s Objection, pp. 22- 23. Plaintiff’s counsel litigated most of those cited cases and in each case (with the exception of Farrell⁹), the court merely addressed whether the facts alleged in the plaintiff’s own complaint, if true, were sufficient to support a claim. See, e.g., Mihok v. Medtronic, 119 F. Supp. 3d 22, 35 (D. Conn. 2015) (“While the *allegations in the Complaint* are generally pled and are at times barebones, *the Complaint may be construed to allege* that Defendant Greenwich engaged in sales of the System to patients, sold . . . the System containing a defective catheter, performed a surgical implantation procedure for the sole purpose of delivering the System . . . , and the catheter later fractured, causing Mihok's injuries . . . In addition, *the Complaint contends* that Defendant Greenwich ‘furthered the marketing of the [System] . . . by serving as the party who made the final delivery of the product to . . . Michael Mihok.’”). (Emphasis added.) This case is beyond the stage of considering only the four corners of the Complaint.

The evidence before this Court demonstrates that there is no genuine issue of material fact that the surgery to install the Ethicon Prolift was a service, not a sale. Dr. Bercik was asked at his deposition whether he knew of any hospital that sells pelvic mesh products directly to patients. He replied that he was “not aware that medical devices are allowed to be sold to patients.” P. 55 (Bercik Depo.). His testimony confirms there is no genuine issue of material fact that hospitals in the United States do not sell pelvic mesh products to patients. Rather, they are implanted in patients through surgery. As Stamford Hospital addressed in depth in its initial memorandum of law, courts throughout the country have held that the implantation of a device

⁹As stated in Footnote 16 of its memorandum of law in support of the Motion for Summary Judgment, Stamford Hospital concedes that this Court has issued decisions denying summary judgment in the Farrell case on this issue because of an issue of fact. However, because neither decision contained any analysis, it is difficult to determine the basis for them or whether they could be applicable.

through surgery is a service, not a sale of a product. Stamford Hospital is not a product seller as a matter of law and it is entitled to summary judgment on the CPLA claim.

CONCLUSION

For the foregoing reasons and for those presented in its initial Memorandum of Law, Stamford Hospital respectfully requests that the Court grant its motion for summary judgment.

**DEFENDANT,
STAMFORD HEALTH SYSTEM
D/B/A STAMFORD HOSPITAL**

/s/ Simon I. Allentuch .
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CERTIFICATION

I hereby certify that a copy of the foregoing was sent via email to the following counsel
of record on the 30th day of September, 2016:

Brenden P. Leydon, Esq.
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/s/ Simon I. Allentuch
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D/B/A STAMFORD HOSPITAL : **NOVEMBER 14, 2016**

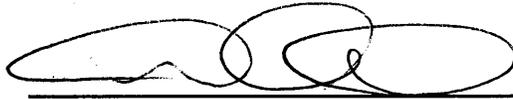
DECLARATION OF SIMON I. ALLENTUCH

Simon I. Allentuch declares under penalty of perjury pursuant to 28 U.S.C. § 1746 and the Supremacy Clause of the United States Constitution:

1. I am over the age of 18 and believe in the obligation of an oath.
2. I make this Declaration in support of Stamford Hospital's Motion for Summary Judgment.
3. I am an attorney duly admitted to practice law before the courts of the State of Connecticut and a principal in the law firm, Neubert, Pepe & Monteith, P.C., counsel for Defendant, Stamford Hospital.
4. Attached as Exhibit 1 are portions of Dr. Richard Bercik's deposition testimony, dated November 4, 2016.
5. Attached as Exhibit 2 are portions of Robin Sherwood's deposition testimony, dated September 20, 2016.
6. Attached as Exhibit 3 are documents to be filed under seal between Robin Sherwood and Ethicon.
6. Attached as Exhibit 4 is the July 13, 2011 FDA Public Health Notification.

7. Attached as Exhibit 5 are portions of Dr. Brian Hines' deposition testimony, dated March 25, 2014.

**DEFENDANT,
STAMFORD HEALTH SYSTEM
D/B/A STAMFORD HOSPITAL**



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EXHIBIT 1

SUPERIOR COURT
COMPLEX DOCKET
JUDICIAL DISTRICT OF WATERBURY
AT WATERBURY
STATE OF CONNECTICUT

CV-1406025333-S

-----x

ROBIN SHERWOOD and GREG HOELSCHER
Plaintiffs

-vs-

STAMFORD HEALTH SYSTEM, INC.,
D/B/A STAMFORD HOSPITAL,

Defendant

-----x

Deposition of RICHARD BERCIK, M.D., a Witness, in
the hereinbefore-entitled action, taken by the
Defendant, pursuant to Notice before Victorine D.
Hennessey, a duly qualified Notary Public in and
for the State of Connecticut, held at the Law
Offices of Neubert, Pepe & Monteith, 195 Church
Street, 13th Floor, New Haven, Connecticut on
November 4, 2016 beginning at 10:00 a.m.

DEL VECCHIO REPORTING
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S T I P U L A T I O N S

It is hereby stipulated and agreed by and between counsel for the respective parties that all formalities in connection with taking of this deposition, including time, place, sufficiency of and the authority of the officer before whom it is being taken may be and are hereby waived.

It is further stipulated and agreed that objections other than as to form are reserved to the time of trial.

It is further stipulated and agreed that the reading and signing has not been waived and a Notary Public will notarize said deposition.

It is further stipulated and agreed that the deposition is to be filed with the Superior Court at Waterbury, Connecticut upon request.

* * * * *

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1 investigator for the AMS Astora 522 studies. I
2 think I testified to that in a prior deposition.

3 Q You did.

4 A Those studies have closed now since Astora
5 has closed and we just recently -- I am also now a
6 principal investigator for a similar 522 study for
7 Coloplast for their Restorelle mesh, which we just
8 initiated that study this month.

9 Q Great.

10 Can you just briefly describe for the record
11 your current position within the Yale-New Haven
12 health system?

13 A Certainly.

14 I am an assistant professor in the clinical
15 track at the Department of Obstetrics and Gynecology
16 and Reproductive Sciences at Yale-New Haven Medical
17 School. I'm employed by the medical school. I also
18 have a similar appointment in the Department of
19 Urology. My position is really 100 percent
20 clinical, although I do do some research, as I
21 mentioned the clinical trials. My time really is
22 about 95 percent patient care, direct patient care.

23 Q Do you serve on any committees that are
24 responsible for stocking surgical products like
25 surgical mesh in the hospital?

1 one?

2 A Well, if my math is correct, probably
3 about 26 months.

4 Q Okay.

5 A Because it came out in October and
6 probably it was December of -- no, I'm wrong, it was
7 less than that, it was 2008 until the end of 2009,
8 2010.

9 Q Okay.

10 A So my math is wrong.

11 Q Maybe a year-ish?

12 A Yeah, a little over a year.

13 Q I don't expect to hold you to specific
14 dates, but that's the general timeframe?

15 A Yes, sir.

16 Q And why did you stop using it?

17 A Well, I had a case actually -- and I
18 testified on this case -- by the name of Pam Wicker
19 who had a significant chronic pain issue that did
20 not go away and that was my first patient that I
21 recall that was my patient that I had inserted
22 material where I had that issue. And so, that
23 combined with the fact that I knew that there were
24 lighter-weight meshes that were coming out and we
25 had certainly some information in the literature

1 started seeing more literature with regard to those
2 complications in and around that 2008/2009
3 timeframe.

4 Q And were you a preceptor for Ethicon as
5 well?

6 A I was an ad hoc preceptor. So, there were
7 occasionally times -- so, I didn't have a long-term
8 contract with them.

9 Q Okay.

10 A Occasionally a physician might want to be
11 trained. Usually our institution was the ones that
12 I trained at. I didn't travel. I trained one of my
13 partners and one of the people in the community who
14 wanted to and I had like a one-day contract to do
15 that.

16 Q So, they paid you to do that, right?

17 A They did, yes.

18 Q And even during that timeframe, you didn't
19 get any extra information from them about
20 complications or issues with the device from J & J?

21 A I did not. Not that I recall.

22 Q And when I say J & J, you know I mean J &
23 J/Ethicon?

24 A Yes, sir.

25 Q Then it says, "in addition, it is expected

1 you know, the added complication of, you know, the
2 numerosity of adverse outcomes, the severity of the
3 adverse outcomes, the duration of the adverse
4 outcomes, that wasn't really available until the
5 2008/2009 timeframe and beyond?

6 A Yeah, I'd have to go back and actually
7 probably do a little search and look at the
8 timeframe of studies that were published in order to
9 answer that well.

10 Q To your understanding, though, it wasn't
11 out there?

12 A Not to my understanding at this point.

13 Q Hence your opinion that the manufacturer
14 was holding back?

15 A Yes, and I think that opinion is based, as
16 I said, on some information I had seen and some of
17 the other litigation of internal documents that
18 there was some concern with regard to that.

19 Q Okay. Now, when the FDA alert -- strike
20 that.

21 When the FDA one came out in 2008, the public
22 health notification, up until that point in time,
23 how many patients had you implanted Prolift in?

24 A I'm not really sure because it wasn't the
25 only device I was using at the time. I was using

1 also the AMS and the Bar devices. You're talking
2 about 2006/2007 until the end of 2008. I would
3 guess probably 150 to 200, something like that.

4 Q And that's consistent, I think, with what
5 you said in the Farrell deposition.

6 Did you -- when the FDA one came out, did you
7 go back and contact any of those patients to say,
8 hey, we have new information you might want to be
9 aware of?

10 A We generally follow our patients -- a
11 routine following up, you know, we see them four or
12 five times the first year and then annually
13 thereafter, so I didn't think it was necessary to
14 necessarily call patients because we were continuing
15 to see them.

16 Q Right.

17 A And we had pretty good compliance from all
18 of our patients.

19 Q And the same question, when you stopped
20 using the Prolift, did you reach back to the
21 patients in whom you had implanted Prolift and say,
22 hey, look, we don't use this anymore or words to
23 that effect because of complications and severity of
24 pain, et cetera, et cetera?

25 A No, we didn't reach back. We had prepared

1 a letter to send out when it was removed from the
2 market, but it wasn't 2008. We never sent that
3 letter out. We had internal conversations with our
4 internal legal department and they preferred we
5 didn't, so we didn't. But we didn't do it with the
6 2008 alert.

7 Q Right.

8 A The 2008 alert when we looked at that --
9 and the reason we didn't go back and contact
10 patients -- because it, basically, reported both on
11 prolapse mesh and slings, it gave a number of the
12 complaints, but it didn't give us any idea of what
13 percentage that was.

14 Q Okay. And how do you quantify, you know,
15 it says rare, how do you quantify rare?

16 A That meaning is different for everybody.

17 Q Right.

18 A For me I think of rare as being certainly
19 less than one percent and probably less frequent
20 than -- I think probably less than one percent.

21 Q And that's the word that the bulletin
22 used, right?

23 A Yeah. Yes.

24 Q Okay. What could the notice have said to
25 patients after 2008, I mean, is there even -- you

1 treated know about it?

2 A Correct.

3 Q Did you read both your depositions in the
4 Farrell case?

5 A I've read the most recent one, which I
6 think was the expert one. I did not go back and
7 read the fact one.

8 Q I'm just looking at the expert one. Was
9 there anything in there that you particularly wanted
10 to change or that you sort of disagreed with in
11 hindsight?

12 A Yeah, the only -- I don't think there's
13 anything in there that I would disagree with. There
14 was some questions with regard to -- and this was on
15 the topic of how the Prolift mesh changes under
16 force. You know, what would be the force that a
17 person would exert, you know, in normal every day
18 activity. And, you know, I said that I thought that
19 the average force was probably around two to three
20 Newtons per millimeter squared and it's probably
21 just a little bit higher, it's probably about five.

22 Q Fair enough. I'm just going to run
23 through some of the things I asked you there to make
24 sure I've got it on the record.

25 You are not critical of Dr. Hines or Stamford

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1 Hospital for stocking the Prolift in the 2005/2006,
2 2007/2008 timeframe, I take it?

3 A No.

4 MS. FUSCO: Objection to form.

5 THE WITNESS: I'm not critical of Dr.
6 Hines whatsoever and I'm certainly no expert in
7 hospital process, so I don't have an opinion
8 one way or the other.

9 BY MR. STOCKMAN:

10 Q Okay. Yale stocked it, correct?

11 A Yes, they did.

12 Q Do you know of any other hospitals that
13 were stocking it at that time?

14 A No, I only worked at Yale at the time, so
15 not to my knowledge.

16 Q You attended society meetings and read the
17 literature, presumably there were lots of hospitals
18 stocking it in the 2005/'06/'07/'08 timeframe?

19 A That would be my assumption, yes.

20 Q And you have no basis to be critical of
21 Stamford Hospital as we sit here today for stocking
22 the Prolift?

23 A Correct.

24 Q And you certainly don't intend to offer
25 any opinion about that at the time of trial?

1 around the end of 2013/2014 and it was then when I
2 really started looking at properties of mesh
3 material and the different mesh materials and how
4 they respond and how they act.

5 So, I really started thinking about something
6 being defective -- and not being an expert in that
7 sort of thing -- somewhere in that process, you
8 know, 2014 -- '13, '14, '15.

9 Q Is it your opinion that all mesh is
10 inherently defective?

11 A No, no, that is not my opinion.

12 Q Okay.

13 A I think there is a difference based upon
14 the characteristics and specifications of the
15 material.

16 Q You still use mesh today?

17 A Yes, sir.

18 Q Just a different brand?

19 A Yes, I use a different -- a
20 lighter-weight, larger pore mesh that has different
21 response under load.

22 Q You use the Elevate, right?

23 A I did.

24 Q I take it you stopped using the Elevate?

25 A I stopped using Elevate, you know, most

1 it's Randall Kumpf.

2 Q Do you know why Yale stopped stocking the
3 Prolift?

4 A Well, I think when I stopped -- when I
5 made a transition to Elevate, I guess the number
6 that was being used was going down, so it didn't
7 warrant keeping it in stock and that's why it went
8 to an ad hoc basis.

9 Q Okay. To your knowledge, did Yale
10 participate in the manufacturer of the mesh?

11 A No.

12 Q Did Yale sell the mesh independently of
13 providing it for surgery?

14 A Not to my knowledge.

15 Q Do you know of any hospital that
16 participated in the manufacturer of mesh anywhere in
17 the country?

18 A I don't.

19 Q Do you know of any hospital that sells the
20 mesh independent of providing it for surgical
21 procedures?

22 A I know hospitals swap back and forth
23 between them. When St. Rae's was a separate entity,
24 they would swap back and forth, I don't know if they
25 were selling it or not, that's my only -- in that

1 (Whereupon, a brief recess was
2 held.)

3 BY MR. STOCKMAN:

4 Q Do you have -- did you bring your records
5 today with you?

6 A I didn't bring them.

7 MS. FUSCO: They're all electronic. He
8 didn't print anything out. I have a copy.

9 BY MR. STOCKMAN:

10 Q Do you have an understanding of the
11 treatment that you rendered to the patient?

12 A I do.

13 Q Okay. Do you recall when you first saw
14 her?

15 A Well, the first time I saw her was in
16 2008, I think it was March, and I believe she was
17 coming because of her complaint was mostly vaginal
18 pain and dyspareunia at the time.

19 Q And do you recall what, if anything, you
20 concluded -- you examined her, I take it?

21 A I did.

22 Q And do you recall what your conclusion was
23 about the causes of her vaginal pain and
24 dyspareunia?

25 A Do we have a copy of it?

1 symptomatology?

2 A Yes, sir.

3 Q And discussed possible removal -- did I
4 just say removal?

5 A That's as good as --

6 MR. STOCKMAN: Numerosity is a real word.
7 Removal isn't. So, let's go back.

8 (Whereupon, a brief discussion
9 was held off the record.)

10 BY MR. STOCKMAN:

11 Q So, you thought more likely than not that
12 the Prolift was causing her issues and that's why
13 you discussed removal of the Prolift with her?

14 A More likely than not I felt that the
15 Prolift was contributing to the problem that she
16 had, yeah. Based on this note, I don't think it was
17 the only thing because I also mentioned the
18 colpopexy, but I would not have recommended removal
19 or even had the conversation about removal unless I
20 thought it was, you know, significantly contributing
21 to her complaints.

22 Q Now, just in your notes it says "including
23 removal of the SSLF suture," can you just explain
24 that to me?

25 A So, Dr. Hines had put a stitch from the

1 back of the cervix to the sacrospinous ligament,
2 which we use SSLF, which stands for sacrospinous
3 ligament fixation. And so, when I examined her and
4 movement of the cervix did create some discomfort
5 going to the right side, that's why I would also
6 have a conversation of not just taking out the
7 graft, but also taking out that stitch.

8 Q And you discussed revision/removal of the
9 anterior graft. How does one revise the anterior
10 graft?

11 A So, revise -- well, we do revision when
12 there is an erosion, which doesn't pertain here, but
13 sometimes we'll also do a revision at that time if
14 you had somebody who had a very taut arm which was
15 bothering them, you can go in and simply release
16 that arm, cut it, and so that was not uncommonly
17 done at that time.

18 In her, most likely because the graft wasn't
19 just one area that was tender, it was firm and
20 palpable throughout, I probably would have removed
21 that central portion of the graft similar to what
22 Dr. Raz did.

23 Q Just help me to understand, how are her
24 complaints here related to a defect with the
25 product?

1 A Well, I think that one of the things that
2 happens with the product -- and I don't know that I
3 knew this then, but I know it now -- is that you
4 have placed under load, loss of porosity of the
5 mesh, so porosity is the open spaces where the good
6 tissue grows through and when you have loss of
7 porosity, you get scar plate formation which is
8 fibrosis that bridges from one part of the pore to
9 the other side of the pore and with that fibrosis,
10 there's no area for normal collagen and tissue to
11 grow into. And because of the configuration and
12 knit of the mesh, the arm seem to be particularly
13 susceptible to a loss of porosity under tension.

14 And so, that's how I think -- that's the main
15 defect, not the only one, but I think it's one of
16 the main ones.

17 Q Okay. So, we'll get to the others in a
18 second.

19 Once that happens, the loss of porosity, does
20 the material contract, does it harden, what's the
21 effect inside the body?

22 A Well, you get a thicker scar. She was
23 identified subsequent to this as having cords in
24 that area both lateral to the vagina on both sides
25 and so you do see a thicker scar, a harder scar,

1 actually in 2008 would have been to remove, I wasn't
2 going to just -- that mesh was palpable and firm, so
3 I probably would have just removed it at that time,
4 too.

5 Q Okay. I guess that's what I was driving
6 at.

7 There was indication back then to take the
8 whole thing -- the central portion out along with
9 the -- not the deep arms, but along with the other
10 arms, even back in 2008?

11 A Yes, sir.

12 Q Okay. All right. And so, it looks like
13 you sent her for pelvic floor rehabilitation
14 therapy?

15 A We did. You know, she had what I
16 sometimes refer to as spasm of the muscles, they
17 certainly seemed to be very painful. I talked with
18 her about using some vaginal Valium suppositories to
19 relax those muscles, we talked a little bit about
20 Botox therapy, and we also talked about physical
21 therapy, we call it myofascial release; it's sort of
22 like an acupressure type of treatment for the pelvic
23 floor. And I think at that time she was comfortable
24 with the idea of physical therapy, but not
25 necessarily about Botox or medication, as I recall.

1 read things and had a couple of patients of my own
2 who were -- and had treated some other people's
3 patients who I saw these complications in and I felt
4 that it was related to -- I didn't know as much
5 about it then as I do now, but I thought it was
6 related to the construction of the mesh, in general
7 terms.

8 Q Okay. Does Yale do any -- I'll strike
9 that.

10 MR. STOCKMAN: All right. I might be
11 done. Just give me five minutes to talk to my
12 counsel here.

13 (Whereupon, a brief recess was
14 held.)

15 MR. STOCKMAN: All right. Back on the
16 record.

17 BY MR. STOCKMAN:

18 Q Did the Prolift come with any guarantee or
19 warranty on the box to you or to your patients that
20 it was effective?

21 A Not that I'm aware of.

22 Q You certainly never represented to your
23 patients that the Prolift was a guarantee?

24 A No, in fact, I always tell patients
25 there's no guarantee in any surgery.

1 Q And not just because of the inherent risk
2 of surgery, but because of the complications that
3 you were aware of at least in 2005, 2006, 2007,
4 2008, correct?

5 A Certainly we never used any words like
6 warranty or guarantee.

7 Q Okay. Do you have any information in this
8 case that a warranty or a guarantee of any sort was
9 given to Miss Sherwood by the hospital or by Dr.
10 Hines?

11 A Not to my knowledge.

12 Q Did Miss Sherwood ever say to you the
13 hospital or Dr. Hines guaranteed or warrantied or
14 promised that this would work?

15 A No, sir.

16 Q Did she ever say to you in any of the care
17 and treatment that you rendered to her that anybody
18 from the hospital or Dr. Hines tried to cover up the
19 issues with the product?

20 A Not that I recall, no.

21 Q You've said before that you've now come to
22 the conclusion that the mesh is defective and that
23 it's not porous enough. How did you reach that
24 conclusion, is it based on research, studies, how
25 did you come to that conclusion?

1 CERTIFICATE

2 STATE OF CONNECTICUT

3 ss: New Haven

4 COUNTY OF NEW HAVEN

5

6 I, Victorine D. Hennessey, a Notary
7 Public in and for the State of Connecticut, duly
8 commissioned and qualified and authorized to
9 administer oaths, do hereby certify that I was
10 attended at the law office of Neubert, Pepe &
11 Monteith, 195 Church Street, 13th Floor, New Haven,
12 Connecticut, on November 4, 2016, starting at 10:00
13 a.m., by counsel for the respective parties as
14 appears in the herein-entitled cause and the
15 deponent named in the foregoing deposition, to wit:
16 RICHARD BERCIK, M.D.; that said deponent was by me
17 duly sworn and thereupon testified as appears in the
18 foregoing deposition; that said deposition was taken
19 stenographically by me in the presence of counsel
20 for the respective parties and reduced to
21 typewriting under my direction; that the foregoing
22 is a true and correct transcript of the testimony.

23 I also certify that I am neither of
24 counsel nor attorney to either of the parties to
25 said suit, nor am I an employee of either party to

Page 92

1 said suit, or of either counsel in said suit, nor am
2 I interested in the outcome of said cause.

3 Witness my hand and Seal as such Notary
4 Public at New Haven, Connecticut this 7th day of
5 November, 2016.

6

7

8

9

VICTORINE D. HENNESSEY
COURT REPORTER
NOTARY PUBLIC

10

11

12 My Commission Expires:

13 November 30, 2020

14

15 CSR NO. 00208

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EXHIBIT 2

SUPERIOR COURT
COMPLEX DOCKET
AT WATERBURY

-----/

ROBIN SHERWOOD and GREG
HOELSCHER,

v

DOCKET NUMBER:
UWY-CV-14-6025333-S

STAMFORD HEALTH SYSTEM,
INC. D/B/A STAMFORD HOSPITAL

-----/



DEPOSITION OF ROBIN SHERWOOD, taken in
accordance with the Connecticut Practice Book at the
law offices of Tooher Woel & Leydon, 80 Fourth
Street, Stamford, Connecticut 06905, before Mercedes
Marney-Sheldon, RPR, a Registered Professional
Reporter and Notary Public, in and for the State of
Connecticut on Tuesday, September 20, 2016, at 10:15
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S T I P U L A T I O N S

1
2
3 IT IS HEREBY STIPULATED AND AGREED by and
4 between counsel representing the parties that each
5 party reserves the right to make specific objections
6 at the trial of the case to each and every question
7 asked and of the answers given thereto by the
8 deponent, reserving the right to move to strike out
9 where applicable, except as to such objections as
10 are directed to the form of the question.

11 IT IS FURTHER STIPULATED AND AGREED by and
12 between counsel representing the respective parties
13 that proof of the official authority of the Notary
14 Public before whom this deposition is taken is
15 waived.

16 IT IS FURTHER STIPULATED AND AGREED by and
17 between counsel representing the respective parties
18 that the reading and signing of this deposition by
19 the deponent is not waived.

20 IT IS FURTHER STIPULATED AND AGREED by and
21 between counsel representing parties that all
22 defects, if any, as to the notice of the taking of
23 the deposition are waived.

24 Filing of the Notice of Deposition with
25 the original transcript is waived.

1 him, if he broke it, he bought it.

2 Dr. Staskin was leaving the hospital
3 at that point so he was not looking for new
4 patients. He gave me the name of someone else to
5 go to and I did.

6 Q Let me get to that in a second. So
7 Dr. Staskin was telling you you should have
8 surgery to sever the arms of the mesh; is that
9 right?

10 A That's what my take away was.

11 Q Okay. And did he explain to you what
12 that would do for you?

13 A No.

14 Q So he recommended you see another --
15 either go back to Dr. Hines or see someone else
16 he recommended?

17 A Yes.

18 Q Who did he tell you to go see?

19 A Jill Peters-Gee in Hartford.

20 Q Before we get to Dr. Gee, I saw a
21 reference in your records to a Dr. Porges?

22 A Yes.

23 Q Who is Dr. Porges?

24 A I believe Dr. David Porges was the
25 head of urogynecology at NYU Hospital. The

1 hospital was down on First Avenue. He was
2 recommended by Dr. Hines.

3 Q Did you ever go see him?

4 A I did.

5 Q And when was that, do you remember?

6 A Not exactly.

7 Q Was that in -- did you see him in
8 2008?

9 A Yes, I think so. I don't know if I
10 saw him before or after Dr. Gee.

11 Q All right. Tell me -- withdrawn.
12 Were your symptoms changing during
13 2008 as you were seeing these different
14 physicians or were they constant or similar?

15 A I don't recall exactly. It didn't go
16 away. I had resumed having intercourse and it
17 was painful.

18 Q All right. So you saw Dr. Porges.
19 You told him about your symptoms; is that right?

20 A Uh-huh.

21 Q And that was also in 2008; correct?

22 A Yes.

23 Q Did you bring him your medical
24 records?

25 A I don't remember.

1 Q What about Dr. Staskin? Did you get
2 your medical records and bring them to him?

3 A I don't remember. When I left
4 Dr. Hines' practice he wrote the procedures. I
5 asked him to write down what had been done so I
6 could communicate that. And so I don't know the
7 answer about when the medical records --

8 Q I'm sorry. Go ahead. I didn't mean
9 to cut you off.

10 A I think I took the little sheet of
11 paper to one or two doctors before I --

12 Q So when Dr. Staskin, for example, met
13 with you, he did an exam, he looked at the piece
14 of paper from Dr. Hines listing the surgeries
15 that he performed and he listened to your oral
16 history; is that what he was relying on?

17 A I don't remember exactly.

18 Q Okay. All right. Let's go back to
19 Dr. Porges. What -- tell me about what you --
20 what Dr. Porges told you.

21 A I believe he's the first doctor that
22 I recall saying, I think your mesh needs to come
23 out. And he said he could do it but it would be
24 a series of surgeries and they would all be
25 abdominal.

1 Q Did you tell him you were interested
2 in doing that? What was your response?

3 A I guess I felt like I needed to get
4 more information. You know, I asked him some
5 questions. You know, have you done this before?
6 Do you still put mesh in people? Exactly what he
7 said, I didn't, you know -- I don't know.

8 Q Did he tell you whether he had done
9 it before?

10 A He inferred that he had taken mesh
11 out.

12 Q He inferred that he had taken mesh
13 out?

14 A That's what my takeaway was. But his
15 information was a little vague. And I didn't
16 really want to have a series of abdominal
17 surgeries so I thought I should keep moving.

18 Q Okay.

19 MR. ALLENTUCH: Why don't we take a
20 break for five minutes and we'll continue.

21 MS. FUSCO: It was just a half hour
22 ago.

23 MS. GOODSTEIN: Two minutes. I need
24 a little break.

25 MR. ALLENTUCH: It will be two

1 minutes. I understand you want to finish,
2 but just two minutes.

3 (Off the record.)

4 BY MR. ALLENTUCH:

5 Q When you were talking with
6 Dr. Staskin and he recommended that you have
7 surgery to cut the arms of the mesh, was he
8 talking about the Prolift?

9 A I assume he was.

10 Q Okay. And Dr. --

11 A That's the only thing that was
12 written on the prescription sheet of paper
13 besides the sacrospinous ligament fixation.

14 Q I was going to try to pronounce that
15 correctly but I failed a number of times. I'm
16 glad you took the lead there.

17 A I talked over you. I'm sorry.

18 Q No. I would have butchered it.

19 And Dr. Porges, when he was -- he was
20 telling you that you should have the mesh
21 removed, was he also talking about the Prolift?

22 A Yes.

23 Q You told me a few moments ago that
24 Dr. Staskin recommended that you see Dr. Gee in
25 Hartford?

1 A Yes.

2 Q Did you do that?

3 A Yes.

4 Q And, again, you were complaining --
5 that was also in the first half of 2008, like
6 Dr. Porges; is that right?

7 A Yes. I don't know the exact dates I
8 think I saw all these people before I saw
9 Dr. Bercik, or they were sort of clumped up. I
10 think I paid for Dr. Porges out of my pocket
11 because I was afraid my insurance company was
12 going to drop me or something. I was sort of in
13 a state of like what am I going to do, what am I
14 going to do. The sky is falling.

15 Q Your insurance was through your
16 husband's work; is that right?

17 A Yes.

18 Q What does your -- what kind of work
19 does your husband do?

20 A He's an economist and a trader and he
21 was working at a hedge fund at the time.

22 Q So tell me about your visit with
23 Dr. Gee. What did you tell her?

24 A I told her I was having tightness in
25 my abdomen. I felt like I had bands, you know,

1 radiating from my hips to my uterus. My back
2 hurt. My leg hurt all the time. And my sitz
3 bones hurt when I sit for very long.

4 She was very sympathetic. But she
5 referred me to another doctor.

6 Q What did she -- was she a -- sorry.
7 Was Dr. Gee a urogynecologist?

8 A Yes.

9 Q But she didn't do mesh excision
10 surgery.

11 A No.

12 Q Is that what she told you?

13 A Yes.

14 Q And is that why she referred you to
15 somebody else?

16 A Uh-huh.

17 Q All right. About the same time, were
18 you seeing Dr. Shea for gallbladder problems?

19 A Uh-huh.

20 MS. GOODSTEIN: You need to say yes.

21 THE WITNESS: Yes. Yes.

22 BY MR. ALLENTUCH:

23 Q You were in a lot of pain -- is this
24 different than the gastrological problems we were
25 talking about before, correct?

1 A It's different.

2 Q All right. And you were in a lot of
3 pain; is that right, from the gallbladder?

4 A Yes. That was kind of an acute
5 episode.

6 Q All right. What can you -- were you
7 on narcotic pain killers because of the pain?

8 A No.

9 Q Did you have your gallbladder
10 removed?

11 A I did.

12 Q When was that?

13 A Well, I know it was in 2008 and I
14 think it was in March or April.

15 Q All right. And was Dr. Shea treating
16 you for this?

17 A Well, she wanted me to see the
18 gastroenterologist. I had to have a test at the
19 hospital called a HIDA scan, and it was sort of
20 diagnosed and I -- Dr. Khaghan wanted to take my
21 gallbladder out but I wanted to think on it more
22 to make sure that that's what I really needed to
23 do. I didn't want to just -- oh, let's have
24 another surgery thing.

25 Q Could you describe the pain for me

1 that you were experiencing as a result of your
2 gallbladder problems in March or April of 2008?

3 A Yes. I had like intense pain here in
4 my shoulder, in my neck. I was vomiting.

5 Q So was the pain was where your
6 kidneys are on your right side?

7 A Just under my ribs.

8 Q Just under your ribs, okay.

9 A Yes.

10 MS. FUSCO: Do you want to describe
11 it? Is that the front or the --

12 THE WITNESS: The front.

13 BY MR. ALLENTUCH:

14 Q I also can't really see either.

15 A Right upper quadrant just under the
16 ribs in the front.

17 Q All right. Thank you.

18 And on a scale of 1 to 10, what was
19 that pain like?

20 A 10.

21 Q 10. So what you were doing with your
22 gallbladder? Were you still trying to deal with
23 the Prolift mesh problem at the same time?

24 A Yes. It didn't go away.

25 Q And you described before how you

1 were -- it was a "holy cow" moment. Is this --
2 was this gallbladder problem part of that?

3 A No. That was in the future at the
4 "holy cow" moment.

5 Q Oh, that was in the future.

6 When was the "holy cow" moment then?
7 Maybe I misunderstood.

8 A The last time I went to Dr. Hines in
9 2007.

10 Q Okay. But we're in March of 2008 now
11 so I see, this is --

12 A Yeah.

13 Q But that feeling had carried over; is
14 that right, that you were just very upset about
15 your medical condition and all these problems you
16 were facing?

17 A Yes.

18 Q Okay. I understand.

19 Did you have the gallbladder surgery?

20 A I did. I called Dr. Present in New
21 York and I told him everything. And I said, I'm
22 probably going to have this taken out. What
23 should I do? And he gave me the name of a
24 surgeon there. And had it taken out.

25 I had another episode like that --

1 they are acute episodes. I think I had a stone
2 in the duct or something and just vomiting and
3 intense pain like you're begging someone to cut
4 you open and take the pain away.

5 Q All right. And once you had the
6 surgery, did those problems from your gallbladder
7 go away?

8 A For a little while. But six weeks
9 after the surgery, I had a similar attack that
10 was quite similar to those. And that turned out
11 to be -- you know, I had to see a few different
12 people. I saw Dr. Shea first.

13 I saw someone Dr. Salke recommended,
14 and then I went to a doctor at Yale. So it was a
15 difficult diagnosis, but it's called Sphincter of
16 Oddi disorder.

17 Q Was the surgery at Yale for your
18 gallbladder?

19 A No. It was at Mount Sinai.

20 Q I'm sorry. I didn't hear the name of
21 the disorder. What's it called again?

22 A Sphincter of Oddi Disorder.

23 Q Is that something you still suffer
24 from today?

25 A Yes.

1 Q Do you still get acute episodes from
2 time to time?

3 A From time to time. Infrequently.

4 Q When you say "acute," the pain is
5 like a 10; is that right?

6 A Yes, yes.

7 Q And where is the pain when you have
8 these episodes? The same place you described
9 before?

10 A Right -- yes.

11 Q So it turned out your gallbladder was
12 not the problem but it was this disorder; is that
13 right?

14 A It was the problem. I had an
15 obstructing stone I believe, or I had stones or
16 sand. And the doctors tell me that the reason I
17 have this is because I have a very tiny common
18 bile duct. So my body produces little stones,
19 they can plug it up or I can eat fat, produce too
20 much bile and it will just stop and close. I'm
21 careful about what I eat.

22 Q All right. How common were these
23 episodes in 2008 from this Oddi disorder?

24 A Frequent. They happened every few
25 days.

1 Q How about in 2009, were they --

2 A Under control.

3 Q Under control?

4 A Uh-huh.

5 Q So they just happened from time to
6 time in 2009?

7 A Yes. I got a drug to take that will
8 open the duct back up in 15 or 20 minutes.

9 Q And the doctor who is treating you
10 for this is at Yale; is that right?

11 A Yes.

12 Q And what's the name of that doctor?

13 A I think his last name is Jamidar.
14 It's Priya Jamidar or Jamidar Priya. I never
15 know which direction it goes.

16 Q When did you start seeing
17 Dr. Jamidar?

18 A Probably by summer of 2008.

19 Q Okay.

20 A I think that Dr. Shea might have made
21 a call and, you know, helped me verify that he
22 was the right kind of person.

23 Q Let's go back to the Prolift.

24 You told me you saw Dr. Gee, or
25 Peters-Gee, and she referred you to other

1 doctors; is that right?

2 A One other doctor.

3 Q Was that Dr. Surrells (ph.)?

4 A Surrells, yes.

5 Q What about Dr. Lasalla?

6 A Who?

7 Q Dr. Lasalla?

8 A I don't know that name.

9 Q Did you go see Dr. Surrells?

10 A I did.

11 Q When did you go see Dr. Surrells?

12 A It's a guess. Maybe in June.

13 Q You saw Dr. Gee in May and then you
14 went to see Dr. Surrells sometime the next month;
15 is that approximately right?

16 A Probably.

17 Q What did Dr. Surrells tell you?

18 A He wanted to take out the mesh.

19 Q Is Dr. Surrells affiliated with a
20 particular practice?

21 A I think so, but I don't know the name
22 of it. It's right by the hospital in Norwalk.

23 Q All right. So Dr. Surrells wanted to
24 take out the Prolift, what was your -- is that
25 right?

1 A Yes.

2 Q And what was your response? What did
3 you tell him?

4 A I was very cautious at that point. I
5 asked him a lot of questions and I didn't have
6 complete confidence in him so I didn't schedule
7 the surgery. The office called me a couple times
8 to schedule it. He said he had done training on
9 cadavers. And I said is that to take them out
10 and put them in, and I got a lot of different
11 answers. So I, you know, put the car in gear and
12 kept moving.

13 Q Did he tell you why he wanted to take
14 out the Prolift?

15 A Not in medical terms, just because it
16 was getting -- it was shrinking. And causing me
17 problems.

18 By this time, I had a complaint that
19 I felt like my vagina was shortening/

20 Q I take it when you went to see
21 Dr. Surrells, you brought the same piece of paper
22 from Dr. Hines, he did a medical exam and took an
23 oral history; is that what happened?

24 A Yes. I think so. I can't recall
25 exactly what I took. I took myself. I was not

1 having any trouble getting doctors to say that I
2 had an issue with mesh shrinking inside or
3 changing my architecture.

4 Q Right. They all -- everybody you saw
5 told you the Prolift was a problem.

6 A Yeah. Nobody told me they wanted --
7 I didn't get two answers that were the same.

8 Q And so is it fair to say that by June
9 of 2008, you had definitively concluded that you
10 needed to do -- you needed to take the Prolift
11 out?

12 A At some point I came to the knowledge
13 that that's where I needed to go.

14 Q But that's what all the doctors were
15 telling you?

16 A Yes.

17 Q Did you see a Dr. Siegel during the
18 May June 2008 time period?

19 A I don't know. I don't think so. Is
20 it for the same --

21 Q So I have some notes here. I will
22 just tell you what I have.

23 A Okay.

24 Q "Evaluation of RUQ pain following
25 cholecystectomy patient to consider ERCP."

1 Does that refresh your recollection
2 at all?

3 A Yes. Yes, I recall. Dr. Khaghan
4 sent me to a group. I didn't see Dr. Siegle. I
5 saw Seth Cohen in the practice. So ERCP is a
6 procedure that they use to diagnose Sphincter of
7 Oddi, but it's kind of risky. It can give you
8 pancreatitis.

9 So with all of these other things I
10 had going on, I wasn't really game to just try
11 something that could make me worse. So again, I
12 collected his opinion. I thought about it.
13 Dr. Shea said get another opinion. I don't want
14 you getting sicker. And then I went to Jamidar.

15 Q And all during this period, middle of
16 2008, you were having chronic migraines too; is
17 that right?

18 A Yes.

19 MS. FUSCO: I'm going to object to
20 the form, though, because that can be a
21 diagnosis.

22 BY MR. ALLENTUCH:

23 Q Okay. Were you having migraine after
24 migraine in the summer and fall of 2008?

25 A I'm not going to say yes to that

1 because I was seeing a doctor for migraines. And
2 I think that I was having some luck with the
3 control of those.

4 Q Okay. So Dr. -- I have Dr. Grosberg
5 wrote in his notes that, in September of 2008,
6 that "there's a longstanding episodic migraines
7 which have evolved into a pattern of chronic
8 migraine with medication overuse."

9 Does that ring any bells as to --
10 does that refresh your recollection as to what
11 was going on in the summer or fall of 2008 with
12 your migraines?

13 A Yes. I think that he told me I was
14 getting rebound headaches from using the rescue
15 drug and then Naprosyn or Advil continuously.

16 Q How were the migraines affecting your
17 life? I know you had a lot of other medical
18 problems going on, but...

19 A Well, they weren't adding any joy to
20 my life. They were there, but I actually had
21 confidence in Dr. Grosberg, and he explained
22 everything carefully and he assured me that they
23 had many things and we would find something. I
24 was not dwelling on migraines because I had found
25 this doctor who I was pretty sure had -- you

1 know, had it under control.

2 Q What I'm trying to understand, you've
3 told me about your Oddi syndrome, the gallbladder
4 problems, your problems with the Prolift and the
5 repeat migraines, how were those things, you
6 know -- all four of those things and the other
7 problems you were having -- affecting your
8 ability to enjoy life during 2008?

9 MS. FUSCO: Objection to form.

10 Go ahead.

11 THE WITNESS: I don't think I was
12 enjoying life very much.

13 BY MR. ALLENTUCH:

14 Q All right.

15 A I was committed to getting better.

16 Q And was it the -- was the key
17 impediment to you enjoying life the fact that you
18 had so many different problems coming from
19 different parts of your body in 2008?

20 A I think that's accurate.

21 Q Yeah. All right. We talked before a
22 little about Crohn's disease.

23 A Uh-huh.

24 Q There are subsequent references in
25 your medical records to Crohn's disease. I'm not

1 clear, do you suffer from Crohn's disease or did
2 you have Crohn's disease?

3 A No. No. From my understanding, if
4 you have Crohn's disease there's a genetic test
5 that would be positive.

6 I did ask the person in the practice
7 I see now, Jennifer Barrow, if she could amend
8 the diagnosis because I haven't had a problem and
9 I've had colonoscopies that showed no problems
10 except scarring. So I don't think you would find
11 that now.

12 Q Okay. So going back to the Prolift,
13 you told me that you saw *Dr. sural, decided not
14 to treat with him. What was the next step that
15 you took in dealing with the problems you had
16 with the Prolift?

17 A I saw Dr. Bercik somewhere in there.
18 I liked him a lot and he's very sympathetic. He
19 didn't have a definitive -- you know, he had a --
20 sort of an answer to a sort of start something,
21 maybe release the mesh, maybe take part of it
22 out. But I didn't feel like he had done that
23 very often. And he was very forthright.

24 Q Are you saying that Dr. Bercik
25 recommended a process whereby he would first cut

1 the arms of the Prolift, and if that didn't
2 provide relieve he would then move onto a second
3 surgery, which was a total excision of the
4 Prolift?

5 A I don't think I discussed it in that
6 much detail. He said the right side of my inner
7 pelvis was very tight and that I needed to have
8 that released or let go.

9 Q Okay. And I have -- according to my
10 notes, you met with Dr. Bercik on March 25th,
11 2008. Does that sound about right?

12 A It sounds right.

13 Q All right. So you've now seen
14 Dr. Gee and Dr. Bercik and Dr. starves and
15 Dr. Porges. What did you do next to deal with
16 your problems with the Prolift?

17 A I think I stopped looking for a
18 while. I started looking for answers online. I
19 tried to educate myself more. I read blogs from
20 women -- I found that there were other people
21 with issues.

22 Q So is that what you did during -- was
23 that all taking place during 2009?

24 A I don't know when I started that. I
25 did just -- I do recall just feeling like I --

C E R T I F I C A T E

STATE OF CONNECTICUT)

) ss.:

COUNTY OF FAIRFIELD)

I, MERCEDES MARNEY, Court Reporter and Notary Public within and for the state of Connecticut, do hereby certify:

That ROBIN SHERWOOD, the witness whose deposition is hereinbefore set forth, was duly sworn by me, and that such deposition is a true record of the testimony given by the witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have here unto set my hand this 20th day of September, 2016.


 Mercedes Marney - Shorthand Reporter
 Notary Public - State of Connecticut
 Account Number: 167303
 Date Appointed: 08/07/2014
 Expiration Date: 08/31/2019

EXHIBIT 3

THIS DOCUMENT IS BEING
SUBMITTED UNDER SEAL
PURSUANT TO A
CONFIDENTIALITY STIPULATION
AND ORDER

EXHIBIT 4

Archived Content

The content on this page is provided for reference purposes only. This content has not been altered or updated since it was archived.

UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication

Date Issued: July 13, 2011

Audience:

- Health care providers who implant surgical mesh to repair pelvic organ prolapse and/or stress urinary incontinence
- Health care providers involved in the care of patients with surgical mesh implanted to repair pelvic organ prolapse and/or stress urinary incontinence
- Patients who are considering or have received a surgical mesh implant to repair pelvic organ prolapse and/or stress urinary incontinence

Medical Specialties: gynecology, urogynecology, urology, general surgery, internal medicine, family practice, emergency medicine

Device:

Surgical mesh is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material or absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence.

Background:

Pelvic Organ Prolapse

Pelvic organ prolapse (POP) occurs when the tissues that hold the pelvic organs in place become weak or stretched. Thirty to fifty percent of women may experience POP in their lifetime with 2 percent developing symptoms. When POP happens, the organs bulge (prolapse) into the vagina and sometimes prolapse past the vaginal opening. More than one pelvic organ can prolapse at the same time. Organs that can be involved in POP include the bladder, the uterus, the rectum, the top of the vagina (vaginal apex) after a hysterectomy, and the bowel.

Stress Urinary Incontinence

Stress urinary incontinence (SUI) is a leakage of urine during moments of physical activity, such as coughing, sneezing, laughing, or exercise.

Purpose:

On Oct. 20, 2008, the FDA issued a Public Health Notification and Additional Patient Information on serious complications associated with surgical mesh placed through the vagina (transvaginal placement) to treat POP and SUI.

Based on an updated analysis of adverse events reported to the FDA and complications described in the scientific literature, the FDA identified surgical mesh for transvaginal repair of POP as an area of continuing serious concern.

The FDA is issuing this update to inform you that serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**. This is a change from what the FDA previously reported on Oct. 20, 2008. Furthermore, it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk. This Safety Communication provides updated recommendations for health care providers and patients and updates the FDA's activities involving surgical mesh for the transvaginal repair of POP.

The FDA continues to evaluate the effects of using surgical mesh to repair SUI and will communicate these findings at a later date.

For detailed information, please see: [**Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse. \(/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf\)**](#)

Summary of Problem and Scope:

In the Oct. 20, 2008 FDA Public Health Notification, the number of adverse events reported to the FDA for surgical mesh devices used to repair POP and SUI for the previous 3-year period (2005 – 2007) was “over 1,000.” Since then, from Jan. 01, 2008 through Dec. 31, 2010, the FDA received 2,874 additional reports of complications associated with surgical mesh devices used to repair POP and SUI, with 1,503 reports associated with POP repairs and 1,371 associated with SUI repairs. Although it is common for adverse event reporting to increase following an FDA safety communication, we are concerned that the number of adverse event reports remains high.

From 2008 – 2010, the most frequent complications reported to the FDA for surgical mesh devices for POP repair include mesh erosion through the vagina (also called exposure, extrusion or protrusion), pain, infection, bleeding, pain during sexual intercourse (dyspareunia), organ perforation, and urinary problems. There were also reports of recurrent prolapse, neuro-muscular problems, vaginal scarring/shrinkage, and emotional problems. Many of these complications require additional intervention, including medical or surgical treatment and hospitalization.

In order to better understand the use of surgical mesh for POP and SUI, the FDA conducted a systematic review of the published scientific literature from 1996 – 2011 to evaluate its safety and effectiveness. The review showed that transvaginal POP repair with mesh does not improve symptomatic results or quality of life over traditional non-mesh repair. The FDA continues to evaluate the literature for SUI surgeries using surgical mesh and will report about that usage at a later date.

In particular, the literature review revealed that:

- Mesh used in transvaginal POP repair introduces risks not present in traditional non-mesh surgery for POP repair.

- Mesh placed abdominally for POP repair appears to result in lower rates of mesh complications compared to transvaginal POP surgery with mesh.
- There is no evidence that transvaginal repair to support the top of the vagina (apical repair) or the back wall of the vagina (posterior repair) with mesh provides any added benefit compared to traditional surgery without mesh.
- While transvaginal surgical repair to correct weakened tissue between the bladder and vagina (anterior repair) with mesh augmentation may provide an anatomic benefit compared to traditional POP repair without mesh, this anatomic benefit may not result in better symptomatic results.

The FDA's literature review found that *erosion* of mesh through the vagina is the *most common and consistently reported mesh-related complication* from transvaginal POP surgeries using mesh. Mesh erosion can require multiple surgeries to repair and can be debilitating for some women. In some cases, even multiple surgeries will not resolve the complication.

Mesh contraction (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA since the Oct. 20, 2008 *FDA Public Health Notification*. Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain.

Both mesh erosion and mesh contraction may lead to severe pelvic pain, painful sexual intercourse or an inability to engage in sexual intercourse. Also, men may experience irritation and pain to the penis during sexual intercourse when the mesh is exposed in mesh erosion.

The complications associated with the use of surgical mesh for POP repair have not been linked to a single brand of mesh.

Recommendations for Health Care Providers:

As stated in the Oct. 20, 2008 Public Health Notification, the FDA continues to recommend that health care providers should:

- Obtain specialized training for each mesh placement technique, and be aware of the risks of surgical mesh.
- Be vigilant for potential adverse events from the mesh, especially erosion and infection.
- Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.
- Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
- Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall in POP repair using surgical mesh.
- Provide patients with a copy of the patient labeling from the surgical mesh manufacturer if available.

In addition, the FDA also recommends that health care providers:

- Recognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications.
- Choose mesh surgery only after weighing the risks and benefits of surgery with mesh versus all surgical and non-surgical alternatives.

- Consider these factors before placing surgical mesh:
 - Surgical mesh is a permanent implant that may make future surgical repair more challenging.
 - A mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications.
 - Removal of mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible and may not result in complete resolution of complications, including pain.
 - Mesh placed abdominally for POP repair may result in lower rates of mesh complications compared to transvaginal POP surgery with mesh.
- Inform the patient about the benefits and risks of non-surgical options, non-mesh surgery, surgical mesh placed abdominally and the likely success of these alternatives compared to transvaginal surgery with mesh.
- Notify the patient if mesh will be used in her POP surgery and provide the patient with information about the specific product used.
- Ensure that the patient understands the postoperative risks and complications of mesh surgery as well as limited long-term outcomes data.

Recommendations for Patients:

Before Surgery

Be aware of the risks associated with surgical mesh for transvaginal repair of POP. Know that having a mesh surgery may put you at risk for needing additional surgery due to mesh-related complications. In a small number of patients, repeat surgery may not resolve complications.

Ask your surgeon about all POP treatment options, including surgical repair with or without mesh and non-surgical options, and understand why your surgeon may be recommending treatment of POP with mesh.

In addition, ask your surgeon these questions before you agree to have surgery in which surgical mesh will be used:

- Are you planning to use mesh in my surgery?
- Why do you think I am a good candidate for surgical mesh?
- Why is surgical mesh being chosen for my repair?
- What are the alternatives to transvaginal surgical mesh repair for POP, including non-surgical options?
- What are the pros and cons of using surgical mesh in my particular case? How likely is it that my repair could be successfully performed without using surgical mesh?
- Will my partner be able to feel the surgical mesh during sexual intercourse? What if the surgical mesh erodes through my vaginal wall?
- If surgical mesh is to be used, how often have you implanted this particular product? What results have your other patients had with this product?
- What can I expect to feel after surgery and for how long?
- Which specific side effects should I report to you after the surgery?
- What if the mesh surgery doesn't correct my problem?

- If I develop a complication, will you treat it or will I be referred to a specialist experienced with surgical mesh complications?
- If I have a complication related to the surgical mesh, how likely is it that the surgical mesh could be removed and what could be the consequences?
- If a surgical mesh is to be used, is there patient information that comes with the product, and can I have a copy?

After Surgery

- Continue with your annual and other routine check-ups and follow-up care. There is no need to take additional action if you are satisfied with your surgery and are not having complications or symptoms.
- Notify your health care provider if you have complications or symptoms, including persistent vaginal bleeding or discharge, pelvic or groin pain or pain with sex, that last after your follow-up appointment.
- Let your health care provider know you have surgical mesh, especially if you plan to have another surgery or other medical procedures.
- Talk to your health care provider about any questions you may have.

If you had POP surgery, but do not know whether your surgeon used mesh, ask your health care provider at your next scheduled visit.

FDA Activities:

The FDA is working in several areas to assess and improve the safety and effectiveness of urogynecologic mesh products. The FDA will:

- Convene the Obstetrics-Gynecology Devices Panel of the Medical Device Advisory Committee, on September 8-9, 2011. The panel will discuss and make recommendations regarding the safety and effectiveness of transvaginal surgical mesh for POP and SUI.
- Explore regulatory solutions to answer questions about the safety and effectiveness of urogynecologic mesh products that are now being marketed and those that will be reviewed for marketing in the future.
- Continue to monitor adverse events reported to FDA associated with surgical mesh used to repair POP and SUI, as well as assessing any and all data as it becomes available.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect a problem with surgical mesh, we encourage you to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program ()**. Health care personnel employed by facilities that are subject to the **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** should follow the reporting procedures established by their facilities. Device manufacturers must comply with the **Medical Device Reporting (MDR) regulations (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)**.

To help us learn as much as possible about the adverse events associated with surgical mesh to repair POP and SUI, please include the following information in your reports, if available:

- Manufacturer's name
- Product name (brand name)
- Catalog number

- Lot number
- Size
- Date of implant
- Date of explant (if mesh was removed)
- Details of the adverse event and medical and/or surgical interventions (if required)
- Type of procedure (e.g., anterior or posterior repair, sacral colpopexy, sling procedure for SUI)
- Surgical approach: (e.g., vaginal, abdominal, laparoscopic)
- Reason for mesh implantation: (e.g., POP of the uterus, bladder, rectum, vaginal apex or bowel, SUI)
- Specific postoperative symptoms experienced by the patient with time of onset and follow-up treatment

Contact Information:

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV (mailto:DSMICA@FDA.HHS.GOV?subject=), 800-638-2041 or 301-796-7100.

This document reflects the FDA's current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices.

Additional Information

- [Urogynecologic Surgical Mesh Implants \(/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm\)](/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm)
- [Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse \(July 2011\) \(PDF - 243KB\) \(/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf\)](/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf)
- [Press Release: Surgical placement of mesh to repair pelvic organ prolapse poses risks \(/NewsEvents/Newsroom/PressAnnouncements/ucm262752.htm\)](/NewsEvents/Newsroom/PressAnnouncements/ucm262752.htm) [ARCHIVED]
- [Federal Register Notice: Urogynecologic Surgical Mesh \(http://www.gpo.gov/fdsys/pkg/FR-2011-07-14/pdf/2011-17695.pdf\)](http://www.gpo.gov/fdsys/pkg/FR-2011-07-14/pdf/2011-17695.pdf)
- [Federal Register Notice Amendment: Urogynecologic Surgical Mesh \(http://www.gpo.gov/fdsys/pkg/FR-2011-08-15/pdf/2011-20644.pdf\)](http://www.gpo.gov/fdsys/pkg/FR-2011-08-15/pdf/2011-20644.pdf)

More in Safety Communications
[\(/MedicalDevices/Safety/AlertsandNotices/default.htm\)](/MedicalDevices/Safety/AlertsandNotices/default.htm)

[Information About Heparin \(/MedicalDevices/Safety/AlertsandNotices/ucm135345.htm\)](/MedicalDevices/Safety/AlertsandNotices/ucm135345.htm)

[Reducing Risks Associated with Medical Device Misconnections \(/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm\)](/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm)



EXHIBIT 5

1 MR. LEYDON: Yes.

2 THE WITNESS: Well, I don't do this
3 surgery now.

4 BY MR. LEYDON:

5 Q What do you mean when you say you don't do
6 this surgery now?

7 MS. CILANO: He doesn't do this surgery
8 now.

9 MR. LEYDON: I think he can explain.

10 MS. CILANO: Objection. He's answered it.

11 You can answer again that you don't do
12 this surgery now.

13 MR. LEYDON: Or however you want to answer
14 it.

15 THE WITNESS: So no -- first of all, the
16 product that we used in Ms. Farrell doesn't
17 exist on the market any longer, so we don't do
18 that. And subsequent to Ms. Farrell's surgery,
19 and, you know, the experience over, you know,
20 months, years after that, I changed my practice
21 how and in what patients I would use
22 transvaginal mesh.

23 BY MR. LEYDON:

24 Q How so?

25 A I became aware that the -- that the mesh

1 exposure that had sort of garnered all of the -- you
2 know, all the attention as the -- the main
3 complication, if you will, associated with the use
4 of vaginal mesh, that that really wasn't the
5 complication that -- that I was aware of and
6 concerned about. It was contraction and tightening
7 of vaginal mesh, which happened to Ms. Farrell, that
8 changed how I would -- how I would place vaginal
9 mesh, the age of the patient that I would place
10 vaginal mesh, and -- and whether or not I would
11 place vaginal mesh in opposite compartments in the
12 vagina, as was done for Ms. Farrell.

13 Q So if Ms. Farrell was to come to you
14 today, is it fair to say you would not have done
15 this procedure the way you did it?

16 A That's correct.

17 Q Is that in part because of what happened
18 to Ms. Farrell?

19 A My hesitancy is -- are you asking the
20 question specifically about Mary Beth Farrell as an
21 individual, if she were to come in today, or a
22 generic person?

23 Q No. My first question was if someone like
24 her came in today.

25 A Yeah.

1 Q I believe your answer was you would not
2 have done the same procedure you did with her.

3 A That's correct.

4 Q And my follow-up question was: Is the
5 reason for that, at least in part, because of your
6 personal experience in what happened to Ms. Farrell?

7 A That's correct.

8 Q And is that also because of further
9 information that's come out about problems with this
10 type of mesh and its use in that way?

11 MR. SCHACK: Objection to form.

12 THE WITNESS: No.

13 BY MR. LEYDON:

14 Q What are the other reasons for it, or is
15 it solely because of what happened to Ms. Farrell?

16 A Ms. Farrell was the first of two or three
17 patients that I had operated on that, unfortunately,
18 had this problem with contracted mesh and pain.
19 I'm -- I'm in business to try and help women. I can
20 deal with certain types of risk associated with
21 surgery. Surgery has risk. After -- after
22 witnessing just in my own practice what could
23 happen, though rarely, but what could happen to a
24 patient like Ms. Farrell, I changed how I was using
25 vaginal mesh.