

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-Abbrevo (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 Cheryl 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/knowning 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 SPOLIATION 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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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. Mittenthal 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.
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- Exhibit PP:** Feb. 18, 2011 Litigation Hold Notice, ETH.MESH.07983156
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- Exhibit SS:** James P. Mittenthal 9/25/13 Deposition, excerpts
- Exhibit TT:** CAPA070011 Summary Report, starting at ETH.MESH.09479227
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Exhibit VV: James P. Mittenthal 5/14/13 Deposition, excerpts