

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

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SYSTEM PRODUCTS LIABILITY	:
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**PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR
A FINDING OF SPOLIATION AND FOR SANCTIONS**

Defendants Ethicon, Inc. and Johnson and Johnson (collectively “Ethicon”) have lost, destroyed, or disposed of tens of thousands, if not hundreds of thousands, of documents and other evidence containing information vital to this litigation. Defendants’ spoliation of evidence was systematic and continual over the last ten years. It was not limited to one employee, to a set of employees, or to a department. Instead, it was a systematic failure at all levels, from Ethicon’s sales personnel to its president. As a result, Ethicon has produced numerous important witnesses who worked there for several years and have few, if any, documents in their custodial files. In 2010, seven years after a litigation hold had been instituted, Ethicon removed all information from the hard drive of its outgoing worldwide president, Renee Selman.

Aside from the obvious impropriety, Ethicon's document destruction has severely prejudiced the Plaintiffs for the upcoming bellwether trials. Certainly, Defendants should not benefit from gaps in the Plaintiffs' story that Defendant created. If Defendants cannot provide a complete production due to its own spoliation, justice and fairness require the Court to even the playing field by punishing Defendants. As there is no question that Ethicon destroyed important evidence, the law requires a remedy. The proverbial slap on the hand is not enough,

for it would only incentivize these and other Defendants to do the same. Rather, Plaintiffs respectfully suggest that when spoliation is as systematic, and as harmful to the other side, as it has been in this litigation, then the appropriate remedy is a default judgment against the spoliator. Specifically, Plaintiffs request default judgments against Ethicon in the Lewis case, and in the initial bellwether TVT-O and Prolift cases. In all cases, the Court should strike Ethicon's learned intermediary defense and give a spoliation instruction to the jury. The Court should also strike any statute-of-limitations defenses in all cases, and should charge Ethicon with the reasonable costs and fees associated with this motion.

Ultimately, the reason that Ethicon lost and destroyed thousands of documents is not the key issue. Whether Ethicon's behavior was willful or negligent, Ethicon is culpable under the law. But it is remarkable that so much information could be lost or destroyed when a litigation hold has been in place for ten years. As demonstrated by the testimony of James Mittenthal, Ethicon's corporate representative on the issue, Ethicon failed to implement, supervise, or monitor its litigation hold. Instead, Ethicon left to individual employees the decision about how and where to preserve documents. When employees left, their documents were destroyed wholesale, unless the outgoing employee took measures to prevent that from happening. Then, even when that soon to be ex-employee (with little incentive to take the appropriate measures) did take measures to preserve the documents, Ethicon still destroyed many of those files.

Because Plaintiffs have the burden of proof, the less information Defendants produce, the more difficult it becomes for Plaintiffs to meet their burden to the Court and the jury. The rules of evidence and Fourth Circuit case law give this Court broad discretion to sanction Defendant for its spoliation, so that it does not benefit from destruction of evidence. The Court should exercise that discretion and grant Plaintiffs' motion.

BACKGROUND

I. ETHICON HAS LOST OR DESTROYED THOUSANDS UPON THOUSANDS OF DOCUMENTS THAT RELATE TO CRITICAL PERIODS IN THE DEVELOPMENT AND MARKETING OF THE PRODUCTS AT ISSUE.

Ethicon destroyed thousands of important documents for several key former Ethicon officers, including the head of the company, and for other key employees, such as the sales representative for the first bellwether trial. Ethicon has also lost or destroyed several videos produced by one of its expert witnesses, and has destroyed thousands of documents from Medscand Medical A.B. (“Medscand”), the original manufacturer of the TVT product.

A. Ethicon has produced few if any documents for many key company leaders.

The following are examples of important Ethicon officers and employees, starting with its five-year worldwide president, whose custodial files were, at best, severely inadequate.

- **Renee Selman**, worldwide president, 2005-2010: Ethicon has admitted that it “did not maintain” Ms. Selman’s hard drive.¹ As president of the company, Ms. Selman “had responsibility for setting certain key policies, defining strategy, direction, overall responsibility for some of the company’s actions.”² Ms. Selman was president during a critical period, marked by consistent interaction between Ethicon and the FDA on various issues.³ She was a key part of the team communicating with the FDA regarding the FDA’s Public Health Notification in 2008.⁴

Given Ms. Selman’s role as a high-level decision-maker at Ethicon, her hard drive surely

¹ Ex. A, James P. Mittenenthal 8/13/13 Dep., at 248:20-249:3.

² *Id.* at 248:11-16.

³ For example, there were FDA inspections of key Ethicon Facilities in 2005 and 2008. (*See* Ex. B, Establishment Inspection Report for 8/29/05-9/08/05, ETH.MESH07281437-07281458; Ex. C, Establishment Inspection Report for 8/11/08-9/05/08, ETH.MESH02252211-02252224). The FDA cleared several new Ethicon SUI and POP devices during this period, including the TVT-Secur (2005), TVT-Exact (2010), TVT-Abbrevio (2010), and Prolift and Prolift+M (2008). And, the FDA issued a key Public Health Notification regarding complications associated with transvaginal placement of surgical mesh on October 20, 2008. (Ex. D, *FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence*, ETH.MESH.02310655-02310657).

⁴ *See* Ex. E, Devon Prutzman 10/17/08 e-mail to Renee Selman and others.

contained vital information about Ethicon's policies, safety procedures, marketing strategies, and numerous other key issues. All of that information is gone. Ms. Selman testified that she was aware of the litigation hold, she believed that it applied to the entire TVT family of products, she knew not to delete relevant documents, and she followed procedures closely, placing documents in properly designated folders.⁵ But Ethicon has only produced about 25 documents for Ms. Selman, a remarkably low number for someone who was head of the company for five years, and has admitted that it destroyed all documents that Ms. Selman has saved on her hard drive.⁶

- **Ramy Mahmoud**, chief medical officer and worldwide president of evidence-based medicine, August 2007-July 2010: Mr. Mahmoud headed four departments and, as such, was involved in quality board discussions and determinations, including decisions on handling product complaints and post-market surveillance activities of its high-risk products such as the POP and TVT.⁷ Mr. Mahmoud testified that he complied with all litigation hold notices.⁸ However, Ethicon has only produced 27 documents,⁹ where there should be thousands or tens of thousands, in Mr. Mahmoud's custodial file.

- **Charlotte Owens**, global medical director, Gynecare, September 2003-August 2005: Dr. Owens worked in product development, marketing and sales activities.¹⁰ She provided information for regulatory agencies about new products.¹¹ She helped to draft the instructions for use ("IFU") for the Prolift product.¹² She also reviewed adverse events to determine whether

⁵ Ex. F, Renee Selman 6/20/13 Dep. 29:12-38:13; 39:5-43:13.

⁶ Ex. G, Christy Jones 6/18/13 letter to Bryan Aylstock.

⁷ Ex. H, Ramy Mahmoud 7/15/13 Dep. at 40:17-41:7.

⁸ *Id.* at 68:2-7.

⁹ Although there were 111 documents in his custodial file, 84 of those were from Mr. Mahmoud's prior employment with other Johnson & Johnson companies.

¹⁰ Ex. I, Charlotte Owens 6/19/13 Dep. at 85:1-17.

¹¹ *Id.* at 87:20-24.

¹² *Id.* at 100:22-101:3.

the complications were related to Ethicon's device.¹³ Ethicon has produced all of six (6) documents from Dr. Owens's custodial file. Yet, a search for "Owens" across Ethicon's production returns approximately 14,000 documents.

- **Sean O'Bryan**, senior project manager in regulatory affairs, November 2001-April 2005: Mr. O'Bryan submitted annual reports to the FDA detailing safety and product developments.¹⁴ He was the regulatory lead on the TVT-Blue and TVT-O projects, which involved creating the regulatory strategy and product development.¹⁵ Mr. O'Bryan helped to draft the IFU for TVT-O.¹⁶ Mr. O'Bryan also prepared and submitted the TVT-O 510(k) application to the FDA.¹⁷ Yet, Ethicon has produced only 54 documents in Mr. O'Bryan's custodial file. A search for "O'Bryan" across the entire Ethicon production returns approximately 5,500 documents.

- **Laura Angelini**, vice president of global strategic marketing for Ethicon Surgical Care, among other positions, employed by Johnson & Johnson since 1991: Ms. Angelini worked on the TVT from its infancy, from 1997-2005.¹⁸ She was Ethicon's corporate designee to testify as to agreements with Ulf Ivar Ulmsten, one of the original developers of the TVT product; as to amounts paid to Mr. Ulmsten by Ethicon or Medscand, the company for which he worked; and as to services rendered by Mr. Ulmsten or any affiliated entities.¹⁹ In late 2005, she quit for a few weeks, changed her mind, and then was re-hired in the same position.²⁰ However, during that short period (after the TVT litigation hold had been issued), Ethicon destroyed all of those

¹³ *Id.* at 105:19-106:21.

¹⁴ Ex. J, Sean O'Bryan 6/06/13 Dep. at 34:4-22.

¹⁵ *Id.* at 39:1-6; 40:1-9.

¹⁶ *Id.* at 110:12-17.

¹⁷ *Id.* at 95:11-14.

¹⁸ Ex. K, Laura Angelini 9/17/13 Dep. at 10:4-23.

¹⁹ See Ex. L, Plaintiffs' 8/05/13 Rule 30(b)(6) Deposition Notice, at ¶¶ 2, 5, 8; see also Ex. M, Laura Angelini 9/16/13 Dep. at 51:5-8 (indicating her status as a corporate designee).

²⁰ Ex. M, Angelini 9/16/13 Dep. at 19:12-17.

documents by purging her computer of all files.²¹ As such, Plaintiffs have no custodial file for Ms. Angelini from 1997 through 2005, during which time she helped to develop Ethicon's marketing strategies for the new TVT products. Ms. Angelini has further testified that she does not know how to locate documentation about Ethicon's payments to Mr. Ulmsten or Medscand.²²

- **Jennifer Paine**, worldwide director of regulatory affairs, among other positions, June 2004-December 2009: Ms. Paine worked on the TVT product line for roughly a year and a half (July 2007-December 2009).²³ Ethicon produced only 71 documents in Ms. Paine's custodial file. Given her position, she surely had regular contact with the FDA and other regulatory agencies. Yet, Ethicon did not produce a single e-mail sent to or from Ms. Paine as part of her custodial file.

- **Price St. Hillaire**, various sales and marketing positions, including marketing director, 1999 through 2008.²⁴ Mr. St. Hillaire was Product Director of Ethicon's incontinence line, so he would have been involved with the relevant devices (including TVT). However, he does not recall being made aware of a litigation hold during his time at Ethicon.²⁵ Still, Mr. St. Hillaire did not destroy any relevant documents, and he left all of his physical files and his laptop in his office when he left the company.²⁶ Yet, Ethicon has not produced these files and has apparently destroyed every single one of the documents he had retained..²⁷

- **Cheryl Bogardus**, various positions including worldwide marketing director, January 2001 through May 2007. Though she does not recall being told to preserve documents, Ms.

²¹ *See id.* at 53:13-55:16.

²² *Id.* at 204:3-205:12, 243:21-244:8.

²³ Ex. N, Jennifer Paine 6/13/13 Dep. at 23:14-24:17.

²⁴ Ex. O, Price St. Hillaire 7/11/13 Dep. at 13:25-25:17.

²⁵ Ex. P, Price St. Hillaire 7/12/13 Dep. at 332:10-336:14.

²⁶ *Id.* at 343:5-345:12.

²⁷ *See* Ex. Q, Ben Watson 6/27/13 e-mail to Andrew Faes.

Bogardus left all of her paper and electronic documents behind when she left Ethicon in 2007.²⁸

Ms. Bogardus also stated that she would have sent or received about 100 e-mails per day, and she left a file cabinet full of documents.²⁹ Yet, Ethicon produced no custodial file for her, and again has apparently destroyed every single one of the documents that she had retained.³⁰

- **Gregory Jones**, various regulatory positions, including worldwide director of regulatory affairs, 1989-2003. Mr. Jones kept electronic copies of documents, such as 510Ks, regulatory strategies, FDA correspondence, documents regarding the products of other manufacturers, and audit reports.³¹ He was not aware of any effort made to preserve those documents at the time that he left Ethicon.³² As a result, Ethicon only produced about 20 documents in Mr. Jones's custodial file.

- **Rick Isenberg**, worldwide director of medical affairs, 1999-2002: Despite Mr. Isenberg's key role in the company, only a single (one-page) document was produced from his Human Resources file, and no custodial file could be produced.³³ Additionally, no personnel file was produced for Mr. Isenberg.³⁴

- **Patricia Hojnoski**, senior project manager and contracting position in regulatory affairs, 2002-2009. Ms. Hojnoski testified that she would have complied with any document retention policies or litigation holds that were communicated to her, she would not have destroyed any relevant documents, and she would have preserved copies of any handwritten

²⁸ Ex. R, Cheryl Bogardus 8/30/13 Dep. at 19:4-31:22.

²⁹ *Id.* at 31:10-15; 26:7-27:12.

³⁰ Ex. S, Ben Watson 8/11/13 e-mail to Andrew Faes.

³¹ Ex. T, Gregory Jones 8/20/13 Dep. at 47:15-55:25.

³² *Id.* at 54:24-55:7.

³³ Ex. U, Ben Watson 8/29/13 e-mail to Andrew Faes.

³⁴ Ex. V, Rick Isenberg 11/05/13 Dep. (rough) at 53:17-54:4.

notes that she created.³⁵ Yet, Ethicon produced only six documents in her custodial file, and has apparently destroyed every other document that she had retained over that seven year period.

- **Jill Schiaparelli**, project director for strategic growth, 2000-2007. Ms. Schiaparelli worked with Dr. Todd Heniford, an advocate of light mesh materials who is now an Ethicon expert witness. A 2004 e-mail from Ms. Schiaparelli describes Dr. Heniford's opinion that "we need to reduce the mass and inflammatory response in the current mesh."³⁶ Despite Ms. Schiaparelli's long-term involvement with "strategic growth" of the Ethicon's mesh products, Ethicon has no custodial file for her.³⁷ Again, the only explanation is that Ethicon has destroyed each and every one of the documents in her custodial file.

B. Ethicon has produced few if any documents for other important employees, including the sales representative for the first bellwether case.

Ethicon has admitted that in addition to losing or destroying documents associated with these key company officers, Ethicon also lost or destroyed documents associated with numerous employees involved in the sale and marketing of the TVT and POP products, including the specific sales representative involved in the first bellwether case. The problem is not isolated. Ethicon has admitted that it was able to produce custodial files for less than half of the sales representatives for the 30 bellwether cases.³⁸ Additionally, Ethicon has admitted having no database or other mechanism for tracking information provided by sales representatives to physicians or patients.³⁹

- **Paul Courts**, sales representative: Mr. Courts, the sales representative for the first bellwether trial (Carolyn Lewis), had only 35 documents in his "custodial file." Yet, the

³⁵ Ex. W, Patricia Hojnoski 4/16/13 Dep. at 20:17-27:25; 44:13-45:11.

³⁶ Ex. X, Jill Schiaparelli 5/02/04 e-mail to Karen Zaderej and several others.

³⁷ Ex. Y, 11/19/13 e-mail from Benjamin Watson to Andrew Faes.

³⁸ Ex. Z, Christy Jones 4/2/13 letter to Bryan Aylstock, at p. 1.

³⁹ Ex. AA, Ethicon response to Plaintiffs' Request for Admission No. 153.

“custodial files” of other witnesses revealed that Mr. Courts had been copied on many more documents. At his deposition, Mr. Courts admitted that he would have had CDs and visual aids that fell within the litigation hold, but he had no idea whether any of it had been preserved.⁴⁰

- **Troy Mohler**, sales representative, May 2004-May 2012: Despite this eight-year employment, Ethicon only produced 186 documents in Mr. Mohler’s custodial file. Mr. Mohler testified that he would not have destroyed any electronic or hardcopy material.⁴¹ He testified that he routinely received physician education materials (slide decks), and that he handed over a binder of all his physician call notes (from 2004 through 2012) when he left the company.⁴² Yet, Plaintiffs did not receive any slide decks, or Mr. Mohler’s call note binder, in his production. Mr. Mohler also had procedural videos relating to the TVT and other products on his laptop and iPad.⁴³ Clearly, videos that Mr. Mohler showed to implanting physicians are important evidence.

- **Allison London Brown**, marketing director for women’s health and urology, 2004-2007, employee from 1997: Ms. Brown’s duties included “[d]irect[ing] the launch of first new Pelvic Floor segment” and “[d]evelop[ing] and execut[ing] worldwide strategy for the Pelvic Floor and Incontinence markets.”⁴⁴ Despite her key role at Ethicon, Defendants produced *no* custodial file for Ms. Brown.⁴⁵

C. Ethicon has lost or destroyed almost every video produced by Dr. Heniford on the benefits of using lighter mesh material.

⁴⁰ Ex. BB, Paul Courts 7/16/13 Dep. at 388:13-391:8.

⁴¹ Ex. CC, Troy Mohler 6/07/13 Dep. at 43:14-44:2; 55:10-56:19; 62:20-64:6.

⁴² *Id.* at 17:24-18-9, 236:13-237:5.

⁴³ *Id.* at 62:20-64:6.

⁴⁴ Ex. DD, Curriculum vitae of Allison London Brown, p. 2.

⁴⁵ Ex. EE, 9/6/2013 E-mail from Kelly Crawford to Cheryll Calderon, et al.

As noted, Dr. Heniford was an advocate for using lightweight, large-pore mesh materials in products to be implanted in the human body. He created several videos for Ethicon.⁴⁶ Ethicon produced to Plaintiffs' counsel one of these videos, starring Dr. Heniford, entitled "Benefits of Lightweight Meshes." In the video, Dr. Heniford states that "heavyweight meshes should not be used anywhere in the human body, and there is no excuse to continue to do so."⁴⁷ Plaintiffs requested Dr. Heniford's other videos on this topic, but counsel for Ethicon has stated that they "have not been able to locate any additional videos."⁴⁸ Dr. Heniford is now an expert witness for Ethicon, even though Ethicon's TVT products are still being made from the heavyweight "old old" mesh products Ethicon had been using decades earlier in hernia applications.⁴⁹

D. Ethicon destroyed 600 pounds of documents from Medscand.

Another important example of Ethicon's document destruction involves roughly 600 pounds of important documents provided to Ethicon by Medscand, which was the original manufacturer of the TVT product. Ethicon admits that all relevant research, testing, and studies should have been collected and preserved.⁵⁰ During the development of the TVT product, Mr. Ulmsten performed studies on behalf of Medscand. Mr. Isenberg, the former worldwide director of medical affairs, testified that Mr. Ulmsten's studies were "sort of the cornerstone of [Ethicon's] marketing campaign related to safety and efficacy of the TVT."⁵¹

To date, Defendant has been unable to produce documents and data relating to these studies, other than one binder. Ethicon claims that all other documents from these studies were

⁴⁶ Ex. X, Jill Schiaparelli 5/02/04 e-mail to Karen Zaderej and several others.

⁴⁷ Ex. FF, Benefits of Lightweight Meshes video.

⁴⁸ Ex. GG, Benjamin Watson 11/15/13 e-mail to Bryan Aylstock.

⁴⁹ See Ex. HH, Robert Rousseau 8/18/99 e-mail to Chao-Chen Chen, ETH.MESH.09275875.

⁵⁰ Ex. A, Mittenthal 8/13/13 Dep. at 108:9-12, 126:24-127:21; 162:7-163:11.

⁵¹ Ex. II, Rick Isenberg 11/06/13 Dep. (rough) at 421:13-19.

destroyed in a fire.⁵² Medscand is no longer in business. One internal e-mail estimates that the documents weighed a total of 600 pounds.⁵³ Mark Yale, Ethicon's former manager of worldwide customer quality, testified that he was aware of the Medscand "document dump," that he remembered a search for those documents, and that he had no recollection of them being found.⁵⁴ Plaintiffs can only assume that these documents were lost or destroyed.

At the time, a series of e-mails contemplated what to do with these documents. Ultimately, two Ethicon employees—Lisa Kaiser and Wanda Patire-Singer—agreed that clinical studies, shelf life studies, and batch history records should be kept in particular locations. They further agreed that "actual product retains" should be scrapped unless a litigation hold were in place.⁵⁵ Yet, despite these conclusions, and despite the fact that a litigation hold was in place, the documents were apparently destroyed.

II. IN ADDITION TO ITS DOCUMENT DESTRUCTION, ETHICON'S LACK OF OVERSIGHT OVER ITS LITIGATION HOLD CAUSED THE LOSS OF THOUSANDS OF DOCUMENTS.

Ethicon has issued litigation hold notifications for all of the products covered in this MDL.⁵⁶ None of the litigation holds were removed at any time.⁵⁷ As such, litigation holds have continually existed at Ethicon from (at the latest) May 22, 2003, through the present. But despite these holds, thousands upon thousands of documents were lost or destroyed. That much is undisputed. For instance, Mr. Mittenthal testified as follows:

⁵² Ex. JJ, Benjamin M. Watson 11/05/13 letter to Thomas P. Cartmell, at p. 4.

⁵³ Ex. KK, E-mail string beginning with ETH.MESH.05220458, at ETH.MESH.05220460 (Jeffery Everett 11/03/05 e-mail to Kathleen Carbone).

⁵⁴ Ex. LL, Mark Yale 8/7/13 Dep. at 240:2-23.

⁵⁵ Ex. KK, E-mail string beginning with ETH.MESH.5220458, at ETH.MESH.05220458 (Wanda Patire-Singer comments to Lisa Kaiser e-mail).

⁵⁶ See Exhibits MM-RR, litigation hold notices dated May 22, 2003 (ETH.MESH.00875544); April 27, 2006 (ETH.MESH.01949009); April 21, 2008 (ETH-10733); Feb. 18, 2011 (ETH.MESH.07983156); Feb. 23, 2011 (ETH.MESH.05094929); and July 20, 2011 (ETH.MESH.04945246).

⁵⁷ Ex. A, Mittenthal 8/13/13 Dep. at 197:4-15.

Q: ... The bottom line is that you learned about data destruction by Ethicon and Johnson & Johnson regarding documents that should have been produced in this case; right?

THE WITNESS: I learned about data loss. I wouldn't adopt the same words as you used with the use of the word loss instead of destruction.

Q: Would you agree with me that there are potentially relevant documents that Ethicon or J&J has been unable to produce in this litigation?

THE WITNESS: There are -- there are indications that there have been potentially relevant documents that the company has been unable to produce.⁵⁸

Additionally, a letter from Ethicon attorney Christy Jones, dated April 2, 2013, states that Ethicon was unable to produce complete custodial files for the sales representatives for 16 of the 30 bellwether cases. She wrote that Ethicon was "having difficulty finding a meaningful volume of documents for many of the reps who left since implementation of the holds."⁵⁹ In other words, Defendant admitted it was lacking large quantities of relevant documents for more than half of the sales representatives for the bellwether cases.

One reason that the litigation holds were ineffective is that Ethicon has not had a written policy regarding document retention at any time relevant to this motion.⁶⁰ Ethicon also did not make a centralized litigation hold folder available to employees through their Outlook accounts until 2007.⁶¹ Until then, employees were expected to create their own litigation hold folders.⁶² Even after the centralized litigation hold folder was set up, in March 2007, no one was required to use it. Rather, employees "had the option to use the litigation hold folders, to move or copy materials into those folders if they chose, or to appropriately file the information in their own

⁵⁸ *Id.* at 27:10-20, 216:8-20 (objections omitted).

⁵⁹ Ex. Z, Christy Jones 4/2/13 letter to Bryan Aylstock.

⁶⁰ Ex. SS, James P. Mittenthal 9/25/13 Dep. at 371:8-373:11.

⁶¹ *See id.* at 307:6-309:18, 484:16-485:12.

⁶² *Id.*

filing systems provided they were able to then identify it in a going-forward basis. ... [T]he folders are not mandatory.”⁶³

Ethicon also took no steps to ensure that documents associated with outgoing employees were preserved. Until recently, it was Ethicon’s policy to delete (or, “wipe”) the information from the hard drives of departing employees, unless there was a “franchise-specific exception” for the employee’s hard drive.⁶⁴ In other words, the IT department deleted all information—including relevant information that the employee intended to be preserved—unless somebody specifically told them not to do so.⁶⁵ If an employee did not specifically tell Ethicon to save certain documents on the employee’s way out the door, Ethicon deleted those documents.⁶⁶ As Mr. Mittenthal put it: “there is an expectation that the employee is during their tenure complying with their records management requirements in general and then during the exit process would ensure that those materials are appropriately transferred.”⁶⁷

In 2002, Ethicon was cited in an internal audit for its lack of a formal records management program.⁶⁸ In 2006, a consultant’s audit reached the conclusion that Ethicon’s document retention program was failing. Specifically, a report from Business Edge Solutions concluded that “[t]he current paper-based method of document management and retention has

⁶³ Ex. A, Mittenthal 8/13/13 Dep. at 231:7-12, 232:4. Ethicon also left it completely up to its employees to take steps to preserve hard copies of documents and physical evidence. *Id.* at 105:20-106:13.

⁶⁴ Ex. SS, Mittenthal 9/25/13 Dep. at 332:23-334:6.

⁶⁵ *Id.*

⁶⁶ *See* Ex. A, Mittenthal 8/13/13 Dep. at 232:9-233:13. Ethicon admits that turnover in the medical device industry exists, and any reasonable document litigation hold would include policies and procedures to preserve an outgoing employee’s data. *Id.* at 62:9-63:11.

⁶⁷ *Id.* at 250:14-19.

⁶⁸ Ex. TT, CAPA070011 Summary Report, at ETH.MESH.09479228.

become untenable. Ethicon's document management approach cannot sustain the current roster of development efforts and poses a significant compliance risk."⁶⁹

Yet, it was not until 2007 that Ethicon instituted a Corrective And Preventative Action ("CAPA"). This five-year delay occurred even though, as Mr. Mittenthal explained, the 2002 audit was the "root cause," or the "rationale for implementing the CAPA."⁷⁰ Ethicon described the basis for CAPA070011 as follows: "Ethicon is not compliant to J&J Corporate records management requirements. Ethicon cannot appropriately provide all relevant documents in case of litigation or inspection."⁷¹

Many employees did not understand that they were supposed to preserve documents, or how they were supposed to do it. For instance, employees had different interpretations as to what needed to be preserved.⁷² Some employees were simply unaware of the litigation hold requirements, or they did not follow them.⁷³ With regard to sales representatives, Mr. Mittenthal acknowledged that "there was not a well-founded understanding of the policies by all of the sales reps"⁷⁴ Further, "because the sales reps had an uneven knowledge of the procedures ... the sales managers could not be in the position to make certificates that all the materials were properly complied with during the separation period."⁷⁵ Mr. Mohler, a former Ethicon sales representative, testified that the litigation hold notices failed to adequately explain what needed to be preserved.⁷⁶ In fact, Ethicon employees' understanding of the litigation hold process was

⁶⁹ Ex. UU, ETH.MESH.04611734, *Executive Summary: Medical, Regulatory and Quality Systems Diagnostic*, at p. 9, ¶ 8.

⁷⁰ Ex. SS, Mittenthal 9/25/13 Dep. at 465:19-466:1; *see also* Ex. RR at ETH.MESH.09479228.

⁷¹ Ex. TT, CAPA070011 Summary Report, at ETH.MESH.09479227.

⁷² Ex. A, Mittenthal 8/13/13 Dep. at 225:25-227:12.

⁷³ Ex. SS, Mittenthal 9/25/13 Dep. at 559:19-560:2.

⁷⁴ Ex. VV, James Mittenthal 5/14/13 Dep. at 218:19-25.

⁷⁵ *Id.* at 220:21-221:2.

⁷⁶ Ex. CC, Mohler Dep. at 27:1-17.

so faulty that Johnson & Johnson's legal department conducted a "re-education" program for "approximately 150 sales reps, sales managers, and legal counsel" in April 2013.⁷⁷

Mr. Mittenthal acknowledged that "[t]he litigation hold procedure's not effective if nobody follows it."⁷⁸ Still, Ethicon took no responsibility for overseeing the treatment of documents by employees, as "it was not a responsibility or a requirement that those folders be populated during the time of the employee's employment."⁷⁹ Rather, Ethicon's method of oversight was simply to ask about the locations of various documents during exit interviews.⁸⁰ When asked at his deposition, Mr. Mittenthal could not identify one step taken by Ethicon to determine whether employees were preserving documents during their employment.⁸¹

Ethicon also continued other procedures that prevented backup documents from being available. Despite the litigation hold, Ethicon continued to destroy backup tapes, on the theory that those backups were not subject to the litigation hold.⁸² Ethicon also continued, for several years, annual purges to remove all documents from the system that were at least two years old.⁸³

ARGUMENT

I. LEGAL STANDARDS

"Spoliation refers to the destruction or material alteration of evidence or to the failure to preserve property for another's use as evidence in pending or reasonably foreseeable litigation."

Silvestri v. Gen. Motors Corp., 271 F.3d 583, 590 (4th Cir. 2001).⁸⁴ "The duty to preserve

⁷⁷ Ex. A, Mittenthal 8/13/13 Dep. at 244:8-245:4.

⁷⁸ Ex. SS, Mittenthal 9/25/13 Dep. at 494:11-16.

⁷⁹ *Id.* at 510:23-511:16.

⁸⁰ *Id.*

⁸¹ *See id.* at 510:23-515:20.

⁸² Ex. A, Mittenthal 8/13/13 Dep. at 153:24-157:15.

⁸³ Ex. VV, Mittenthal 5/14/13 Dep. 215:13-217:2.

⁸⁴ Federal law applies to spoliation motions, which are based upon evidentiary issues, not substantive law. *See Hodge v. Wal-Mart Stores, Inc.*, 360 F.3d 446, 449 (4th Cir. 2004). Thus, Fourth Circuit spoliation law applies to all bellwether cases, regardless of origin.

material evidence arises not only during litigation but also extends to that period before the litigation when a party reasonably should know that the evidence may be relevant to anticipated litigation.” *Id.* at 591. As part of that duty, a party is responsible for identifying all sources of potentially relevant evidence and preserving the evidence. *See, e.g., Zubulake v. UBS Warburg LLC*, 229 F.R.D. 422, 432 (S.D.N.Y. 2004) (*Zubulake V*) (stating that counsel must become fully familiar with the client’s document retention policies). The party is under an obligation to implement an appropriate litigation hold, and to ensure that all relevant documents are being preserved pursuant to the hold. *See, e.g., Zubulake v. UBS Warburg LLC*, 220 F.R.D. 212, 217-18 (S.D.N.Y. 2003) (*Zubulake IV*).

Federal Rule of Civil Procedure 37(d)(1)(A) allows courts to sanction parties for failure to appear at a deposition or failure to produce evidence. A court has wide discretion in determining the appropriate sanction for spoliation. “When a party destroys, alters or fails to preserve property for use as evidence in reasonably foreseeable litigation such that the judicial process is disrupted, a trial court may use” its inherent power to control the judicial process “to determine an appropriate sanction.” *King v. Am. Power Conversion Corp.*, 181 Fed. App’x 373, 376 (4th Cir. May 17, 2006) (unpublished) (citing *Chambers v. NASCO, Inc.*, 501 U.S. 32, 45–46 (1991); *Silvestri*, 271 F.3d at 590. The available remedies include, but are not limited to, “dismissal or judgment by default, preclusion of evidence, an adverse inference instruction, a monetary fine, and/or an assessment of attorney’s fees and costs.” *Taylor v. Mitre Corp.*, No. 1:11-cv-01247 (LO/IDD), 2012 WL 5473715, at *4 (E.D. Va. Sept. 10, 2012).

In *Ayers v. Sheetz, Inc.*, No. 3:11-cv-00434, 2012 WL 5183561 (S.D. W. Va. Oct. 18, 2012), this Court stated that spoliation sanctions may be imposed when the moving party establishes:

(1) [T]he party having control over the evidence had an obligation to preserve it when it was destroyed or altered; (2) the destruction or loss was accompanied by a

culpable state of mind; and 3) the evidence that was destroyed or altered was “relevant to the claims or defenses of the party that sought the discovery of the spoliated evidence, to the extent that a reasonable fact finder could conclude that the loss evidence would have supported the claims or defense of the party that sought it.

Id. at *2.

II. ETHICON CLEARLY HAS SPOLIATED RELEVANT EVIDENCE, CAUSING SUBSTANTIAL PREJUDICE TO PLAINTIFFS.

“[A]nyone who anticipates being a party or is a party to a lawsuit must not destroy unique, relevant evidence that might be useful to an adversary.” *Zubulake IV*, 220 F.R.D. at 217. Ethicon has dramatically failed to meet this obligation to Plaintiffs. An analysis of the factors discussed in *Ayers* demonstrates that the Court should severely sanction Defendant.

A. Ethicon had control over the evidence and an obligation to preserve it.

It cannot be seriously disputed that Ethicon controlled the evidence at issue and had the obligation to preserve it. The information that was lost or destroyed was either in Ethicon’s physical possession (such as the boxes from Medscand) or available on Ethicon’s computer system (such as Ms. Selman’s hard drive) before being lost or destroyed. By implementing a litigation hold in 2003, Ethicon acknowledged that it had an obligation to preserve documents. Thus, the first element of the *Ayers* test is clearly met.

B. Ethicon had a culpable state of mind.

As to the second *Ayers* element, Ethicon had a culpable state of mind both because it intentionally destroyed documents, and because its efforts to preserve documents were severely inadequate. The “culpable” state of mind requirement does not require willful destruction. Rather, “three possible states of mind that would satisfy the culpability requirement: bad faith/known destruction; gross negligence, and ordinary negligence.” *Thompson v. U.S. Dep’t*

of Housing and Urban Dev., 219 F.R.D. 93, 101 (D. Md. 2003)⁸⁵ (citing *Residential Funding Corp. v. Degeorge Fin. Corp.*, 306 F.3d 99, 108 (2d Cir. 2002)); *see also United Med. Supply Co. v. United States*, 77 Fed. Cl. 257, 267-68 (2007) (stating that Fed. R. Civ. P. 37(d) was modified in 1970 to remove any requirement that spoliation be willful to merit sanctions).

Ethicon's conduct demonstrates bad faith/known destruction, gross negligence, and ordinary negligence. As to some of the spoliation that occurred, one could easily infer bad faith. For instance, the complete destruction of the hard drive of the outgoing world-wide president, at a time when a litigation hold had been in place for years, is truly remarkable. Undoubtedly, Ms. Selman's hard drive had numerous documents that could have been useful to Ethicon; thus, the Court should infer that there was also some very damaging information on that hard drive—information that would have been harmful to Ethicon in this litigation. Otherwise, it would have made no sense to delete everything.

The destruction of the Medscand data also evinces bad faith by Ethicon. Hundreds of pounds worth of boxes do not get destroyed by accident, particularly when the people managing those documents actually discuss whether they need to be preserved. They decided the answer was yes if a litigation hold was in place, which it was, and yet those documents were destroyed.⁸⁶ These boxes undoubtedly contained information useful to Ethicon. Therefore, the logical inference is that those boxes also contained harmful information, leading to their destruction.

Other document destruction might fall into the category of either negligence or gross negligence. Ethicon nominally had a litigation hold in policy, but as plainly demonstrated by both testimony and end results, Ethicon did very little to ensure that documents were actually

⁸⁵ The spoliation elements laid out by this Court in *Ayers* are the exact same elements laid out in *Thompson*, which of course is an opinion from another Fourth Circuit district court.

⁸⁶ Ex. II, E-mail string beginning with ETH.MESH.5220458, at ETH.MESH.05220458 (Wanda Patire-Singer comments to Lisa Kaiser e-mail).

being preserved. Instead, decisions about whether and how to preserve documents were left to individual employees, including outgoing employees. Failing to monitor document retention by employees during their employment may constitute ordinary negligence, but failing to take steps to preserve documents when employees leave is gross negligence. It is simply not a realistic expectation that outgoing employees—who have little or no reason to care—would take steps to preserve their documents.

Based on the wide-spread destruction of documents at Ethicon, while a litigation hold was theoretically in place, the Court should have no difficulty in concluding that Defendant had a “culpable” state of mind. Because culpability encompasses everything from ordinary negligence to willful conduct, the “culpable” standard merely requires that the Defendant have some degree of fault. *See Victor Stanley, Inc. v. Creative Pipe, Inc.*, 269 F.R.D. 497, 529 (D. Md. 2010) (stating that “any fault — be it bad faith, willfulness, gross negligence, or ordinary negligence — is a sufficiently culpable mindset”); *see also Residential Funding*, 306 F.3d at 108 (stating that “[t]he sanction of an adverse inference may be appropriate in some cases involving the negligent destruction of evidence because each party should bear the risk of its own negligence”); *Beaven v. Dep’t of Justice*, 622 F.3d 540, 555 (6th Cir. 2010) (stating that an adverse inference due to spoliation “should be available even for the negligent destruction of documents if that is necessary to further the remedial purpose of the inference”). Whether the Court concludes that Ethicon was negligent, grossly negligent, or willful in destroying evidence, the Court should find that Ethicon had a culpable state of mind.

C. The missing evidence is highly relevant to Plaintiffs’ claims.

The last element, relevance to Plaintiffs’ claims, is also clearly present on these facts. In this context, relevant evidence is that evidence that would “naturally have been introduced into

evidence.” *Vodusek v. Bayliner Marine Corp.*, 71 F.3d 148, 156 (4th Cir. 1995). The *Thompson* court explained that lost or destroyed evidence is relevant if “a reasonable factfinder could conclude that the lost evidence would have supported the claims or defenses of the party that sought it.” *Thompson*, 219 F.R.D. at 101 (D. Md. 2003).

Given the sheer volume of information that was lost or destroyed, it is unfathomable that none of it would have been relevant to the Plaintiffs’ claims. Plaintiffs’ claims include negligence, strict liability (including defective design and failure to warn), fraud, negligent misrepresentation, negligent infliction of emotional distress, breach of express and implied warranties, violations of consumer protection laws, and punitive damages. While the specific elements will vary due to particular state laws, Plaintiffs will have to prove that the product was sold in an unreasonably dangerous condition with insufficient warnings (strict liability), that Ethicon’s actions fell below the standard of care (negligence), that Ethicon in some way deceived the Plaintiff (fraud, violation of consumer protection laws), or that the product was not what Ethicon claimed it to be (breach of warranties). For punitive damages, Plaintiffs will have to show an evil motive, or at least that Ethicon was reckless.

Because of Ethicon’s spoliation, Plaintiffs lack information from the files of the former head of the company, from other key leaders in regulatory compliance and marketing, and from many of the sales representatives who would have communicated directly with the Plaintiffs’ physicians—including the sales representative for the first bellwether case. All of this information is highly relevant. In addition, the very safety data upon which Ethicon based its TVT marketing campaign, and which Ethicon has touted in multiple marketing and regulatory documents, has been destroyed.

For instance, the destruction of Ms. Selman's hard drive surely affects Plaintiffs' ability to prove every claim on the above list. As someone who "had responsibility for setting certain key policies, defining strategy, direction, overall responsibility for some of the company's actions,"⁸⁷ Ms. Selman no doubt had information on her hard drive about the safety of the products at issue (or lack thereof), about what steps Ethicon did or did not take to ensure the safety of the products at issue, about communications with the FDA, about marketing strategies, and about numerous other topics pertinent to this litigation. Ethicon destroyed all of it.

Documents missing from those who handled adverse event reports and product complaints, such as Mr. Mahmoud, also likely contain important information that would have assisted Plaintiffs' case. These issues are particularly relevant to strict liability claims—was the product unreasonably dangerous?; to negligence claims—did Ethicon respond reasonably to such complaints?; and to warranty claims—did the product perform as Ethicon claimed that it would? The information could also be relevant to punitive damages issues.

The documents missing from marketing leaders, such as Ms. Angelini and Mr. St. Hillaire, would shed light onto what Ethicon viewed as the strengths and weaknesses of its products, and onto what information it hid from the public in an effort to increase sales. Such information would be highly relevant to Plaintiffs' fraud and negligent misrepresentation claims, as well as their claims under state consumer protection laws.

The absence of any custodial file for Jill Schiaparelli, along with Ethicon's production of only one of Dr. Heniford's videos, leaves Plaintiffs without valuable impeachment material. Ms. Schiaparelli's 2004 e-mail shows that Dr. Heniford was advocating lighter mesh materials at that time.⁸⁸ And, the one video produced shows that Dr. Heniford believed it was irresponsible to

⁸⁷ Ex. A, Mittenthal 8/13/13 Dep. at 248:11-16.

⁸⁸ Ex. X, Jill Schiaparelli 5/02/04 e-mail to Karen Zaderej and several others.

use heavy mesh materials.⁸⁹ Additional videos and e-mails on that topic would be valuable impeachment evidence, now that Dr. Heniford is an expert witness supporting Ethicon. Yet, due to Defendants' spoliation, none of those materials are available to Plaintiffs.

The destruction of hundreds of pounds worth of information from Medscand leaves Plaintiffs without important information about the development of the TVT product, which Ethicon's medical director described as the "cornerstone" of Ethicon's marketing campaign.⁹⁰ This information is critical to Plaintiffs' ability to assess the validity of Ethicon's TVT marketing materials, particularly given that Ethicon has admitted to paying millions of dollars to the key researchers behind the TVT products.⁹¹

Additionally, Ethicon has acknowledged it is unable to produce a meaningful number of documents for more than half of the sales representatives for the 30 bellwether cases.⁹² The sales representatives would have important information about Ethicon's marketing strategies and, most importantly, about communications between themselves and treating physicians. Such information is pertinent not only to Plaintiffs' claims, but also to Ethicon's defenses. Given that each case includes a failure-to-warn claim, and that defendants have uniformly raised the learned intermediary defense, the sales representative documents are critical. Yet for many of the cases before this court, including the *Lewis* bellwether case, Ethicon destroyed those documents.

Ethicon should not profit from its admitted failure to preserve those documents.

Of course, Plaintiffs have no way to know precisely what is missing. *See Samsung Elecs. Co. v. Rambus, Inc.*, 439 F. Supp. 2d 524, 561 (E.D. Va. 2006), *abrogated on other grounds by*

⁸⁹ Ex. FF, Benefits of Lightweight Meshes video.

⁹⁰ Ex. II, Isenberg 11/06/13 Dep. at 421:13-19.

⁹¹ *See* Ex. M, Angelini 9/16/13 Dep. at 272:24-274:21 (concluding that Ethicon paid Professor Ulmsten more than \$7 million); 291:11-292:3 (stating that Professor Nilsson was likely paid from 1997 or 1998 through at least 2008, even though Plaintiffs were only given information about payments in 2008).

⁹² Ex. Z, Christy Jones 4/2/13 letter to Bryan Aylstock.

See Samsung Elecs. Co. v. Rambus, Inc., 523 F.3d 1374 (Fed. Cir. 2008) (stating that “litigation adversaries cannot, and cannot be expected to, demonstrate with certainty the content of destroyed documents”). But there is every reason to believe that the missing documents would have aided Plaintiffs’ case. Thus, the Court should find that Defendant spoliated evidence and should issue an appropriate sanction.

D. The Court should reject any argument that the documents are otherwise available.

Ethicon cannot reasonably deny that all of these documents were lost or destroyed. Thus, it will likely take the position that Plaintiffs have not been harmed because many of the destroyed documents were produced from other files. The Court should not be swayed by such an argument for several reasons.

First, as explained, numerous high-level people had little to no custodial files. Any communications solely among people whose hard drives or other documents were destroyed would be completely lost, and key leaders undoubtedly had communications that were not generally shared. Second, any documents produced by the witness and not shared, such as notes and drafts, would not be otherwise produced. Third, communications between an employee and an outside third party would obviously not be produced from another employee’s files. Fourth, to the extent that documents did exist elsewhere within the millions of documents produced by Ethicon, it is likely that Plaintiffs missed documents due to not having an established custodial file for each witness. For instance, as noted above, a search for “O’Bryan” returned approximately 5,500 documents. That search likely returned documents for people other than Sean O’Bryan, and it may have missed some legitimate references to Sean O’Bryan where only his first name was used in a communication, or where someone misspelled his name. Finally,

the missing Heniford videos and those 600 pounds of Medscand documents are just gone. Thus, Defendants' production has been extremely inadequate.

III. A DEFAULT JUDGMENT IS THE MOST APPROPRIATE SANCTION; THE COURT SHOULD ALSO ISSUE A SPOILIATION INSTRUCTION AND LIMIT DEFENDANT'S AVAILABLE DEFENSES.

Once the Court determines that Defendant spoliated evidence, it has broad discretion in choosing the appropriate sanction. *Silvestri*, 271 F.3d at 590. The sanction "should be molded to serve the prophylactic, punitive, and remedial rationales underlying the spoliation doctrine." *Id.* Here, the most appropriate sanction would be to grant a default judgment in the first bellwether case, *Lewis*, as well as the first TVT-O and Prolift cases. The spoliation in this case was extreme—starting with nearly all of the information in the files of Ethicon's five-year worldwide president, as well as boxes and boxes of Medscand documents related to the development of the TVT products. Plaintiffs' ability to prove their claims has been severely compromised by Defendant's actions. As such, default judgments are appropriate. Plaintiffs realize the Court is unlikely to grant default judgments for the entire litigation. But forcing Defendant to pay judgments in one case for each product line offers the right balance between punishing Defendant's severe spoliation and allowing it to fight the vast majority of cases. It also serves as a warning to Ethicon and any other defendants who may be tempted to destroy damaging documents in violation of the law.

Additionally, in all cases the Court should issue a spoliation instruction, strike the learned intermediary defense, and strike any statute-of-limitations defenses. A spoliation instruction is clearly appropriate, given the large volume of missing documents that likely would have aided Plaintiffs' effort to prove their claims. The specifics of the instruction should be worked out for each case, but the Court should enter an order now indicating that a spoliation instruction will be

issued in all bellwether trials. Without such an instruction, Defendant would benefit from its destruction of documents, and future defendants would have no incentive to institute effective document retention procedures.

Striking Defendant's learned intermediary defense is appropriate because of the information missing from so many of the sales representatives and other marketing witnesses. Ethicon should not be permitted to argue that it satisfied its duty to warn by providing information to physicians when it has left Plaintiffs with an incomplete picture as to what information was actually conveyed to physicians. Striking any statute-of-limitations defenses is also appropriate because fraudulent concealment generally will toll the statute of limitations, and Plaintiffs have been deprived of thousands of marketing and sales documents that likely would demonstrate deception of consumers by Ethicon.

Finally, the Court should order Defendant to pay all reasonable costs and fees associated with this motion. If Defendant had complied with its duty to preserve evidence, none of the work on this motion would have been necessary.

CONCLUSION

Defendant Ethicon, Inc. failed miserably to comply with its duty to preserve evidence. Numerous long-term officers and other employees, including the head of the company, were able to produce few if any documents in response to discovery requests. This evidence has been lost or destroyed. Defendant's spoliation of evidence has caused great prejudice to Plaintiffs, who have the burden of proving their claims. Justice, fairness, and the law all require more than the proverbial "slap on the hand."

Consequently, Plaintiffs respectfully request that the Court enter an order:

- (1) Granting default judgments to Plaintiff Carolyn Lewis and the Plaintiffs in the first TVT-O bellwether trial and the first Prolift bellwether trial;

- (2) Declaring that the Court will issue a spoliation instruction to the jury at every bellwether trial;
- (3) Striking Defendant's learned intermediary defense for every trial;
- (4) Striking any statute-of-limitations defenses for every trial; and
- (5) Charging Plaintiffs' reasonable costs and attorney's fees associated with this motion to Defendant.

Plaintiffs further request any other relief that this Court deems just and proper.

Dated: December 2, 2013

Respectfully submitted,

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Plaintiffs' Co-Lead Counsel

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing memorandum on December 2, 2013, using the Court's CM-ECF filing system, thereby sending of the filing to all counsel of record for this matter. To the extent that any exhibits are confidential, place-holders have been filed electronically, and the exhibits have been e-mailed and/or sent by Federal Express to the Court and to counsel for Defendant Ethicon, Inc.

/s/ D. Renee Baggett_____

INDEX OF EXHIBITS

- Exhibit A:** James P. Mittenenthal 8/13/13 Deposition, excerpts
- Exhibit B:** Establishment Inspection Report, 8/29/05-9/08/05, starting at ETH.MESH.07281437
- Exhibit C:** Establishment Inspection Report, 8/11/08-9/05/08, starting at ETH.MESH.02252211
- Exhibit D:** *FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence*, starting at ETH.MESH.02310655, dated Oct. 20, 2008
- Exhibit E:** Devon Prutzman 10/17/08 e-mail to Renee Selman and others
- Exhibit F:** Renee Selman 6/20/13 Deposition, excerpts
- Exhibit G:** Christy Jones 6/18/13 letter to Bryan Aylstock.
- Exhibit H:** Ramy Mahmoud 7/15/13 Deposition, excerpts
- Exhibit I:** Charlotte Owens 6/19/13 Deposition, excerpts
- Exhibit J:** Sean O'Bryan 6/06/13 Deposition, excerpts
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- Exhibit M:** Laura Angelini 9/16/13 Deposition, excerpts
- Exhibit N:** Jennifer Paine 6/13/13 Deposition, excerpts
- Exhibit O:** Price St. Hillaire 7/11/13 Deposition, excerpts
- Exhibit P:** Price St. Hillaire 7/12/13 Deposition, excerpts
- Exhibit Q:** Ben Watson 6/27/13 e-mail to Andrew Faes
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- Exhibit V:** Rick Eisenberg 11/05/13 Deposition (rough), excerpts
- Exhibit W:** Patricia Hojnoski 4/16/13 Deposition, excerpts

Exhibit X: Jill Schiaparelli 5/02/04 e-mail to Karen Zadarej and several others

Exhibit Y: Benjamin Watson 11/19/13 e-mail to Andrew Faes

Exhibit Z: Christy Jones 4/2/13 letter to Bryan Aylstock

Exhibit AA: Ethicon response to Plaintiffs' Request for Admission No. 153

Exhibit BB: Paul Courts 7/16/13 Deposition, excerpts

Exhibit CC: Troy Mohler 6/07/13 Deposition, excerpts

Exhibit DD: Curriculum vitae of Allison London Brown

Exhibit EE: Kelly Crawford 9/6/2013 e-mail to Cheryl Calderon, et al.

Exhibit FF: Benefits of Lightweight Meshes video

Exhibit GG: Benjamin Watson 11/15/13 e-mail to Bryan Aylstock

Exhibit HH: Robert Rousseau 8/18/99 e-mail to Chao-Chen Chen, ETH.MESH.09275875.

Exhibit II: Rick Isenberg 11/06/13 Dep. (rough), excerpts

Exhibit JJ: Benjamin M. Watson 11/05/13 letter to Thomas P. Cartmell

Exhibit KK: E-mail string beginning with Wanda Patire-Singer 11/7/05 e-mail to Lisa Kaiser and Mark Yale, ETH.MESH.5220458

Exhibit LL: Mark Yale 8/07/13 Deposition, excerpts

Exhibit MM: May 22, 2003 Litigation Hold Notice, ETH.MESH.00875544

Exhibit NN: April 27, 2006 Litigation Hold Notice, ETH.MESH.01949009

Exhibit OO: April 21, 2008 Litigation Hold Notice, ETH-10733

Exhibit PP: Feb. 18, 2011 Litigation Hold Notice, ETH.MESH.07983156

Exhibit QQ: Feb. 23, 2011 Litigation Hold Notice, ETH.MESH.05094929

Exhibit RR: July 20, 2011 Litigation Hold Notice, ETH.MESH.04945246

Exhibit SS: James P. Mittenthal 9/25/13 Deposition, excerpts

Exhibit TT: CAPA070011 Summary Report, starting at ETH.MESH.09479227

Exhibit UU: *Executive Summary: Medical, Regulatory and Quality Systems Diagnostic*, ETH.MESH.04611734

Exhibit VV: James P. Mittenthal 5/14/13 Deposition, excerpts

EXHIBIT A

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EXHIBIT E

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EXHIBIT F

Confidential - Subject to Protective Order

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 - - -

5 IN RE: ETHICON, INC. :
6 PELVIC REPAIR SYSTEM, :
7 PRODUCTS LIABILITY LITIGATION : MDL NO. 2327
8 THIS DOCUMENT RELATES TO ALL CASES :

9 - - -

10 VOLUME I
11 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

12 Thursday, June 20, 2013

13 - - -

14 Videotaped deposition of RENEE
15 ELAYNE SELMAN, held at DRINKER BIDDLE &
16 REATH, L.L.P., One Logan Square, 18th &
17 Cherry Streets, Philadelphia, Pennsylvania,
18 commencing at approximately 9:11 a.m.,
19 before Rosemary Locklear, a Registered
20 Professional Reporter, Certified Realtime
21 Reporter, Certified Court Reporter (NJ) and
22 Notary Public.

23
24 GOLKOW TECHNOLOGIES, INC.
25 877.370.3377 ph|971.591.5672 Fax
 deps@golkow.com

1 A. Don't destroy any documents. I
2 mean, nothing was deleted. I don't recall
3 the exact processes, but we were trained
4 that, you know, hang onto your documents.

5 Q. And what was your understanding
6 as to why that was important?

7 A. In case it was needed in the
8 future for any kind of proceeding.

9 Q. For the court proceedings,
10 potentially?

11 A. Potentially, yes.

12 Q. Okay. So if you look at Exhibit
13 2000, this was a document that was provided
14 to us. It has a Bates number, you'll see,
15 in the right-hand corner.

16 And through -- through the
17 course of the day, Miss Selman, I may refer
18 to those for the record periodically and
19 also to help you navigate through some of
20 the documents by using maybe the last three
21 numbers of the document.

22 This document is
23 ETH.MESH.00875544 and it's titled "J&J Law
24 Department Document Preservation Notice."

25 Do you see that?

1 A. Yes.

2 Q. It states, "Do Not Destroy,
3 Specified Documents"; right?

4 A. Yes.

5 Q. And the date of this is May 22nd,
6 2003, so this document was in place prior to
7 the time that you arrived as president of
8 the company; is that right?

9 A. Yes.

10 Q. And -- and the -- if you see the
11 -- the subject line or the re. clause, it
12 states, "Hold Notice for Kandell versus
13 Ethicon, Inc."

14 I take it that that is a hold
15 notice related to that litigation that is
16 going on.

17 Is that your understanding?

18 A. Yes.

19 Q. Now, it states, "Ethicon, Inc.
20 has been named in a lawsuit arising out of
21 the alleged use of TVT."

22 Do you see that?

23 A. Yes.

24 Q. And then -- strike that.

25 Let me ask you a question: Do

1 you think this litigation hold notice was in
2 place when you arrived at the company in
3 2005 as president?

4 A. I don't -- I don't recall, but
5 based on the date on this.

6 Q. Would there be a process where
7 the company would let you know if the hold
8 notice was cancelled and you could start
9 destroying documents, or how did that work?

10 A. I -- I don't recall notifications
11 of suddenly we're not under a document hold.
12 I think we would err on the side of always
13 keep your documents.

14 Q. This talks about a lawsuit and it
15 talks about TVT.

16 What does TVT stand for?

17 A. Transvaginal tape.

18 Q. Have you ever heard it called
19 tension-free tape or tension-less vaginal
20 tape?

21 MR. SNELL: Objection. Form.

22 THE WITNESS: No.

23 MR. CARTMELL: Okay.

24 BY MR. CARTMELL:

25 Q. We'll talk about that in a little

1 bit.

2 But when this says maintain
3 your documents, do not destroy documents
4 related to TVT, would that be interpreted to
5 mean the entire family of TVT products?

6 A. I would -- would assume so.

7 Q. Okay. At least based on your
8 understanding, out of an abundance of
9 caution, you would try to keep all documents
10 related to the -- the family of TVT
11 products. Is that fair?

12 A. Yes.

13 Q. If you'll go to Exhibit 2001,
14 you'll see this is another document that was
15 provided to us in this litigation by Johnson
16 & Johnson. The number is ETH.MESH.01949009.
17 Again, it states, "J&J Law Department
18 Document Preservation" Noticed -- "Notice,
19 Do Not Industry, Specified Documents."

20 Do you see that?

21 A. Yes.

22 Q. And this is dated April 27th,
23 2006; correct?

24 A. Yes.

25 Q. That was after the time that you

1 started as president of Ethicon Women's
2 Health & Urology?

3 A. Correct.

4 Q. Is your belief that this hold --
5 this is a litigation hold notice; correct?

6 A. Correct.

7 Q. And is your belief that this
8 litigation hold notice was in place during
9 the time that you were serving as the
10 president of the company?

11 A. Yes.

12 Q. Do you recall this?

13 A. I don't recall specific
14 litigation hold notices. I know that we had
15 them, I just don't recall each individual
16 one.

17 Q. The subject line or the re.
18 clause here says, Hold notice for Lana
19 Keeton versus Gynecare, et al.; right?

20 A. Yes.

21 Q. And again it talks about Gynecare
22 and Ethicon are parties to a lawsuit
23 involving TVT device.

24 Do you see that?

25 A. Uh-huh.

1 Q. So would your understanding be
2 that all documents related to the TVT family
3 of products would need to be preserved by
4 you, subject to this litigation hold notice?

5 MR. SNELL: Objection. Form.
6 Document speaks for itself.

7 You can answer.

8 THE WITNESS: The -- I would
9 never see a document like this.

10 What would happen is there
11 would be a specific notice from within the
12 company that would lay out exactly what
13 somebody needed to do. So this document per
14 se I don't recall I've ever seen, but there
15 would have been specific instructions about
16 what all employees should do.

17 MR. CARTMELL: Okay.

18 BY MR. CARTMELL:

19 Q. Let me ask you, there's a bolded
20 and underlined section that states, failure
21 to preserve these materials could result in
22 Court-imposed penalties or sanctions on both
23 the company and/or individual employees. Do
24 not discard, destroy or alter in any way any
25 of the documents, electronic or paper,

1 described below and please ensure that these
2 instructions are followed.

3 Do you see that?

4 A. Yes.

5 Q. This sort of document, though,
6 that we're looking at in Exhibit 2001, would
7 that be sent out to all employees of the
8 company?

9 A. I don't recall this specific
10 document, but the understanding to not
11 discard, that would be clear.

12 Q. The second page, if you'd turn to
13 that, there is a section entitled
14 "Instructions For Handling Electronic
15 Materials."

16 Do you see that?

17 A. Yes.

18 Q. And this talks specifically about
19 E-mails and attachments to E-mails and
20 specifically talks about creating an E-mail
21 folder to store or preserve these documents;
22 is that correct?

23 A. Yes.

24 Q. So is -- is -- are these the
25 types of instructions that you were just

1 talking about a minute ago?

2 A. Yes.

3 Q. So just explain how you, as the
4 president of the company, when this
5 litigation hold came out would preserve
6 E-mails and electronic documents.

7 A. I mean, we knew not to delete
8 things. I mean, it was really that simple.

9 Q. Well, and this sounds like you
10 would have to create an E-mail folder on
11 your computer in order to put all that --
12 all the E-mails and electronic documents in
13 there; is that right?

14 A. It looks like it. Or some kind
15 of eRoom or -- I'm not sure.

16 Q. What's an eRoom?

17 A. Just I guess a new folder titled
18 whatever. And I'm not sure where it sat on
19 the server. I guess that's what I'm getting
20 at.

21 Q. During the time that you were
22 president of Ethicon Women's Health &
23 Urology, did you actually create those
24 folders or store those documents for
25 litigation purposes?

1 A. I recall creating some folders or
2 my administrative assistant helped me create
3 folders. I don't remember the exact
4 process.

5 Q. Who was your administrative
6 assistant?

7 A. During part of the time, most of
8 the time it was Sandy Pompilio.

9 Q. And you said part of the time, so
10 when was it that she no longer was your
11 assistant?

12 A. I don't recall the exact time
13 frame. She retired close to the -- she
14 retired before I left, I guess.

15 Q. But close to the time that you
16 left?

17 A. Right.

18 Q. And who became your assistant
19 after Sandy?

20 A. I cannot recall her name.

21 Q. It was a short period of time, I
22 take it?

23 A. Yes. Yes.

24 Q. A matter of months?

25 A. I think so, yes.

1 Q. So you would preserve -- and let
2 me ask you this: Were you very careful to
3 make sure you were preserving all E-mails
4 related to the TVT family of products?

5 A. We -- we generally just didn't
6 delete things. I mean, that was the safest.
7 If in doubt, don't delete.

8 Q. Keep it all.

9 A. Keep it all.

10 Q. Okay. And put it all in the
11 place that was designated for it to be
12 placed by the company; correct?

13 A. Right. In some fashion.

14 Q. If you look at the next exhibit
15 that was provided to us, Exhibit 2002, and
16 this is ETH.MESH.05224752. Tell us what
17 this is.

18 MR. SNELL: Take your time and
19 look at it.

20 MR. PAKETT: I'm sorry. Was
21 that 2002 or 2022?

22 MR. SNELL: 2002.

23 MR. PAKETT: Okay. Thank you.

24 THE WITNESS: Okay.

25 BY MR. CARTMELL:

1 Q. This looks like an E-mail that
2 was sent to actually hundreds of people.

3 Do you see that?

4 A. Right.

5 Q. And it's from compliance
6 information update. That's up at the top.
7 And then the date is October 30th of 2008.

8 Do you see that?

9 A. Right. Yes.

10 Q. And this was actually an E-mail
11 to hundreds of people within the company
12 that was sent by you and others; correct?

13 A. Yes.

14 Q. I take it you were sending this
15 as one of the leaders of -- of the company
16 related to litigation that was pending; is
17 that correct?

18 A. Yes. It was from all of the
19 presidents of Ethicon so it was a general,
20 this is what everyone should do.

21 Q. And tell us what this is, the
22 general communication to these employees.

23 A. That it's a -- a notification of
24 how to handle litigation holds and ways to
25 follow the process in terms of Outlook

1 mailbox and, you know, just specifics on how
2 to do it.

3 Q. If you'd turn to last three, 759
4 in the Bates number, it states, "NEW
5 Procedures for Managing Litigation Holds
6 effective November 6, 2008."

7 Do you see that?

8 A. I see it up there.

9 Q. It's actually on --

10 MR. SNELL: On the previous
11 page.

12 BY MR. CARTMELL:

13 Q. -- Page 759 are the last three
14 numbers of the Bates.

15 A. Oh, okay.

16 Q. It states, the procedures
17 described below are being implemented by the
18 Johnson & Johnson Law Department.

19 Was it the Johnson & Johnson
20 law department that handled the compliance
21 issues and litigation holds?

22 A. I -- I don't recall specifically
23 where the notice -- notices came from.

24 Q. Okay. Well, it looks like here
25 that they -- they're implemented by Johnson

1 & Johnson, the law department at Johnson &
2 Johnson.

3 Do you see that?

4 MR. SNELL: Objection. Form.
5 The document speaks for itself.

6 THE WITNESS: Okay. Yes.

7 BY MR. CARTMELL:

8 Q. And then it says, introducing
9 enhanced procedures for managing litigation
10 holds.

11 Why were the procedures being
12 enhanced? Do you remember?

13 A. I have no idea.

14 Q. If you'd turn to the next page,
15 your signature is at the bottom. It states,
16 Renee Selman, worldwide president.

17 Do you see that?

18 A. Yes.

19 Q. And then at the top, compliance
20 with hold notices is important. All of you
21 are aware that strict compliance with these
22 holds is essential to the ability of the
23 company to defend itself in court in the
24 cases filed against it. There are numerous
25 examples of companies who negligently failed

1 to preserve documents required for
2 litigation and, as a consequence, infuriated
3 the judge presiding over the case, were
4 subject to fines or penalties or, in extreme
5 circumstances, had difficult judgments
6 entered against them.

7 Do you see that?

8 A. Yes.

9 Q. Was that being stated by the
10 company to try to tell employees how
11 important it was to make sure they keep all
12 documents for purposes of litigation?

13 A. Yes.

14 Q. And then it says, we are making
15 compliance with hold notices easier.

16 A couple paragraphs down it
17 says, beginning November -- excuse me.
18 Strike that.

19 A couple paragraphs down it
20 states, beginning November 6th, 2008, you
21 will see a litigation hold folder appear in
22 the Outlook mailbox and a litigation hold
23 folder on your desktop.

24 Tell us what that was.

25 A. It -- it appears they

1 automatically created the litigation hold
2 folder in your Outlook.

3 Q. Okay. You sent this letter.

4 Do you remember that happening?

5 A. Folders being set up
6 automatically?

7 Q. Right.

8 A. Yes.

9 Q. And was it your belief -- strike
10 that.

11 Did you follow the procedures
12 closely for litigation holds?

13 A. Yes.

14 Q. And was your understanding that
15 the company was having difficulty with
16 employees following the practices or the
17 policies set up to follow litigation holds?

18 MR. SNELL: Objection. Form.

19 BY MR. CARTMELL:

20 Q. Or do you remember?

21 A. I wasn't aware of that.

22 Q. The next exhibit, 2003, I
23 believe, this is an E-mail from, at the top,
24 if you start at the top, from Scott Jones
25 dated February 1st of 2011 but I -- I want

EXHIBIT G

BUTLER | SNOW

June 18, 2013

VIA E-MAIL

Bryan Aylstock, Esq.
Aylstock, Witkin, Kreis & Overholtz
17 E. Main Street, Suite 200 (32502)
Post Office Box 12630
Pensacola, Florida 32591

RE: *In re: Ethicon, Inc. Pelvic Repair System, Products Liability Litigation,*
MDL No. 2327

Dear Bryan:

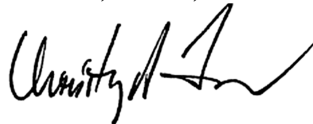
I am writing to update you on the issues I raised in my June 13, 2013 letter concerning Renee Selman's custodial file.

We have continued to search for the hard drive that Ms. Selman would have used at the time of her departure in February 2010. Based on what we have learned, it appears that the drive was delivered to the IT department. However, due to an oversight, the IT department was not instructed to image or maintain the drive.

Please let me know if you have any questions.

Very truly yours,

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC



Christy D. Jones

CDJ:fsw

cc: Tom P. Cartmell
D. Renee Baggett

ButlerSnow 16736397v1

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BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC

EXHIBIT H

Confidential - Subject to Protective Order

1 IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN
2 DISTRICT OF WEST VIRGINIA-CHARLESTON DIVISION

3
4 -----

IN RE: ETHICON, INC. :
5 PELVIC REPAIR SYSTEM, :
PRODUCTS LIABILITY LITIGATION : MDL NO. 2327

6 -----

THIS DOCUMENT RELATES TO ALL CASES

7

8

9 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

10 - - -

July 15, 2013

11 - - -

12

13

14 Deposition of RAMY MAHMOUD, M.D., held
15 at DRINKER BIDDLE AND REATH, LLP, 105 College
16 Road East, Suite 300, Princeton, New Jersey,
17 commencing at approximately 9:20 a.m., before
18 Margaret M. Reihl, a Certified Realtime
19 Reporter, Certified Court Reporter and Notary
20 Public for the State of New Jersey.

21

22

23

GOLKOW TECHNOLOGIES, INC.
24 877.370.3377 ph|917.591.5672 fax
deps@golkow.com

25

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1 have reported to your subordinates, I don't want to ask
2 you to name them all.

3 A. No, it was a very small number. It
4 might have been perhaps three. I don't recall the
5 exact number.

6 Q. Who were the people in Germany that
7 reported to you or your subordinates?

8 A. I don't recall the names. I can tell
9 you that their function was preclinical research. At
10 one point there may also have been a medical affairs
11 physician in Germany and at other times not.

12 Q. The preclinical research that was
13 performed in Germany during your time with Ethicon, did
14 it involve any of the transvaginal tapes or
15 transvaginal mesh?

16 A. I don't recall.

17 Q. Go ahead and tell me what were your
18 responsibilities as chief medical officer of Ethicon
19 and vice president in charge of evidence-based
20 medicine?

21 A. So there were four departments that
22 comprised evidence-based medicine. One of them was
23 preclinical research. One of them was health economics
24 and reimbursement. One of them was clinical
25 development, and the last was medical affairs.

Confidential - Subject to Protective Order

1 Q. What was the third one? I'm sorry.

2 A. Clinical development.

3 Q. And so all four of these departments
4 reported to you?

5 A. Yes, each of those departments had a
6 designated leader, and each of those leaders reported
7 to me.

8 Q. Who was the leader for preclinical?

9 A. Well, that changed over time.

10 Q. Okay.

11 A. When I first arrived it was a Dr. Mark
12 Storch, and then I later hired a new leader for
13 preclinical research. His name was Larry Johnson.

14 Q. And who was the leader for health
15 economics and research?

16 A. Health economics and reimbursement.

17 Q. I'm sorry, reimbursement, excuse me.

18 A. For the majority of the time that I was
19 there, the leader was named Sheri Dodd.

20 Q. And who was the leader for clinical
21 development?

22 A. Jessica Shen.

23 Q. Is that Cheng?

24 A. Shen, S-h-e-n.

25 Q. And I believe you told me the medical

1 A. Yes.

2 Q. Did you have an understanding during
3 your tenure or were you aware of this document hold?

4 A. Almost certainly. I didn't discard
5 documents pretty much at all. I operate under the
6 general assumption that nothing could be discarded
7 unless I knew specifically that it could.

8 Q. And what was your process for that? I
9 mean, was there a policy that you were to discard or
10 destroy documents that were not subject to litigation
11 holds or some other sort of hold periodically?

12 A. There was a document retention policy
13 for the company as a whole, to which I would have
14 adhered, but I cannot recite for you what that policy
15 was.

16 Q. Was it your understanding that -- well,
17 back up and strike that.

18 Throughout your time at Ethicon, did you
19 retain all of your documents related to pelvic mesh
20 products, to the best of your knowledge?

21 A. I'm confident that I complied with the
22 retention policy, which included retaining all the
23 documents for which a document hold notice had been
24 issued.

25 Q. And you understood or you operated under

EXHIBIT I

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4

5 _____
6 IN RE: ETHICON, INC.
 PELVIC REPAIR SYSTEM,
 PRODUCTS LIABILITY LITIGATION MDL NO. 2327
7 _____

8 THIS DOCUMENT RELATES TO ALL CASES

9 *****

10 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

11
12
13 VIDEOTAPED DEPOSITION OF
 CHARLOTTE OWENS, M.D.

14 VOLUME 1

15
16 Atlanta, Georgia

17
18 Wednesday, June 19, 2013
19
20
21
22

23 Reported by: MICHELLE M. BOUDREAUX, RPR
24 Golkow Job No. 66788

1 A So at that time, the medical director was
2 responsible for contributing to the development of the
3 devices that we were going to bring to market.

4 Q In what way?

5 A Providing either direct or indirect medical
6 support. What I mean is either giving information back
7 based on our own background experience or after working
8 with consultants and key opinion leaders, who may be
9 experts in the field. We would also review product
10 complaints.

11 We would also work with the sales and
12 marketing team to develop information that would
13 educate them on the product and the use of the product.
14 We would contribute to the development of what we used
15 to call IFUs, instructions for use, patient brochures,
16 kind of like the in-house medical person to help with
17 issues that required an MD's attention.

18 Q So you had to be copied on a lot of emails.
19 You were covering a lot of different facets within the
20 organization.

21 A From time to time. You know, sometimes they
22 would have a discussion prior to bringing you in,
23 depending on what the situation was.

24 Q Look, I've seen your travel schedule. Your

1 contribute, but again, I don't want to give the
2 impression that all of this was on one person.

3 Q No, but you were asked to contribute?

4 A Correct.

5 Q Okay. So that would be professional -- when
6 you say "education," that's what you mean, professional
7 education?

8 A But also to the sales force and, you know,
9 others within the company.

10 Q So you helped with marketing?

11 A Yes.

12 Q Okay. IFU product development is what I
13 wrote down. Is that --

14 A Yes.

15 Q And marketing, which is the -- providing the
16 education to the sales force?

17 A Yes.

18 Q Anything else, or is that the big categories?

19 A I think those are the big categories.

20 Q All right. So you also provided information
21 to the regulatory agencies or to the -- well, to the
22 regulatory agencies for new products that you were
23 bringing to the market, correct?

24 A Yes.

1 using the hammock style, and half are performing it in
2 the U-style, the obturator style. Do you follow me?

3 A I don't recall that at all.

4 Q All right. That's just awful, awful. I'll
5 get back to the training question.

6 A Okay.

7 Q Now, did you validate -- did you participate
8 in validating -- participating in validation studies
9 for the IFU?

10 MR. BROWN: Objection.

11 Q (By Mr. Keith) In regards to the TVT-Secur?

12 A So for the IFU, the -- you know, the
13 instructions for use were based on a lot of different
14 things, not just a study, but pretty much the design of
15 the product, key ways to use the device that would
16 enable the practitioner to place it as it was, you
17 know, intended to. So that may or may not be
18 associated with a validation study.

19 Q All right. So here's my understanding, you
20 have an IFU --

21 A Yes.

22 Q -- okay? Did you participate in drafting
23 IFUs while at Gynecare?

24 A Yes.

1 Q What products?

2 A I remember Prolift. I do not believe I was a
3 part of the TVT-Secur, nor the TVT Obturator.

4 Q All right. So we have a draft of an IFU,
5 Gynecare has come up with this, and then my
6 understanding is we've got to validate this IFU, this
7 instruction for use, and that's what that stands for,
8 that the doctors can actually read that and then
9 complete the procedure based upon the reading of the
10 IFU. Do I understand that correctly?

11 A You do.

12 Q Okay. And the validation study, that's what
13 that's for?

14 A Correct.

15 Q Okay. All right. So your memory is you
16 don't believe you did any of that in regards the
17 TVT-Secur?

18 A Or the TVT Obturator.

19 Q Okay. The only one that you may have
20 developed protocol for was the Prolift?

21 A Correct.

22 Q Okay. What about clinical expert reports,
23 did you -- was that part of your responsibility?

24 A Yes.

1 requirement around the world for you to submit your
2 protocols to institutional review boards or ethics
3 committees, whose primary focus is on the safety of the
4 patient.

5 Q Was ethics something important to you?

6 A Absolutely.

7 Q Okay. Was it important to you during your
8 time at Gynecare?

9 A Absolutely.

10 Q Still important to you?

11 A Absolutely.

12 Q Okay. Was safety your first responsibility
13 as the medical affairs director?

14 A Yes.

15 Q Okay. Did you -- as medical affairs
16 director, was your first priority to ensure the safety
17 of the patient and protect the patient?

18 A Yes.

19 Q Okay. Now, you also, as part of your
20 responsibilities, if I understand correctly -- you
21 called it something else. I call it defense of device.
22 I can't remember what you called it, review product
23 complaints. Part of your responsibility was to defend
24 the devices or complaints against the device that were

1 lodged by patients or doctors, correct?

2 MR. BROWN: Objection.

3 THE WITNESS: I'm not sure I like the

4 term "defend."

5 MR. KEITH: I didn't figure you would,
6 but I -- but it is what it is. But you were
7 responsible --

8 THE WITNESS: For reviewing --

9 MR. KEITH: -- for responding to
10 accusations against the company that were
11 lodged by either patients or their doctors?

12 MR. BROWN: Objection.

13 THE WITNESS: My -- I wouldn't even say
14 people accused or made accusations. What
15 would happen is we might hear of an -- of an
16 adverse event, we might be informed in
17 writing of an adverse event, we may see in
18 literature that there were adverse events,
19 and then we would evaluate whether or not
20 they were attributable to the device or some
21 other factor.

22 Q (By Mr. Keith) Dr. Owens, to be fair to
23 me --

24 A Right.

EXHIBIT J

CONFIDENTIAL - Subject to Protective Order

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 *****

5 IN RE: ETHICON, INC. MDL No. 2327
6 PELVIC REPAIR SYSTEM,
7 PRODUCTS LIABILITY
8 LITIGATION

9 *****

10 THIS DOCUMENT RELATES TO ALL CASES

11 *****

12 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

13

14 VIDEOTAPED DEPOSITION OF SEAN M. O'BRYAN

15

16 Thursday, June 6th, 2013

17 9:53 a.m.

18

19 Held At:

20 Campbell Campbell Edwards & Conroy, PC

21 One Constitution Center

22 Boston, Massachusetts

23

24 REPORTED BY:

25 Maureen O'Connor Pollard, RPR, CLR, CSR #149108

1 adverse event and determine if there needed to
2 be further actions?

3 A. No.

4 Q. Do you believe that you actually
5 completed and worked on the annual report for
6 TVT Classic during your time at Ethicon?

7 A. I would have been responsible for the
8 end report.

9 Q. During your work on the annual report,
10 one of the things that would be in an annual
11 report would be a review of complaints, correct?

12 A. Right. There would be a group that
13 would feed into -- that information into me, I
14 would make sure that that was included within
15 the annual report.

16 Q. And you would rely upon that group,
17 whether it's post-marketing surveillance or
18 customer quality, to provide you with accurate
19 information about the complaints that were
20 received?

21 A. Yes. They would attest that it was
22 complete and accurate.

23 There is a distinction. I don't think
24 we quantified all complaints. Again, I think
25 they had to reach a certain level of criticality

1 A. When I was at Ethicon I did work -- I
2 was involved with Ethicon, the TVT Blue product.

3 Q. What was your work related to TVT
4 Blue?

5 A. I acted as the regulatory lead for
6 that product.

7 Q. And what do you mean by "regulatory
8 lead"? Was it similar to your work with TVT
9 Classic?

10 A. It would have included working on the
11 development, the strategy, the regulatory
12 strategy, being part of the development team.
13 Proposed change comes in, we pull together all
14 disciplines of the team, I would have been the
15 regulatory person on that team.

16 Q. Similar to your work on TVT-O?

17 A. Yes, sir.

18 Q. And did you ultimately work on the
19 510(k) associated with TVT Blue?

20 A. I must have. But I don't have a lot
21 of recollection of TVT Blue as a submission.

22 Q. What about with laser cut mesh?

23 A. Same answer; I most likely did, but I
24 don't have recollection of a submission
25 associated with laser cut mesh.

1 Q. You worked on TVT-O, the obturator
2 approach?

3 A. Yes, I did.

4 Q. How would you describe your role with
5 TVT-O?

6 A. I was the regulatory lead on the
7 development team responsible for the regulatory
8 strategy and providing regulatory input towards
9 the development of that product.

10 Q. And for TVT-S, what was your role?

11 A. TVT-S, I was not so much involved
12 because I was departing Ethicon, moving up to
13 Massachusetts. I believe I had transitioned
14 prior to becoming the designated regulatory lead
15 for that product.

16 Q. Do you recall that you started on that
17 product, but then you were getting ready to
18 leave?

19 A. I had some very early involvement,
20 yes, so -- you know, not formalizing regulatory
21 strategy, but some work on initial
22 considerations in draft.

23 Q. Outside of the TVT family of products
24 and Monitorr that we've discussed, what other
25 products did you work on while at Ethicon?

1 Q. And it's entitled actually "Modified
2 Gynecare TVT Obturator System Special 510(k)," correct?
3

4 A. Yes.

5 Q. And if you turn to -- on the bottom
6 you can see the Bates numbers -- if you turn to
7 the Bates number that is 934, and there's a date
8 at the top that says November 10, 2003. Do you
9 see that?

10 A. Yes.

11 Q. And this is, on November 10, 2003 is
12 when you, in fact, submitted the 510(k) for
13 TVT-O to the FDA, correct?

14 A. Yes.

15 Q. And again, it's described up in the
16 corner as "Special 510(k): Device Modification:
17 Gynecare TVT Obturator System," correct?

18 A. Yes.

19 Q. And it states "Modified Device" off to
20 the left there. Do you see that, "Modified
21 Device"?

22 A. Yes.

23 Q. And "Gynecare submits this
24 Notification of Intent to market a modification
25 to the TVT System as described within this

1 that we were just looking at, right?

2 A. Right.

3 Q. I'd like to talk about during the
4 design and development phase -- let me back up.

5 That was the IFU as presented to the
6 FDA in November of 2003, correct?

7 A. Correct.

8 Q. And that was the one upon which the
9 FDA would have based its decision about whether
10 or not to approve this Special 510(k)?

11 A. Correct.

12 Q. If you back up in time earlier in the
13 year of 2003, during the design and development
14 phase before sending that IFU to the FDA, you
15 were part of the team that created that IFU, is
16 that right?

17 A. Yes, I was a member of the team.

18 MR. ZONIES: I'm going to hand you
19 what's been marked as Exhibit T-473.

20 (Whereupon, Exhibit Number T-473,
21 E-mail chain, Bates ETH.MESH.06879415
22 through 9417, was marked for
23 identification.)

24 BY MR. ZONIES:

25 Q. And it's a series of e-mails, and like

EXHIBIT K

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 - - -

5
6 IN RE: ETHICON, INC. : MDL NO. 2327
7 PELVIC REPAIR SYSTEM, :
8 PRODUCTS LIABILITY :
9 LITIGATION :

10 - - -

11 AND VARIOUS OTHER CROSS-NOTICED ACTIONS

12 - - -

13 September 17, 2013

14 - - -

15 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

16 Videotaped deposition of LAURA
17 ANGELINI taken pursuant to notice, was held at the
18 law offices of Riker Danzig Scherer Hyland &
19 Perretti LLP, Headquarters Plaza, One Speedwell
20 Avenue, Morristown, New Jersey, beginning at 9:10
21 a.m., on the above date, before Ann Marie Mitchell,
22 a Federally Approved Certified Realtime Reporter,
23 Registered Diplomate Reporter and Notary Public for
24 the State of New Jersey.

25 - - -

26 GOLKOW TECHNOLOGIES, INC.
27 877.370.3377 ph|917.591.5672 fax
28 deps@golkow.com

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1 Q. Could you please state your full name
2 for the record?

3 A. Laura Angelini.

4 Q. And who do you work for?

5 A. I work for Johnson & Johnson.

6 Q. What is your job for Johnson &
7 Johnson?

8 A. My current job up to the end of --
9 until the end of this week is vice president, global
10 strategic marketing for Ethicon Surgical Care.

11 Q. How long have you worked for Johnson
12 & Johnson?

13 A. For over 22 years.

14 Q. So that would have put you starting
15 about when?

16 A. July 15, 1991.

17 Q. Have you worked on a product called
18 TVT?

19 A. I did.

20 Q. For what period of time did you work
21 on TVT?

22 A. I worked on TVT between the beginning
23 of 1997 until the end of 2005.

24 Q. Did you also work on Prolift?

25 A. I worked -- not directly, but people

EXHIBIT L

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEM,
PRODUCTS LIABILITY LITIGATION

MDL NO. 2327

THIS DOCUMENT RELATES TO ALL CASES

**NOTICE TO TAKE ORAL DEPOSITION
OF DEFENDANTS THROUGH DESIGNATED WITNESSES**

TO: Defendants ETHICON, INC. and Johnson & Johnson, Inc. (hereinafter "Defendants")
and their Attorneys of Record.

Please take notice that pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs, by and through their counsel, will take the videotaped deposition of Defendants' corporate designees on September 5, 2013 at the offices of Riker Danzig in Morristown, New Jersey. The witness(es) shall be prepared to testify concerning the subject matters identified in Exhibit "A", attached hereto. The witness shall produce documents identified in Exhibit "B", attached hereto, prior to the deposition. The deposition will be taken before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure, and will continue day-to-day until the examination is completed.

DEFINITIONS

All definitions and rules of instructions set forth in Fed. Rule Civ. P. 30(b)(6) shall apply to all requests for information herein. To the extent a term commonly in use in the medical device industry is not defined herein, it shall be understood to be consistent with the meaning commonly ascribed to that term in the medical device industry.

1. "Concerning" means referring to, describing, evidencing, or constituting. See LR Civ. P 26.2(c)(7).



2. “Defendants”, “Ethicon, Inc.”, “Johnson & Johnson Inc.”, “you” or “your” refers to, without limitation, Ethicon, Inc., Johnson & Johnson Inc., and all business entities with which it is or has been affiliated, together with any predecessor, successor, parent, or subsidiary entity as well as any officer, director, employee, attorney, agent, or representative of any such other business entity previously described herein.

3. “Document” is synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure and expressly includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. A draft or non-identical copy is a separate document. *See* LR Civ. P. 26.2(c)(2); *see also* FR Civ. P 34(a).

4. “TVT” includes the TVT “classic” Tension Free Vaginal Tape System device cleared by the FDA on or about January 1, 1998, the TVT-Obturator, TVT-Secur, TVT-Abbrevio, TVT-Exact, TVT SCION, and the IVS (Intravaginal slingplasty device) which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI). The term “TVT” also includes any kits or tools designed to be sold with the TVT including, but not limited to the TVT-AA and TVT-D.

5. “Relevant Time Period” means the time period from when you first developed, designed, distributed, licensed, manufactured, marketed or sold TVT to the present.

This 5th Day of August, 2013.

EXHIBIT "A"

DEPOSITION SUBJECT MATTER

Pursuant to Rule 30(b)(6), the deponent(s) must have knowledge and shall be able to testify concerning the following subject matters:

1. The identity of and the terms and conditions of any and all agreements between Defendants and Medscand Medical A.B. or any other corporation or entity in which Medscand Medical A.B. has an ownership interest concerning TVT including but not limited to any license and supply agreements, asset purchase agreements, manufacturing agreements, research or study related agreements, and any amendments thereto.

2. The identity of and the terms and conditions of any and all agreements between Defendants and Ulf Ivar Ulmsten, the Estate of Ulf Ivar Ulmsten, Contape S.A., or any other corporation or entity in which Ulf Ivar Ulmsten had an ownership interest, including but not limited to, any consulting agreements, consulting and technology agreements, investigator related agreements, research or study related agreements, cancellation agreements, settlement agreements, and any amendments thereto.

3. The identity of and the terms and conditions of any and all agreements between Defendants and Professor Carl Gustaf Nilsson or any corporation or entity in which he has/had an ownership interest, including but not limited to, any consulting agreements, consulting and technology agreements, investigator related agreements, research or study related agreements, cancellation agreements, settlement agreements, and any amendments thereto.

4. The identity of and the terms and conditions of any and all agreements between Defendants and Christian Falconer, M.D., Masoumah Rezapour, M.D., Ingegerd Olsson, M.D., or Nina Kuuva, M.D., or any corporations or entities in which they have an ownership interest,

including but not limited to, any consulting agreements, consulting and technology agreements, investigator related agreements, research or study related agreements, cancellation agreements, settlement agreements, and any amendments thereto.

5. Amounts paid by Defendants to Ulf Ivar Ulmsten, the Estate of Ulf Ivar Ulmsten, Contape S.A., and/or Medscand Medical A.B and the reason for the payments. This includes but is not limited to payments made in connection with the following: (1) milestone payments as referenced in ETH.MESH.08696090-ETH.MESH.08696091; (2) purchase price; (3) additional payments as referenced in ETH.MESH.05972841-ETH.MESH.05972842; (4) royalties or similar payments as referenced in ETH.MESH.08692681-ETH.MESH.08692683; (5) professional and consulting fees; (6) consideration for agreement not to compete as referenced in ETH.MESH.08692681; (7) consideration for exclusive relationship with Defendants as referenced in ETH.MESH.08692681; (8) consideration for assignment of rights as referenced in ETH.MESH.08692682; (9) consideration for assistance in locating an experimental lab as referenced in ETH.MESH.08692683; and (10) out-of-pocket business and travel expenses and costs.

6. All amounts paid by Defendants to Carl Gustaf Nilsson or to any corporation or entity in which Carl Gustaf Nilsson is an owner or shareholder and the reason for such payments.

7. All amounts paid by Defendants to Christian Falconer, M.D., Masoumah Rezapour, M.D., Ingegerd Olsson, M.D., or Nina Kuuva, M.D, or to any corporation or entity in which any of them are owners or shareholders, and the reasons for such payments.

8. Services rendered by Ulf Ivar Ulmsten or Contape S.A., or any other corporation or entity owned by Ulf Ivar Ulmsten or Contape S.A. including but not limited to participation in any advisory boards and performance of any studies, research or testing of any medical devices

including but not limited to services rendered in connection with obtaining regulatory approval of TVT as referenced in ETH.MESH.08696089-ETH.MESH.08696090.

9. Services rendered by Carl Gustaf Nilsson or any other corporation or entity owned by Carl Gustaf Nilsson including but not limited to participation in any advisory boards and performance of any studies, research or testing of any medical devices..

10. Services rendered by Christian Falconer, M.D., Masoumah Rezapour, M.D., Ingegerd Olsson, M.D., or Nina Kuuva, M.D, or any corporation or entity owned by them or in which they are shareholders.

11. Location, retention, storage and organization of documents and exemplars related to the above subject matters.

EXHIBIT "B"

DOCUMENT REQUESTS

Please produce or if already produced, identify exact bates ranges with a brief identification of each document:

1. All documents relied upon by the deponent in preparing for this deposition.
2. All communications between Defendants and Ulf Ivar Ulmsten, Contape S.A., Medscand Medical A.B. and/or their representatives concerning Defendants' acquisition of TVT.
3. All agreements between Defendants and Ulf Ivar Ulmsten, the Estate of Ulf Ivar Ulmsten, Medscand Medical A.B., and/or Contape S.A. concerning TVT including but not limited to license and supply agreements, asset purchase agreements, manufacturing agreements, consulting agreements, consulting and technology agreements, cancellation agreements, settlement letters, and any amendments thereto.
4. All communications between Defendants and Ulf Ivar Ulmsten, the Estate of Ulf Ivar Ulmsten, Medscand Medical A.B., and/or Contape S.A. and/or their representatives concerning the above referenced agreements.
5. All documents provided by Ulf Ivar Ulmsten, Contape S.A. and/or Medscand Medical A.B. to Defendants as required by the above referenced agreements including but not limited to all studies, data and other materials related to TVT as referenced in ETH.MESH.08696089-ETH.MESH.08696090.
6. All documents reflecting amounts paid by Defendants to Ulf Ivar Ulmsten, the

Estate of Ulf Ivar Ulmsten, Contape S.A., Medscand Medical A.B. in connection with above referenced agreements.

7. All agreements between Defendants and Carl Gustaf Nilsson or any entity or corporation in which he is an owner or shareholder including but not limited to consulting agreements and any amendments thereto.

8. All agreements between Defendants and Christian Falconer, M.D., Masoumah Rezapour, M.D., Ingegerd Olsson, M.D., or Nina Kuuva, M.D., or any entity or corporation in which they are owners or shareholders including but not limited to consulting agreements and any amendments thereto.

9. All communications between Defendants and Carl Gustaf Nilsson concerning the above referenced agreements.

10. All documents reflecting amounts paid by Defendants to Carl Gustaf Nilsson.

11. All documents reflecting amounts paid by Defendants to Christian Falconer, M.D., Masoumah Rezapour, M.D., Ingegerd Olsson, M.D., or Nina Kuuva, M.D.

12. All exemplars of any products obtained by Defendants from Ulf Ivar Ulmsten, the Estate of Ulf Ivar Ulmsten, Contape S.A., Medscand Medical A.B.

EXHIBIT M

CONFIDENTIAL - Subject to Protective Order

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 IN RE: ETHICON, INC. : MDL NO. 2327
5 PELVIC REPAIR SYSTEM :
6 PRODUCTS LIABILITY :
7 LITIGATION :
8 :

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Monday, September 16, 2013

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Videotaped 30(b)(6) Deposition of
LAURA ANGELINI held at Riker Danzig Scherer Hyland
Perretti LLP, Headquarters Plaza, One Speedwell
Avenue, Morristown, New Jersey, on the above date,
beginning at 9:34 a.m., before Kimberly A. Otherwise,
a Certified Realtime Reporter, Certified Court
Reporter, and Notary Public.

GOLKOW TECHNOLOGIES, INC.

877.370.3377 ph | 917.591.5672 fax

deps@golkow.com

1 Then in January 2000 I was promoted
2 director of marketing for Gynecare. In the meantime
3 the division name was moved from women's health to
4 Gynecare. I stayed in that position as director of
5 marketing between the year 2000 and mid-2001. In
6 June, around June I think, mid-2001 roughly, I was
7 promoted vice president for Gynecare EMEA. And then
8 I stayed in that job until the end of 2005. At the
9 end of 2005 I was moved to a position of vice
10 president, marketing for Ethicon Endo-Surgery EMEA.
11 I stayed in that job for a few weeks.

12 Then I resigned, left the company, in
13 December 2005, came back to Johnson & Johnson a few
14 weeks later, in January 2006, with the same job I
15 had left, so as vice president, marketing for
16 Ethicon Endo-Surgery Europe, and then stayed in that
17 position until the end of 2009.

18 In January 2009 I was promoted vice
19 president, regional vice president, for eastern
20 Europe for the MD&D, which means Medical Device &
21 Diagnostics, portfolio. I stayed in that position
22 for two years between the years 2010 and 2011.

23 In February 2011 I was promoted vice
24 president, global strategic marketing for the newly
25 formed Ethicon Surgical Care division, which

1 described here. So, for example, "Agreements
2 between Medscand, Ulmsten, Contape and Defendants
3 related to TVT," yes, I reviewed all these
4 documents. Now, if they refer to the numbers listed
5 below, I cannot say.

6 Q I understand. But it sounds like what
7 happened was you received a stack of documents that
8 were supposed to be responsive to our request --

9 A Yes.

10 Q -- and you then reviewed those; is
11 that fair?

12 A Yes.

13 Q You did not do any additional work to
14 find documents or information other than look at the
15 documents that were provided to you by counsel and
16 talk to the two individuals that you told us; is
17 that fair?

18 MS. CRAWFORD: Objection.

19 THE WITNESS: As I told you, I -- you
20 know, I spoke with Mary Amore to locate some of the
21 contracts referred to these doctors. So I would
22 suppose the answer to your question is no, because I
23 did do some additional work to locate some of these
24 documents. However, I didn't locate all the
25 documents because of the fact that in my computer

1 there is no files or storage anymore of some of the
2 documents that date back to these years. I mean, we
3 are talking about 15 years ago. Some of the
4 documents are not -- based on the Italian law are
5 not existing anymore.

6 BY MR. CARTMELL:

7 Q Ms. Angelini, you -- strike that.

8 Ms. Angelini, you mentioned that
9 because your computer was turned in and cleared,
10 there are some documents that you believe are
11 missing?

12 A Uh-huh, yes.

13 Q What documents, if you can tell me, do
14 you believe are missing?

15 A Some of the contracts of the original
16 contracts related to the consulting services of the
17 doctors listed in the deposition notice are not
18 documents that I was able to review with my counsel.
19 Therefore, I am assuming that these documents are
20 missing.

21 Q You're talking about agreements
22 between certain paid consultants that we've asked
23 about; right?

24 A Yes.

25 Q Other than some agreements that

1 existed between paid consultants of Ethicon or
2 Johnson & Johnson that are missing, are there any
3 other documents that you believe are missing as a
4 result of your computer being wiped out?

5 A Well, all the e-mails generated at
6 that time for any other -- any type of, you know,
7 interaction between me in my position as European
8 business manager for the TVT product and my
9 colleagues, my worldwide colleagues, who were
10 responsible for the same product in the other
11 regions of the world. I mean, I had all my e-mail
12 documentation. That e-mail documentation is not --
13 between, you know, the years -- with respect to this
14 product between the years 1997 and 2006, when I came
15 back, all this e-mail documentation is not present
16 anymore in my computer.

17 Q You believe that all of your e-mails
18 from 1997 until 2006 that would reflect your
19 interactions with the paid consultants are no longer
20 in existence; right?

21 MS. CRAWFORD: Objection.

22 THE WITNESS: I didn't say that. I
23 said they are not on my computer. I don't know
24 whether they are in existence in any part of the
25 company stored or copied anywhere.

EXHIBIT N

Confidential - Subject to Protective Order

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 IN RE: ETHICON, INC. : MDL NO. 2327
5 PELVIC REPAIR SYSTEM :
6 PRODUCTS LIABILITY :
7 LITIGATION :
8 :

9 - - -
10 - - -
11 THIS DOCUMENT RELATES TO ALL CASES
12 - - -
13 Thursday, June 13, 2013
14 - - -
15 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER
16
17 Videotaped Deposition of JENNIFER M. PAINE
18 held at Riker Danzig Scherer Hyland Perretti LLP,
19 Headquarters Plaza, One Speedwell Avenue,
20 Morristown, New Jersey, on the above date, beginning
21 at 9:38 a.m., before Kimberly A. Otherwise, a
22 Certified Realtime Reporter, Certified Court
23 Reporter, and Notary Public.
24 - - -
25
26 GOLKOW TECHNOLOGIES, INC.
27 877.370.3377 ph | 917.591.5672 fax
28 deps@golkow.com

1 It looks like that's about a two-year job; correct?

2 A That's correct.

3 Q Did you have any involvement with TVT mesh
4 in the second job as manager of regulatory affairs
5 from July of 2005 to July of 2007?

6 A It's possible that I had some involvement
7 with TVT in that time frame. It's difficult for me
8 to say exactly when I would have. What I can tell
9 you is that the early part of that time frame I
10 believe I would have only been working on new
11 product development projects, so not necessarily
12 covering products that were already launched in the
13 market at that time.

14 Q Okay. So if we then go from July of 2007
15 to December of 2008, it says worldwide director of
16 regulatory affairs; correct?

17 A That's correct.

18 Q During that time frame, were you involved
19 with TVT mesh?

20 A At that time I believe that I was covering
21 the Women's Health & Urology business in total and
22 so, yes, I would have had oversight to folks who
23 were working on the TVT product line.

24 Q Okay. Would you say most of your
25 involvement with TVT mesh would have been during

1 that time period of July 2007 to December of 2008?

2 A Probably the majority of it would be.

3 There may have been some, as I said, prior to that.

4 Q So it looks like that's a period of about
5 17 months; correct?

6 A Yes.

7 Q Okay. And during your time period -- what
8 does a worldwide director of regulatory affairs for
9 women's health do?

10 A So in that role I was a participant on the
11 Women's Health & Urology board. Again, I'm not
12 exactly sure of what time frame that role was
13 present. But I had oversight to the regulatory team
14 that was supporting the -- all of the women's health
15 products, which was a fairly expansive portfolio of
16 products, including some hardware and software
17 devices as well as the mesh products.

18 Q Okay. What do you do I mean on --

19 A Oh, I'm sorry.

20 Q On a day-to-day basis, I mean, what does
21 the worldwide director of regulatory affairs do? Do
22 you walk into the office, read catalogs, sip coffee,
23 go talk to the secretaries? You know, I mean, what
24 do you do?

25 MS. KABBASH: Objection.

EXHIBIT O

1 instructions were appropriate, and I think that the
2 witness should answer as he sees fit. I don't think we
3 should waste any more time, though.

4 MR. SLATER: Hang on. You're instructing this
5 witness that if I ask him a direct, straightforward yes
6 or no question, that it's appropriate for him to give a
7 long, for example, sound bite or a talking point,
8 despite the fact that it's not responsive? You realize
9 that would be obstruction and a failure to answer
10 truthfully and accurately.

11 MS. SCALERA: First of all, Adam, I haven't
12 instructed the witness as to anything. Secondly, I just
13 wanted to counter your statement on the record. Just to
14 be clear.

15 BY MR. SLATER:

16 Q Mr. St. Hilaire, if I ask for a yes or no
17 answer, please either say yes, no or I can't answer with
18 a yes or no. And then the jury that watches this video
19 would decide if you were being credible when you said
20 you couldn't answer with a yes or no. Okay?

21 MS. SCALERA: Objection.

22 THE WITNESS: I will try my best.

23 BY MR. SLATER:

24 Q Thank you very much.

25 Okay. You worked at Ethicon Women's Health &

1 Urology from June 1999 to November 2008; correct?

2 A Yes.

3 Q You started as a sales representative in
4 June 1999 and held that position till February 2001;
5 correct?

6 A To the best of my recollection, yes.

7 Q What medical devices were you selling during
8 that time period?

9 A The suite of products included Thermachoice,
10 the Gynecare Morcellator, Versapoint, Interceed, TVT,
11 couple of other things that I really don't remember.

12 Q From July 2000 to February 2001 you were a
13 sales trainer; correct?

14 A To the best of my recollection.

15 Q From February of 2001 to December of 2001, you
16 were a sales training manager; correct?

17 A That sounds correct.

18 Q From December 2001 till August 2005 you were a
19 divisional sales manager within Ethicon; correct?

20 A That sounds correct.

21 Q What was your responsibility as a divisional
22 sales manager during that time?

23 A I had a team of sales representatives, and
24 functionally the role was to coach, train and develop
25 my sales team.

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1 Q The role of the sales representatives in
2 Ethicon is to sell the devices that are within their
3 portfolio; correct?

4 A That's correct.

5 Q During the time period of December 2001 --
6 well, I'll come back to it, actually. Withdrawn.

7 Between August 2005 and November of 2007, you
8 were product director, marketing director worldwide
9 within Ethicon; correct?

10 A Best of my recollection, yes.

11 Q One of the things you did during that time
12 period was managed the continence health platform
13 product pipeline, that's something that's stated on your
14 resume. What does that mean?

15 A That means I manage the incontinence platform,
16 the products as well as during my tenure as the
17 marketing director worldwide, looking at next generation
18 or future projects.

19 Q During that period, did the pipeline include
20 the TVT Secur device?

21 A To the best of my recollection, I didn't -- I
22 didn't have that responsibility within my -- within
23 my -- within my purview.

24 Q What devices did you oversee in managing the
25 incontinence health platform product pipeline?

1 A So at the time, TVT, TVT-O was within -- was
2 within my span. And there were some other -- other
3 items that we were looking at from a future standpoint.
4 And honestly, I don't remember -- I don't remember.
5 It's been five, six years. I don't remember all the
6 projects that we were looking at from a future
7 standpoint.

8 Q Was one of the products you were looking at
9 from a future standpoint the TVT-Secur?

10 A To the best of my knowledge or my recollection,
11 TVT-Secur I think was either already in play or
12 launching or, you know, to the best of my recollection.
13 I didn't have personal responsibility for Secur.

14 Q Did you have personal responsibility for the
15 TVT device between August 2005 and November 2007?

16 A Depending on when that was, earlier on when I
17 was a product director, I managed a couple of products.
18 I managed a urodynamic device, and I managed TVT.

19 Q During what period of time did you manage TVT
20 as a product director in Ethicon?

21 A To the best of my recollection, sometime in --
22 sometime in either late 2005 or 2006. I don't -- I
23 really -- it's hard to -- to really give you a firm date
24 and time of when I had it, but it was within my
25 responsibility early on as a product director.

1 Q Was that the beginning of your responsibility
2 to manage TVT -- I mean I want to know the span.

3 A Sure.

4 Q When did you start, when did you end managing
5 TVT?

6 A So when I went into marketing, I started
7 managing Monitorr which is a urodynamic device, and then
8 if I remember correctly, I started taking on TVT and
9 TVT-O. And then as I progressed, then I moved into the
10 worldwide role which was more pipeline management, and
11 then after that into the group role where I had
12 responsibility for the -- for the portfolio.

13 Q All right. Let me break this down.

14 A Sure.

15 Q With regards to TVT, when did your
16 responsibility to oversee that device begin?

17 A You know, again, I don't -- I can't tell you
18 exact date or month. I'm guessing if I -- to the best
19 of my recollection, probably sometime in 2006. I
20 don't -- I don't remember the exact dates. It's been a
21 long time.

22 Q As a product director, you began to have
23 responsibility for the TVT in sometime around early
24 2006?

25 A Again, to the best of my recollection. I can't

1 give you an exact, firm date.

2 Q As a product director in Ethicon, when did you
3 first have responsibility to oversee the TVT-O?

4 A Again, probably during that time. 2006ish.
5 I don't -- I don't really remember the exact dates.

6 Q Did you ever have responsibility to oversee the
7 TVT Secur?

8 A I did not. I did not have personal
9 responsibility for overseeing TVT Secur.

10 Q Let's just do something for the record.

11 MR. SLATER: Do we have the witness's CV handy
12 that we can just put a sticker on it, put an exhibit
13 sticker on?

14 MR. MIRACLE: Adam, this is Trent, we've got a
15 copy. We can do that.

16 MR. SLATER: Terrific, thank you. You guys can
17 just tell me what number we put on it.

18 MS. MAIMBOURG: It's getting marked right now.

19 (Extraneous discussion re exhibit marking.)

20 MR. SLATER: Can we give it to the witness,
21 please, the marked exhibit?

22 MS. MAIMBOURG: He has it.

23 BY MR. SLATER:

24 Q Mr. St. Hilaire, we've marked an Exhibit as
25 T2063, is that your current resume?

1 A Looks -- yeah. Looks fairly current.

2 (The above-referred to document was marked

3 Deposition Exhibit No. T2063 for identification

4 by the Court Reporter, and a copy is attached

5 hereto.)

6 BY MR. SLATER:

7 Q Well, have you looked at this before this

8 moment, say in the last week?

9 A I can't -- I don't remember looking at my

10 resume this week, but yeah, this is a fair

11 representation, this is my resume, yes.

12 Q Look, sir. Is this your current resume, the

13 exhibit we've just marked as T2063?

14 A Yes.

15 Q Okay. Did you prepare for this deposition?

16 A How do you mean?

17 Q Did you meet with lawyers and prepare for

18 your -- for this deposition?

19 A I did.

20 Q How many times?

21 A We met via conference call once, and then we

22 met in person once.

23 Q How long did the conference call last?

24 A To the best of my recollection, two, three

25 hours, roughly three hours, I believe.

1 Q How long did the in-person meeting last?

2 A About eight hours.

3 Q When did the conference call take place?

4 A If I remember, I think it was last Friday, last
5 Thursday or Friday. I think it was Friday.

6 Q The in-person eight-hour meeting, when did that
7 take place?

8 A Yesterday.

9 Q Did you meet with counsel this morning to
10 prepare for the deposition as well?

11 A Very briefly.

12 Q How long?

13 A 15 minutes.

14 Q One of the things you did was -- rephrase.

15 You were the U.S. launch leader for the
16 Prosima; correct?

17 A That's correct.

18 Q And what was your responsibility as U.S. launch
19 leader for the Prosima?

20 A To work with the functional groups around the
21 commercialization plan for the Prosima product. So
22 basically working with all the functional areas,
23 regulatory, Q/A, et cetera, on what the plans would be
24 to eventually launch that product into market.

25 Q And what was the commercialization plan for the

1 Prosima in simple terms? What was that plan?

2 A Can you be more specific? Just the over --

3 I just want to make sure I'm following -- I'm following
4 your question.

5 Q I want to know the overview for how you
6 commercialized and promoted and marketed the Proxima.
7 What was the -- what was the need that it was supposed
8 to be meeting and how was it supposed to be meeting that
9 need.

10 A Okay. So to the best of my recollection, the
11 product was designed to be a product that you would --
12 you would market to pelvic floor repair surgeons
13 that had another option for them doing their pelvic
14 floor repair surgeries. It was a mesh implant
15 with -- to best of my memory, with a -- with a device
16 that was held in place in the vagina and it was
17 marketed to pelvic floor surgeons as another option for
18 them to do their pelvic floor repairs.

19 Q Was the Proxima marketed with the idea that it
20 would be an option for surgeons who were not generally
21 skilled enough to utilize the Prolift?

22 A To the best of my recollection, it was a
23 product that was designed for surgeons who wanted to use
24 mesh and perhaps weren't -- weren't going to use Prolift
25 in the near future, from the best of my recollection.

1 Q That had not been using the Prolift based on
2 the fact that their skill set was such that that was
3 something that was not really a viable option, so your
4 company came out with Prosima with the idea this could
5 be a little easier to use and more attractive; correct?

6 A I wasn't there when Prosima was launched. So
7 in the early -- from the best of my recollection, the
8 plan was to launch it to pelvic floor surgeons as
9 another option for them to use instead of native tissue
10 repair or the Prolift product.

11 Q Was the Prosima targeted to less skilled
12 surgeons than those that would be using the Prolift?

13 A I just -- I want to understand what you mean
14 by less skilled.

15 Q Surgeons whose skill set would not allow them
16 to safely and effectively utilize the Prolift?

17 A I don't -- I mean I can't speak to their skill
18 set, but I can speak to the fact that I think that -- my
19 recollection is that product was designed for surgeons
20 who perhaps didn't want to use Prolift at the time,
21 for either perhaps they didn't have the -- perhaps they
22 didn't have enough pelvic floor cases that they were
23 doing routinely, and perhaps they weren't ready to move
24 to Prolift, and so this was another option for them to
25 address the -- the need, the patient need.

1 Q On your resume it says you were global launch
2 leader next generation pelvic floor mesh. Is that the
3 Prolift+M?

4 A That's correct.

5 Q As product director, did you have
6 responsibility for the Prolift?

7 A I did when I was a product director. Later in
8 my tenure as product director, I had responsibility for
9 Prolift.

10 Q When did your responsibility for Prolift begin?

11 A I don't recall the exact date, it was, you
12 know, just judging on the time that I was -- as a
13 product director and marketing director, probably was
14 late -- later -- later in 2006. I don't remember the
15 exact date, to be honest.

16 Q Sometime in 2006 you began to have
17 responsibility for the Prolift?

18 A That sounds reasonable.

19 Q And what were your responsibilities with regard
20 to the Prolift?

21 A So I -- my responsibility for Prolift was sales
22 support, managing the brand, the marketing collaterals,
23 KOL engagement, typically the -- the downstream
24 component -- component of being a brand manager
25 managing, forecasting, those kind of things.

1 Q In 2006 you were a product director within the
2 marketing department of Ethicon; correct?

3 A Correct.

4 Q And it was during 2006 that you began to have
5 responsibility for the Prolift; correct?

6 A To the best of my recollection.

7 Q And your responsibilities included such things
8 as sales support, managing the brand, overseeing
9 marketing collaterals, key opinion leader engagement,
10 downstream components and forecasting; correct?

11 A Best of my recollection, yes.

12 Q In November 2007, your title changed from
13 product director and marketing director worldwide to
14 U.S. group marketing director; correct?

15 A Correct.

16 Q What were your responsibilities as U.S. group
17 marketing director?

18 A So I had responsibility for the continence
19 health platform as well as the pelvic floor platform,
20 and so I had a marketing team that reported in to me
21 that managed those brands.

22 Q Who did you report to during that time period?

23 A To two different people, I reported to Kevin
24 Mahar and then subsequently I reported to Lynn Hall.

25 Q As U.S. group marketing director, when you say

1 you were responsible for the continence health platform
2 and the pelvic health platform, what does that mean?

3 A I had a team that reported to me that managed
4 the brands that fell within continence health. So the
5 brands that fell within continence health were the TVT
6 family of brands and the pelvic floor side was Prolift.

7 Q So the marketing teams that were responsible
8 for the marketing of the TVT line of products, those
9 marketing people, the product directors, for example,
10 reported to you; correct?

11 A That's correct.

12 Q As U.S. group marketing director from
13 November 2007 to November 2008, there was a group of
14 marketing people, product directors who were responsible
15 for the Prolift device and the marketing of that device
16 and they reported to you; correct?

17 A That's correct.

18 Q What I'd like to do and try and see if you can
19 help me out, I think we got a little organized, I'd like
20 to mark as an exhibit a document that -- the first email
21 is February 6, 2007, from Kevin Mahar. The Bates number
22 on the first page is ETH.MESH 00719198, if we could mark
23 that as the next exhibit, please.

24 (The above-referred to document was marked

25 Deposition Exhibit No. T2064 for identification

EXHIBIT P

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

9)
IN RE: ETHICON, INC.)
10 PELVIC REPAIR SYSTEM,)
PRODUCTS LIABILITY)
11 LITIGATION) MDL NO. 2327
_____)

12
13
14
15
16 THIS DOCUMENT RELATES TO ALL CASES
17 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER
18 VIDEOTAPED DEPOSITION OF:
19 PRICE ST. HILAIRE
20 VOLUME 2
21 Thursday, July 12, 2013; 9:12 a.m.

24 Reported By:
Cathy A. Wood, RMR, RPR
25 CSR No. 2825

1 preparation for this deposition he's being instructed
2 not to answer 'cause it's attorney-client or work
3 product?

4 MS. MAIMBOURG: Right.

5 BY MR. MIRACLE:

6 Q Have you ever been deposed before --

7 A I have not.

8 Q -- this deposition?

9 A I have not.

10 Q Are you familiar with the term litigation hold,
11 Mr. St. Hilaire?

12 A Uh, vaguely, yes.

13 Q Okay. And how is it you're familiar with that
14 phrase?

15 A Just through my career I've heard litigation
16 hold, uh, around, uh, the company says you have to hold
17 on to documents or not destroy documents, that's the
18 context.

19 Q And why is it they're telling you, to your
20 understanding, not to destroy documents or to hold on to
21 data or documents?

22 A So I can use example within my current employ,
23 it's because of either pending or current litigation and
24 they want to make sure documents are held.

25 Q All right. And during your time with -- with

1 Ethicon, do you recall being made aware of any
2 litigation holds?

3 A I don't recall specifically.

4 Q How about generally, as we sit here today, do
5 you recall ever being -- hold on just a second.

6 A Sorry.

7 Q Ever being made aware that there was a
8 litigation hold and that you shouldn't destroy or
9 otherwise erase emails, documents, Power Points,
10 whatever the case may be?

11 A I don't have a specific recollection, but it's
12 reasonable in the time that I was there that -- that a
13 litigation hold notice would have -- would have come to
14 me, so I don't remember specifically what or when.

15 Q So you're saying in the eight or nine years you
16 were with Gynecare or Ethicon, it's reasonable to assume
17 that you would have been subject to a litigation hold at
18 some point during that time frame?

19 A It's reasonable. I just don't remember
20 specifically when.

21 MR. MIRACLE: Need 1500.

22 MR. SMITH: This is marked as T2083.

23 THE WITNESS: Thank you.

24 BY MR. MIRACLE:

25 Q I'm going to give you a second to look at that.

1 A Okay.

2 Q Okay. Have you had a chance to look at that?

3 A Yes, at the time of this e-mail, just to be
4 clear, I wasn't in Marketing at the time, I was in the
5 sales force.

6 Q Sure.

7 (The above-referred to document was marked
8 Deposition Exhibit No. T2083 for identification
9 by the Court Reporter, and a copy is attached
10 hereto.)

11 BY MR. MIRACLE:

12 Q I guess my question to you would be now I have
13 shown you this document, you've had a chance to look at
14 it, do you recall ever seeing this particular document,
15 this particular email?

16 A I certainly don't recall this specific email.

17 MR. MIRACLE: What did we mark this?

18 MR. SMITH: T2083.

19 BY MR. MIRACLE:

20 Q And, just for the record, the document we're
21 talking about is a May 22nd, 2003, email which purports
22 to be a preservation notice that was issued by J & J Law
23 Department, and it's been marked as T2083, and it's your
24 testimony that you don't recall seeing this.

25 A Not specifically, okay.

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1 Q Do me a favor, look down towards the bottom of
2 the first page below where it says May 22nd, 2003, do
3 you see that?

4 A Yes, I do, sir.

5 Q Could you read the paragraph below that into
6 the record?

7 A Sure. "Hold notice for Kandell versus Ethicon,
8 Inc., et als. Ethicon, Inc. has been named in a lawsuit
9 arising out of the alleged use of TVT. In connection
10 with this matter, it is vital to preserve all documents
11 relating in any way to the below-listed subject matters
12 until contrary written notice is received from the J & J
13 Law Department. Failure to preserve these materials
14 could result in court-imposed penalties or sanctions on
15 both the company and/or individual employees."

16 Q If you flip the page and read the first page on
17 the next page, please.

18 A Starting from, "Do not discard"?

19 Q Please.

20 A "Do not discard, destroy or alter in any
21 way" -- "in any way any of the documents, electronic or
22 paper, described below. Please ensure that these
23 instructions are followed."

24 Q As we sit here today, do you recall, after
25 reading that to help refresh your memory, on receiving

1 any specific litigation hold notice or a preservation
2 notice during your employment with Ethicon?

3 A Again, I don't -- I don't specifically remember
4 a specific preservation hold. Do I remember these
5 coming across, it's reasonable that these have come
6 across, but I don't remember a specific one.

7 Q All right.

8 A And I certainly don't remember this one
9 specifically.

10 Q And certainly as an employee for either -- for
11 Ethicon, you would follow the letter and the intent of
12 any preservation notice or hold notice that would come
13 across your email account or across your desk, right?

14 A Certainly, to the best of my ability,
15 absolutely.

16 Q And as we sit here today, do you recall ever,
17 aside from these hold notices, do you recall ever having
18 occasion to or -- or necessarily having done -- erased
19 emails you've either sent or received from the database
20 or from -- from your hard drives or your computers?

21 A Not to my recollection.

22 Q Would you have ever had any need or necessity
23 to do so?

24 A Not to my recollection.

25 Q And were you ever directed by anyone within the

1 specifically.

2 Q You could have done it, you just don't
3 remember?

4 A Sure, yeah.

5 Q As we sit here today, you certainly don't
6 remember proactively destroying any of the documents
7 that would have been subject to this specific
8 preservation --

9 A No, sir.

10 Q -- notice?

11 And to that extent, when you left the company
12 in 2008, it would be your assumption that any of the
13 documents in the categories we have read from this
14 preservation notice would have been either in your
15 computer, in your hard drive, in your phone, any of the
16 things you handed back in at the time of your
17 separation --

18 A That's correct.

19 Q -- from the company; is that right?

20 A That's correct.

21 Q So in any event, the fact that we have been
22 produced nothing that was in your computer or hard drive
23 or anything else that you've submitted to the company on
24 your separation with the company in 2008 --

25 A Uh-huh.

1 Q -- certainly in your time with the company for
2 eight or nine years, there would be more than zero
3 documents that should have been produced, is that an
4 accurate assessment?

5 A I think that's reasonable.

6 MS. MAIMBOURG: Objection.

7 BY MR. MIRACLE:

8 Q But as far as you know, those documents or
9 emails or data or emails or any of the things that are
10 listed in this preservation notice that would apply to
11 yourself, those would have disappeared after your
12 separation from the company?

13 MS. MAIMBOURG: Objection.

14 THE WITNESS: I'm sorry, I didn't understand
15 your question.

16 BY MR. MIRACLE:

17 Q Those would have disappeared after your
18 separation from the company?

19 MS. MAIMBOURG: Objection to the term
20 disappear.

21 BY MR. MIRACLE:

22 Q That those were present when you left?

23 A So I tendered my laptop, and I left everything
24 in my office. So everything was on my laptop when I
25 separated from the company. What happened after I left

1 the company with the laptop, I can't speak to or
2 speculate to.

3 Q Do you recall in 2008 when you left the company
4 what the procedure was, or if there was a procedure, for
5 turning in all the company materials, computers,
6 laptops, tablets, phones whatever the case may be?

7 A I don't remember the specific procedure. To
8 the best of my recollection, I turned in my -- my laptop
9 and my badge and my AMEX and things of that nature to my
10 supervisor. So I don't remember the specific procedure,
11 but -- but that's -- to my recollection, that's what I
12 did.

13 MR. MIRACLE: Let's take a five-minute break.
14 We may be pretty close to being done.

15 THE VIDEOGRAPHER: Videotape deposition off
16 record at 12:10 p.m.

17 (Brief recess was taken.)

18 THE VIDEOGRAPHER: Videotape deposition is now
19 returning to record at 12:23 p.m.

20 BY MR. MIRACLE:

21 Q Mr. St. Hilaire, over the last two days of
22 giving this deposition, uh, you stated several times
23 that it's been -- in all fairness to you, it's been
24 awhile since you've worked for Ethicon, it's been four
25 to five years since you separated from the company; is

EXHIBIT Q

Andrew N. Faes

From: Ben Watson <Ben.Watson@butlersnow.com>
Sent: Thursday, June 27, 2013 9:29 PM
To: Andrew N. Faes
Cc: Christy Jones; Donna Jacobs; Tom P. Cartmell; Bryan Aylstock; 'Renee Baggett'
Subject: RE: Price St. Hilaire

Andrew,

Price St. Hilaire separated in October 2008. We have not located data for him.

From: Andrew N. Faes [mailto:afaes@wcllp.com]
Sent: Wednesday, June 26, 2013 8:42 AM
To: Ben Watson
Cc: Christy Jones; Donna Jacobs; Tom P. Cartmell; Bryan Aylstock; 'Renee Baggett'
Subject: RE: Price St. Hilaire

Mr. Watson:

I am just following up on this request. Is there any new information regarding Price St. Hilaire's custodial file?

Thanks

Andrew N. Faes

Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1176
Fax 816-531-2372
afaes@wcllp.com
<http://www.wagstaffcartmell.com>

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From: Andrew N. Faes
Sent: Monday, June 24, 2013 9:56 AM
To: Ben Watson
Cc: christy.jones@butlersnow.com; donna.jacobs@butlersnow.com; Tom P. Cartmell; Bryan Aylstock; 'Renee Baggett'
Subject: Price St. Hilaire

Mr. Watson:

The deposition of Price St. Hilaire is scheduled for 07-11-13. Our records indicate that we currently have no custodial file for this witness. Can you advise when we can expect to receive the complete custodial file for this witness?

Thanks

Andrew N. Faes

Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1176
Fax 816-531-2372
afaes@wcllp.com
<http://www.wagstaffcartmell.com>

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EXHIBIT R

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1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 Master File No. 2:12-MD-02327

5 * * * * *

6 IN RE: ETHICON, INC. PELVIC * MDL 2327
7 PRODUCTS REPAIR SYSTEM * Joseph R. Goodwin
 U.S. District
8 LIABILITY LITIGATION * Judge

9 * * * * *

10 THIS DOCUMENT RELATES TO ALL CASES
11 AND VARIOUS OTHER CROSS-NOTICED ACTIONS

12

13 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

14

15 VIDEOTAPED DEPOSITION OF CHERYL H. BOGARDUS
16 The Executive Center at Exchange Place, LLC

17 21 W. Main Street

18 Waterbury, Connecticut

19 August 30, 2013 10:13 a.m.

20

21

22 Reported by: Maryellen Coughlin, RPR/CRR

23

24 Golkow Technologies, Inc.

 877.370.3377 ph|917.591.5672 fax

25 deps@golkow.com

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1 Q. So you didn't look in any files
2 that you might have had at home or any office
3 relating to that subject?

4 A. No.

5 Q. Are you aware that in connection
6 with the discovery in this case that Ethicon was
7 unable to produce any custodial file for you? In
8 other words, a file containing documents,
9 electronic or paper documents that you had had
10 when you were at the company, are you aware of
11 that?

12 A. I was told that.

13 Q. Okay. And do you have any
14 understanding regarding why it is that the
15 company -- what is your understanding regarding
16 why it is that the company does not have any
17 files relating to you when you were at the
18 company, a custodial file for you?

19 A. I have no idea.

20 Q. No?

21 A. Why they don't have records of my
22 e-mails?

23 Q. Right.

24 A. I don't know.

25 Q. Okay. When you left the employment

1 of Ethicon, which I guess was in 2007 --

2 A. Yes.

3 Q. -- around May of 2007.

4 When you left Ethicon, did you
5 delete, discard or destroy any paper or
6 electronic documents that you might have had in
7 your office or on your computer at that time?

8 A. No.

9 Q. So as far as you know, all of those
10 documents would have been still on your computer
11 or in the company's computers or in your files at
12 the time you left, right?

13 A. Yes.

14 Q. Did you take copies of -- either
15 originals or copies of any documents --

16 A. No.

17 Q. -- when you left the company?

18 A. No, I did not.

19 Q. Prior to the termination of your
20 employment, did you ever take any documents or
21 did you ever have any documents either on any
22 home computer or in any files that you maintained
23 at your home, that is to say Ethicon-related
24 documents?

25 A. I don't remember anything

1 specifically. I kept records of the required
2 documents that I was required to sign, like the
3 secrecy agreement and things like that, but I did
4 not keep anything that was company related to my
5 job or would have been confidential.

6 Q. Okay. So I take it from that that
7 you may have at home a file that contains things
8 like an agreement between -- an employment
9 agreement or a confidentiality agreement that you
10 might have had with Ethicon, but you would not
11 have any files relating to let's say business
12 matters?

13 A. No.

14 Q. Okay. And would the same be true
15 of your home computer?

16 A. Yes.

17 Q. Okay. So as far as you know
18 sitting here today, the only documents that you
19 would be aware of that would relate to let's say
20 pelvic floor products at Ethicon, those, if they
21 existed at the time of your termination, they
22 would be on the company's computers or in the
23 company's files, and you don't have any copies;
24 is that fair?

25 A. It is fair to say I don't have any

1 copies.

2 Q. Okay.

3 A. I don't know -- I know the day I
4 left I hadn't touched anything --

5 Q. Okay.

6 A. -- and that's all I know.

7 Q. Okay. Do you have any reason to
8 believe before you left that any -- not
9 immediately before you left but at any time
10 before you left that any documents relating to
11 pelvic floor products had been deleted, discarded
12 or destroyed?

13 A. No. I mean, certainly not
14 intentionally and --

15 Q. Okay.

16 A. You normally delete things not to
17 fill up your e-mail, so I'm sure I deleted
18 something at some time.

19 Q. So other than in the ordinary
20 course of business when an e-mail comes in and
21 you don't feel you need it anymore or it's a
22 trivial e-mail, other than that sort of routine
23 thing that we all do, you don't recall any
24 particular deleting, discarding or --

25 A. No.

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1 Q. -- disposal or destruction of
2 documents?

3 A. No, I don't.

4 Q. Are you aware that Ethicon had a
5 practice of routinely getting rid of documents as
6 part of a formal document retention program?

7 A. There was a document retention
8 program. I don't remember the specifics of it.

9 Q. Okay. Do you remember that as part
10 of that document retention program there was an
11 annual purge of documents where people were
12 suppose to go through and get rid of stuff that
13 was not needed?

14 A. I don't remember that it was
15 annual.

16 Q. Okay.

17 A. I don't remember the specifics of
18 it.

19 Q. Do you recall ever having done it?

20 A. I don't recall having done it, but
21 I would only guess that if it was a requirement I
22 would have done it.

23 Q. Okay. Do you recall having ever
24 received a memo or a note or something or some
25 kind of e-mail communication telling you, okay,

1 it's time to comply with the document retention
2 program?

3 A. Yes. Vaguely, yes, because there
4 was a process in place, and part of that process
5 would have been getting some type of notification
6 at some time.

7 Q. Okay. And do you recall that as
8 part of that process you were also from time to
9 time told that certain documents should be held
10 on to because of litigation?

11 A. I don't remember ever being told to
12 hold on to a document because of litigation.

13 Q. Never?

14 A. Never.

15 Q. And you don't remember ever getting
16 either a e-mail or a written communication
17 telling you to hold on to documents?

18 A. No, I don't remember that. I mean,
19 specific to a legal matter?

20 Q. Either specific to a legal matter
21 or in particular a --

22 A. Or any time. I don't remember ever
23 being asked to hold on to any documents.

24 Q. Okay. During the course of your
25 work at Ethicon, where did you -- if you kept

1 paper or electronic documents, where did you keep
2 them? And I take it -- by that I mean
3 physically, if it was paper, or electronically
4 where was it stored if it was electronic or if
5 there's some other place.

6 A. Well, I obviously had files in my
7 workspace --

8 Q. Okay.

9 A. -- and on my computer.

10 Q. Okay. And other than files that --
11 now, in your workspace, I take it that would be
12 in -- you had an office?

13 A. I had an office until the last six
14 months I was there.

15 Q. Okay. And I don't want to make
16 this more complicated than it needs to be but,
17 'cause you may have moved, but I'm trying to get
18 a sense of -- let's talk about in the last six
19 months when you were there. Did you still have
20 the same files, maintain basically the same
21 collection of files that you had had the six
22 months prior to that, or was it like a new set of
23 files?

24 A. I don't remember.

25 Q. Okay.

1 A. I had five different positions in
2 six years --

3 Q. Right.

4 A. -- and I'm sure I passed files on
5 to other people. I must have. I'm guessing
6 again but.

7 Q. At the time you left, paper
8 files --

9 A. Mm-hmm.

10 Q. -- where were they located and how
11 voluminous were they?

12 A. Well, I had a small cubicle, so
13 they weren't that voluminous.

14 Q. Okay.

15 A. But they were in file drawings.

16 Q. About how many file draws?

17 A. I'm trying to remember.

18 Q. Was it like a four- or five-draw
19 file cabinet or was it like a smaller file
20 cabinet next to your desk?

21 A. There was a two-draw file cabinet
22 that was, you know, about three, four feet long.

23 Q. Okay. So, in other words, the draw
24 was about three or four feet deep?

25 A. No, long.

1 Q. Oh, wide. So it was like lateral
2 files?

3 A. Wide, yes, wide.

4 Q. Okay. So two draws about three or
5 four feet long?

6 A. (Witness nods.)

7 Q. And were those two draws relatively
8 full of files?

9 A. I don't remember.

10 Q. Okay. Were there files in both,
11 files in both draws?

12 A. Yes.

13 Q. Okay. And it probably was not
14 completely jammed full of documents, right, or
15 was it?

16 A. I don't remember. That was a long
17 time ago, over six years ago.

18 Q. Okay. I appreciate that. Now --
19 and for electronic documents, those would be on
20 your computer, right?

21 A. (Witness nods.)

22 Q. Did you have some kind of a system
23 of how you filed e-mails? How did you do that?

24 A. Probably a system in my own head,
25 but I filed typically by people and subject.

1 Q. Actually, you're getting ahead of
2 me.

3 Did you use like a program like
4 Outlook or something like that to keep track of
5 your e-mails?

6 A. Yes, Outlook.

7 Q. Okay. And so you could set up your
8 own little folders in Outlook?

9 A. Folders, right.

10 MS. MAIMBOURG: You know what,
11 Cheryl, wait until he finishes asking the
12 question 'cause you two are talking over each
13 other.

14 THE WITNESS: Sorry.

15 MR. SHERIDAN: Yeah, I was going to
16 say that. I will try not to interrupt you --

17 THE WITNESS: Sorry.

18 MR. SHERIDAN: -- but it will make
19 it more easy for the court reporter to get
20 everything.

21 So you used Outlook and you set up
22 a system of folders to save e-mails, right?

23 A. Yes.

24 Q. And the folders were just folders
25 that you set up yourself based on what you

1 thought was a good way to organize your e-mails,
2 right?

3 A. Yes.

4 Q. Okay. And when you left the
5 company, that -- as far as you know, that e-mail
6 structure and folder structure was still in
7 place?

8 A. Yes.

9 Q. So e-mails that you had saved there
10 should still have been there, right?

11 A. Yes.

12 Q. Okay. Now, you were with Ethicon
13 from approximately 2001 until I guess it was
14 about May of 2007, right?

15 A. Right.

16 Q. A period of about six and a half
17 years?

18 A. A little less, yes.

19 Q. Okay. And during the course of
20 that period of time, would it be fair to say you
21 had a lot of communications that related to
22 pelvic floor products?

23 A. During the time I was there, I
24 worked on the incontinence and pelvic floor area,
25 my first two years and four months, and then

1 until the last about six months I was there I
2 didn't have -- my work didn't involve
3 commercialization of incontinence and pelvic
4 floor products.

5 Q. Okay. Well, during the period of
6 time when you were working on incontinence and
7 pelvic floor products, do you have any idea how
8 many e-mails you would have either sent -- that
9 you sent or received that would relate to those
10 issues?

11 A. I have no idea.

12 Q. Would it have been thousands?

13 A. I have no way of quantifying my
14 work 12 years ago and how much -- and how many
15 e-mails I sent or received.

16 Q. Okay. Did you send or receive a
17 lot of e-mails during your work at Ethicon during
18 that period of time?

19 A. What would a lot be? I don't know
20 what you mean by this.

21 Q. How about would you send or receive
22 let's say a hundred e-mails a day?

23 A. Possibly.

24 MS. MAIMBOURG: Could I just
25 clarify? Are you talking about the early 2000

1 period? Remember, she said she only dealt with
2 incontinence the first two years and four
3 months --

4 MR. SHERIDAN: Okay.

5 MS. MAIMBOURG: -- and then her
6 last six months. And certainly I think people's
7 e-mail habits changed over that decade, so I'm
8 just trying to seek some clarification as to what
9 you're asking her.

10 Q. Okay. During the period of time
11 that you had some involvement with incontinence
12 or pelvic floor products, would it be fair to say
13 you sent or received something on the range of a
14 hundred e-mails a day?

15 A. Yes.

16 Q. Okay. During the course of your
17 work at Ethicon, did anyone ever ask you to
18 collect and save any documents relating to
19 incontinence or pelvic floor products?

20 Let me amend that. In connection
21 with any type of litigation.

22 A. No, not that I remember.

23 Q. Okay. Could you please describe
24 for us your educational background after high
25 school?

EXHIBIT S

Andrew N. Faes

From: Ben Watson <Ben.Watson@butlersnow.com>
Sent: Sunday, August 11, 2013 3:19 PM
To: Andrew N. Faes
Cc: Tom P. Cartmell; Bryan Aylstock; Christy Jones; Donna Jacobs; 'Renee Baggett'
Subject: RE: Cheryl Bogardus

Andrew,

We do not have a custodial file for Cheryl Bogardus. Her separation date was May 7, 2007.

From: Andrew N. Faes [mailto:afaes@wcllp.com]
Sent: Saturday, August 10, 2013 12:33 PM
To: Ben Watson
Cc: Tom P. Cartmell; Bryan Aylstock; Christy Jones; Donna Jacobs; 'Renee Baggett'
Subject: Cheryl Bogardus

Mr. Watson:

The deposition of Cheryl Bogardus is scheduled for 8-30-13. I don't see that we have received any custodial file on this witness other than her personnel file. Can you advise if there is a custodial file for this witness, and if so, when we can expect to receive it?

Thanks

Andrew N. Faes

Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1176
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<http://www.wagstaffcartmell.com>

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EXHIBIT T

Confidential - Subject to Protective Order

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 *****

5 IN RE: ETHICON, INC. MDL No. 2327
6 PELVIC REPAIR SYSTEM,
7 PRODUCTS LIABILITY LITIGATION

8 *****

9 THIS DOCUMENT RELATES TO ALL CASES

10 *****

11 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

12

13 VIDEOTAPED DEPOSITION OF GREGORY R. JONES

14 Tuesday, August 20th, 2013

15 9:05 a.m.

16

17

18 Held At:

19 Radisson Hotel

20 200 Genesee Street

21 Utica, New York

22

23

24 REPORTED BY:

25 Maureen O'Connor Pollard, RPR, CLR

1 Q. Would you agree with me that Ethicon,
2 with respect to the TVT system, had a
3 responsibility to train physicians before using
4 their device?

5 A. No.

6 MR. COMBS: Object to the form.

7 BY MR. BALEFSKY:

8 Q. Sorry. Let me ask that again, we had
9 objection from your counsel.

10 Would you agree that Ethicon, with
11 respect to the TVT system, had a responsibility
12 to train physicians before they used the TVT
13 device?

14 A. No.

15 Q. Now, while you were employed at
16 Ethicon, I assume you kept a custodial file of
17 all of the documents that you generated, and
18 e-mails, etcetera?

19 A. I had a filing system.

20 Q. Could you just explain to me briefly
21 what your filing system was?

22 A. I had an administrative assistant who
23 took care of that.

24 Q. Who was that?

25 A. Her name was Carmen Goble.

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1 Q. Carmen, spell her last name?

2 A. G-O-B-L-E.

3 Q. Do you know whether she's still
4 employed by Ethicon or J&J?

5 A. I don't know.

6 Q. When was the last time you had any
7 contact with Ms. Goble?

8 A. Ten years.

9 Q. What type of file system did she
10 maintain for you?

11 A. We had a paper filing system. I'm
12 sure she kept things electronically. We kept
13 the 510(k)s. We kept the regulatory strategies.
14 We filed FDA correspondence with the appropriate
15 510(k)s. We had 510(k)s from other
16 manufacturers. We kept all of our audit
17 reports. Those are the things that come to
18 mind.

19 Q. Did you have a computer at work?

20 A. We did.

21 Q. And I assume you sent e-mails and
22 other correspondence to different people within
23 the organization?

24 A. Yes.

25 Q. And did you have a procedure for

1 saving those?

2 A. Not that I can recall.

3 Q. Did you -- do you recall ever
4 receiving a document that told you not to
5 destroy any of your files with respect to the
6 TVT?

7 A. Not specifically for TVT, but I
8 remember getting those types of notices in
9 general.

10 Q. When you say "in general," were they
11 not for a specific product? Were they for
12 specific products, or were they just general
13 notices?

14 A. Just general notices when there was
15 litigation.

16 Q. Well, the litigation involving a
17 particular product, would it be specific to that
18 product?

19 A. My recollection, we would get a notice
20 when there was a litigation on a particular
21 product.

22 Q. And it would be your procedure to
23 follow that notice, correct?

24 A. Yes.

25 Q. Let me show you a document that we've

1 marked T-3140.

2 (Whereupon, Exhibit Number T-3140,
3 5/22/03 e-mail chain, Bates
4 ETH.MESH.00875544 through 546, was
5 marked for identification.)

6 BY MR. BALEFSKY:

7 Q. I ask you to take a look at that
8 (handing).

9 (Witness reviewing document.)

10 A. Yes. What's your question?

11 BY MR. BALEFSKY:

12 Q. My question is; can you identify the
13 document that I just handed you?

14 A. Yes.

15 Q. And can you tell me what it is?

16 A. Preservation notice from the law
17 department.

18 Q. Do you recall receiving this
19 preservation notice in May of 2003?

20 A. Not specifically.

21 Q. You were employed by the company on
22 May 22nd, 2003?

23 A. I left of the company in 2003, I just
24 don't remember what month.

25 Q. Do you recall whether you left in

1 November of 2003?

2 A. No, I don't.

3 Q. Well, let's assume for a second that
4 you were still employed by Ethicon on May 22,
5 2003, okay?

6 A. Mm-hmm.

7 Q. This e-mail was sent to -- it looks
8 like it was sent to "DL-ETHUSSO, All Ethicon."
9 What does that mean, "All Ethicon"?

10 A. I don't know specifically.

11 Q. So you don't recognize that
12 designation?

13 A. No.

14 Q. Could that -- well, let me ask you
15 this.

16 Do you understand that to mean that
17 this e-mail was sent to all Ethicon employees?

18 A. That would be my guess.

19 Q. Okay. I don't want you to guess.

20 A. That would be -- I don't know what
21 this specific designation means, but that's my
22 answer.

23 Q. Would it be your understanding that
24 this document was sent to all Ethicon employees
25 on May 22nd, 2003?

1 A. I believe so.

2 Q. Now, if you look at the first
3 paragraph of the document, above -- the first
4 page, it says "Please review the document hold
5 notice below and ensure that you do the
6 following."

7 Do you see that?

8 A. Yes.

9 Q. It says "Identify any documents in
10 your possession which may be related to this
11 notice." Right?

12 A. Yes.

13 Q. It says "Appropriately segregate such
14 documents and/or otherwise mark them so that
15 they are preserved from any destruction,"
16 correct?

17 A. Yes.

18 Q. "Keep such documents in a safe place."
19 It was signed by Rita McIntyre.

20 Do you know who Rita McIntyre is?

21 A. I remember.

22 Q. Who was she?

23 A. She was a nurse in our complaint
24 handling department.

25 Q. And then below that it says

1 "Preservation notice. Do not destroy specified
2 documents," right?

3 A. Correct.

4 Q. And down below it says "Re: Hold
5 notice for Kandell versus Ethicon, Inc., et
6 als." It says "Ethicon, Inc. has been named in
7 a lawsuit arising out of the alleged use of
8 TVT."

9 Do you see that?

10 A. Yes.

11 Q. That's the TVT product that you were
12 responsible for, correct?

13 A. Correct.

14 Q. And then it says "Failure to preserve
15 these materials could result in court-imposed
16 penalties or sanctions or both, the company
17 and/or individual employees," correct?

18 A. Correct.

19 Q. And then on Page 2 of the document it
20 talks about the kinds of documents that were
21 required to be preserved, correct?

22 A. Correct.

23 Q. Okay. And assuming you were employed
24 by the company on May 22nd, 2003, you would have
25 abided by this notice, correct?

1 A. Correct.

2 Q. And it says, in the middle of the page
3 there, it says "Subject matters of documents to
4 be preserved," it says "TVT." It says "Hold all
5 documents, memoranda, notes, files, e-mails,
6 etcetera, relating to TVT."

7 A. Yes.

8 Q. And then under Number 3, "Regulatory,"
9 it says "All final draft communications with
10 regulatory authorities regarding the TVT,
11 including FDA correspondence and inspection
12 records, 483's, IND, NDA, BLA and other
13 regulatory files and audit files, including
14 product monograph files (as applicable),"
15 correct?

16 A. Correct.

17 Q. Did you have documents concerning TVT
18 in your possession or control when you last
19 worked at J&J Ethicon?

20 A. I don't recall.

21 Q. Well, if you had received this notice,
22 you would have preserved the documents, correct?

23 A. Yes.

24 Q. Did anyone at Ethicon take an image of
25 the hard drive of your computer on or before

1 your last day of work at Ethicon?

2 A. Not that I can recall.

3 Q. Were any of your work documents
4 transferred from your computer or filing
5 cabinets to another person on or before your
6 last day of work for Ethicon?

7 A. No.

8 MR. BALEFSKY: Counsel, I would -- we
9 were told that Mr. Jones has no custodial file,
10 we were not given any custodial file for
11 Mr. Jones, and I would just make a request that
12 we get it.

13 MR. COMBS: I'll pass that along.
14 We'll make an inquiry into the status of that.
15 Obviously Mr. Jones separated from the company
16 more than half a decade before this litigation
17 started, so I'm sure that probably plays a
18 bearing.

19 BY MR. BALEFSKY:

20 Q. To your knowledge, Mr. Jones, was that
21 litigation hold notice ever rescinded during
22 your time at Ethicon?

23 A. When I was at Ethicon?

24 Q. Yes.

25 A. Not that I can recall.

EXHIBIT U

Andrew N. Faes

From: Ben Watson <Ben.Watson@butlersnow.com>
Sent: Thursday, August 29, 2013 8:28 PM
To: Andrew N. Faes
Cc: Tom P. Cartmell; 'Renee Baggett'; Bryan Aylstock; Donna Jacobs; Christy Jones
Subject: RE: Richard Isenberg

Andrew,

We looked into this and his separation date was September 24, 2002. No data has been located, so there is no custodial file. We also checked with HR, and they have been unable to locate anything beyond what was produced.

From: Andrew N. Faes [mailto:afaes@wcllp.com]
Sent: Thursday, August 29, 2013 6:25 PM
To: Ben Watson
Cc: Tom P. Cartmell; 'Renee Baggett'; Bryan Aylstock; Donna Jacobs; Christy Jones
Subject: RE: Richard Isenberg

Mr. Watson:

I'm just following up on this request. Is there any word yet on the Isenberg personnel file or custodial file?

Andrew N. Faes

Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1176
Fax 816-531-2372
afaes@wcllp.com
<http://www.wagstaffcartmell.com>

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From: Andrew N. Faes
Sent: Friday, August 23, 2013 11:39 AM
To: Ben Watson
Cc: Tom P. Cartmell; 'Renee Baggett'; Bryan Aylstock; donna.jacobs@butlersnow.com; christy.jones@butlersnow.com
Subject: Richard Isenberg

Mr. Watson:

The deposition of Richard Isenberg is scheduled to take place within the next 30 days. It appears that we only have a single page document for his Human Resource file. Can you please produce the entire Human Resource file for Richard Isenberg as soon as possible? Also, can you confirm that there is no custodial file for Richard Isenberg?

Thanks

Andrew N. Faes

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EXHIBIT V

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CONFIDENTIAL DOCUMENT

EXHIBIT W

CONFIDENTIAL - Subject to Protective Order

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

- - -

4 IN RE: ETHICON, INC. PELVIC : MDL NO. 2327
5 REPAIR SYSTEM, PRODUCTS :
6 LIABILITY LITIGATION :

- - -

7 IN RE: : SUPERIOR COURT OF
8 PELVIC MESH/GYNECARE : NEW JERSEY
9 LITIGATION : LAW DIVISION -
10 : ATLANTIC COUNTY
11 :
12 : MASTER CASE 6341-10
13 :
14 : CASE NO. 291 CT

15 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

- - -

16 Tuesday, April 16, 2013

- - -

17 Videotaped Deposition of PATRICIA HOJNOSKI
18 held at Riker Danzig Scherer Hyland Perretti LLP,
19 Headquarters Plaza, One Speedwell Avenue,
20 Morristown, New Jersey, on the above date, beginning
21 at 9:34 a.m., before Kimberly A. Otherwise, a
22 Certified Realtime Reporter, Certified Court
23 Reporter, and Notary Public.

- - -

24 GOLKOW TECHNOLOGIES, INC.
25 877.370.3377 ph | 917.591.5672 fax
 deps@golkow.com

1 exact time of year it was.

2 Q When you began working in June of 2002,
3 would you have been trained on the document
4 retention policy at or about the time that you
5 started your employment?

6 A I believe I was, at least within that
7 first few months. There were training requirements
8 to meet.

9 Q From time to time you would receive
10 litigation document hold notifications from Johnson
11 & Johnson legal department; correct?

12 A Correct.

13 Q And when you were first employed in June
14 of 2002, there was already a document retention or
15 document litigation hold notice in place; correct?

16 A I don't recall.

17 MR. THORNBURGH: Go ahead and mark as
18 Exhibit No. 53 a copy of the May two thousand -- I'm
19 sorry -- May 3rd, 2002, document preservation
20 notice. Okay?

21 (Exhibit No. T-53 was marked for
22 identification.)

23 BY MR. THORNBURGH:

24 Q Have you had a chance to review that
25 document?

1 A I'm still looking. Is this specifically
2 asking about a specific product?

3 Q I'm actually going to be asking you
4 questions about it. But if you look at -- who's it
5 from, first off?

6 A Ethicon Interactive Communications.

7 Q And who's Ethicon Interactive
8 Communications?

9 A I'm sorry. I don't know that.

10 Q Is that a part of the Ethicon US branch?

11 A It sounds like it is. I'm not familiar
12 with any specific department being referred to as
13 Ethicon Interactive Communications.

14 Q But it's got the same ETHUS --

15 A Correct.

16 Q -- word after the Ethicon Interactive
17 Communications; right?

18 A Correct.

19 Q Based on that, would it be your
20 understanding that that came from Ethicon US?

21 A Yes.

22 Q And that was sent to DL-ETHUSSO. Do you
23 know what that is?

24 A I don't.

25 Q Okay. And then after that what does it

Confidential - Subject to Protective Order

1 say?

2 A All_Ethicon@ETHUS.JNJ.com.

3 Q So this document would have been sent to
4 all of the employees at Ethicon J&J?

5 A It appears so, but I can't state for sure.
6 I wasn't at Ethicon at that time and I wasn't part
7 of the party who sent the e-mail.

8 Q And the subject is Document Retention
9 Annual Purge; correct?

10 A Yes.

11 Q And it says: "We are all responsible for
12 reviewing our files each year to ensure that we are
13 in compliance with Ethicon Records Retention Policy
14 (PL566-001)"; correct?

15 A Correct.

16 Q And that PL566-001, the Ethicon retention
17 policy, is attached to this document if you turn to
18 Bates No. ETH.MESH.07425072.

19 Do you see that there?

20 MR. COMBS: Object to the form.

21 THE WITNESS: I'm sorry. I don't.

22 BY MR. THORNBURGH:

23 Q Okay. So from -- and I apologize. From
24 time to time I may refer to Bates numbers.

25 A Okay.

1 Q So I know that this is your first
2 deposition --

3 A Uh-huh.

4 Q -- and you may not know what I mean when I
5 say "Bates numbers." So a Bates number is a number
6 that the parties or the defendant in this case would
7 have designated at the bottom of the page so that we
8 could follow each other --

9 A Okay.

10 Q -- as we reference those Bates numbers.
11 Okay?

12 So if you look at Bates number ending in
13 072, it's an e-mail -- or, I'm sorry, it's a
14 document that says "J&J Law Department"; correct?

15 A Correct.

16 Q And it says "Document Preservation
17 Notice"?

18 A Yes.

19 Q And it's February 13th, 2002; right?

20 A Uh-huh.

21 Q So this would have been the document
22 preservation notice that would have been in place
23 when you were first employed in June of 2002;
24 correct?

25 MR. COMBS: Object to the form.

1 BY MR. THORNBURGH:

2 Q Does it appear that way at least?

3 A It appears that way, but I don't know if
4 there was another notice that came out in between
5 that time. Since I wasn't there, I don't -- I can't
6 state for sure if this was the one that was in
7 effect.

8 Q Okay. And it says: "In connection with
9 the upcoming company records clean out, it is vital
10 to preserve all documents relating in any way to the
11 matters on the attached 'PRESERVATION NOTICE
12 REPORT'"; right?

13 A Yes.

14 Q And then it goes on to say: "Failure to
15 preserve these materials could result in the
16 imposition of harsh penalties or sanctions"; right?

17 A Yes.

18 Q And then it goes on to say: "Do not
19 discard, destroy or alter in any way any of the
20 documents (electronic or paper) described below.
21 Please ensure that these instructions are followed."

22 Would that have -- that admonition, would
23 that be based on your memory consistent with what
24 the deposition -- with what the document
25 preservation notice would have been in place at the

Confidential - Subject to Protective Order

1 time that you were employed in June of 2002?

2 MR. COMBS: Object to the form.

3 THE WITNESS: I agree that if this is
4 the one that was in effect in June 2002, this is
5 what we would have followed.

6 BY MR. THORNBURGH:

7 Q And you would have followed the document
8 retention notice?

9 A Yes, I would.

10 Q You wouldn't have destroyed any of the
11 documents --

12 A No.

13 Q -- within your possession?

14 A No, I would not.

15 Q You would have maintained those documents
16 in the course of -- the business course that was in
17 place at Johnson -- at Ethicon throughout your
18 employment?

19 A Yes.

20 Q You would have preserved electronic
21 documents either electronically or they would have
22 been retained in hard copy?

23 A Yes.

24 Q And if you turn with me to the Bates
25 number ending in 076 -- actually, let me just back

1 up. Let's go to 075 first. You see there's a
2 definition there?

3 A Yes.

4 Q And it says -- what types of
5 communications or documentations were you -- strike
6 that.

7 What types of communications or documents
8 were covered by this document retention policy?

9 A The document here states that the record
10 is "any form of written, electronic or audiovisual
11 communication generated internally or externally for
12 ETHICON'S use, including but not limited to," and
13 then there's a list of what would be -- need to be
14 maintained.

15 Q Okay. And that would include any written
16 memos, letters, or reports; microfilm or microfiche;
17 electronic or Intranet files, tapes, and discs,
18 e-mail memos; computer and word processing tapes and
19 discs; completed forms; ledger and notebooks;
20 slides, movies, video and audiotapes; photographs,
21 pictures, and microscope slides?

22 A Correct.

23 Q And those documents were to be retained
24 for the lifetime of the product?

25 A I'm not sure. Looking at this, I don't

1 know how long those needed to be maintained for.

2 Q If you go to the next page, under "Policy
3 Statements" it says: "Records shall be retained for
4 a period not to exceed three years, except as
5 indicated in the appended exception lists"; right?

6 A Yes.

7 Q It says: "The three year period shall
8 comprise the current calendar year plus the two
9 previous calendar years"; correct?

10 A Correct.

11 Q So assuming that this was the document
12 retention policy in place, there were certain
13 documents that needed to be retained for at least a
14 three-year period of time?

15 A Correct.

16 Q And if there were litigation holds that
17 were sent to you from time to time, that may extend
18 that hold period beyond the three years that are
19 identified in this policy; correct?

20 A Correct.

21 Q And you would have complied with both the
22 policy retention that we have here as Exhibit No. 53
23 or any litigation holds that would have been sent to
24 you; right?

25 A Yes.

1 made it -- stated this morning that there should be
2 a custodial file.

3 MR. COMBS: Anybody else want to
4 place anything on the record before we resume?

5 Okay. Let's have a deposition.

6 (Video record resumed.)

7 THE VIDEOGRAPHER: We're back on the
8 record. The time is 10:51 a.m.

9 BY MR. THORNBURGH:

10 Q Thank you, Ms. Hojnoski, for allowing us
11 to have that discussion about your custodial file.

12 A You're welcome.

13 Q And I'm going to try to move away from
14 that discussion with -- I just want to ask one
15 question, though. While you're in your office and
16 you're reviewing your regulatory filings or getting
17 ready to prepare regulatory filings, do you take
18 handwritten notes?

19 A I might.

20 MR. COMBS: Object --

21 THE WITNESS: I usually do things
22 electronically.

23 BY MR. THORNBURGH:

24 Q Okay. So you -- there are occasions that
25 you would write out your thoughts on paper, though;

1 correct?

2 A There might be. Usually I stick to
3 electronic.

4 Q Okay.

5 A But I can't say I've never written out a
6 note by hand for a submission.

7 Q Okay. And if you had made handwritten
8 notes, you would have preserved those in your -- in
9 the hard copy in accordance with the hard copy
10 retention policy?

11 A Yes.

12 MR. COMBS: Object to the form.

13 BY MR. THORNBURGH:

14 Q All right. I want to turn back to your
15 resume, which was marked as Exhibit No. 53 I
16 believe; right?

17 A 52.

18 Q 52. And on your -- prior to your
19 employment with Ethicon, what was your experience in
20 the medical device industry?

21 A Prior to working at Ethicon, I worked for
22 EBI as a senior regulatory affairs specialist. And
23 prior to that I worked at C.R. Bard as a senior
24 regulatory affairs specialist.

25 Q What products did you work -- let's talk

EXHIBIT X

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CONFIDENTIAL DOCUMENT

EXHIBIT Y

Andrew N. Faes

From: Ben Watson <Ben.Watson@butlersnow.com>
Sent: Tuesday, November 19, 2013 11:20 AM
To: Andrew N. Faes
Cc: Tom P. Cartmell; 'Renee Baggett'; Bryan Aylstock; Christy Jones; Donna Jacobs; William Gage
Subject: RE: 4th request: deposition scheduling and production

Andrew,

We have looked into this and we have no data for Jill Shiaparelli. Her separation date was June 1, 2007.

Michael Harm is in Germany and we are working on trying to get his consent. I'll update you as this progresses. As far as I know, neither witness is set for deposition yet.

Benjamin M. (Ben) Watson

Butler Snow LLP
Direct: (601) 985-4551
Fax: (601) 985-4500
Ben.Watson@butlersnow.com

BUTLER | SNOW

About Butler Snow

Bio

V-Card

P.O. Box 6010
Ridgeland, MS 39158-6010

Suite 1400
1020 Highland Colony Parkway
Ridgeland, MS 39157

From: Andrew N. Faes [<mailto:afaes@wcllp.com>]
Sent: Tuesday, November 19, 2013 11:07 AM
To: Ben Watson
Cc: Tom P. Cartmell; 'Renee Baggett'; Bryan Aylstock; Christy Jones; Donna Jacobs; William Gage
Subject: 4th request: deposition scheduling and production

Mr. Watson:

Please see the attached correspondence.

Andrew N. Faes

Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1176
Fax 816-531-2372
afaes@wcllp.com
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From: Andrew N. Faes
Sent: Friday, November 15, 2013 9:56 AM
To: william.gage@butlersnow.com
Cc: Tom P. Cartmell; 'Renee Baggett'; 'Bryan Aylstock'; 'christy.jones@butlersnow.com'; Ben Watson; donna.jacobs@butlersnow.com
Subject: 3rd request Deposition scheduling and production

William:

Can you give me a timeframe of when we can expect the production of Jill Schiaparelli's and Michael Harm's complete custodial file?

Thanks

Andrew N. Faes
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From: Andrew N. Faes
Sent: Tuesday, November 05, 2013 10:48 AM
To: william.gage@butlersnow.com
Cc: Tom P. Cartmell; 'Renee Baggett'; Bryan Aylstock; christy.jones@butlersnow.com; Ben Watson; donna.jacobs@butlersnow.com
Subject: RE: Deposition scheduling and production request

William-

I am following up on my correspondence of 9-4-13. Can you give me a timeframe of when we can expect the production of Jill Schiaparelli's and Michael Harm's complete custodial file?

Thanks

Andrew N. Faes
Wagstaff & Cartmell LLP
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From: Andrew N. Faes

Sent: Wednesday, September 04, 2013 4:17 PM

To: donna.jacobs@butlersnow.com; Ben Watson

Cc: Tom P. Cartmell; 'Renee Baggett'; Bryan Aylstock; william.gage@butlersnow.com; christy.jones@butlersnow.com

Subject: Deposition scheduling and production request

Ben/Donna:

Please see the attached correspondence.

Andrew N. Faes

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EXHIBIT Z

BUTLER | SNOW

April 2, 2013

VIA E-MAIL

Bryan Aylstock, Esq.
Aylstock, Witkin, Kreis & Overholtz
17 E. Main Street, Suite 200 (32502)
Post Office Box 12630
Pensacola, Florida 32591

RE: *In re: Ethicon, Inc. Pelvic Repair System, Products Liability Litigation,*
MDL No. 2327

Dear Bryan:

I appreciate your, Tom's and Renee's taking the time on short notice to talk this morning with Donna, Ben and me. As we discussed, during our collection of materials for the sales reps for the 30 bellwethers, we have become concerned that some documents may not have been preserved despite the fact that appropriate legal holds and separation procedures are and have been in place.

As we discussed with you last week, we are presently focusing on those sales reps who were responsible for the territory in which the implant took place at the time of the implant. This is approximately 30 reps. Approximately 16 of those reps whose documents we are presently collecting are former employees. Some of them left the company before legal holds were in place, so we will have no documents for them.

At this point, we are also having difficulty finding a meaningful volume of documents for many of the reps who left since implementation of the holds. To some degree this is not surprising. Given the role of the sales reps, we would not expect to find a large volume of documents. It is my understanding that most of them do not work in an office, they do not keep so-called "call notes" like pharmaceutical reps, and they generally do not communicate with surgeons in writing. Nevertheless, for a number of these sales reps, we are finding less than we would expect to find.

As we discussed, there have been detailed policies in place to retain documents, including numerous litigation holds. There have also been reminders about those holds. In fact, I understand that there is a very specific procedure pertaining to sales reps for retaining materials, which is a part of the company's overall retention efforts.

It appears, based on what we have found to date, despite the company's best efforts, many of the reps and their managers may not have understood the hold notices and policies and

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BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC

Bryan Aylstock, Esq.

April 2, 2013

Page 2

that their materials may not have been retained following their departure. As I made clear during our call today, we are bringing this to your attention now in an effort to be as transparent about this issue as possible, as soon as possible.

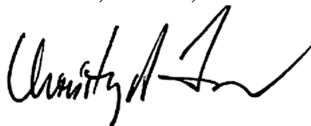
We are still in the process of conducting interviews and continuing our investigation, and it is possible we might locate materials for at least some of these former reps. For example, I understand that yesterday we may have found at least some materials for a couple of reps that the district manager held on to. As I assured you today, we are working hard to pin this down as quickly as possible. However, we do not expect to have a lot of materials to produce for these former reps on Monday, and we are not optimistic that our efforts will turn up a lot more as we continue our search efforts. We are continuing to take steps to address this going forward and continue to educate individuals about the legal hold.

As I mentioned, we would like to work with you to come up with a mutually agreeable way to address the situation. For example, I know there is a continuation of the ESI 30(b)(6) deposition later this month. We will work with the deponent to make sure he can provide testimony with respect to the procedures in place regarding retention so that you have a clearer understanding of that. In addition, we are in the process of collecting materials for any active reps we have identified who have been assigned to the implant and/or revision hospitals at issue so that you can have the benefit of those materials. We expect that those materials will be available to you in a few weeks.

Thank you for your professionalism in talking this through with us today. Please let me know if you have any questions.

Very truly yours,

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC

A handwritten signature in black ink, appearing to read "Christy D. Jones", with a stylized flourish at the end.

Christy D. Jones

CDJ:fsw

cc: Tom P. Cartmell
D. Renee Baggett

ButlerSnow 15936107v1

EXHIBIT AA

REQUEST NO. 153: Admit that you did not track when the TVT patient brochures were delivered to any individual physician's office.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 153. Defendants admit that Ethicon did not maintain a centralized tracking system or database for this type of information and that no law or regulation requires that Ethicon maintain a centralized tracking system or database. The manner and means of monitoring the supply of patient brochures to surgeons' facilities fell under the purview of the individual sales representative.

EXHIBIT BB

Paul Courts

1 CAUSE NO. DC-12-14350
2
3 LINDA BATISTE, § IN THE DISTRICT COURT
§
4 Plaintiff, §
§
5 v. § 95TH JUDICIAL DISTRICT
§
6 JOHN ROBERT MCNABB, M.D., §
JOHNSON & JOHNSON, and §
7 ETHICON, INC., §
§
8 Defendants. § DALLAS COUNTY, TEXAS

9
10
11 ORAL AND VIDEOTAPED DEPOSITION
12 PAUL COURTS
13 TUESDAY, JULY 16, 2013
14
15

16 ORAL AND VIDEOTAPED DEPOSITION OF PAUL COURTS,
17 produced as a witness at the instance of the Plaintiff,
18 and duly sworn, was taken in the above-styled and
19 numbered cause on the above-referenced date from
20 9:20 a.m. to 6:11 p.m., before Deana Tarver, CSR,
21 Certified Shorthand Reporter in and for the State of
22 Texas, reported by realtime stenographic method, at the
23 offices of Thompson & Knight, LLP, 1722 Routh Street,
24 Suite 1500, Dallas, Texas, pursuant to the Texas Rules of
25 Civil Procedure.

1 A. -- because we went to a computer system that
2 allowed us to e-mail and do things like that.

3 Q. And you have that -- you have that same access
4 today?

5 A. Uh-huh. But it's not a primary product now,
6 so I focus on other products. I'm at a different
7 company.

8 Q. What company are you at now?

9 A. Ethicon Surgical Care. We have several
10 different products. TVT is not the primary product, but
11 it is my product. So me sending out studies on TVT this
12 year, that's not happening.

13 Q. All right. All right. Other than the
14 studies, the -- the CDs, what else did you ever have in
15 your possession from Ethicon relating to marketing or
16 training of TVT products?

17 MR. HEWES: Objection.

18 THE WITNESS: We used to have visual aids,
19 but we don't have -- we don't do those anymore.

20 BY MR. FREESE:

21 Q. What kind of visual aids?

22 A. We used to have hard copies back in 2009.

23 Q. What did you do with the visual aids that you
24 had in 2009?

25 A. We use the iPads and computers now.

1 Q. Oh, I -- what did you do --

2 A. They were -- they were --

3 Q. -- with the visual aids that you had in 2009?

4 A. They were left with -- with the company at
5 meetings.

6 Q. You -- you left them with doctors?

7 A. They collected -- no, with the company at
8 meetings, at national meetings. They were collected when
9 we went to digital, to computers and stuff.

10 Q. So Ethicon collected visual aids that you had
11 at 2- -- in 2009?

12 A. At -- at a meeting.

13 Q. What --

14 A. Either 2009 or 2010, one of the two years.

15 Q. Where was the meeting?

16 A. I don't recall.

17 Q. Were you told to bring everything in your
18 possession dealing with TVT training aids to that
19 meeting?

20 A. With all -- all products that we carried
21 visual aids in our hand to the meeting, yes.

22 Q. Who told you to do that?

23 A. I don't recall.

24 Q. And do you know what happened to them?

25 A. No.

1 Q. Do you know if they were destroyed?

2 A. I doubt it.

3 MR. HEWES: Objection.

4 BY MR. FREESE:

5 Q. Do you know if they were preserved?

6 A. I don't know.

7 MR. HEWES: Hold on. Asked and answered.

8 Objection.

9 BY MR. FREESE:

10 Q. Well, they certainly would fall under the --
11 the category of all the litigation holds that I showed
12 you earlier, wouldn't they?

13 MR. HEWES: Objection.

14 THE WITNESS: I don't know.

15 BY MR. FREESE:

16 Q. Well --

17 A. I mean, yes. Yes.

18 Q. Yeah. I mean, I can show you ones back to
19 2003. I mean, we can go over the categories if you want.

20 A. You understand that you're asking me a
21 question and you feel -- I feel I'm being attacked of
22 something I'm answering. I'm simply telling you, I don't
23 know what they did, what the company did with visual aids
24 I left at a meeting. I don't know.

25 Q. But the visual aids would fall within the

1 definition of the documents that -- that --

2 A. Yes.

3 Q. Okay. -- were instructed to be maintained,
4 and you have no idea where they are?

5 A. (Indicating.)

6 Q. And you have no idea if the company preserved
7 them?

8 A. No.

9 Q. All right. All right. What else did you
10 have, sir?

11 A. That's about it, --

12 Q. Are you sure?

13 A. -- that I can think of right now.

14 Q. Okay.

15 A. Uh-huh.

16 Q. Well, what about all of the things your lawyer
17 just listed for you a little while ago? Let's see if I
18 can find them here. You talked about DVDs. Did you ever
19 have any DVDs?

20 A. You just -- we just talked about those.

21 Q. Well, those -- you said -- you called them
22 CDs.

23 A. Well, I'm --

24 Q. Are the DVDs the same thing?

25 A. DVDs, CDs, they're also the same thing. Yes.

EXHIBIT CC

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 * * *

5 IN RE: ETHICON, INC.

6 PELVIC REPAIR SYSTEMS MDL NO. 2327

7 PRODUCTS LIABILITY LITIGATION

8 * * *

9 LISA SCHNEEBERGER INGRAM,

10 Plaintiff,

11 vs.

CASE NO. 2:12-cv-9300

12 ETHICON, INC., et al.,

13 Defendants.

14 * * *

15 Deposition of TROY MOHLER, Witness
16 herein, called by the Plaintiff for
17 cross-examination pursuant to the Rules of Civil
18 Procedure, taken before me, Kathleen W. Phillips,
19 a Notary Public in and for the State of Ohio, at
20 the offices of Tucker Ellis, 41 South High Street,
21 Suite 1225, Columbus, Ohio, on Friday, June 7,
22 2013, at 3:00 o'clock p.m.

23 * * *

24
25 Job No. CS1678179

1 A. No.

2 Q. I've taken a number of sales rep
3 depositions throughout the years and it seems
4 sort of consistently sales representatives
5 usually have or maintain a storage locker.

6 Did you maintain a storage locker
7 by any chance?

8 A. Yes, in my house. That's what I'm
9 referring to.

10 Q. Okay. What types of things would
11 you maintain related to the TVT products or
12 the -- or the POP or mesh products -- pelvic
13 mesh products in this storage cabinet in your
14 home?

15 A. Samples. Marketing materials.

16 Q. Anything else?

17 A. That's mainly it. I mean, some
18 studies as well.

19 Q. Anything else?

20 A. No.

21 Q. So, you -- you kept at your house
22 in a storage locker samples of the products?

23 A. Yes.

24 Q. Marketing materials. What -- what
25 types of marketing materials would you have

1 kept in the storage locker?

2 A. The company would give out
3 marketing materials, basically pamphlets, sales
4 aids.

5 Q. Advertising promotional
6 educational material?

7 A. Mainly, yes.

8 Q. For physicians and for patients?

9 A. Yes.

10 Q. What about objection handlers or
11 information that you could look at but not
12 necessarily need to show the physician or the
13 patient?

14 A. No.

15 MS. MAIMBOURG: Objection. You can
16 answer.

17 BY MR. THORNBURGH:

18 Q. And let me -- let me ask a better
19 question. What about training manuals?

20 A. I didn't keep those in my locker.

21 Q. Did you ever receive a training
22 manual?

23 A. Yes.

24 Q. Okay. Where did you keep that?

25 A. I kept that in my house.

1 Q. What was your understanding of the
2 litigation hold letter?

3 A. Not -- I mean --

4 MS. MAIMBOURG: I'm going to object
5 to that. If you want to show it to him, maybe
6 that would help. I mean, he's not even a current
7 employee.

8 MR. THORNBURGH: I'm just -- I
9 understand that, but I'm just -- I'm just trying
10 to find some background information. That's all.

11 MS. MAIMBOURG: You can answer.

12 THE WITNESS: I just -- I mean, I
13 knew they were in some sort of -- sort of present
14 litigation against the company, but they didn't
15 give us a legal breakdown of what essentially it
16 meant. I mean, if they did, I didn't really -- I
17 didn't pay attention, to be honest. I don't know.
18 BY MR. THORNBURGH:

19 Q. Did you ever have any meetings
20 with your managers or anybody else at Ethicon
21 or Johnson & Johnson regarding what your
22 obligations were in preserving documents that
23 you may have received from the company as a
24 result of a litigation hold letter?

25 A. Yeah, we had annual -- annual

1 you -- did you have a file on your computer
2 called Ethicon studies or how did you --

3 A. I don't know what it was called,
4 but something like that.

5 Q. Separated by product maybe or --

6 A. Yes.

7 Q. And this would have been for both
8 computers? So, you would have maintained the
9 same type of information in the computer that
10 you received in 2004 as you would on the
11 computer that was upgraded in approximately
12 2008?

13 A. Yes.

14 Q. Would you ever delete any Ethicon
15 related material or TVT related material or SUI
16 or pelvic organ prolapse related material from
17 your computer?

18 A. No. I was afraid to.

19 Q. Why were you afraid to delete
20 stuff?

21 A. I -- I never knew what I was truly
22 allowed to delete or not, so just to be safe --

23 Q. So, you just kept it all?

24 A. -- saved it all, yes.

25 Q. I bet you had quite a bit by the

1 end of your tenure.

2 A. Yes.

3 Q. How many e-mails do you think you
4 were receiving -- I mean, I don't know if
5 you're like me, but I go -- some days a hundred
6 and fifty and some days three hundred e-mails.
7 Were you receiving about that many e-mails
8 or --

9 A. No.

10 MS. MAIMBOURG: Objection as to form.

11 BY MR. THORNBURGH:

12 Q. About how many e-mails would you
13 receive on a daily basis?

14 A. As a sales rep, maybe five to ten.

15 Q. What e-mail addresses did you use?

16 A. I think it was --

17 MS. MAIMBOURG: Do you mean for
18 business?

19 MR. THORNBURGH: Yeah.

20 THE WITNESS: I think it was just my
21 name. I remember T Mohler at I T S dot J and J
22 dot com.

23 BY MR. THORNBURGH:

24 Q. I'm sorry? T Mohler at I T S
25 dot --

1 had reviewed the -- the record retention policy
2 and the legal -- J & J's legal department's
3 preservation hold notice, right?

4 A. Yes.

5 Q. What was -- what was your
6 recollection of the record retention policy at
7 Ethicon and Johnson & Johnson?

8 A. Not much. Not knowing -- no
9 recollection.

10 Q. Right. I think you -- I think
11 your testimony was, you erred on the side of
12 caution, so you didn't destroy anything?

13 A. That is correct.

14 Q. You just kept it all on your
15 laptop or in your -- if you had paper
16 materials, you kept the paper materials in your
17 home or in the storage cabinet?

18 A. Yes.

19 Q. And returned all those to Johnson
20 & Johnson or Ethicon at the date of your
21 departure?

22 A. Yes.

23 Q. Do you remember having turned
24 over, for instance, marketing materials at the
25 time that you departed?

1 A. Yes.

2 Q. And you can say that definitively?

3 A. Yes.

4 Q. And that would have been things
5 like brochures, patient brochures?

6 MS. MAIMBOURG: Objection.

7 BY MR. THORNBURGH:

8 Q. Or doctor promotional pieces?

9 A. Sales aids.

10 Q. How about the IFU? Did you keep
11 an IFU at your home?

12 A. Yeah. I mean, yes, if I would
13 have had that, I would have turned it over as
14 well.

15 Q. And you didn't delete anything
16 from your computer or throw any of the hard
17 copy material away prior to handing it over to
18 Ethicon, correct?

19 A. Yes.

20 Q. It says -- number five says,
21 has the complete paper and electronic
22 records cleanout per PS-0000117 on site
23 paper/electronic records cleanout and
24 PR-0000018 company procedure for records
25 retention schedule been completed.

1 Q. Okay. What would you use the iPad
2 for?

3 A. Just to show videos -- information
4 out in the field.

5 Q. So, you would -- it would be the
6 same situation where you would go to the
7 Ethernet or intranet, download it, certain
8 materials to your iPad, and then you would be
9 able to play back for the doctors or nurses
10 certain videos or show them certain
11 information?

12 A. Yes.

13 Q. Okay. What type of videos did you
14 have on your iPad?

15 A. Procedural videos mainly.

16 Q. For like the TVT-O procedure?

17 A. THERMACHOICE. TVT-O. Trying to
18 think what else might have been on there.
19 VERSASCOPE. VERSAPOINT.

20 Q. Okay. Did you delete anything
21 from your iPad prior to leaving Ethicon?

22 A. Not that I recall.

23 Q. Well, did you have a different
24 policy with your iPad than you had with your
25 computer? Remember, you testified that you

1 were -- that you erred on the side -- erred on
2 the side of caution by not deleting anything
3 from your -- from your computer. Would you
4 have a different policy for your iPad?

5 A. Well, with the iPad, they did
6 allow us to use it for more -- some personal
7 use if we wanted to in terms of apps and things
8 like that. So, if I deleted anything, it was
9 personal apps.

10 Q. Everything else would have been
11 saved on the iPad?

12 A. Any company information would have
13 been saved.

14 Q. It would have been turned over to
15 Ethicon at the time of your departure?

16 A. Yes.

17 Q. So, you would have had certain
18 procedural videos, correct?

19 A. Yes.

20 Q. Regarding at least the TVT-O. Any
21 other TVT products?

22 A. All the TVT products would have
23 had a video related to them.

24 Q. Okay. And you recall that
25 specifically having these videos on your

1 laptop?

2 A. Yes.

3 Q. Or on your iPad, and did you use
4 those frequently with doctors?

5 A. If it was a physician who I was
6 talking about with the product, yes.

7 Q. Okay. What other types of
8 information, data, materials would have been on
9 your iPad?

10 A. E-mails mainly.

11 Q. Was your e-mail, the e-mail that
12 you used the same on your iPad as it was on
13 your laptop?

14 A. Yes.

15 Q. So, if you sent an e-mail from
16 your iPad, it would show up in your sent items
17 on your laptop?

18 A. Yes.

19 Q. Would you keep patient brochures
20 or any marketing material on your iPad?

21 A. I think there were electronic
22 sales aids on there as well.

23 Q. But that was a new and interesting
24 technology for you as a salesperson to use your
25 iPad while showing promotional materials or

1 you say that after 2008, you'd go to physicians
2 and you'd say, hey, Doc, you need to be handing
3 out this patient brochure to all of your
4 Plaintiffs -- or all -- sorry, strike that.

5 MS. MAIMBOURG: No, let's not strike
6 that.

7 BY MR. THORNBURGH:

8 Q. Doctor, you need to be handing out
9 the patient brochure to all of your patients.
10 Did you record those types of conversations
11 with doctors?

12 A. No.

13 Q. How did you know which doctors you
14 had a conversation with about what the next
15 time you saw that doctor?

16 A. Notes.

17 Q. What notes?

18 A. My own notes in my -- in my
19 recordkeeping that I had. You know, I had
20 basically a binder that kept notes on calls.

21 Q. Okay. And so that binder would
22 have been something that you would have kept
23 and maintained through your employment with
24 Ethicon until you left in 2012?

25 A. Yes.

1 Q. And that's something that you
2 would have provided to Ethicon when you left
3 the company, right?

4 A. Yes, so we had that continuum of
5 calls to figure out what was going on.

6 Q. So, there's probably a record of
7 the conversations that you were saying that you
8 had contained somewhere because you would have
9 given that file or that -- those notes to
10 Ethicon, and so if Ethicon didn't produce
11 those -- that -- those notes to me or to
12 Plaintiff's counsel, that's no fault of your
13 own because you handed those over to Ethicon
14 when you left the company, correct?

15 A. That's what I remember doing.

16 Q. And you did it because you
17 received the litigation hold letter in 2011 and
18 one in 2006. You probably don't remember the
19 2006 one. I can show it to you if you want,
20 but you recall receiving that litigation hold
21 letter regarding TVT-O in 2011, right?

22 A. I recall receiving those and
23 that's why I was very safe on everything I
24 kept.

25 Q. And so these notes that you would

EXHIBIT DD

ALLISON LONDON BROWN

14104 Wyndfield Circle
Raleigh, NC 27615

allison.londonbrown@gmail.com
Phone: 615.945.8368

GLOBAL HEALTHCARE PRODUCT, BRAND MANAGEMENT & MARKETING LEADER

Extensive experience in building brands, driving revenue in the Med Device, Technology, CPG, B2B, and Pharma sectors

- Responsible for uncovering new trends, acquiring technologies and finding ways to employ data that have added >\$100 MM to a \$10 MM P&L, creating new segments & turned around flagship brands
- Launched > 80 new products, brands, services resulting in 5-7 year accretive results for top global Healthcare companies.
- Advising C-level HC administrators, NGOs, governmental leaders, and CEOs using data analytics, population management & business intelligence.
- Developing strategies to add top line growth, cumulative gross margin, and drive savings through engagement campaigns, technological enablers and performance efficiencies
- Managed key customer partnerships within associations, professional and consumer sectors (GPO, IDN, Food, Mass, Drug)

PROFESSIONAL EXPERIENCE

STANLEY HEALTHCARE SOLUTIONS, a div. of STANLEY BLACK&DECKER, Boston MA **2012**

Chief Operating Officer/ Chief Commercial Officer

Responsible for global portfolio of technology based products for Patient Security, Resident Safety (Long-term Care), Supply Chain Management, Consulting Services (EPIC/Meditech EHR Implementation), EMEA & Asia-PAC; Revenues of \$225MM

- Led major organizational restructuring of SBU units to functions, hired high-performing leadership team for segments: Acute Care, Long-Term Care, B2B & Government channels, Global Marketing & new revenue generating Services lines
- Led brand development & awareness program utilizing market research, data analysis, multi-media/digital campaigns & PR; taking awareness from <3% to >20%
- Led marketing department expansion; building lead generation group & programs, product management enhancement & expansion, selection & hiring of new PR and marketing firm, development of new marketing research analytics
- Led \$274MM acquisition of AeroScout (RTLS); leader for all sales, marketing, service and product integration activities
- Devised plans for channel expansion of current products, market expansion into global territories
 - Led expansion into surgi-center/alternate care facilities; incremental sales of >\$10MM
 - Led sales force effectiveness program including deployment of Salesforce.com, forecasting excellence & discount-approval process to minimize price erosion
 - Implemented pricing & promotional plans including new pricing for LTC market & new product launches

CHEMENCE MEDICAL PRODUCTS, Alpharetta, GA

2011

President

Created new business strategy, transitioning private label company into branded, compliant medical-device corporation

- Led deal structure to raise \$1.75MM through partner channel
- Developed business plan to grow revenues to >\$380MM within 5 years, gross margin of >75%, net profit of 26% and ROI of 7.5:1 through highly effective distribution networks, new product planning and DTC line extensions

HEALTHWAYS, INC. Franklin, TN

2009-2011

Vice-President, Well-Being Strategy, Corporate Branding and Corporate Communications

Leader for Healthways strategic positioning, corporate brand development and communications

- Responsible for Healthways brand development, directed brand strategy/positioning, proactively generating over 4.4B impressions equaling an ad-value >\$60MM; 374% increase over 2009
- Partnered with Government Affairs to position Healthways position on Healthcare Reform; Led presentations to various governmental groups to inform/educate on opportunities to lower healthcare costs and improve overall well-being
- Responsible for coordination with Science, Product Development on agenda setting of the direction of well-being research, including becoming the single standard outcomes metric, proving value of interventions aimed at well-being improvement

Vice-President, Solution Sector Leader

Led Solution development of the Wellness Sector and Direct-to Consumer market development, including market analysis, business development (M&A) strategies and behavioral change interventions

- Led solution development process including governance, stage-gates & resource matrix
- Developed Government and Medicare segmentation strategies and program roadmap
- Led development of Weight Loss Program, innergy™, in conjunction with Johns Hopkins University
- Led & developed Direct-to-Consumer Business leveraging company assets in the Consumer market

ALLISON LONDON BROWN**PAGE TWO****GE HEALTHCARE**, Maternal-Infant Care, Laurel MD; Bangalore, India**2007 – 2009****General Manager, Maternal / Fetal Care;**

Grew a declining, 30+ year-old mature business by building organizational marketing and clinical skills and developing a new business strategy within the “pregnancy” segment. Managed P&L, product development roadmap, and L&A strategy.

- Developed and implemented strategic plans to grow business from \$50MM to \$300MM
- Identified and led contract negotiations for business development deals; led business case development, marketing, clinical evidence planning, and distribution strategies
- Built new R&D, Engineering, Marketing, and Clinical Development team, in the US and Bangalore, India
- Winner of 2008 Quality Award; 77% reduction in complaint rate, 95% improvement in response time
- Facilitated plans to grow overseas market share from 25% to 40%

JOHNSON & JOHNSON, Family of Companies, New Brunswick, NJ**1997 – 2007****Ethicon**, Somerville, NJ**Group Product Director**, Ethicon Products, US Plastic Surgery Sales & Marketing**2007**

Led newly formed Plastic Surgery Sales and Marketing team and managed Dermabond Marketing team. Reversed negative company perception of plastic surgery market; successfully addressed un-focused segmentation and positioning for multiple customer groups and the lack of sales team engagement.

- Led pilot sales force in growing customer base and developing sales targets and grew the business by 150%
- Devised a strategy to target elite surgeons working with post-Bariatric patients and re-deploying education strategies that positioned Ethicon as an ethical partner that understands patients and surgeons needs
- Led team to identify key Dermabond segments, prioritized segments by analyzing buying behaviors, clinical needs and clinical study portfolio; developed specific positioning, driving Dermabond to hit 2007 revenue goal

WW Marketing Director, Ethicon Women’s Health & Urology**2004 – 2007**

Directed the launch of first new product in the Pelvic Floor segment. Developed and executed worldwide strategic plans and a global brand marketing strategy for the Pelvic Floor and Incontinence markets.

- Global Launch Leader for GYNECARE TVT SECUR (SUI) – exceeded \$1MM in 6 weeks pre-launch; Uncovered new positioning and revenue growth by moving procedure from the OR into the office
- US Launch Leader for GYNECARE PROLIFT (Pelvic Floor) – exceeded forecast by 310% and drove business growth from \$10MM to \$90MM. Maximized clinical outcomes by training selected and limited target audiences
- Devised 1st Global Market Research; including segmentation, psychographics, pricing, and concept testing
- Created the Pelvic Floor Academy – an educational online program to teach/enhance surgical and anatomic skills

McNeil Consumer & Specialty Pharmaceutical Division, Ft. Washington, PA**2002 - 2004****Senior Associate Marketing Manager**, Pediatric Brands and Motrin Futures

Refocused marketing for Children’s Tylenol Chews & Seasonals, reversing a 14% market share decline.

- Identified a key technology that was developed for Adult line and convinced Board to explore use in Children’s products, leading to the CT Meltaways product
- Developed entire Meltaways marketing/launch strategy; Spearheaded multi-media promotional strategy, partnering with Radio Disney & Family Fun magazine, through print, PR, radio, TV and strong focus on internet ads and loyalty programs
- Analyzed cough, cold and flu segment to match symptom, drug, and customer buying behaviors; Re-branded, re-formulated and re-launched new line in 6 months; eliminated skus, maximized shelf space, and simplified decision process for mothers
- Developed and managed professional marketing strategies for pediatric brands by partnering with AAP and J&J Pharma brands to distribute and market Pediatric OTC brands to Pediatricians

Portfolio/Project Manager

- Managed growth portfolio for Motrin and Pediatric franchises (Children’s Tylenol, Children’s Motrin); recommending projects to board and developing rolling 18-month portfolio and resource planning map.
- Partnered with Pharma research group in creation of new OTC, topical analgesic product line, including patches and creams

Personal Care Group, Skillman, NJ**1999 - 2002****Various Global R&D Leadership roles**, Oral Health, Women’s Health franchises**Johnson & Johnson Medical**, Juarez, Mexico**1997 – 1999****Technical Services Engineer, Drapes**, Packs & Gowns

LEADERSHIP INITIATIVES

Aegis Women's Health	Chairman of the Board
Council on Economic Development	Member, Mentor
Women's Business Leaders (WBL)	Member, Strategic Planning Committee
Scion Cardio-Vascular	Board Member; New product pipeline/launch, marketing ,& distribution initiatives
Hollis Group Ltd	Board Member; Inventors and developer of laparoscopic devices
GE Healthcare	GE Women's Network Founding Member - Chesapeake Hub
Johnson & Johnson Companies	Women's Leadership Council, Women of Color sub-committee

ACADEMIC AND RESEARCH EXPERIENCE

- **MBA** w/Honors, Marketing/General & Strategic Management, Fox School of Business, Temple University, 2003
- **MS**, Textile Chemistry, Concentration in Bio-Polymers, North Carolina State University, Raleigh, NC, 1995
Thesis: "Textile Composite Wound Dressing."
 - Developed and obtained grants for original research program.
 - Developed partnerships with Colleges of Textiles, School of Vet Medicine, Food Sciences & Chemistry
 - Developed biodegradable polymeric wound dressings of chitosan, poly D,L lactic acid, poly ε-Caprolactone
 - Researched synthesis and effects of sterilization on biodegradable polymers; complete cell culturing to understand epithelialization and healing rates
- **BS**, Apparel and Textiles, Option in Textile Science, Concentration in Chemistry, Math and Physics, Auburn University, Auburn, AL, 1993 Thesis: "*Biomedical Polymers.*" Advisor: Dr. Ian Hardin

PATENTS AND PUBLICATIONSBook Publication:

Bioactive Fibers and Polymers; Chapter 7, A Hybrid Bioabsorbable Wound Dressing,
A. London Brown, A. E. Tonelli, S. M. Hudson, and B. S. Gupta. Ed: J. Vincent Edwards & Tyrone L.Vigo. American Chemical Society Publication, 2001.

Patents:

- | | |
|---|-------------------------|
| ▪ US 6946,585 & EP1203571A2 – <i>Absorbent Article</i> | September 20, 2005 |
| ▪ US 6,595,042 – <i>Method of Demonstrating Breathability.</i> | July 22, 2003 |
| ▪ US 7,645,227 – <i>Implants and Methods for Pelvic Floor.</i> | January 12, 2010 |
| ▪ US20080287596 – <i>Instruments for Implanting Implantable Prostheses.</i> | Filed November 20, 2008 |
| ▪ US20050165373 – <i>Absorbent Article.</i> | Filed July 28, 2005 |

Presenter and Author

- *Wellness in the Workplace*, Corporate Wellness Magazine, January 2011
- *Trends on Wellness in the Workplace*, AHIP Wellness Webinar, June 2010
- American Chemical Society Convention, August 1999
Biopolymers Section: *Textile Composite Wound Dressing*
- 14th Southern Biomedical Engineering Conference - Louisiana State University Medical Center, April 1995
- American Chemical Society Polymer Symposium - Pennsylvania State University, June 1994
Title of Paper: *Textile Composite Wound Dressing*

Awards for Advertising/Education Programs: Marketing and Concept Leader

- ETHICON Women's Health & Urology: Anatomy Review Training Module
 - 2008 AMI Salon – Award of Excellence; Category: Interactive Media
 - 2008 HCMA IN-AWE Award (Gold); Category: Medical Education/Interactive Allied Healthcare Professionals
 - 2008 Summit Creative Awards Trophy (Bronze); Category: Interactive Media – Health/Medicine
- ETHICON Women's Health & Urology: Gynecare TVT SECUR Professional Education DVD-ROM
 - 2007 Telly Award (Bronze); Category: Non-Broadcast Productions – Pharmaceuticals
 - 2007 Summit Creative Awards Trophy (Bronze); Category: Interactive Media – Health/Medicine

EXHIBIT EE

From: Crawford, Kelly [<mailto:KCRAWFORD@RIKER.com>]

Sent: Friday, September 06, 2013 1:39 PM

To: 'Cheryll Calderon'

Cc: Adam Slater; Jeff Grand; 'Jillian Roman'; Bryan Aylstock; Renee Baggett; Donna Jacobs; Scalera, Mary Ellen; Kabbash, Maha

Subject: Allison London Brown - Deposition

Please see the attached resume for Allison London Brown, a witness listed in New Jersey CMO 10. As per Judge Higbee's instructions, please identify the attorney who will be taking the lead at the deposition next week.

Cheryll, to answer your question below, there was no custodial production for Allison London Brown. She left the company in 2007.



Kelly S. Crawford | Partner

Riker Danzig Scherer Hyland & Perretti LLP

Headquarters Plaza | One Speedwell Avenue | Morristown, NJ 07962-1981

t: 973.451.8417 | f: 973.451.8635 | KCRAWFORD@RIKER.com | www.riker.com

From: Cheryll Calderon [<mailto:ccalderon@mskf.net>]

Sent: Tuesday, September 03, 2013 2:35 PM

To: Kabbash, Maha; Crawford, Kelly; Scalera, Mary Ellen

Cc: Adam Slater; Karen Kelsen

Subject: Allison London Brown

Maha, Kelly and Mary Ellen,

Has there been a custodial production made for Allison London Brown? All I see is the HR File but I may have missed it. Can you identify for me which productions the custodial productions were made in or explain why there is a lack of custodial file for the witness?

Thanks,
Cheryll

MAZIE SLATER KATZ & FREEMAN LLC
ATTORNEYS AT LAW

Cheryll A. Calderon, Esq.

Mazie Slater Katz & Freeman, LLC

103 Eisenhower Parkway
Roseland, NJ 07068

(973) 228 - 9898 (main office)
(973) 228 - 0303 (fax)

ccalderon@mskf.net

www.mskf.net

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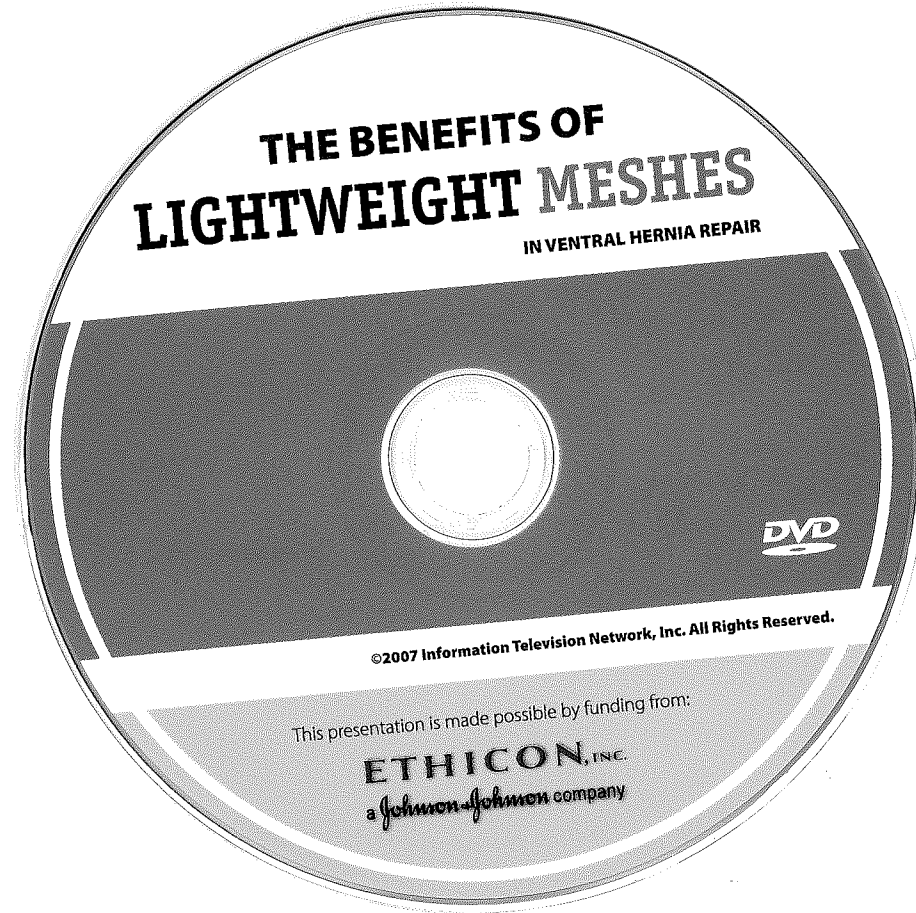
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EXHIBIT FF



THE BENEFITS OF
LIGHTWEIGHT MESHES
IN VENTRAL HERNIA REPAIR

Hosted by B. Todd Heniford M.D.
Chief of Gastrointestinal and Minimally Invasive Surgery at Carolinas Medical Center

Refined surgical techniques and a growing array of mesh products are revolutionizing the art of hernia repair. Mesh has become a key component in successful hernia repair procedures. While there are a number of mesh products available, as you'll see in this program, mesh made from lightweight polypropylene mesh is the superior synthetic choice for hernia patients. This lightweight mesh has about a quarter of the foreign body of heavy-weight mesh and studies have shown that it triggers less of an inflammatory response and patients can actually feel the difference. Also, in this program we discuss the need for a tissue-separating barrier on one side of the mesh, which is a special consideration in ventral hernia repair.

This presentation is made possible by funding from:
ETHICON, INC.
a Johnson & Johnson company

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A black and white photograph of a tennis player in mid-swing, wearing a white shirt and shorts, with a tennis racket in hand.

Compilation of Findings for the Well-Informed Surgeon

The Benefits of Lightweight Meshes in Ventral Hernia Repair

THE BENEFITS OF LIGHTWEIGHT MESHES
IN VENTRAL HERNIA REPAIR

Featuring B. Todd Heniford, M.D.

A black and white photograph of a golfer in mid-swing, wearing a striped shirt and a cap, with a golf club in hand.

EXHIBIT GG

From: [Ben Watson](#)
To: [Bryan Aylstock](#); [Daniel Thornburgh](#); [William Gage](#)
Cc: [Ben Anderson](#); ["Tom P. Cartmell \(tcartmell@wcllp.com\)"](#); [Renee Baggett](#); [Betsy Williams](#); [Rich Freese](#); [Andrew N. Faes](#)
Subject: RE: Heniford DVDs
Date: Friday, November 15, 2013 4:04:52 PM

Bryan,

We have previously looked into this issue and have not been able to locate any additional videos. We have again asked our team for any additional leads. If we find anything else, we will let you know next week.

Benjamin M. (Ben) Watson

Butler Snow LLP
Direct: (601) 985-4551
Fax: (601) 985-4500
Ben.Watson@butlersnow.com

BUTLER | SNOW

About Butler Snow

Bio

V-Card

P.O. Box 6010 Suite 1400
Ridgeland, MS 39158-6010 1020 Highland Colony Parkway
Ridgeland, MS 39157

From: Bryan Aylstock [mailto:BAylstock@awkolaw.com]
Sent: Friday, November 15, 2013 12:55 PM
To: Daniel Thornburgh; Ben Watson; William Gage
Cc: Ben Anderson; 'Tom P. Cartmell (tcartmell@wcllp.com)'; Renee Baggett; Betsy Williams; Rich Freese; Andrew N. Faes
Subject: RE: Heniford DVDs

Ben/William,

I know everyone is extremely busy but unless I've missed some emails it is now been over three weeks since we made this request (and I followed up since then), and we have heard absolutely nothing. Did I miss something? If not, what gives? We know this exist as do you so please produce them immediately. If they have been destroyed, please let us know that as well.

Thanks,
Bryan

From: Daniel Thornburgh
Sent: Wednesday, October 23, 2013 12:40 PM
To: Ben Watson; Bryan Aylstock; William Gage
Cc: Ben Anderson; 'Tom P. Cartmell (tcartmell@wcllp.com)'; Renee Baggett; Betsy Williams
Subject: RE: Heniford DVDs
Importance: High

Ben,

I received the production today; however, Ethicon only produced the final version of the 2007 DVD called the "Benefits of Lightweight Meshes" which does not fully respond to plaintiffs' multiple requests for the production of "all videos (whether final or in draft form) related to Dr. Heniford's CDs or DVDs." We have reason to believe additional media exists. For example, the attached document indicates that in 2004, Dr. Heniford sent at least one other dvd or cd to Ethicon. Does that or any other CD or DVD exist? If so, please produce it along with all other DVDs or CD related to Dr. Heniford. If no other DVDs, CDs, video clips or other related media exists related to Dr. Heniford, then please certify that reasonable steps were taken to locate and produce the requested material. With Dr. Heniford's deposition scheduled for Nov. 21, 2013, it is imperative that you produce these additional materials immediately so that we have a reasonable opportunity to review the same prior to his deposition.

Let me know if you have any questions.

Regards,

Dan Thornburgh

From: Ben Watson [<mailto:Ben.Watson@butlersnow.com>]
Sent: Monday, October 21, 2013 9:45 PM
To: Daniel Thornburgh; Bryan Aylstock; William Gage
Cc: Ben Anderson; 'Tom P. Cartmell (tcartmell@wcllp.com)'; Renee Baggett; Betsy Williams
Subject: RE: Heniford DVDs

Dan,

No problem. We will send you a copy tomorrow.

From: Daniel Thornburgh [<mailto:DThornburgh@awkolaw.com>]
Sent: Monday, October 21, 2013 8:26 PM
To: Ben Watson; Bryan Aylstock; William Gage
Cc: Ben Anderson; 'Tom P. Cartmell (tcartmell@wcllp.com)'; Renee Baggett; Betsy Williams
Subject: RE: Heniford DVDs
Importance: High

Ben,

Please also federal express the Heniford CDs/DVDs (or any other related material that you sent to Crivella West today, per your below email) to my office by tomorrow for overnight delivery. Thanks in advance.

Sincerely,

Daniel Thornburgh
Aylstock, Witkin, Kreis & Overholtz

17 E. Main Street, Ste 200
Pensacola, FL 32502

From: Ben Watson [<mailto:Ben.Watson@butlersnow.com>]
Sent: Monday, October 21, 2013 4:56 PM
To: Bryan Aylstock; William Gage
Cc: Ben Anderson; 'Tom P. Cartmell (tcartmell@wcllp.com)'; Renee Baggett; Daniel Thornburgh; Betsy Williams
Subject: RE: Heniford DVDs

Bryan,

This is being shipped to Crivella West tonight.

Thanks.

From: Bryan Aylstock [<mailto:BAylstock@awkolaw.com>]
Sent: Friday, October 18, 2013 5:23 PM
To: William Gage; Ben Watson
Cc: Ben Anderson; 'Tom P. Cartmell (tcartmell@wcllp.com)'; Renee Baggett; Daniel Thornburgh; Betsy Williams
Subject: RE: Heniford DVDs

William/Ben,

Following up here as well. Please let us know ASAP.

Thanks
bryan

From: Bryan Aylstock
Sent: Tuesday, October 08, 2013 1:02 PM
To: William Gage; Ben Watson
Cc: Ben Anderson; Tom P. Cartmell (tcartmell@wcllp.com); Renee Baggett; Daniel Thornburgh
Subject: Heniford DVDs
Importance: High

Ben/William,

As you know we previously requested all videos (whether final or in draft form) related to Dr. Heniford's CDs or DVDs on heavyweight/small pore hernia meshes but I don't believe those have been produced yet. Attached is the email from May 4, 2004 that discusses a video clip from Heniford that was sent to Jill Schiaparelli. Please produce the video clip that was sent to Ms. Schiaparelli and all others from Dr. Heniford related to this issue. Can you please let us know when we can expect these materials?

Thanks,
Bryan

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EXHIBIT HH

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CONFIDENTIAL DOCUMENT

EXHIBIT II

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CONFIDENTIAL DOCUMENT

EXHIBIT JJ

BUTLER | SNOW

November 5, 2013

By Email

Thomas P. Cartmell, Esquire
Wagstaff & Cartmell, LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112

Re: In re Ethicon, Inc. MDL

Dear Tom:

Please accept this letter in response to your letter of late Friday afternoon, November 1, 2013, requesting information by Monday, November 4, 2013. As you know, by letter dated October 11, 2013, from Maha Kabbash, we provided an extensive explanation of the efforts undertaken to respond to inquiries relating to these issues. That communication and others outlined the efforts we recently have taken, including, but not limited to, the additional information we have identified relating to contract and payments with consultants such as Professor Ulmsten, Professor Nilsson and Professor Falconer. Below are specific responses to the numbered items in your November 1, 2013 letter.

1. Any and all documents, including the supply agreement between Ethicon in Scandinavia or elsewhere in the EU (not sure if the local entity who was supplying was Ethicon Scotland or elsewhere) and Medscand or Ulmsten or others, related to the IVS that Ulmsten and others were using during the years 1994 and 1997, as Angelini testified. This would obviously include all of the manufacturing documents, specs, etc. related to the supply of the mesh during that time.

As we have previously communicated, we have had discussions with numerous individuals, including: (1) Axel Arnaud; (2) the former Director of New Business Development (“NBD”) at Gynecare France who negotiated the 1997 Licensing Agreement (who left the company about ten years ago), and (3) a former employee of the Ethicon entity in Edinburgh (which is now closed) and the J&J entity in Brussels (who worked on setting up the quality processes at Medscand in the late 1990’s to enable TVT to be CE marked for sale in Europe). None of them recalls that there was a supply agreement between Ethicon and Medscand for the supply of mesh before the 1997 License Agreement was implemented. To the contrary, the former Edinburgh employee indicated that it would have been very unlikely that such an agreement would have existed, because at that time, all Ethicon mesh distributed in all of Europe was being sold through Ethicon Edinburgh, and that entity was not selling mesh directly to

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Ridgeland, MS 39158-6010*

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601.985.4551
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BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC

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doctors or hospitals, but rather through distributors. Further, as we understand it, Medscand had pre-existing relationships with medical device distributors in Europe due to the sale and distribution of other medical device products with which Ethicon had no involvement. We continue to investigate this issue through leads we have been able to identify to attempt to ascertain information about how Medscand procured mesh for use in the TVT Device prior to the implementation of the 1997 Licensing Agreement, but to date we have not identified the existence of any such supply agreement.

I believe we previously communicated in response to your email dated October 22, 2013 to William Gage regarding Ms. Angelini's deposition testimony that the construction of the Prolene mesh used in Gynecare TVT was changed prior to the 1998 launch of the product in the United States. As William has indicated to you in telephone conferences in September, Ms. Angelini believes that portion of her testimony was mistaken, and she intends to correct her testimony at the continuation of her deposition in November. As you are aware, other witnesses have testified that no such change occurred, and we refer below to the bates numbers of documents that support this. These documents are referenced as examples only and are not intended to be an exclusive list.

ETH.MESH.01816990
ETH.MESH.09275943
ETH.MESH.09264884
ETH.MESH.09263410-ETH.MESH.09263411
ETH.MESH.02181293-ETH.MESH.02181294
ETH.MESH.00862321
ETH.MESH.09274188-ETH.MESH.09274193
ETH.MESH.02265320-ETH.MESH.02265327
ETH.MESH.01218446-ETH.MESH.01218449
ETH.MESH.02219202-ETH.MESH.02219210

We further note that, to the extent that Ms. Angelini provided this mistaken testimony on this issue or speculation as to the existence of a supply agreement for the mesh used by MedScand, it was in her capacity as a fact witness, as the subject of the supply of mesh and mesh construction of Gynecare TVT are not matters on which she was designated as a corporate representative.

Understanding that that it is our current belief, supported by our extensive investigation, that the mesh used in TVT never changed, in an effort to be as responsive as possible, we have accelerated attempts to ascertain the scope of manufacturing specifications that would apply generally to Ethicon's Prolene revision one, old construction mesh as would have been in place during the periods of time from 1994 through 1997, whether those documents still exist, whether they have been produced already and, if not, and how we can best provide relevant and responsive information to plaintiffs in this regard.

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2. Any and all documents related to the CE mark obtained for the TVT in the EU including all submissions to regulatory agencies or from regulatory agencies or simply any and all correspondence to or from regulatory agencies related to the TVT.

Preliminarily, we would note that TVT classic is a Class IIB product. The rules and regulations under the Medical Device Directive, as applicable over time, apply to these products in connection with CE marks. Class IIB products do not require pre-market approval submissions to either a regulatory agency or to a Notified Body. Defendants have produced the Design History Files and Technical File for the TVT product for the period of time that the legal manufacturer of the product was Ethicon Sarl. These documents go back to 2002. These are the files maintained in connection with the MDD requirements. We are making additional efforts to confirm the completeness of these materials and will produce additional documents, if any, we locate connection with that effort.

Upon information and belief, for the period of time between 1999 and 2002, the TVT product was CE marked under the entity Johnson & Johnson International in Belgium and the notified body involved most likely was TUV Product Services CE 0123.

Additionally, documents related to the Technical File that may have existed in earlier time frames were recently located through Ethicon's affiliate in Germany, many of which appear to have similar information to the Technical Files and other documents previously produced. Those documents have been collected, but still are being processed for production.

Upon information and belief, the Notified Body used by Medscand for the TVT product prior to 1999 was CE0543 Presafe Denmark A/S, Tuborg Parkvej 8, DK-2900 Hellerup, Country : Denmark.

Additional documents related to the product recently were identified through Ethicon's affiliate in Scotland. Those documents have been collected, but still are being processed for production.

Finally, as you are aware, the issue of OUS regulatory documents has been the subject of motion practice and Ethicon is in the process of collecting regulatory materials from countries identified by plaintiffs. The list of countries included a number of EU countries and we will produce additional documents filed in connection with the CE mark, if any, pertaining to TVT for those countries as they are collected.

3. Any and all documents related to the CE mark obtained for the IVS device for which Ethicon was supplying mesh or any other component parts.

To date, our inquiry in this regard has not identified any evidence of the existence of a CE mark for the TVT product prior to the execution of the 1997 Licensing Agreement. We continue to investigate possible leads and sources to identify information in Ethicon's possession

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about how and where the product was sold and distributed by Medscand prior to Ethicon's involvement. See the response to No. 2, above, regarding submissions to regulatory agencies.

4. Any and all patient level data, protocols, study reports, correspondence or documents related to any study in the EU involving the IVS device or the TVT device between the years 1993 and 1999.

We have discussed this issue with Laura Angelini, Axel Arnaud, the former NBD director at Gynecare France referenced above, and the former Edinburgh employee referenced above. None of them has any recollection that the company received such information in the years surrounding the execution of the Licensing Agreement, as the company did not sponsor those trials and therefore did not own the information.

As also has been previously communicated, Ethicon has been able to identify one binder of what appears to be patient level data from a Scandinavian study. It is not clear to us at this time what the time frame is from this information. This binder of documents was referenced in an email chain circa 2005 (Exhibit 410 – 6/4/13), relating to a pallet of twelve cases of Medscand materials that were in the possession of Cooper Surgical around the time it purchased Medscand. The documents in this binder appear to be in Swedish and appear to involve IVS MED PROLENE SLINGA MULTICENTERSTUDIE at Vaxjo center and they reference (patiennummer 1 – 30). The documents from the binder have been collected and processed, but due to the Swedish language content, review is not yet complete to enable production. Based upon our investigation with Ethicon, it appears that the other contents of this case, except for the binder described above, were destroyed in the Secur-Archiv fire that occurred in Lausanne, Switzerland that began on September 25, 2009.

The remaining 11 cases of documents, seven of which purportedly contained product retains, and four of which purportedly contained lot documentation, are not in Ethicon's possession. To the best of our current understanding, those cases had been in a storage facility in Sweden until early 2006, at which time they were disposed of, as they no longer served any business purpose.

As we have communicated previously, we remain unaware of other sources to search for clinical information from the Ulmsten/Scandinavian trials, other than what has already been produced and marked in depositions – the published studies and the interim analysis of the Scandinavian study prepared by Medscand in 1997 and signed by Dr. Margareta Eriksson.

If additional clinical information related to the Scandinavian studies is located as we investigate other issues, we will make you aware of it promptly.

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5. The shareholders agreement dated February 12, 1997 among Jan Johansson, Professor Ulf Ulmsten, and Dr. Nils Stormby, the amendment dated March 6, 1998, and any other amendments thereto, as well as any other Medscand shareholder agreements in Ethicon's or Johnson & Johnson's possession.

We have conducted a diligent inquiry and produced non-privileged TVT-related due diligence files in the possession of Ethicon Somerville. These were primarily located in Production 157, and identified by Bates ranges among the documents listed in Section 6 of Mr. Watson's September 10 correspondence, and in William Gage's email to you dated September 26, 2013. We have ascertained that we are in possession of a document entitled "Shareholder Agreement" identifying the Company as "Medscand Medical Aktieolag" and the parties as Medscand Aktiebolag, Ulf Ulmsten and Jan Johansson, bearing a date of February 12, 1997. The document is not signed. We are in possession of a document entitled "Supplement to Shareholders' Agreement, identifying the company as "Medscand Medical AB" and the parties as Medscand AB, Ulf ULMsten and Jan Johansson. The document has a date of March 6, 1998. It is not signed. These documents are in the process of production. If necessary, we can try to provide copies of these documents outside of the ESI protocol in order to get them to you more quickly.

6. The Device Master Record for the TVT Retropubic device created and maintained by Medscand Medical.

This request seeks documents that had not previously been specified in detail. Upon receipt of your November 1, 2013 letter identifying this information as a specific area of interest, we began a targeted investigation to obtain responsive information. As you know, a Device Master Record ("DMR") is a collection of documents maintained for FDA compliance purposes. Medscand never marketed the TVT product in the United States. We are attempting to ascertain whether a DMR was ever created during time frames when Medscand had responsibility for manufacture of the TVT product after the implementation of the 1997 Licensing Agreement and if so, whether those documents exist and are in the possession of Ethicon.

7. Revisions 1-6 of the TVT-2 Preventia Risk analysis document. Revision 7 of this document can be found at: eth.mesh.06696465-06696474.

We have been able to locate Revision 5 of the TVT-2 Preventia Risk Analysis. It was released in production 96 at Bates Range ETH.MESH.07295614-ETH.MESH.0729522.

Any previous versions of this document likely would have been in the possession of Medscand. We have not been able to locate any earlier versions, but if they are located, we will provide them to you as quickly as possible.

In summary, we have made every reasonable effort to produce documents related to the issues raised in advance of the upcoming Laura Angelini deposition scheduled for

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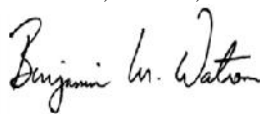
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November 14 and 15, 2013. Given the fact that our searches have been conducted at ex-US entities, involving documents spanning over a decade that may be located in files maintained outside of the affiliates' premises – if they exist at all – we may not have been able to locate some of the documents prior to the deposition despite our best efforts.

Please do not hesitate to reach out to us to discuss these issues further.

Sincerely,

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC

A handwritten signature in black ink, appearing to read "Benjamin M. Watson". The signature is written in a cursive, flowing style.

Benjamin M. Watson

BMW:fsw

cc: Bryan Aylstock, Esq.
Renee Baggett, Esq.

ButlerSnow 18275866v1

EXHIBIT KK

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CONFIDENTIAL DOCUMENT

EXHIBIT LL

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 - - -
IN RE: ETHICON, INC. : MDL NO. 2327
5 PELVIC REPAIR SYSTEM, :
PRODUCTS LIABILITY :
6 LITIGATION :

7 THIS DOCUMENT RELATES TO ALL CASES

8 - - -
9 AND VARIOUS OTHER CROSS-NOTICED ACTIONS

10 - - -
11 August 7, 2013

12 - - -
13 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

14 Videotaped deposition of MARK C. YALE
taken pursuant to notice, was held at the law
15 offices of Riker Danzig Scherer Hyland & Perretti
LLP, Headquarters Plaza, One Speedwell Avenue,
16 Morristown, New Jersey, beginning at 9:35 a.m., on
the above date, before Ann Marie Mitchell, a
17 Federally Approved Certified Realtime Reporter,
Registered Diplomat Reporter and Notary Public for
18 the State of New Jersey.

19
20
21 - - -
22
23 GOLKOW TECHNOLOGIES, INC.

877.370.3377 ph|917.951.5672 fax

24 deps@golkow.com
25

1 document dump.

2 Q. Did you ever recall that Medscand did
3 that, a document dump?

4 A. I became aware of that later, yes.

5 Q. Do you know where those are?

6 A. No.

7 Q. Nobody had asked you in your time
8 managing the litigation issues and documents, where
9 are those Medscand documents?

10 A. I remember someone looking for them,
11 but I don't ever remember an outcome.

12 Q. You don't remember anybody finding
13 them?

14 A. I don't remember anybody finding
15 them.

16 Q. It's a bunch of pallets of documents.
17 Somebody described it as 500 pounds of documents.

18 MR. HUTCHINSON: Object to form.

19 THE WITNESS: I do not know where
20 they were.

21 BY MR. ZONIES:

22 Q. Can you look into that for me?

23 A. Not anymore.

24 Q. When you were doing your quality
25 engineering and TVT-S and laser-cut mesh was going

EXHIBIT MM

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