

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

Nonetheless, plaintiffs have filed an over-reaching motion for default judgment and other severe penalties that exaggerates the scope of the issue by focusing on custodians who separated from the Company years ago, before there was any legal obligation to preserve materials in connection with this litigation and by presuming that documents were improperly destroyed any time an employee's custodial file contains fewer documents than plaintiffs think it should. Putting aside all of plaintiffs' overblown rhetoric, the inadvertent loss of certain Ethicon employees' documents in the context of Ethicon's substantial document production does not justify spoliation sanctions.

**First**, Ethicon did not have a duty to preserve files belonging to many of the employees identified by plaintiffs because of the timeframe during which they left the Company. **Second**, sanctions are also inappropriate because the failure to preserve was unintentional and Ethicon thus lacked a "culpable" state of mind. The Company made substantial efforts to employ litigation holds and, as a result, retained and produced millions of pages of documents potentially relevant to this litigation. The fact that certain individuals mistakenly failed to follow written retention procedures upon leaving Ethicon does not demonstrate "culpable" conduct on the part of the Company. **Third**, plaintiffs cannot establish that evidence relevant to their claims was lost. In fact, thousands of documents to or from the individuals about whom plaintiffs complain were produced through other sources. Plaintiffs' claims in this litigation will turn on: (1) whether the products at issue are defective; (2) whether they carried appropriate warnings; and (3) whether they caused the specific injuries alleged by the bellwether plaintiffs. Plaintiffs have no basis – other than sheer speculation – for their contention that they lack any materials relevant to these key questions. And **fourth**, even if the Court were to determine that a sanction were required, plaintiffs' requests for a default judgment, the striking of defenses and adverse jury

instructions are far too extreme because plaintiffs cannot demonstrate “bad faith,” “extreme prejudice” or “intentional” misconduct.

To be clear, Ethicon is extremely troubled that certain employees did not follow written retention procedures, and the Company takes plaintiffs’ concerns very seriously. Ethicon continuously takes steps to improve its retention procedures and – since discovering this problem – has instituted a number of additional policies and procedures to minimize the risk of retention issues arising in the future. The reality is, however, that the overwhelming majority of documents collected in litigation are never used at trial. A recent survey found that the ratio of the average number of discovery pages to the average number of exhibit pages is 1,044 to 1. *See* Lawyers for Civil Justice, Civil Justice Reform Grp. & U.S. Chamber Inst. for Legal Reform, Litigation Cost Survey of Major Companies 16 (2010), <http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/Duke%20Materials/Library/Litigation%20Cost%20Survey%20of%20Major%20Companies.pdf>. Thus, the fact that plaintiffs might have obtained more documents – in addition to the millions they already have – does not mean, by any stretch, that the lost documents have impeded plaintiffs’ efforts to prosecute this litigation. Indeed, the facts suggest precisely the opposite.

For all of these reasons, discussed further below, plaintiffs’ motion should be denied.<sup>1</sup>

## **BACKGROUND**

### **A. The MDL Plaintiffs’ Claims**

This MDL proceeding was created on February 7, 2012 to address claims related to approximately a dozen of Ethicon’s pelvic mesh products, including Ethicon’s TVT and Prolift

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<sup>1</sup> Ethicon has requested oral argument on plaintiffs’ motion, and the parties are working with the Court to identify a mutually agreeable date for such argument.

products. *See In re Am. Med. Sys., Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, 844 F. Supp. 2d 1359 (J.P.M.L. 2012). Plaintiffs in the MDL proceeding, including Carolyn Lewis, who has been selected as the first bellwether-trial plaintiff, allege personal injury claims based on their use of these products. (*See, e.g.,* Compl., *Lewis v. Johnson & Johnson*, No. 2:12-cv-04301, Dkt. No. 1 (July 25, 2012).) According to plaintiffs, the material from which the products are made is “biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Pelvic Mesh Products.” (*Id.* ¶ 18.) Plaintiffs claim that “[w]hen mesh is inserted in the female body according to the manufacturers’ instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.” (*Id.*) Plaintiffs further allege that defendants “omitted the risks, dangers, defects, and disadvantages of the Pelvic Mesh Products, and advertised, promoted, marketed, sold and distributed the Pelvic Mesh Products as safe medical devices when Defendants knew or should have known that the Pelvic Mesh Products were not safe for their intended purposes.” (*Id.* ¶ 39.) Based on these allegations, plaintiffs allege a variety of product-liability causes of action, including claims for negligence, strict liability (design defect, manufacturing defect and failure to warn) and breach of express and implied warranties. (*Id.* ¶¶ 65-110.)

#### **B. The History Of The Litigation**

Before 2008, only a handful of isolated cases addressing Ethicon’s pelvic mesh products were filed in state courts, some of which included medical malpractice claims. (*See* Decl. of Benjamin M. Watson (“Watson Decl.”) ¶¶ 2-3 (attached as Ex. 1).) Discovery in these cases, if any, was comprised of general source materials. (*Id.* ¶ 3.) Nonetheless, in an abundance of caution, Ethicon issued litigation holds with respect to three cases that involved certain TVT products. (*Id.*)

In 2008, approximately five pelvic mesh cases were filed in state court in New Jersey. (*Id.* ¶ 4.) While a litigation hold notice was issued in connection with one of these cases in April 2008 (*id.*), the very small number of cases pending at that time did not constitute a critical mass of cases alerting Ethicon to the widespread litigation that would come in the following years. Again, document production was comprised of general source materials in 2008. (*Id.*) More than two years later, on October 12, 2010, the New Jersey Supreme Court ordered the centralized management of the pending pelvic mesh cases in New Jersey state court involving Ethicon and its parent company, Johnson & Johnson (“J&J”). (*Id.* ¶ 5.) It was only after centralized management of the New Jersey state court actions that the pelvic mesh litigation “began to pick up speed.” (*Id.* ¶ 6.) Between October 14, 2010 and February 6, 2012, approximately 400 pelvic mesh cases were filed in New Jersey state court. (*Id.*) “In contrast to the prior trickle of cases, this large number of filings signaled the creation of a mass tort.” (*Id.*) By early 2012, there were approximately 54 cases involving Ethicon’s mesh products pending in federal courts around the country, all of which were transferred to this Court pursuant to the JPML’s order creating this MDL proceeding on February 7, 2012. (*Id.* ¶ 7.)

Based on the timeline of the litigation, any reasonable expectation of litigation capable of triggering a general and widespread duty to preserve and collect documents from a wide range of custodians with respect to a wide range of products did not arise until sometime between 2008 and 2010, when a sufficient number of cases involving the products at issue were pending to warrant consolidated treatment by the New Jersey Supreme Court. At the very earliest, such a generalized duty arose when the first litigation hold notice was issued in a New Jersey case in April 2008.

**B. Ethicon's Document Retention Efforts & Litigation Holds**

Ethicon and its affiliates employ more than 11,000 people worldwide and have offices in more than 50 countries. (*See* Decl. of James P. Mittenthal ("Mittenthal Decl.") ¶ 18 (attached as Ex. 2).) As a medical device manufacturer, Ethicon operates in a "highly regulated environment . . . with respect to record retention" and has established "robust policies, schedules and procedures governing retention that apply even in the absence of litigation." (*Id.* ¶¶ 19-20; *see also* Decl. of Lisa Kaiser ("Kaiser Decl.") ¶¶ 4-5 (attached as Ex. 3).) Pursuant to these policies, Ethicon retains a large volume of documents related to its products, including "design history files (DHF's), laboratory notebooks, technical reports, labeling content and FDA submissions." (Mittenthal Decl. ¶ 22.) Ethicon also has in place significant "training programs and protocols to educate its associates as to record retention." (Kaiser Decl. ¶¶ 11-13.)

In addition to its general document retention policies and training, Ethicon has taken added steps to "promote appropriate record retention in connection with the commencement of litigation regarding its pelvic mesh products," including the issuance of litigation hold notices, which direct employees to retain documents pertaining to filed litigation. (Mittenthal Decl. ¶ 29; *see also* Kaiser Decl. ¶¶ 14-15.) The litigation hold notices issued in the New Jersey and MDL pelvic mesh cases since 2008 have been broad in scope, requiring employees to preserve many categories of materials related to the products at issue, including but not limited to documents regarding: "(1) Labeling; (2) Pharmacovigilance/Quality/Post-Market Surveillance; (3) Regulatory; (4) Discovery, Research and Development and Quality Engineering; (5) Product Communications; (6) Marketing and Sales Material; (7) Professional Education; (8) Manufacturing Documents and Equipment; and (9) Medical Affairs and Clinical Studies; and (10) Distribution." (Mittenthal Decl. ¶ 34.) By 2008, Ethicon had established a centrally-

managed document repository that allowed employees to move documents relevant to litigation into a folder for preservation. (*Id.* ¶ 35.) The litigation hold notices issued at and after this time directed employees how to use these repositories. (*Id.*) However, individual employees were given the flexibility to “manage their information and records in different ways during their employment and at their departure (e.g., using the litigation hold folders, using other folders that are retained, copying materials) that proved most conducive to business use” when complying with litigation holds. (*Id.* ¶ 38.)<sup>2</sup> Ethicon made a “conscientious effort to educate its employees as to their responsibilities to preserve information” pursuant to the hold notices and requires employees to complete annual training on legal hold notices. (*Id.* ¶ 40.) Specifically, Ethicon required its employees to complete annual training that explains what hold notices are, how to read them, and their legal ramifications – and then tests the employees on that information. (Kaiser Decl. ¶¶ 14-15; Mittenthal Decl. ¶ 42.)

In addition to requiring its employees to comply with litigation holds on an ongoing basis, Ethicon has also had in place, at all relevant times, a written procedure for preserving documents relevant to litigation when employees leave the Company. Pursuant to Company policies, the departing employees’ managers are responsible for instructing the employees to review their “electronic files against any Preservation Notices in effect.” (Mittenthal Decl. ¶ 46.) Departing employees are also responsible for working with their managers to complete an “Exit Checklist & Certificate of Compliance For Records Disposition” prior to leaving the Company

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<sup>2</sup> Plaintiffs claim that “Ethicon has not had a written policy regarding document retention at any time relevant to this motion.” (Mot. at 12.) That statement is untrue, as explained above. Plaintiffs also argue that Ethicon’s litigation hold policies were “ineffective” because employees were not “required” to use centralized litigation hold folders. (*Id.*) However, as Mr. Mittenthal has explained, Ethicon’s practice of providing litigation hold folders as a resource, while allowing employees to determine which retention method is most convenient, is consistent with the well-founded philosophy that an individual is in the best position to understand and manage his or her information and records. (Mittenthal Decl. ¶¶ 36-38.)

that instructs employees to preserve any documents that have been retained for litigation. (*Id.*) The Company's Information Technology ("IT") department was responsible for transferring the departing employee's electronic files to a CD before repurposing the employee's hard drive only if it was required by the employee's manager. (*Id.*)

**C. Problems Identified During Document Collection Efforts**

Despite the document retention and litigation hold policies outlined above, discovery conducted in the MDL proceeding over the course of the last year has revealed that proper steps were not taken to preserve electronic files when certain employees who have been identified as "custodians" of documents potentially relevant to the pelvic mesh litigation left the Company. (*See* Mittenthal Decl. ¶¶ 47-50.) Ethicon's attorneys discovered this issue in Spring 2013 in connection with a massive custodial collection effort, and upon learning of the lack of electronic files for certain employees, immediately alerted plaintiffs' counsel to the problem and offered a deposition to assist plaintiffs in understanding the underlying facts. (*See* Ex. Z to Pls.' Mem. In Supp. of Mot. For Sanctions.) As additional issues were later identified, counsel for Ethicon again reached out to plaintiffs to advise them of their findings.

In an attempt to determine why certain former employees' electronic files were not preserved upon their departure from the Company, Ethicon asked James Mittenthal, its retained 30(b)(6) representative regarding e-discovery efforts, to conduct an investigation into the issue. Pursuant to his investigation, Mr. Mittenthal concluded that, for most of the former employees at issue, "the employee understood and properly preserved documents while working at Ethicon," but electronic files were nonetheless lost because "upon the employee's departure or separation from the company, his or her electronic data were not properly transferred . . . [and] the contents of the employee's hard drive were not preserved." (Mittenthal Decl. ¶ 50.) According to Mr. Mittenthal, this occurred because of a misunderstanding on the part of either the employee, who



“assumed” everything on his or her hard drive would be preserved and failed to identify relevant materials for his or her manager, or the manager, who did not effectively communicate to IT that certain materials on the employee’s hard drive needed to be preserved. (*Id.*) Mr. Mittenthal also noted that in other, “rare circumstances,” electronic data were lost “because the former employee misunderstood the requirements to preserve documents, notwithstanding the litigation hold notices issued.” (*Id.*)

In their motion, and the supplement to that motion filed nearly a month later, plaintiffs identify 22 current and former Ethicon employees who they claim did not properly preserve electronic documents (or whose documents were not properly preserved when the employees left the Company), including: Renee Selman, the former president of Ethicon’s Women’s Health & Urology business; a number of employees in the clinical, medical, marketing and regulatory departments; and two sales representatives. (*See* Pls.’ Mem. In Supp. of Mot. For Sanctions (“Mot.”), Dkt. No. 953, at 3-9; Pls.’ Notice of Supplement In Supp. Of Mot. For Sanctions (“Supplement”), Dkt. No. 996, at 1-4.) However, 13 of these individuals left Ethicon before 2008, the earliest possible date that Ethicon could have had a general obligation to preserve documents on a widespread basis with respect to the pelvic mesh products at issue in this litigation.<sup>3</sup> In addition, a number of the individuals identified by plaintiffs would not have had a significant number of documents related to this litigation in their personal files because of the nature of their roles with the Company. (Mittenthal Decl. ¶¶ 81, 84.) For example, Mr.

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<sup>3</sup> These individuals include Rick Isenberg (departed 2002), Gregory Jones (departed 2003), Amy Godwin (departed 2004), Charlotte Owens (departed 2005), Sean O’Bryan (departed 2005), Laura Angelini (departed 2005), Kendra Munchel (departed 2005), Zenobia Walji (departed 2005), Jill Schiaparelli (departed 2005), Patricia Hojnoski (departed 2006; returned in 2008 as contract employee with limited administrative responsibilities for one year), Cheryl Bogardus (departed 2007), Allison London Brown (departed 2007), and John Clay (departed 2007). (*See* Mittenthal Decl. ¶ 61). As discussed in Mr. Mittenthal’s declaration, plaintiffs have misstated the dates of employment for some of these individuals by including periods of time when they were working for other entities. (*Id.*)

Mittenthal noted that it is “unsurprising” that “relatively few documents were directly collected from sales representatives such as Paul Courts and Troy Mohler” because the “role of a medical device sales representative at Ethicon is not document-intensive.” (*Id.* ¶¶ 81-82.) Another individual listed by plaintiffs, Susanne Landgrebe, experienced a crash of her hard drive in 2009, after her involvement with pelvic mesh products ended. (*Id.* ¶ 84.) Therefore, Ms. Landgrebe’s pre-2009 documents are no longer accessible. (*Id.*)<sup>4</sup> Other employees’ custodial files may be missing documents for other, similar reasons that have nothing to do with a failure to follow the Company’s preservation notices, as set forth in more detail in Mr. Mittenthal’s declaration. (*Id.*)

Notably, Ethicon has produced documents and communications to and from the 22 individuals identified in plaintiffs’ motion from multiple sources other than their own files. As Mr. Mittenthal explains, the fact that a specific former employee’s individual “custodial file” contains few or no documents does not mean that few or no documents related to that individual were produced in this litigation. (*Id.* ¶¶ 70-73.) This is because an employee’s “custodial file” merely includes documents that were collected directly from that employee’s individual hard copy or electronic files. (*Id.* ¶ 65.) Since employees regularly store documents in other “common source” locations – or transfer documents to those locations – Ethicon was still able to produce documents from employees whose custodial files were not fully preserved. (*Id.* ¶¶ 66-69.)

Importantly, the documents that will be most relevant to plaintiffs’ product-liability claims, i.e., documents pertaining to the product design, regulatory documents, marketing materials, complaints regarding pelvic mesh products and other post-market surveillance

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<sup>4</sup> Susanne Landgrebe recently located an old personal hard drive, which she was unaware she had. Ms. Landgrebe believes it may contain some work-related documents, which she believes would likely be duplicative of documents already produced from other sources. Ethicon is in the process of obtaining these documents and will produce responsive documents, if any.

evidence, are maintained centrally at Ethicon – not in individual custodian files – and have been collected and produced. (*Id.* ¶ 68; *see also* Kaiser Decl. ¶ 17.) Thus, for example, while plaintiffs complain that they have only 20 documents for Gregory Jones even though he “kept electronic copies of . . . 510ks . . . FDA correspondence” and other regulatory materials (Mot. at 7), plaintiffs ignore the fact that such regulatory submissions, correspondence and documents are stored in common files and “have been produced from the appropriate central sources of record.” (Mittenthal Decl. ¶ 84.)

In addition, many employees store their documents in central electronic filing locations, such as shared “L drives” on the Company’s computer system, which were searched for relevant documents in connection with Ethicon’s document production. (*Id.* ¶ 69.) Moreover, because Ethicon employees work collaboratively, electronic documents created or received by one employee are often found in the files of another employee with whom he or she worked. In fact, a search of Ethicon’s production thus far revealed that the Company has produced hundreds – and, in the overwhelming majority of cases, thousands – of emails and corresponding attachments to or from *each of the 22 individuals* identified in plaintiffs’ motion as having few or no electronic files. (*Id.* ¶ 70.) By way of example, Ethicon has produced approximately 8,503 of Renee Selman’s emails and attachments, 17,125 of Price St. Hilaire’s emails and attachments, 4,430 of Nancy Leclair’s emails and attachments, 5,520 of Cheryl Bogardus’s emails and attachments and 14,651 of Allison London Brown’s emails and attachments. (*Id.*)

Thus, “even where an individual’s ‘custodial file’ does not contain any documents, as shown above,” it is likely that many of the “individual’s documents (including email communications) have been collected and produced from file shares, databases, and other enterprise electronic systems, as well as from other individuals’ ‘custodial files.’” (*Id.* ¶ 73.)

**D. Ethicon's Efforts To Prevent Loss Of Electronic Files Going Forward**

Ethicon examines its policies, training and technology with respect to document retention on an ongoing basis and makes efforts to improve them, where appropriate. (Mittenthal Decl. ¶ 51.) In the last year, and especially since learning that some electronic documents were not preserved upon the departure of certain former employees, Ethicon has implemented a number of additional retention measures “to secure its ability to meet legal hold obligations going forward.” (*Id.* ¶ 52.) For example:

- In June 2012, Ethicon began saving all hard drives of employees who depart the Company. (*Id.* ¶ 56.)
- In December 2012, the third-party vendor that manages the hardware of all Ethicon sales representatives began permanently retaining all hard drive images when a sales representative separates from the Company (or receives replacement equipment). (*Id.* ¶ 53.) Ethicon also took a series of steps to “educate sales representatives as to compliance with litigation hold notices.” (*Id.* ¶ 54.)<sup>5</sup>
- In early 2013, Ethicon joined the “IT Safe” program, under which the hard drive of every employee who leaves the Company is shipped to the IT shared services group for imaging to preserve all information contained therein. (*Id.* ¶ 56.)
- In 2013, Ethicon also launched Outlook Exchange 2010, which allowed emails to be saved permanently in a central location, thereby permitting “more centralized management and storage of documents that have traditionally resided with individual custodians.” (*Id.* ¶ 55.)

**E. Plaintiffs' Other Discovery-Related Allegations**

Plaintiffs also claim in their motion that Ethicon “destroyed” other evidence relevant to their claims, including: (1) “600 pounds of documents” from MedScand, the original manufacturer of the TVT product; and (2) videos allegedly prepared by Dr. Todd Heniford regarding light-weight mesh products. (Mot. at 9-10.) Neither allegation is true.

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<sup>5</sup> Plaintiffs argue that these efforts to educate sales representatives regarding the Company's retention policies are akin to an admission that “Ethicon employees' understanding of the litigation hold process was . . . faulty.” (Mot. at 14-15.) The Court should not accept this “damned if you do, damned if you don't” argument.

1. MedScand Documents

MedScand is a Swedish company, not affiliated with Ethicon or J&J, that initially manufactured the pelvic mesh product TVT. (*See* Decl. of Pamela Downs (“Downs Decl.”) ¶ 3 (attached as Ex. 4).) In 1999, Ethicon purchased the rights to TVT and began manufacturing the product. (*Id.* ¶ 5.) When MedScand was purchased by Cooper Surgical in 2005, Cooper Surgical sought to transition a pallet containing 12 cases of documents pertaining to TVT to Ethicon. (*Id.*) In 2006, Ethicon determined that seven of the 12 cases that contained product retains (i.e. samples of TVT that were past their shelf life) should be discarded because they “no longer served any business purpose.” (*Id.* ¶ 7.) Expired product retains are not ordinarily kept because they are no longer usable and therefore “no longer serve[] a business function.”<sup>6</sup> (*Id.* ¶ 9.) Four of the 12 cases contained documents pertaining to specific batches of mesh. Records reflect that Ethicon decided to send four cases to Ethicon SARL in Neuchatel, Switzerland, for storage. However, Ethicon has been unable to locate these cases. (*Id.* ¶ 10.) The one remaining case of materials – which contained clinical study information – was shipped to an offsite storage facility maintained by a third-party vendor in Neuchatel, Switzerland in February 2006. (*Id.* ¶ 11.) That facility experienced a fire on or around September 24, 2009, and the majority of the MedScand materials were destroyed. (*Id.* ¶ 12.) The only material that did survive was a binder of patient data that has been produced to plaintiffs. (*Id.*) In addition, Ethicon has produced clinical study information related to TVT that was available from other sources, including materials related to studies performed by Ulf Ulmsten, who was involved in the development of TVT (*id.* ¶ 13), which plaintiffs claim were the “cornerstone” of Ethicon’s marketing for TVT

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<sup>6</sup> Plaintiffs criticize a November 7, 2005 email string in which two Ethicon employees discussed that the seven cases of expired product retains that served no continued business purpose need not be retained unless there was a litigation hold in place. (Mot. at 11.) But this was not an unreasonable conclusion, as retention of expired product retains was not warranted.

(Mot. at 10).<sup>7</sup>

2. Heniford Videos

Dr. Todd Heniford is a consultant for Ethicon. Plaintiffs claim that Dr. Heniford “created several videos for Ethicon” regarding the “benefits of using lighter mesh material,” but that Ethicon has only produced one of those videos. (Mot. at 9-10.) Plaintiffs claim that Ethicon’s failure to produce additional videos indicates that Ethicon “lost or destroyed almost every video produced by Dr. Heniford.” (*Id.* at 9.)

Plaintiffs have offered no evidence that another video discussing lighter-mesh material was ever sent to Ethicon by Dr. Heniford, and based on discussions with Dr. Heniford, Ethicon does not have reason to believe that such a video was even made. Dr. Heniford is in the process of producing documents from his files in this litigation and is scheduled to be deposed on January 24, 2014. Ethicon will promptly review those materials and perform additional searches, as appropriate, if Dr. Heniford’s documents indicate that another video discussing light-weight mesh was ever created.

**ARGUMENT**

A party seeking sanctions based on the alleged spoliation of evidence bears the burden of proving that:

(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 factfinder could conclude that the lost evidence would have supported the claims or defenses of the party that sought it.”

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<sup>7</sup> In addition, Ethicon’s responses to plaintiffs’ 225 Requests For Admission include information regarding payments made to MedScand and Ulmsten that plaintiffs claim was lost. (*See* Mot. at 6 (arguing that Ethicon employees have testified that they “do not know how to locate documentation about Ethicon’s payments to Mr. Ulmsten or Medscand”).)

*Ayers v. Sheetz, Inc.*, No. 3:11-cv-00434, 2012 U.S. Dist. LEXIS 149960, at \*6-7 (S.D. W. Va. Oct. 18, 2012) (internal quotation marks and citation omitted). Although a trial court has a “range of options available” to sanction the spoliation of evidence, any sanction adopted should be narrowly tailored to “serve the twin purposes of leveling the evidentiary playing field and . . . sanctioning the improper conduct.” *Loveless v. John’s Ford, Inc.*, 232 F. App’x 229, 236 (4th Cir. 2007) (internal quotation marks and citation omitted); *see also Silvestri v. Gen. Motors Corp.*, 271 F.3d 583, 590 (4th Cir. 2001) (noting that “the applicable sanction [for spoliation] should be molded to serve the prophylactic, punitive, and remedial rationales underlying the spoliation doctrine”) (internal quotation marks and citation omitted).

Here, Ethicon’s inadvertent loss of documents despite the Company’s significant document retention and legal hold policies and efforts does not constitute spoliation because plaintiffs cannot demonstrate that: (1) Ethicon had a legal obligation to preserve files in the possession of many of the 22 employees identified in plaintiffs’ motion and subsequent supplement; (2) the loss of the documents was the result of any “culpable” conduct by the Company; or (3) the evidence at issue was actually lost and would have supported their claims. Further, even if plaintiffs had proven that spoliation occurred, they have not come close to making the showing of “bad faith” or “willfulness” necessary to justify the extreme sanctions they seek.

# **I. ETHICON DID NOT ENGAGE IN SPOILIATION OF EVIDENCE.**

## **A. Plaintiffs Cannot Prove That Ethicon Had A Duty To Retain Many Of The Documents At Issue In Plaintiffs’ Motion.**

Plaintiffs’ motion should be denied because they seek sanctions for the alleged spoliation of evidence that was lost long before the Company had a duty to preserve evidence in connection with this litigation. A party has a duty to preserve material evidence when the party “reasonably

should know that the evidence may be relevant to anticipated litigation.” *Ayers*, 2012 U.S. Dist. LEXIS 149960, at \*5 (internal quotation marks and citation omitted). Importantly, this duty requires the party only to “identify, locate, and maintain information that is relevant to *specific, predictable, and identifiable* litigation.” *Id.* (internal quotation marks and citation omitted, emphasis added). Consistent with this principle, courts have made clear that the mere existence of other litigation involving a product or course of conduct does not give rise to a general duty to retain documents in all subsequent litigation that may one day arise on the same subject matter. Rather, the duty to preserve documents is “proportional” to the scope of the pending cases. *See, e.g., Rimkus Consulting Grp., Inc. v. Cammarata*, 688 F. Supp. 2d 598, 613 (S.D. Tex. 2010) (a party’s obligation to preserve documents in connection with litigation “depends on what is *reasonable* and . . . what [is]. . . *proportional* to that case”).

For example, in *In re Pradaxa (Dabigatran Etexilate) Products Liability Litigation*, plaintiffs alleged spoliation after the defendant pharmaceutical company (“BIPI”) was unable to produce a custodial file for a former employee who used to be BIPI’s Vice-President of Cardiovascular and Metabolic Disease Marketing. MDL No. 2385, 2013 U.S. Dist. LEXIS 137235, at \*5 (S.D. Ill. Sept. 25, 2013). BIPI contended that the custodial file was destroyed in November 2011 – in accordance with the company’s document retention policies – after the employee left the company, and that there was no spoliation because it did not have a duty to preserve evidence until February 2012, when it received plaintiffs’ demand letter. *Id.* at \*8. Plaintiffs disagreed, arguing that BIPI’s pre-litigation duty to preserve evidence arose in 2008, when BIPI was a defendant in litigation related to a single patient who allegedly suffered an “adverse bleeding event” after using Pradaxa. *Id.* at \*35. This was so, according to plaintiffs, because the “allegations in the [prior] litigation [we]re identical to the allegations at issue in this



MDL and as such triggered a duty to preserve evidence relevant to potential Pradaxa product liability litigation.” *Id.* at \*36. The court rejected this argument, explaining that the prior litigation was “not sufficient to trigger a general preservation obligation” in November 2011, when the Vice-President’s custodial files were destroyed. *Id.* at \*42. Instead, the court held that “the duty to preserve did not arise until February 2012 – when the defendants received a demand letter.” *Id.*; *see also, e.g., Brigham Young Univ. v. Pfizer, Inc.*, 282 F.R.D. 566, 572 (D. Utah 2012) (rejecting plaintiff’s argument that Pfizer’s duty to preserve evidence arose “not only from an awareness of [the present] action” but also from “Pfizer’s litigation with other parties”); *Vasudevan Software, Inc. v. Microstrategy Inc.*, No. 11-cv-06637-RS-PSG, 2013 U.S. Dist. LEXIS 48525, at \*6-7 (N.D. Cal. Apr. 3, 2013) (duty to preserve from prior litigation did not extend to “every possible party who” later was involved in similar litigation, but rather only arose after plaintiff “initiate[d] litigation against Microstrategy”); *Point Blank Solutions, Inc. v. Toyobo Am., Inc.*, No. 09-61166, 2011 U.S. Dist. LEXIS 42239, at \*5 (S.D. Fla. Apr. 5, 2011) (no spoliation claim where “the alleged destruction of evidence arose primarily when Defendants were under a duty to *others* . . . but not necessarily these Plaintiffs”).

Here, plaintiffs’ spoliation motion is based on the assertion that Ethicon had a duty to preserve evidence related to this litigation beginning in 2003 (Mot. at 17), in connection with a pelvic mesh lawsuit filed against Ethicon in Oregon state court. (Watson Decl. ¶ 3.) But that was an isolated, quickly settled case – and it was therefore “not sufficient to trigger a general preservation obligation.” *In re Pradaxa*, 2013 U.S. Dist. LEXIS 137235, at \*42. The same is true with respect to the handful of pelvic mesh cases pending before 2008. Because these cases were limited in scope and duration (Watson Decl. ¶ 3), they did not warrant widespread retention of documents belonging to all of the employees at issue in plaintiffs’ motion. Rather, Ethicon’s

obligation was “proportional” to the scope of those limited cases. *Rimkus*, 688 F. Supp. 2d at 613.

By contrast, Ethicon’s legal obligation to preserve information more broadly arose sometime between April 2008 (at the earliest), when the first litigation hold was issued in connection with one of the New Jersey-filed cases (Watson Decl. ¶ 4), and October 2010 – when the New Jersey Supreme Court ordered the centralized management of all the pending pelvic mesh cases, and the pelvic-mesh litigation “began to pick up speed.” (*Id.* ¶ 6.)

Critically, of the 22 employees identified in plaintiffs’ motion and supplement as having “inadequate” custodial files (*see* Mot. at 3-9; Supplement at 1-4), 13 separated from Ethicon before the first New Jersey litigation hold was issued in 2008. (Mittenthal Decl. ¶ 61 (explaining that Owens, O’Bryan, Angelini, Bogardus, Jones, Hojnoski, Isenberg, Schiaparelli, London Brown, Munchel, Clay, Godwin and Walji left Ethicon before the inception of the current litigation).) Five additional employees, including Renee Selman, left before the New Jersey Supreme Court found that there were sufficient cases pending to warrant consolidation in October 2010. (*Id.* ¶ 63.) Thus, the majority of the employees at issue in plaintiffs’ motion separated from the Company before the obligation to preserve arose. In addition, the majority of the TVT materials from MedScand identified in plaintiffs’ motion were discarded in 2006 because they served no business purpose, and other materials were destroyed in a fire at a third-party facility over which Ethicon had no control. (Downs Decl. ¶¶ 7-11.)<sup>8</sup> Accordingly, much of plaintiffs’ motion is based on the loss of documents that occurred at a time when Ethicon had no duty to retain them – or events Ethicon could not control.

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<sup>8</sup> Further, plaintiffs have no evidence that Ethicon had in its possession – much less destroyed – videos made by Dr. Heniford at *any time*. Obviously, Ethicon cannot be blamed for “losing” materials that it never possessed.

**B. Plaintiffs Cannot Establish That Ethicon Had A “Culpable State Of Mind.”**

Plaintiffs’ motion for sanctions should also be denied because plaintiffs cannot establish that the “destruction or loss [of relevant evidence] was accompanied by a culpable state of mind.” *Ayers*, 2012 U.S. Dist. LEXIS 149960, at \*6 (internal quotation marks and citation omitted). “The three possible states of mind that satisfy this requirement are bad faith destruction, gross negligence, and ordinary negligence.” *Sampson v. City of Cambridge*, 251 F.R.D. 172, 179 (D. Md. 2008). Plaintiffs cannot demonstrate culpability here.

As set forth above, Ethicon has engaged in extensive, good-faith efforts to preserve and produce evidence over the course of this MDL. Indeed, even plaintiffs acknowledge that “Ethicon has issued litigation hold notifications for all of the products covered in this MDL” proceeding. (Mot. at 11.) These hold notices unambiguously instructed employees to refrain from “discard[ing], destroy[ing], or alter[ing] in any way any” documents pertaining to the products at issue in the MDL. (Mittenthal Decl. ¶ 33.) As a result of these preservation efforts, Ethicon has been able to collect and produce millions of pages of documents to plaintiffs. (*Id.* ¶ 10.)

According to plaintiffs, the Court should nonetheless find that Ethicon engaged in “negligence or gross negligence” because the Company “did very little to ensure that documents were actually being preserved” pursuant to its document retention policies. (Mot. at 18-19.) But as the Mittenthal declaration makes clear, Ethicon has made an ongoing effort to educate its employees about their responsibilities to preserve information for litigation purposes. (Mittenthal Decl. ¶¶ 40-43.) For instance, employees were required to complete training on legal hold notices on an annual basis during the relevant period. (*Id.*) In addition, Ethicon’s written procedures required employees leaving the Company to work with their managers to review their electronic files, determine whether any hold notices are in effect and complete an “Exit Checklist

& Certificate of Compliance For Records Disposition” in order to appropriately preserve all documents subject to a litigation hold or other retention policy. (*Id.* ¶ 46.) These efforts plainly show that Ethicon did not act with the requisite “culpable state of mind” necessary to impose sanctions. *See, e.g., Danny Lynn Elec. v. Veolia Es Solid Waste*, No. 2:09CV192-MHT (WO), 2012 U.S. Dist. LEXIS 31685, at \*10-11 (M.D. Ala. Mar. 9, 2012) (defendants not culpable where they had “an effective litigation hold policy in place” despite plaintiffs’ contention that “defendants deleted and failed to preserve thousands of emails and failed to implement an adequate litigation hold”).

Plaintiffs also cannot demonstrate that the Company was “culpable” with respect to the other materials at issue in their motion. For example, plaintiffs argue that Ethicon engaged in spoliation with respect to documents created by MedScand, the original manufacturer of TVT, that are no longer available. (*See* Mot. at 10-11, 18.) However, plaintiffs fail to present any facts suggesting that Ethicon acted negligently with respect to these materials. Instead, plaintiffs merely speculate that “[h]undreds of pounds worth of boxes [of documents] do not get destroyed by accident,” and the “logical inference is that those boxes . . . contained harmful information, leading to their destruction.” (Mot. at 18.) But the facts are to the contrary. As set forth above, the majority of the MedScand materials were appropriately discarded because they consisted mostly of expired product retains and therefore had no business purpose (Downs Decl. ¶¶ 7-9), and retention was not warranted. Other documents were destroyed in a fire at a third-party storage facility over which Ethicon had no control – and any relevant documents that survived the fire were turned over to plaintiffs. (*Id.* ¶ 11.)

Plaintiffs’ allegation that Ethicon negligently or intentionally destroyed videos made by Dr. Heniford is even more far-fetched. (*See* Mot. at 9-10, 21-22.) There is no evidence that

Ethicon received such videos in the first place and therefore no basis to conclude that Ethicon negligently or intentionally “lost or destroyed” them. (Mot. at 9.)

For all of these reasons, plaintiffs cannot demonstrate culpability.

**C. Plaintiffs Have No Proof That Evidence Relevant To Their Claims Is Unavailable.**

Plaintiffs have also failed to present facts from which a “reasonable factfinder could conclude that the lost evidence would have supported the claims . . . of the party that sought” the sanctions. *Ayers*, 2012 U.S. Dist. LEXIS 149960, at \*6-7 (internal quotation marks and citation omitted).

*First*, plaintiffs have not shown that the allegedly lost documents would have supported their claims. The standard for establishing that allegedly spoliated evidence is relevant to the claims at issue is “more substantial than that required to satisfy Rule 401 of the Federal Rules of Evidence.” *Digital Vending Servs. Int’l, Inc. v. Univ. of Phoenix, Inc.*, No. 2:09cv555, 2013 U.S. Dist. LEXIS 145159, at \*20-22 (E.D. Va. Oct. 3, 2013). “[R]elevancy must be proven ‘by offering probative evidence, not the hyperbole of argument.’” *Id.* at \*21 (citation omitted). Thus, “[t]he burden is on the aggrieved party to establish a reasonable possibility, based on concrete evidence rather than a fertile imagination, that access to the lost material would have produced evidence favorable to his cause.” *Sampson*, 251 F.R.D. at 180 (quoting *Gates Rubber Co. v. Bando Chem. Indus., Ltd.*, 167 F.R.D. 90, 104 (D. Colo. 1996)); *see also Huggins v. Prince George’s Cnty.*, 750 F. Supp. 2d 549, 563 (D. Md. 2010) (denying motion for spoliation sanctions where the “Plaintiff had not presented sufficient indications” that the documents allegedly lost were “directly relevant” to the claims at issue), *aff’d*, 683 F.3d 525 (4th Cir. 2012).

Here, plaintiffs have no evidence, much less “concrete evidence,” that any of the materials at issue would have been relevant to their claims. Plaintiffs speculate that “[g]iven 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." (Mot. at 20.) However, plaintiffs themselves concede that the key questions in their cases will be whether Ethicon's pelvic mesh products were "sold in an unreasonably dangerous condition with insufficient warnings" and whether Ethicon "deceived the Plaintiff[s]" – or their doctors – about the products. (*Id.*) The answers to these questions will undoubtedly turn on evidence that plaintiffs cannot dispute is already within their possession, such as adverse event reports, materials related to the regulatory approval of the products and their warning labels, and marketing materials communicated to doctors and patients. Plaintiffs suggest that because some electronic files on the hard drives of former employees who worked in the areas of regulatory compliance, marketing, and sales were not preserved, the Court should assume that key documents relevant to these subjects were lost. (Mot. at 21-22.) However, as explained in the attached declarations of James Mittenthal and Lisa Kaiser, documents pertaining to these key subjects are maintained centrally at Ethicon – not in individual custodian files – and have already been produced. (Mittenthal Decl. ¶ 68; *see also* Kaiser Decl. ¶ 17.)

Notably, plaintiffs are unable to point to any specific documents relevant to their claims – such as regulatory submissions, adverse event reports, or draft marketing materials – that they claim are missing from Ethicon's substantial production. The closest plaintiffs come to identifying a supposedly relevant, missing document is their argument that Ethicon destroyed videos about light-weight mesh prepared by Dr. Heniford, which plaintiffs claim could be used as "impeachment" evidence in the event that Dr. Heniford testifies in future cases. (Mot. at 21-22.) But plaintiffs admit that Ethicon already produced a video on this subject matter, and they

have offered no evidence that another video presentation discussing light-weight vs. heavy-weight mesh was ever made, much less that it was sent to Ethicon.

Plaintiffs' speculation that Ethicon lost "important information about Ethicon's marketing strategies and, most importantly, communications between [sales representatives] and treating physicians" (Mot. at 22) is similarly insufficient. For one thing, plaintiffs are wrong that Ethicon only has a "few" documents for the two sales representatives identified in their motion, Paul Courts and Troy Mohler. In addition to the hundreds of documents produced from their custodial files (Mittenthal Decl. ¶ 82), as set forth above, a search of Ethicon's production has revealed that the Company produced approximately 706 emails and attachments to or from Paul Courts and 2,375 emails and attachments to or from Troy Mohler from other employees' files. (Mittenthal Decl. ¶ 70.) Moreover, as Mr. Mittenthal has explained, it is "unsurprising . . . that relatively few documents were directly collected from" these individuals because the job of a medical device sales representative is not "document-intensive." (*Id.* ¶¶ 81-82.) And Ethicon did produce marketing materials given to physicians by sales representatives from other sources.

Finally, plaintiffs complain that the MedScand materials "are just gone" and cannot be found in any file at Ethicon. (Mot. at 24.) But, as set forth above, most of the MedScand materials that plaintiffs reference were either discarded at a time when there was no duty to preserve or lost in a fire at a third-party facility over which Ethicon had no control. Moreover, plaintiffs fail to explain how MedScand's expired product retains, which by their very nature are no longer usable and therefore have no purpose, could possibly have been relevant to their claims. In short, plaintiffs have nothing – other than rank speculation – to support their argument that any of the materials that were lost would have helped them at trial.

***Second***, even if the Court were to assume that the 22 employees identified in plaintiffs'

motion had electronic files on their hard drives that were relevant to this litigation, a substantial portion of these documents were also available and produced from other sources. As courts have recognized, spoliation sanctions are not appropriate where a party is accused of losing or destroying materials that are “cumulative” of other evidence already produced and therefore “not essential” to the case. *Reinsdorf v. Skechers U.S.A., Inc.*, No. CV 10-7181 DDP (SSx), 2013 U.S. Dist. LEXIS 107631, at \*82-83 (C.D. Cal. July 19, 2013); *Johnson v. Next Day Blinds Corp.*, No. WMN-09-2069, 2012 U.S. Dist. LEXIS 95800, at \*9 (D. Md. July 11, 2012) (rejecting spoliation claim where the missing documents were “largely cumulative” and any missing information could be “readily extrapolate[d]” from the documents that were produced).

That is precisely the case here. As set forth above and in the Mittenthal declaration, potentially relevant evidence located on the hard drives of the former employees was likely available in other, common-source locations within the Company and produced from those sources. (See Mittenthal Decl. ¶¶ 70-73.) And because Ethicon employees work collaboratively with one another, the Company has produced hundreds – and in most cases thousands – of emails and attachments sent or received by each of the 22 individuals identified in plaintiffs’ motion as having few or no electronic files.<sup>9</sup> (*Id.* ¶ 70.) For example, Ethicon has produced:

- 4,430 emails and attachments to/from Nancy Leclair;
- 5,578 emails and attachments to/from Zenobia Walji;
- 8,415 emails and attachments to/from Susan Landgrebe;
- 14,651 emails and attachments to/from Allison London Brown;

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<sup>9</sup> These emails almost certainly account for a significant percentage of the documents that would have been saved on these individuals’ lost hard drives. This is so because the overwhelming majority of documents in any given “custodial file” are emails, and even non-email documents are typically circulated by email and would therefore have been captured in the recipients’ files as email attachments.



- 5,520 emails and attachments to/from Cheryl Bogardus;
- 17,125 emails and attachments to/from Price St. Hilaire;
- 4,190 emails and attachments to/from Laura Angelini; and
- 8,503 emails and attachments to/from Renee Selman.

(*Id.*) Thus, “even where an individual’s ‘custodial file’ does not contain any documents,” it is likely that many of the “individual’s documents (including email communications) have been collected and produced” elsewhere. (*Id.* ¶ 73.) As Mr. Mittenthal has explained, this is especially true given the breadth of Ethicon’s collection in this litigation. Because Ethicon collected documents from a large number of custodians who worked directly with the individuals they have identified, as well as many common sources, the Company necessarily produced many of the allegedly “missing” documents related to these individuals from other sources. (*Id.* ¶¶ 75-79.) By way of example, Mr. Mittenthal points to emails sent to some of the individuals identified in plaintiffs’ briefing that were also sent to, and produced in, the custodial files of, on average, a dozen other Ethicon employees. (*Id.* ¶¶ 78-79.)

Plaintiffs argue that the Court “should not be swayed” by evidence that a large portion of the materials they claim were destroyed were actually “produced from other files” because it is *possible* that there are some documents that were not collected elsewhere. (Mot. at 23.) However, the fact that Ethicon has produced a significant number of documents pertaining to the 22 individuals identified in plaintiffs’ brief severely undercuts plaintiffs’ argument that Ethicon should be subject to severe sanctions because it has lost “thousands upon thousands” of documents essential to this case.<sup>10</sup> (*See id.* at 2-3.) And even if some documents included on the

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<sup>10</sup> Plaintiffs argue that “communications between an employee” – including “high-level people” such as Renee Selman – and an outside person would “obviously not be produced from another employee’s files.” (Mot. at 23.) In reality, however, it is highly unlikely that the worldwide president of a business unit, or any other individual  
(*cont'd*)

hard drives at issue were not produced from other locations, plaintiffs have no evidence that any of those materials were relevant to their claims or would have been used at trial. For this reason too, plaintiffs' motion should be denied.

## **II. PLAINTIFFS' REQUESTS FOR EXTREME SANCTIONS SHOULD BE DENIED.**

Even if the Court were to find that some form of sanction were appropriate – which it should not – the sanctions sought by plaintiffs are far too drastic because Ethicon acted in good faith, and any lost documents have not prejudiced plaintiffs' ability to prosecute their claims.

### **A. Default Judgment Would Be Inappropriate Because There Is No Evidence Of Bad Faith Or Extreme Prejudice To Plaintiffs.**

As the Fourth Circuit has explained, default judgments must be “given [particular] scrutiny because they deal with ‘[a] party’s rights to a trial by jury and a fair day in court.’” *Bizprolink, LLC v. America Online, Inc.*, 140 F. App’x 459, 462 (4th Cir. 2005) (citation omitted). In particular, the “severe sanction” of judgment as a matter of law “is only appropriate if the conduct was ‘so egregious as to amount to a forfeiture of [the] claim,’ or if the effect of the conduct was ‘so prejudicial that it substantially denied the’ moving party the ability to pursue or defend a claim. *Loveless*, 232 F. App’x at 236 (quoting *Silvestri*, 271 F.3d at 593). As set forth more fully below, neither circumstance is present here.

**First**, Ethicon did not act in bad faith. A party has acted in bad faith for purposes of spoliation only if it has destroyed potential evidence in a purposeful effort to prevent the other

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*(cont'd from previous page)*

employee, would be communicating with a third party regarding a product without copying or involving other Ethicon employees. (*See* Mittenthal Decl. ¶ 84 (noting that Ms. Selman has testified that “due to her position, she was not the author of many documents and that such documents likely would be associated with other individuals’ ‘custodial files’”).) Plaintiffs also argue that, despite the production of thousands of documents pertaining to the custodians at issue (*see* Mittenthal Decl. ¶ 70), they may have “missed documents due to not having an established custodial file for each witness” (Mot. at 23). This argument should also be rejected because reasonable searches of e-mail addresses and other similar queries would easily identify such documents. (*See* Mittenthal Decl. ¶ 70.)

side from obtaining it. *See, e.g., Cole v. Keller Indus., Inc.*, 132 F.3d 1044, 1047 (4th Cir. 1998) (no bad faith where actions by plaintiff's expert "were [not] undertaken in an effort to prevent the defendant from inspecting and testing the ladder"); *Loveless*, 232 F. App'x at 237 ("[t]here is no indication . . . that Brown's failure to preserve the worksheet was intended to deprive the jury or [opposing party] of any evidence"); *Hawkins v. Coll. of Charleston*, No. 2:12-cv-384-DCN, 2013 U.S. Dist. LEXIS 162714, at \*11 (D.S.C. Nov. 15, 2013) (refusing to impose dismissal sanction because, *inter alia*, "there is not sufficient evidence that Hawkins 'destroyed the evidence with the intention of depriving [the College] of the evidence'" (citation omitted)).

In *Cole*, for example, the plaintiff brought a product-liability suit against the manufacturer of an allegedly defective ladder. 132 F.3d at 1045. During the course of plaintiff's expert's investigation of the ladder, the expert removed one of the steps from the ladder, grounded off the heads of the rivets at the left front of that step, broke the right rivets, which he ultimately lost, and "hacksawed out a portion of the step surrounding the left rear rivet." *Id.* at 1046. The defendant moved for summary judgment based on plaintiff's spoliation, arguing that the destructive testing of the ladder prejudiced it. *Id.* The district court dismissed the case, but the Fourth Circuit reversed, explaining that "absent bad-faith conduct[,] applying a rule of law that results in [judgment as a matter of law] on the grounds of spoliation of evidence is not authorized." *Id.* at 1047. In so ruling, the court reasoned that while the plaintiff's expert destroyed portions of the ladder in the course of his investigation, there was "no evidence that [his] actions were undertaken in an effort to prevent the defendant from inspecting and testing the ladder." *Id.* Because the expert's "mistake" did not rise to the level of bad-faith conduct,

“[t]he remedy chosen by the district court was simply too severe.” *Id.*<sup>11</sup>

The same rationale applies here. As explained in Mr. Mittenthal’s declaration, “any losses of data” in this case “were attributable to some type of *misunderstanding* by an employee and/or a *miscommunication* between a departing employee and his or her manager.” (Mittenthal Decl. ¶ 86 (emphases added).) In other words, there was no selective, intentional destruction of documents known to be relevant to the subject matter of this litigation. (*Id.* ¶ 85; *see also* Decl. of Phu Dao ¶ 7 (attached as Ex. 5) (sworn statement that individual responsible for overseeing IT support for Ethicon was “not aware of anyone [involved in Ethicon’s IT department] having intentionally deleted or destroyed any data that was known at that time to be relevant to the Ethicon pelvic mesh litigation”).) Because there is no evidence that the “mistake[s]” at issue “were undertaken in an effort to prevent [plaintiffs] from” obtaining information relevant to their claims, *Cole*, 132 F.3d at 1047, plaintiffs cannot demonstrate bad faith and are not entitled to a default judgment.

Plaintiffs argue that the Court should nonetheless “infer bad faith” from the fact that electronic documents belonging to Renee Selman, the former president of Ethicon’s Women’s Health & Urology business, were not retained upon her departure from the Company. (Mot. at 18.) According to plaintiffs, the Court should assume “that there was . . . some very damaging information on that hard drive” that “would have been harmful to Ethicon in this litigation” or else Ethicon would not have “delete[d everything.” (*Id.*) However, plaintiffs do not have even one shred of evidence to support this serious allegation. Further, as stated above, James

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<sup>11</sup> “Most of the Fourth Circuit cases involving sanctions for spoliation of evidence arise in the context of a defendant asking for dismissal of a plaintiff’s claims because of destruction of evidence by the plaintiff.” *Sampson*, 251 F.R.D. at 180 n.11. However, “[b]ecause . . . rendering default judgment is equally as harsh a sanction as dismissing the case of a plaintiff with prejudice, [courts have] cite[d] cases involving these sanctions interchangeably.” *Id.* (quoting *Pressey v. Patterson*, 898 F.2d 1018, 1021 n.2 (5th Cir. 1990)).

Mittenthal, who investigated the loss of Ms. Selman's files, confirms that his investigation "did not identify a single instance in which an Ethicon employee selectively and intentionally destroyed documents known to be relevant to the pelvic mesh litigation." (Mittenthal Decl. ¶ 85.) Plaintiffs' argument that the "destruction of the Medscand data also evinces bad faith" because the "logical inference is that those boxes also contained harmful information" that Ethicon purposefully destroyed is similarly baseless. (Mot. at 18.) As set forth in detail above, there is no evidence whatsoever that Ethicon had anything to do with the fire *at a facility owned by a third party* that destroyed many of the MedScand documents – or that the expired product retains that were discarded had any use. Thus, plaintiffs' allegations of intentional document destruction are nothing more than figments of their own imagination.

*Second*, plaintiffs also cannot establish that Ethicon's alleged spoliation caused extreme prejudice. In cases devoid of bad faith, a default judgment is only proper where the loss of information substantially prejudiced the opposing party's ability to prosecute her case. *See Grayson Consulting*, 2013 U.S. Dist. LEXIS 107218, at \*22-23 ("The harsher sanctions of dismissal and default judgment require a showing of bad faith . . . unless the spoliation was so prejudicial that it prevents the non-spoliating party from maintaining his case.") (internal quotation marks and citation omitted). The touchstone of this inquiry is whether the lost information is so "central to the case" that the non-spoliating party does not have "*enough*" information to build her case. *See Hawkins*, 2013 U.S. Dist. LEXIS 162714, at \*10, \*13 (emphasis added) ("The record 'contain[s] enough data' for the College to build its defense. Therefore, content of Hawkins's Facebook page is not so central to the case that its destruction 'substantially denied the defendant the ability to defend the claim.'") (citations omitted). Accordingly, courts have routinely denied requests for the entry of judgment based on "[t]he

availability of other evidence to the moving party.” *Musick v. Dorel Juvenile Grp., Inc.*, No. 1:11CV00005, 2011 U.S. Dist. LEXIS 122580, at \*7 (W.D. Va. Oct. 24, 2011) (entry of judgment was not proper where moving party had sufficient evidence to make its case with regard to causation).

Here, there can be no dispute that plaintiffs have more than “*enough*” information to build their case against Ethicon. As set forth in Section I.C above, plaintiffs have extensive materials related to their claims, including adverse event reports, clinical trial data, regulatory documents, and marketing materials provided to doctors and patients. In addition, they also have hundreds or thousands of emails from each of the individuals at issue in plaintiffs’ motion. Given the substantial discovery provided to plaintiffs in this litigation, it is not surprising that they have been unable to identify any relevant evidence that is supposedly missing – let alone evidence “so central to the case” that they will be unable to present their claims at trial. Plaintiffs’ effort to turn some unfortunate mistakes into a windfall and avoid having to prove their claims at trial should be summarily rejected.

**B. An Adverse Jury Instruction Would Be Inappropriate.**

Plaintiffs’ request for an adverse-inference jury instruction should also be rejected. An adverse-inference instruction “creates a substantial danger of unfair prejudice” by “encourag[ing] the jury to speculate that the missing [information] contained admissions and other information damaging to” the party accused of spoliation. *Morris v. Union Pac. R.R.*, 373 F.3d 896, 903 (8th Cir. 2004); *see also id.* at 900-01 (“When giving such an instruction, a federal judge brands one party as a bad actor, guilty of destroying evidence that it should have retained for use by the jury.”). This prejudice is “all but a declaration of victory” for the opposing side. Laura A. Adams, *Reconsidering Spoliation Doctrine Through the Lens of Tort Law*, 85 Temp. L. Rev. 137, 151 (2013). Accordingly, a court may only permit the jury to draw an “adverse inference”

from a party's spoliation of evidence where the loss of evidence was more than just "negligent;" such an "inference requires a showing that the party knew the evidence was relevant to some issue at trial and that his willful conduct resulted in its loss or destruction.'" *Simms v. Deggeller Attractions, Inc.*, No. 7:12-cv-00038 et al., 2013 U.S. Dist. LEXIS 448, at \*17 (W.D. Va. Jan. 2, 2013) (quoting *Vodusek v. Bayliner Marine Corp.*, 71 F.3d 148, 156 (4th Cir. 1995)). That type of showing cannot be made where the loss of information resulted from mere "inadvertent oversight." See *Carter v. Farmer*, No. 7:12CV00008, 2012 U.S. Dist. LEXIS 127188, at \*12 (W.D. Va. Sept. 7, 2012) (adverse-inference instruction not proper where "the loss of the video resulted from . . . inadvertent oversight"), *aff'd*, 518 F. App'x 158 (4th Cir. 2013); see also *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, No. 3:09cv58, 2011 U.S. Dist. LEXIS 45888, at \*54 (E.D. Va. Apr. 27, 2011) ("There is no doubt that some unknown employee at DuPont or DKI deleted Tad Lee's email account on January 27, 2009, resulting in the loss of his emails. What Kolon has not shown, however, is that the employee intentionally or willfully deleted the account, rather than negligently, or that the employee or DuPont knew . . . that the emails were relevant to some issue at trial") (citation omitted).

As set forth in detail above, there is no evidence that the alleged loss of information was the result of anything other than an oversight by certain Ethicon employees who failed to follow the Company's policies with respect to document retention, most notably when they (or individuals working with them) left the Company. Such "inadvertent" conduct does not reflect knowledge by Ethicon that lost information was relevant to any issue in this litigation or establish that the Company willfully took steps to destroy it. As a result, plaintiffs' request for an adverse-inference instruction should also be denied.

**C. There Is No Basis For Striking Ethicon's Defenses.**

Plaintiffs' proposal to strike Ethicon's statute-of-limitations and learned-intermediary defenses should also be rejected. As courts have noted, because "the purpose of imposing sanctions is to punish and deter, rather than to reward [a party] with some windfall," striking defenses is only appropriate where the lost information actually "would support those defenses." *Alden v. Mid-Mesabi Assocs. Ltd. P'ship*, No. 06-954 (JRT/RLE), 2008 U.S. Dist. LEXIS 123190, at \*17 (D. Minn. Feb. 25, 2008) (declining to strike plaintiff's affirmative defenses to counterclaims because the defendants could not establish that the lost information was sufficiently probative of those defenses); *see also Davis v. Ford Motor Co.*, 375 F. Supp. 2d 518, 521-22 (S.D. Miss. 2005) (denying motion to strike defendant's defenses based on lack of testing and analysis of spoliated vehicle because "plaintiffs' inability to inspect, view or test the actual vehicle involved in this particular rollover accident cannot have impaired their ability to establish their claim based on the alleged design defect in the handling and stability of the Explorer").

Here, plaintiffs cannot establish that any of the lost information has anything to do with Ethicon's defenses. For example, plaintiffs assert that the Court should strike Ethicon's learned-intermediary defense because Ethicon "should not be permitted to argue" that it adequately warned doctors about the risks of pelvic mesh when "information [is] missing from so many of the sales representatives and other marketing witnesses" about what was said to doctors. (Mot. at 25.) But, as set forth above, medical device sales representatives typically do not maintain such documents. (Mittenthal Decl. ¶ 81-82.) Thus, there is no reason to believe that the files of sales representatives would have contained relevant information about their communications with physicians, and marketing materials provided to physicians by sales representatives would have been produced from other sources.

At the very least, even if plaintiffs' argument had potential merit, they would need to



show that documents purportedly relevant to the learned-intermediary defense are missing in a specific case. Needless to say, plaintiffs are free to depose all of the relevant physicians in all the pelvic mesh cases and ask them about their interactions with sales representatives and what sorts of marketing materials they received and/or relied on. They are also free to depose any former employees regarding their communications with doctors and to determine whether any allegedly relevant documents are missing. Plaintiffs have not identified any physician in any case who was allegedly influenced by marketing materials or communications that they allege are not available. For all of these reasons, plaintiffs' request to strike Ethicon's learned-intermediary defense should be rejected.

Plaintiffs are also unable to tie Ethicon's statute-of-limitations defense to the alleged spoliation of documents. According to plaintiffs, Ethicon should not be allowed to invoke a limitations defense because "fraudulent concealment generally will toll the statute of limitations," and it is *possible* that lost documents could "demonstrate deception of consumers." (Mot. at 25.) But in order to prove fraudulent concealment, plaintiffs would have to show that Ethicon took affirmative steps to prevent them from discovering that they had a cause of action against Ethicon, even though they exercised due diligence to discover their claims. *Martin v. Grehn*, No. 13-50070, 2013 U.S. App. LEXIS 19639 (5th Cir. Sept. 25, 2013). In other words, fraudulent concealment tolls claims where there were misstatements *after* the alleged tort occurred – not before. Thus, even if there were evidence that the 22 employees identified in plaintiffs' brief had documents about improper marketing that somehow did not make it into anyone else's files in the entire Company – and there is not – it still would not prove that Ethicon made fraudulent statements to plaintiffs that prevented them from filing suit in a timely manner.

At bottom, plaintiffs are not seeking relief that has any relationship to the lost documents.

Instead, they have simply selected two defenses that they believe will pose the greatest challenge to them at trial and have sought to deprive Ethicon of those defenses in order to give themselves a strategic advantage at trial. For this reason too, the motion should be denied.

**D. Monetary Sanctions, If Any, Should Be Limited To The Expenses Incurred By Plaintiffs In Deposing Ethicon's Corporate Representative And Preparing Their Motion.**

As set forth in detail above, the unintentional loss of documents – much of which occurred before this litigation even began – does not warrant any sanctions. However, Ethicon does recognize that some documents were inadvertently lost, causing both parties to incur additional expenses in discovery. As noted above, Ethicon takes this issue very seriously. For this reason, Ethicon's counsel have worked with plaintiffs for months in an effort to investigate why certain employees' documents were not preserved and determine whether those documents have been produced to plaintiffs from other sources. In addition, promptly after discovery of this issue, Ethicon instituted a number of internal procedures that are designed to minimize the risk that documents potentially relevant to litigation are lost going forward. In short, Ethicon has done everything it reasonably could to rectify the situation and ensure that it does not happen again.

In light of these efforts – as well as the inadvertent nature of the loss of documents and the lack of prejudice to plaintiffs – Ethicon believes that, to the extent the Court finds any sanction to be appropriate, it should be limited to a monetary sanction equal to plaintiffs' expenses related to: (1) the depositions of Ethicon's corporate representative regarding document retention issues; and (2) the preparation of plaintiffs' motion for sanctions.

**CONCLUSION**

For all of the reasons set forth above, the Court should deny plaintiffs' motion.

Dated: January 10, 2014

Respectfully submitted,

ETHICON, INC. AND  
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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

-----X	
<b>IN RE ETHICON, INC., PELVIC REPAIR</b>	<b>:</b> <b>CIVIL ACTION NO. 2:12-md-02327</b>
<b>SYSTEM PRODUCTS LIABILITY</b>	<b>:</b>
<b>LITIGATION</b>	<b>:</b> <b>MDL No. 2327</b>
-----	<b>:</b>
	<b>:</b> Judge Joseph R. Goodwin
This Document Applies To All Actions	<b>:</b>
	<b>:</b>
-----X	

**CERTIFICATE OF SERVICE**

I, David B. Thomas, certify that on January 10, 2014, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ David B. Thomas

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# **EXHIBIT 1**

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

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<b>IN RE ETHICON, INC., PELVIC REPAIR</b>	<b>: CIVIL ACTION NO. 2:12-md-02327</b>
<b>SYSTEM PRODUCTS LIABILITY</b>	<b>:</b>
<b>LITIGATION</b>	<b>: MDL No. 2327</b>
-----	<b>:</b>
	<b>:</b>
This Document Applies To All Actions	Judge Joseph R. Goodwin
	<b>:</b>
	<b>:</b>
-----X	

**DECLARATION UNDER PENALTY OF PERJURY  
(PURSUANT TO 28 U.S.C. § 1746) OF BENJAMIN M. WATSON**

Benjamin M. Watson deposes and says as follows:

1. My name is Benjamin M. Watson. I am over 21 years of age and of sound mind.

Based on my review of records and related inquiries of company personnel, I have personal knowledge of and am competent to testify about the matters stated in this declaration. The facts stated herein are true and correct to the best of my knowledge and are stated under penalty of perjury. In my capacity as an attorney for Ethicon, Inc. and Johnson & Johnson, I submit this declaration in support of Defendants' Response in Opposition to Plaintiffs' Motion for a Finding of Spoliation and for Sanctions and to apprise the Court of the development of the Ethicon pelvic mesh litigation.

2. Prior to 2008, records show that there were a handful of cases filed against Ethicon related to Ethicon's pelvic mesh products. The isolated cases below were not part of a consolidated or other mass tort proceeding.

3. Between 2002 and early 2008, records show that there were four cases in which legal holds were issued for specific pelvic mesh products or product lines. These cases were

resolved long before the current wave of mass litigation. As described below, three of the cases included medical malpractice claims, and all of the cases were resolved in a relatively short period.

- (a) *Brenda and Walter E. Holley v. S. Kam Otey, M.D.; Physicians and Surgeons Clinic Corporation of Amory, Mississippi and John Doe Defendants A through D*, Civil Action No. CV02-113-PFM, filed in Mississippi in March 2002, appears to include claims against the treating physician and his clinic. The Ethicon product at issue was Mersilene mesh.
- (b) *Kandell v. Ethicon, Inc.*, Case No. 16-03-07400, filed in Oregon on or about March 6, 2003, involved TVT, but settled on or around January 24, 2004. It is my understanding documents produced in this case were comprised of general source materials. Copies of non-plaintiff specific documents that have been identified from the *Kandell* production have been produced in this case.
- (c) *Keeton v. Gynecare, et al.*, Case No. 05-24931-CA 30, filed in Florida in December 2005, involved TVT. Summary judgment was entered in the *Keeton* case on or about August 13, 2007. It is my understanding documents produced in this case were comprised of general source materials. Copies of non-plaintiff specific documents that have been identified from the *Keeton* production have been produced in this case.
- (d) *Wallingford v. Johnson & Johnson, et al.*, Docket No. RG07312197, filed in California on February 21, 2007. The Ethicon device at issue was TVT

Classic. The *Wallingford* case was voluntarily dismissed on or about August 18, 2008 before Plaintiffs served written discovery on Ethicon.

4. In 2008, approximately five cases were filed against Ethicon in New Jersey state court, beginning with the case *Lombardi v. Gynecare*, Docket No. 000772-11. Again, a legal hold was issued for that case. Again, document production was comprised of general source materials in 2008. Other cases continued to be filed in both federal and state court.

5. Over the next couple of years, this trickle of cases grew to a larger number, with approximately 45 additional cases filed in 2009. In February 2010, plaintiffs' counsel sought centralized management of approximately 60 cases in New Jersey, and that request was granted on October 12, 2010.<sup>1</sup>

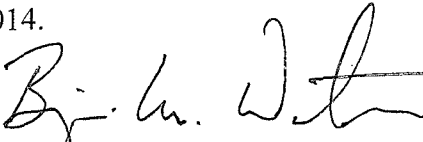
6. After centralized management of the New Jersey state court actions was ordered, the pelvic mesh litigation began to pick up speed. Between October 14, 2010 and February 6, 2012, records show that there were approximately 400 pelvic mesh cases filed in New Jersey state court. In contrast to the prior trickle of cases, this large number of filings reasonably signaled the creation of a mass tort.

7. From 2010 through 2012, the records show that approximately 54 cases were filed in federal courts around the country with respect to Ethicon's pelvic mesh products. Of those 54 cases, three were filed in 2010, thirty-one were filed in 2011 and twenty were filed in 2012. The JMPL's order created the Ethicon MDL proceeding on or about February 7, 2012 and transferred the applicable cases.



8. Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 10 day of January, 2014.

  
BENJAMIN M. WATSON

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<sup>1</sup> Separately from the New Jersey litigation, there were also approximately 18 state court cases filed in other states between 2009 and 2012.

# **EXHIBIT 2**

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

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO ALL CASES</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**DECLARATION OF JAMES P. MITTENTHAL**

James P. Mittenthal declares and says:

**I. BACKGROUND**

1. My name is James Peter Mittenthal. I am over twenty-one years of age and of sound mind. I am competent to affirm all of the matters set out in this Declaration.

2. I am currently employed as the Vice President of Consulting Services at Epiq Systems, Inc., eDiscovery and Litigation Solutions. Previously, from 1985 through 1992, at Legal Support Services Corporation, I developed a suite of law office software and other technology to manage large-scale document productions in product liability and other mass litigation. In 1992, I joined Price Waterhouse, where I spent four years advising law firms and law departments regarding information technology and information management issues, including issues regarding record retention and the discovery life cycle. In 1995, I opened the New York office of Baker Robbins & Company, a national technology consulting firm. Through 16 years at the firm (including its acquisition by Thomson Reuters and merger with Hildebrandt International), I assisted law firms and law departments with technology acquisition, information management, and litigation support, and eventually headed its litigation support group, before

our group transitioned the practice to Epiq in 2011. I hold a bachelor's degree in English (Honors Program) from the University of Michigan and a law degree from Boston University.

3. Over the last 28 years supporting the legal services industry, I have had extensive experience advising corporations, governmental entities, and other organizations regarding user-created information, enterprise and departmental information, archival information, and the supporting infrastructure; retention and disposition of business information and records, both in the ordinary course of business and in connection with litigation, including the implementation of appropriate legal holds; and the assessment, collection, and production of hard copy and electronically stored information in litigation.

## **II. OVERVIEW OF WORK ON BEHALF OF ETHICON**

4. Beginning in or about August 2011, I was asked by Ethicon, Inc. ("Ethicon") to examine the company's efforts with respect to records management and retention and its underlying technology environment, among other topics, to prepare for and provide testimony as a corporate representative in connection with the pelvic mesh litigation in the MDL and New Jersey cases.

5. In connection with my review, I interviewed over 100 different individuals, sometimes on multiple occasions, in connection with network infrastructure, business systems, and records management and retention, including both Ethicon and Johnson & Johnson personnel within Information Technology, Quality Systems, Supply Chain, Regulatory, Research and Development, Marketing, and Sales groups, as well as certain third parties with information and facilities management or collection responsibilities. At least 50 of my interviews were mainly concerned with records management and retention.

6. In addition, I conducted numerous onsite visits to Ethicon's headquarters in Somerville, New Jersey, as well as to the corporate data center and offices in Raritan, New Jersey and the Health Care Systems facilities in Piscataway, New Jersey.

7. In approximately April 2013, I was asked to examine certain record retention issues related to specific custodians who had been found to have few or no documents in their "custodial files." In this context, I spoke to current employees and former employees, including managers, administrative assistants, as well as records management, information technology and human resources personnel. In connection with this aspect of my work, I also requested, received, and reviewed portions of deposition testimony of certain former employees and documents regarding compliance with records retention procedures, such as completed exit checklists.

8. As part of my work, I have provided deposition testimony as a corporate representative on behalf of Ethicon on five different occasions: December 7, 2011; December 4, 2012; May 14, 2013; August 13, 2013; and September 25, 2013. Plaintiffs devoted the last three days of deposition primarily to records retention and the issue before this Court.

### **III. SUMMARY OF FINDINGS**

9. The following is a summary of my key findings, which are set out more fully below:

- Ethicon has produced millions of pages of documents in this litigation, which include design and development, regulatory, marketing, complaints and clinical data documents collected from central sources as well as hundreds of individual custodians working in these functional areas.
- At all time periods relevant to this litigation, Ethicon has had in place written record retention policies, procedures, training, and technology that were reasonably designed to effectuate record retention consistent with its obligations both in the ordinary course of business and in connection with pelvic mesh litigation.

- Beginning in approximately April 2013, Ethicon identified that certain former employees' "custodial files" contained few or no documents. I determined that, in many cases, the employee understood and properly preserved documents while working at Ethicon, but upon the employee's departure or separation from the company, his or her electronic data were not properly transferred to the company due to miscommunication or misunderstanding.
- Both in the normal course and in direct response to the identification of these issues, Ethicon has taken – and continues to take – steps to address them (as well as its record retention and legal hold practices in general) and implement processes to minimize the risk of similar losses of data in the future.
- The impact of the loss of any individual-level data is minimized in light of the following:
  - the modern corporate environment, in which technology infrastructure directs users to create and manage documents and information in centrally stored and managed locations, such as Microsoft SharePoint sites, group or department shares, databases, and other electronic systems, rather than on a drive to which only a single user has access; and
  - the redundancies incorporated into Ethicon's document collection practices (collection from databases and other central sources and collection from numerous custodians within a single functional area).
- At no time during my examination and assessment did I identify any instance in which Ethicon intentionally or selectively destroyed materials known to be relevant to the pelvic mesh litigation.

#### **IV. ETHICON'S DOCUMENT COLLECTION AND PRODUCTION TO DATE HAVE BEEN FAR-REACHING AND SUBSTANTIAL**

10. I understand that, as of December 1, 2013, Ethicon has produced more than 1.5 million documents, comprising more than 10.5 million pages, in connection with this pelvic mesh MDL. Further, Ethicon has produced millions of additional pages of documents in native form.

11. Ethicon collected these documents from a wide range of electronic and paper sources both in and outside the United States. They include both custodial (individual) and non-custodial (general or central) sources.

12. Ethicon's custodial collections took into account more than 250 current or former internal employees who held responsibilities in a wide variety of areas pertaining to Ethicon's pelvic mesh products, including research and development; design and engineering; preclinical testing; clinical development; regulatory; manufacturing; quality and compliance; labeling; marketing; sales; professional education; medical affairs; and post-market surveillance. In addition, I understand that document collections have been performed for more than 150 current and former sales representatives of Ethicon.

13. Typically, Ethicon performed custodial collections for multiple individuals in a department or area. For example, in some areas, such as marketing, more than 35 individuals were the subject of custodial collections. Likewise, Ethicon collected from more than 20 individuals employed in a clinical or medical affairs capacity and more than 15 individuals who had regulatory responsibilities.

14. In addition, significant volumes of electronic and hard copy documents have been collected from non-custodial sources such as group and departmental file shares, databases, websites, other enterprise electronic systems, and warehouse storage facilities.

15. These materials collected from general or central sources encompass the same broad range of subject matters or functional areas identified in paragraph 12 above, including design, regulatory, labeling, copy review (which includes marketing, professional education and training), clinical and preclinical studies, and complaints.

16. Most "files of record" (many of which are required to be maintained and preserved by Ethicon under federal and other regulations) are maintained in general or central sources, rather than in any one individual's custody.

- a. For example, the Design History File, or DHF, is a collection of materials that Ethicon maintains centrally. The DHF memorializes the design and development of a given product. It comprises a vast array of materials, including design drawings, testing reports, meeting minutes, memoranda, and emails. A DHF for a single product may number tens of thousands of pages. Ethicon has produced the DHF for each of the 15 pelvic mesh products at issue in this MDL.
- b. Likewise, Ethicon's applications for 510(k) regulatory clearance for its products are document collections that are maintained centrally. Ethicon has collected and produced the 510(k) application files for each of the pelvic mesh products at issue in this MDL, which include the applications and supporting materials as well as correspondence to and from FDA.
- c. Ethicon has collected and produced Instructions for Use (IFUs), which were included in the packaging of the product, for each of the pelvic mesh products at issue in this MDL. The IFUs and other labeling materials were collected from the AGILE database, a document control application.
- d. Ethicon's copy review of marketing and certain training and professional education materials is conducted on a centrally-maintained electronic database, Blue. Relevant materials from Blue have been collected and produced in this litigation.
- e. Federal regulations require Ethicon to maintain files regarding all reports of complaints or adverse events associated with the products it manufactures. Ethicon maintains its complaint files on enterprise systems,



and is producing in this litigation complaint files regarding the pelvic mesh products at issue, regardless of the country from which the complaint originated.

- f. Ethicon manages information pertaining to clinical research regarding the pelvic mesh products in various Microsoft SharePoint sites, network shares, and the Oracle Clinical database. Each of these central sources has been subject to collection and production.

**V. ETHICON HAS ESTABLISHED SOUND GENERAL RECORD RETENTION POLICIES AND PROCEDURES AND HAS ISSUED TIMELY AND APPROPRIATE HOLD NOTICES IN PELVIC MESH LITIGATION**

17. My fact-finding shows that, at all times relevant to this litigation, Ethicon has had in place written record retention policies, procedures, training, and technologies that were reasonable for a company of its type and size and were designed to facilitate appropriate record retention, both in the ordinary course of its business operations and regulatory framework generally and in connection with pelvic mesh litigation specifically.

**Ethicon's Ordinary Course Record Retention**

18. By way of background, Ethicon employs more than 11,000 people worldwide and has offices, Research & Development centers, and manufacturing facilities in more than 50 countries.

19. As a medical device manufacturer, Ethicon operates in the ordinary course of its business in a highly regulated environment, including with respect to record retention.

20. To comply with its regulatory requirements with respect to record retention, Ethicon has established robust policies, schedules, and procedures governing retention that apply even in the absence of litigation.

21. These policies, schedules, and procedures, which I understand are described more fully in the declaration of Lisa Kaiser, Ethicon's Director of Worldwide Quality Systems, take into account Ethicon's business and operational requirements as well as tax, regulatory, and corporate policy mandates. Ethicon uses a variety of means to drive policy creation, development, and conformity with corporate standards, such as annual audit reviews and the Corrective Action and Preventative Action (CAPA) mechanism.

22. The schedules and procedures provide clear guidance as to how numerous different categories of records and information stored in various formats or "containers" (e.g., paper, electronic) are to be retained. Under Ethicon's ordinary course records retention, many types of records related to its products (including but not limited to pelvic mesh products) are retained for at least the "life of production" (product) or "life of the organization" (Ethicon), including design history files (DHF's), laboratory notebooks, technical reports, labeling content, and FDA submissions.

23. This is not to say, however, that Ethicon or any other company should (or is required to) retain every document for all time.

24. The American Records Management Association (ARMA) and the International Standards Organization (ISO) both provide that, absent a legal, regulatory, historical, or other reason defined in an organization's retention schedule, information should be dispositioned when it no longer has a valid business function or purpose.

25. Ethicon's records retention policies, schedules, and other procedures encompass the above principles, providing overarching reminders that documents should not be retained past their defined retention period unless subject to a hold notice.

26. Ethicon has in place training programs and protocols to educate its employees as to record retention. New employees at Ethicon receive Records and Information Management (RIM) training. An example of a training program from 2011 is attached as Exhibit A.

27. This training provides an overview of the records and information management program, including its benefits and the risks of non-compliance. It provides detailed information regarding other issues such as (i) the lifecycle of records and information; (ii) the distinction between a record and convenience information; (iii) roles and responsibilities with respect to records and information management; (iv) managing electronic records in particular; and (v) legal holds (the last of which will be discussed further in paragraphs 40 to 43 below).

28. Ethicon's training is interactive, requiring employees to "check their understanding" of these issues as they move through the program. Employees are required to re-certify themselves on this training on an annual basis and receive reminder emails if they have not completed the training.

29. In addition to the above "ordinary course of business" practices, Ethicon took specific steps to promote appropriate record retention in connection with the commencement of litigation regarding its pelvic mesh products.

#### **Litigation Hold Notices Issued in Connection with Pelvic Mesh Litigation**

30. In April 2008, Ethicon issued to its employees a series of hold notices pertaining to pelvic mesh litigation in New Jersey, and later, in the MDL. Ethicon issued at least 12 litigation hold notices and/or reminders between April 2008 and the present. The most recent notice was sent in July 2013. I understand that another reminder hold notice will be sent shortly.

31. The first several hold notices were product-specific; each notice pertained only to one or two products at issue in a particular individual case or cases. The hold notices issued

since about 2011 have been “omnibus” in nature and address all 15 products that are at issue in this MDL. The progression of these holds is consistent with my understanding of the development of this litigation, which I understand is set forth more fully in the declaration of Benjamin M. Watson.

32. While the language in the hold notices varies slightly from notice to notice, all of the notices reflect a company that takes its retention obligations both seriously and methodically.

33. For example, the April 2008 hold notice unambiguously instructed employees, **“Do not discard, destroy, or alter in any way any”** documents – regardless of type (e.g., paper, electronic, audio/video files) – pertaining to the subject matters identified (original emphasis). It further provided that **“[f]ailure to preserve these materials could result in Court imposed penalties or sanctions on both the company and/or individual employees”** (original emphasis).

34. The litigation hold notices are broad in scope, delineating numerous categories of materials that employees must preserve regarding the products at issue, including documents pertaining to (1) Labeling; (2) Pharmacovigilance/Quality/Post-Market Surveillance; (3) Regulatory; (4) Discovery, Research and Development and Quality Engineering; (5) Product Communications; (6) Marketing and Sales Material; (7) Professional Education; (8) Manufacturing Documents and Equipment; and (9) Medical Affairs and Clinical Studies; and (10) Distribution. (See, e.g., February 18, 2011, hold notice)

35. Taking advantage of technologies that became prevalent between 2007 and 2008, Ethicon established a separate centrally-managed archive repository, which users viewed on their desktops or in their email systems as “litigation hold folders.” Employees could move or copy documents into the hold folder to easily retain them for litigation purposes. (With further

advances in technology, particularly with respect to the core mail system, the need for a separate third party repository was eliminated by 2013, as discussed in paragraph 55 below.) These litigation hold folders – as well as directives on how to use them – are described in the hold notices.

36. Ethicon and its corporate parent promoted the well-founded philosophy and practice that an individual is in the best position to understand and manage his or her information and records in the ordinary course of business and under a litigation hold, subject to employee education and oversight. Indeed, in my experience, this is the way the large organizations typically manage their legal holds.

37. Consistent with the above philosophy, use of the litigation hold folders was not mandatory, according to the Records Manager. Rather, Ethicon provided the litigation hold folders to employees as one of several retention vehicles.

38. Thus, individuals were provided the flexibility (and in fact did) manage their information and records in different ways during their employment and at their departure (e.g., using the litigation hold folders, using other folders that are retained, copying materials to a CD) that proved most conducive to business use, while complying with their obligations under Ethicon's litigation hold.

39. Because this was true both during an individual's employment and in connection with his or her departure, it may explain (as discussed further below) why some former employees had no documents attributed to them in a "custodial file."

#### **Education and Training on Legal Holds**

40. Ethicon has made an ongoing and conscientious effort to educate its employees as to their responsibilities to preserve information for litigation purposes. In addition to the

guidance regarding compliance contained in the hold notices themselves (including, in some notices, a section addressing “frequently asked questions”), Ethicon has conducted training on the hold notices.

41. As mentioned in the prior section regarding retention in the ordinary course, new employees at Ethicon receive Records and Information Management (RIM) training. This training includes materials specifically directed to developing new employees’ understanding document preservation notices.

42. For example, the 2011 training explains what a document preservation or legal hold notice is and how to read it. It then tests the employee’s understanding of compliance through an exercise. Finally, the training includes a summary discussion of the legal hold requirements. Employees are also required to complete this legal hold training on an annual basis and receive reminder emails if they have not completed the training.

43. My fact-finding revealed a widespread, albeit uneven, understanding by Ethicon employees of both the existence of pelvic mesh-related litigation hold notices and the substantive requirements of the notices.

#### **Other Procedures Affecting Record Retention**

44. Two other procedures are pertinent to Ethicon’s compliance with the retention policies and litigation hold notices discussed above.

45. Ethicon’s “North America Process Specification for Onsite Paper/Electronic Clean-up (PS-0000117)” outlines an annual systematic process for reviewing all paper and electronic company records. It provides a records review checklist to determine each document’s disposition. The first item on the checklist instructs employees to preserve the document if it has to be retained for litigation.

46. Ethicon's procedure for terminating/transferring employees (PR 553-003; attached as Exhibit B) provides that managers are responsible for instructing departing employees/contractors to review their paper and electronic files against any Preservation Notices in effect, prior to separation, using the PS-00000117 procedure. Departing employees are responsible for working with their Manager to complete the "Exit Checklist & Certificate of Compliance For Records Disposition" prior to exiting Ethicon in order to appropriately disposition their records pursuant to business requirements and active preservation hold notices. If required by the terminating/transferring employee's or contractor's/consultant's Manager/Supervisor, Information Technology representatives are responsible for obtaining the computer files and providing a copy of the materials to the Manager/Supervisor in a CD or other format.

## **VI. PRESERVATION ISSUES HAVE BEEN IDENTIFIED IN CONNECTION WITH PELVIC MESH LITIGATION**

47. Notwithstanding Ethicon's efforts documented above, during the course of pelvic mesh litigation over the past year, the parties have raised issues regarding certain individuals' compliance with litigation hold notices, as well as the efficacy of certain procedures regarding departing employees with a potential impact on record retention.

48. In April 2013, I was asked to investigate concerns regarding former sales representatives and their compliance with retention procedures and litigation hold notices. My investigation later expanded to other designated former employees.

49. Specifically, Ethicon was unable to collect and produce electronic data directly from certain former employees who had been identified as custodians of documents potentially relevant to pelvic mesh litigation. In certain cases, hard copy/paper materials were collected and produced on behalf of the individual as part of the individual's "custodial file." In other

instances, the loss of the electronic data resulted in the individual's "custodial file" containing no associated documents.

50. In connection with my fact-finding, I determined that these losses of electronic data occurred despite Ethicon's good faith efforts to ensure compliance with litigation hold notices through policies, procedures, and training. In certain rare circumstances, the electronic data was lost because the former employee misunderstood the requirements to preserve documents, notwithstanding the litigation hold notices issued. In other circumstances (and this was more frequently the case), the employee understood and properly preserved documents while working at Ethicon, but upon the employee's departure or separation from the company, his or her electronic data were not properly transferred to the company. That is, the contents of the employee's hard drive were not preserved because either the manager did not complete the close-out audit or the employee did not communicate the information to be preserved (or incorrectly assumed it would be preserved).

## **VII. ETHICON HAS TAKEN RECENT ACTIONS TO PROMOTE COMPLIANCE WITH PRESERVATION OBLIGATIONS**

51. On an ongoing basis, Ethicon examines and assesses its policies, procedures, training and technology relating to record retention, including legal hold obligations, in light of their efficacy, as well as corporate organizational structure and growth, evolving regulatory and legal requirements, technological developments, accepted best practices, and other considerations.

52. Over the past year or so, Ethicon has implemented a number of measures to secure its ability to meet legal hold obligations going forward, including certain actions that were taken in response to issues identified in connection with this MDL.



53. As to sales representatives, in December 2012, Ethicon instructed C3i, the third party vendor that manages the hardware of all sales representatives, to permanently retain all hard drive images when a sales representative separates from the company (or receives replacement equipment).

54. In addition, Ethicon took a series of steps to further educate sales representatives as to compliance with litigation hold notices. The company held a conference call encompassing approximately 150 current and former sales representatives as well as division managers during which responsibilities to comply with litigation hold notices were restated and clarified and questions were taken. I understand that another similar call is being scheduled as a further reminder.

55. Ethicon has also launched efforts to permit more centralized management and storage of documents that have traditionally resided with individual custodians. For example, in 2013, Ethicon launched Outlook Exchange 2010, which allowed emails to be saved permanently in their customary, centralized, and secure business location. Exchange 2010 removed mailbox size limits and the use of any mailbox “sweep” technology. It also removed the need (and ability) to use local PST folders to save emails that exceeded the centralized mailbox capacity.

56. Ethicon has also moved to ensure that the data of departed employees will be available for business use or collection for litigation purposes, even years after such employees have left the company. In June 2012, Ethicon began saving all hard drives of departed employees, rather than selected file/email information based on the manager’s response to the departing employee’s workflow ticket. In 2013, Ethicon modified its asset collection program such that, once an employee is terminated, a notice is automatically sent to the IT department to retrieve the employee’s company laptop. Also in early 2013, Ethicon joined the “IT Safe”

program. Under IT Safe, once a former employee's laptop is retrieved, that individual's hard drive is shipped to the IT shared services ("ITSS") group for imaging, and all data on the hard drive is preserved.

57. In addition, Ethicon has centralized monitoring of the departure process within the human resources department (HR). Generally, HR will have oversight of the managers and supervisors working with departing employees to confirm managers' awareness and execution of the policies and procedures associated with the departure process, including with respect to departing employees' data.

#### **VIII. RESPONSES TO SPECIFIC FACTUAL ALLEGATIONS IN PLAINTIFFS' BRIEFS**

58. I have been asked to review and respond specifically to certain factual allegations set forth in Plaintiffs' Memorandum of Law and supplemental submission.

59. Plaintiffs incorrectly suggest that a 2002 audit and 2007 CAPA demonstrate that Ethicon's preservation procedures were inadequate. However, as described above, the purpose of the CAPA was to align a formal records program for Ethicon with corporate standards on an ongoing basis. Despite the shorthand description in the CAPA, my fact-finding showed that the CAPA did not take issue with Ethicon's ability to *preserve* relevant information in the case of litigation, including this litigation. Further, the CAPA had nothing to do with pelvic repair documents in particular.

60. Plaintiffs in their briefs specifically identify 22 current or former Ethicon employees about whom Plaintiffs claim retention issues.

61. As an initial matter, well over half of the individuals identified (13 of the 22) – Rick Isenberg (departed 2002), Gregory Jones (departed 2003), Amy Godwin (departed 2004), Charlotte Owens (departed 2005), Sean O'Bryan (departed 2005), Laura Angelini (departed

2005), Kendra Munchel (departed 2005), Zenobia Walji (departed 2005), Jill Schiaparelli (departed 2005), Patricia Hojnoski (departed 2006; returned in 2008 as contract employee with limited administrative responsibilities for one year), Cheryl Bogardus (departed 2007), Allison London Brown (departed 2007), and John Clay (departed 2007) – departed Ethicon before Ethicon issued its April 2008 hold notice.<sup>1</sup>

62. It should be expected that these 13 individuals who departed the company prior to the commencement of these cases and the issuance of a legal hold (and many years before custodial collections were conducted) would have few, if any, documents attributed to them in a “custodial file.”

63. Five other individuals – Renee Selman, Ramy Mahmoud, Jennifer Paine, Price St. Hilaire, and Tom Divilio – departed the company prior to the consolidation of the New Jersey litigation in 2010.<sup>2</sup>

64. Plaintiffs’ claims about the numbers of documents in the “custodial files” of all 22 individuals also fall flat for the independent reasons explained below.

65. In this declaration, I have alluded to the term “custodial file.” It has also been used, in a different context, by Plaintiffs in their brief. The term “custodial file” is properly understood as an organizational and workflow concept in the context of document productions in

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<sup>1</sup> Based on my review of pertinent deposition testimony and personnel files, Plaintiffs mischaracterize the Ethicon tenures and/or pelvic mesh involvement of a number of these 13 individuals. Amy Godwin worked at Ethicon only until 2004; her position in 2007 as “Director of Trial Operations” referenced by Plaintiffs was with an entirely different company – Ortho Biotech. Plaintiffs also incorrectly suggest that Kendra Munchel was Global Marketing Manager of Ethicon from 2005 to 2007; in fact, that position was with Advanced Sterilization Products. In 2005, Laura Angelini left Ethicon for Ethicon Endo-Surgery, which was not involved with pelvic mesh products; thus, when she was “re-hired in the same position” a few weeks after “quitting” in 2005, it was at Ethicon Endo-Surgery. Likewise, while Plaintiffs describe Zenobia Walji as “Worldwide Director, Strategic Planning, 2009-2012,” that position was with Ethicon Endo-Surgery. Ms. Walji’s involvement with Ethicon and pelvic mesh ended more than 8 years ago. Jill Schiaparelli also transferred out of Ethicon to Ethicon Endo-Surgery, and did so in 2005, not 2007, as Plaintiffs claim.

<sup>2</sup> Notably, Jennifer Paine left Ethicon a full year before Plaintiffs say - in December 2008, not 2009.

litigation; that is, it can and should be understood as containing documents that have been collected directly from a particular individual.

66. Plaintiffs' use of the term "custodial file" to suggest that it represents all of the information or documents contributed by that individual to a litigation is misplaced. As explained below, the reliance on the term "custodial file" in that context is based on a misconception of the manner in which individuals create, manage, transmit, and share information and documents in a modern corporate environment, such as within Ethicon.

67. In a modern corporate environment, technology infrastructure is increasingly designed to encourage users to create and manage documents and information in centrally stored and managed locations, such as Microsoft SharePoint sites, group or department shares, databases, and other electronic systems, rather than on a drive to which only a single user has access.

68. The above is true of Ethicon. Indeed, as discussed at the beginning of this declaration, the key design, regulatory, marketing, complaints and other post-market surveillance documents regarding the pelvic mesh products at issue in this MDL are maintained centrally at Ethicon, and have been collected and produced, apart from any "custodial files."

69. Further, the use of central filing locations such as L drives by many workgroups and associated individuals indicates that even drafts or non-final work product of a particular individual may be stored in that shared location, and therefore be available for collection, although not necessarily always attributable to that individual for collection and production purposes.

70. In addition, given the collaborative working environment of Ethicon and the fact that emails necessarily have both a sender and a recipient (or recipients), many documents of a

custodial nature that are in the possession of one individual are also likely to be in the possession of other individuals, some of whom may work in the same functional or subject matter area.

Plaintiffs in their brief complain that the “custodial files” of various individuals contained no or very few documents. But in fact basic searches of names and/or email addresses show that substantial numbers of email communications and attachments to or from each of the 22 individuals cited by Plaintiffs have been produced in the MDL and can be located within the production. These emails are identified on the schedule below:

<b><u>Identified Individual</u></b>	<b><u>Approx. number of produced emails and attachments to/from Identified Individual</u></b>
Renee Selman	8,503
Ramy Mahmoud	3,013
Charlotte Owens	3,664
Sean O'Bryan	4,951
Laura Angelini	4,190
Jennifer Paine	4,632
Price St. Hilaire	17,125
Cheryl Bogardus	5,520
Greg Jones	1,299
Rick Isenberg	1,618
Patricia Hojnoski	3,800
Jill Schiaparelli	3,586
Paul Courts	706
Troy Mohler	2,375
Allison London Brown	14,651

John Clay	984
Kendra Munchel	2,619
Tom Divilio	2,208
Amy Godwin	1,665
Susanne Landgrebe	8,415
Zenobia Walji	5,578
Nancy Leclair	4,430

71. Because of the way individuals in a modern corporate electronic environment create, manage, transmit and/or share information and documents, even assuming perfect compliance with litigation hold procedures, it is very unlikely that any “custodial file” would ever include all documents created or received by that custodian. Unlike a broker-dealer workplace, in which email “journaling” is mandated for regulatory compliance purposes, Ethicon, like other corporate email users that do not journal, could not possibly perfectly capture every email. However, like other medical device companies, Ethicon has policies and procedures to preserve emails that are classified as part of its regulatory framework, regardless of legal hold status. Indeed, as mentioned above, centralized collections of materials like the Design History File and 510(k) files contain emails, and it is not disputed that Ethicon has produced to Plaintiffs those centralized collections, including emails.

72. There are many sources of an employee’s documents, only one of which is his or her “custodial file.” This is particularly true for custodians who have departed the company prior to collection. Indeed, the concept of a “custodial file” as applied to a former employee is a

misnomer, as the documents of the former employee typically are transferred or moved to the custody of someone other than the former employee who has departed.

73. Thus, even where an individual's "custodial file" does not contain any documents, as shown above, it is possible (and in fact is the case here) that substantial numbers of that individual's documents (including email communications) have been collected and produced, from file shares, databases, and other enterprise electronic systems, as well as from other individuals' "custodial files."

74. In addition to the above, other findings from my investigation also fail to support the notion that documents "missing" from particular individuals' "custodial files" were necessarily relevant. To the contrary, as explained below, Ethicon's collection methodology was designed to maximize the production of relevant materials from multiple sources.

75. As an initial matter, Ethicon's collection process has several layers of built-in redundancies. Ethicon's collection included both central sources and custodians, and as to custodians, multiple individuals within functional areas were targeted for custodial collection.

76. For example, while it is true that fewer than 2,000 documents were produced as part of the "custodial file" of one of the more than 35 individuals working in the area of marketing on whom custodial collections were performed (Laura Angelini), more than 330,000 documents were produced in the "custodial files" of other individuals employed in a marketing capacity, not to mention the marketing documents produced from central, group, or shared sources. Plaintiffs' presumption that key marketing documents were lost simply does not follow from the observation that Laura Angelini's "custodial file" contained fewer documents than they might have expected.

Likewise, the “custodial file” of Charlotte Owens, who worked in Medical Affairs, contained no documents. But more 280,000 documents numbering more than from 20 other custodians employed in a medical or clinical capacity have been produced.

77. These redundancies should also be considered in evaluating Plaintiffs’ complaints about John Clay. John Clay was merely one of more than 15 different individuals working in Regulatory Affairs who was identified for custodial collection and, unlike several other of those individuals, he has not been deposed in either a corporate representative or individual capacity. Voluminous regulatory materials have been produced in connection with other “custodial files,” not to mention central source materials.

78. Indeed, the redundant processes that Ethicon has built into its document collection is further demonstrated by looking at the collection and production history of two emails:

- a. Exhibit C to this declaration is an email from a Professional Education Manager to several recipients, including Price St. Hilaire, announcing a cadaver lab training course for surgeons. Although this email was not collected directly from Price St. Hilaire, *it was collected from eight other custodians* and produced to Plaintiffs.
- b. Likewise, Exhibit D is an email from Brian Luscombe, the United States Product Director for Pelvic Reconstructive Surgery, to several recipients, including Paul Courts and Troy Mohler, providing meeting minutes to the Incontinence & Pelvic Organ Prolapse Brand Team. Although this email was not collected directly from Paul Courts or Troy Mohler, *it was collected from 15 other custodians* and produced to Plaintiffs.



79. These two emails were not “lost” simply because they were not associated with the “custodial files” of Mr. St. Hilaire, Mr. Courts, or Mr. Mohler. To the contrary, each of these emails was collected from numerous other custodians and were produced to Plaintiffs. Plaintiffs can see the content of each of these emails. Plaintiffs can also see that the first email was sent to Mr. St. Hilaire, among others, and that the second email was sent to Mr. Courts and Mr. Mohler, as well as other individuals. In short, Plaintiffs already have the same information regarding these emails that they would have had in the event that Ethicon has associated the emails with the “custodial files” of Mr. St. Hilaire, Mr. Courts, and Mr. Mohler.

80. Plaintiffs in their brief indicate that the production of small numbers of documents in the custodial files of certain individuals means that relevant documents must have been lost. Based on my investigation, this suggestion is unfounded as applied to a number of the individuals Plaintiffs identified.

81. First, Plaintiffs’ suggestion is particularly unfounded with respect to current and former sales representatives. I spoke with a number of different sales representatives in the course of my investigation and each emphasized that the role of a medical device sales representative at Ethicon is not document-intensive.

82. Accordingly, it is unsurprising to me that, as compared to non-sales representative employees, relatively few documents were directly collected from sales representatives such as Paul Courts and Troy Mohler (who have been identified by Plaintiffs), and relatively few documents determined to be relevant were produced as part of their respective custodial files. Nevertheless, it should be noted that the “custodial files” of Mr. Courts and Mr. Mohler each contained hundreds of documents.

83. Further, as to Troy Mohler in particular, he testified unequivocally that he read, understood, and complied with Ethicon's record retention policies and legal hold notices and did not destroy any documents that should have been preserved. To the contrary, he testified that he provided his documents to Ethicon upon his departure. These documents included marketing, training, and professional education materials which would have been produced from central sources, such as Blue.

84. In addition, my fact-finding regarding other individuals specifically identified by Plaintiffs (including interviews with such individuals and/or review of sworn testimony) undercuts the presumption that these individuals would have had significant volumes of documents relevant to pelvic mesh litigation that cannot be located from other sources, for example:

- a. Renee Selman – Ms. Selman testified that, due to her position, she was not the author of many documents and that such documents likely would be associated with other individuals' "custodial files."
- b. Tom Divilio – Mr. Divilio had little to no involvement with pelvic mesh products. At most, he may have had minimal involvement in 1998-1999 before any hold notices related to pelvic mesh products were issued.
- c. Greg Jones – As worldwide director of Regulatory Affairs and Quality Assurance for Gynecare, Mr. Jones supervised project managers who were primarily responsible for document-intensive tasks, such as the creation of regulatory submissions. Moreover, while Plaintiffs state that Mr. Jones "kept electronic copies" of 510(k)s and FDA correspondence – incorrectly implying that such documents were somehow unavailable to Plaintiffs by

virtue of them not being associated with Mr. Jones's "custodial file" – relevant 510(k)s that would include such materials have been produced from the appropriate central sources of record.

- d. Susanne Landgrebe – Ms. Landgrebe was involved in the research and development of pelvic mesh products up to approximately 2005. In 2009, Ms. Landgrebe's hard drive crashed, and she was issued a new computer. Since she would have lost any relevant electronic documents at the time of the crash, it is unsurprising that her "custodial file" has a small volume of materials.

85. Finally, in my fact-finding, I did not identify a single instance in which an Ethicon employee selectively and intentionally destroyed documents known to be relevant to the pelvic mesh litigation.

86. Rather, any losses of data were attributable to some type of misunderstanding by an employee and/or a miscommunication between a departing employee and his or her manager.

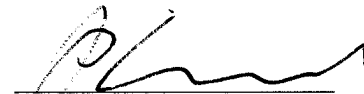
87. This is true of the disposition of Ms. Selman's hard drive. As Plaintiffs themselves acknowledge, Ms. Selman was aware of the litigation hold and complied with it during her time at Ethicon. The loss of her data occurred when she and those who were responsible for her materials upon her departure failed to identify to IT the need to retain her data in connection with applicable legal holds. Rather, they incorrectly assumed that the data would be held even in the absence of their identifying that need.

88. These misunderstandings and miscommunications led to losses of data that were not at the custodian's discretion – there was no deletion of specific emails, email folders, or documents regarding any particular subject matter.

89. Moreover, as demonstrated above, it is reasonable to expect that the vast majority of any relevant documents not found in a particular individual's custodial file were collected and produced from central sources and/or other individuals' "custodial files."

I represent that the foregoing statements are true under the penalties of perjury.


Dated: January 10, 2014




  
James P. Mittenenthal

# **Exhibit A**



Records and Information Management Training - Windows Internet Explorer


**Records and Information Management Training**






### Introduction

#### Course Objectives

Upon completion of this course, you will be able to:

- Understand the Worldwide Records and Information Management program requirements
- Describe the main components of a Records and Information Management program
- Define what a record is and explain the guidelines for creating a record
- Describe the roles and responsibilities involved with Records and Information Management
- Identify what determines whether information is a "record" or whether it is "Convenience Information"
- Follow the guidelines for managing electronic records such as Microsoft Word or Excel documents, e-mails, and documents stored on portable external media such as "jump drives" or CDs
- Follow the proper steps to comply with a Document Preservation Notice
- Interpret and apply the Records Retention Schedule
- Learn the definition and rules for a Records Clean-Up Event
- Understand how to identify and protect a Vital Record
- Understand your role in participating in Records Compliance Audits







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Records and Information Management Training - Windows Internet Explorer


**Records and Information Management Training**


### Introduction

#### What is Records and Information Management?

Records and Information Management, also known as RIM, is concerned with the management of a record's lifecycle from its creation through its use, to its final disposition. The [Worldwide Records and Information Management \(WWRIM\) Policy](#) applies to all of Johnson & Johnson and conveys the overarching requirements related to managing records and information at Johnson & Johnson.

The policy is supported by standards and your local Operating Company procedures – by following your Operating Company's RIM procedures and complying with the WWRIM Policy, you will know how to properly manage your records and information during daily business, and in the case of legal action against the company.

Proper Records and Information Management assures the records we create are authentic, reliable, and useable in supporting the business functions and activities of the company for as long as they are required.



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**Records and Information Management Training**

### Introduction

#### Benefits of a Record and Information Management Program

Some of the main benefits of a strong Records and Information Management (RIM) program include:

Having greater control over the volume and growth of records
 Reducing costs by actively managing records
 Improving overall efficiency
 Showing evidence of compliance with legal and regulatory requirements
 Safeguarding the company's Vital Records and information

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Records and Information Management Training - Windows Internet Explorer

**Records and Information Management Training**

### Introduction

#### Risks of Non-Compliance

Every employee shares legal responsibility for handling records in compliance with Records and Information Management (RIM) requirements as spelled out in the policy, standards, and Operating Company procedures. By not following these requirements, we risk negatively impacting the company and ourselves.

The risks include:

- Damage to company reputation
- Severe fines and penalties
- Imprisonment

#### Company President Sentenced for Intentionally Destroying Documents

...the president of the company, who was found guilty of intentionally destroying documents, was sentenced to prison for 18 months and fined \$1 million.

#### Company Records Illegally Shredded Before Court Hearing

...the company was found guilty of shredding records before a court hearing, resulting in a \$5 million fine and a permanent injunction against future violations.

#### HealFast Fined \$25 Million for Missing Documentation


...HealFast was fined \$25 million for failing to maintain proper documentation, which led to significant delays in regulatory compliance.


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**Records and Information Management Training**




### Introduction

#### Records and Information Management Program

The Records and Information Management (RIM) program within the Johnson & Johnson Family of Companies is comprised of a series of requirements (the Policy and Standards) and the instructions on how to implement those requirements (the Operating Company RIM Procedures).

The Policy, Standards, and Operating Company RIM Procedures address the following functions of Records and Information Management:

- Managing the full lifecycle of a [Record](#): Creation, Use and Retention, Storage, and Final Disposition
- Understanding the concept of [Convenience Information](#)
- Developing and maintaining the [Records Retention Schedule](#)
- Coordinating litigation support, including [Document Hold or Document Preservation](#) procedures
- Protecting [Vital Records](#)
- Conducting [Records Clean-Up Events](#)
- Managing Records of Departing Associates
- Training on Records and Information Management
- Conducting Records Compliance Audits
- Managing of Electronic Records





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**Records and Information Management Training**



### Introduction

#### Lifecycle of Records and Information

Records and information have a lifecycle – that is, they are created, they are used, they are retained as appropriate, they can be stored while waiting for their retention times to be met, and they are disposed of at the end of their lifecycle.


Records and Information Management (RIM) provides a framework for managing records and information throughout all phases of the lifecycle.

For example, the Records Retention Schedule, which is essentially a listing of record types and the amount of time those records must be kept in order to comply with business and legal requirements, is a tool used to help manage the retention and storage phases of the record's lifecycle.

To help with storage of records which have not yet met their retention times but which aren't used on a daily basis, the Operating Company RIM department offers an inactive records storage service.

Finally, records and information do eventually reach a state of final disposition. Often this final disposition involves a controlled destruction of the record after it has met all of its lifecycle (and legal) requirements. However, sometimes a record's final disposition at any given point of review will be an indefinite retention due to ongoing legal or regulatory requirements.

We'll learn more about some of these topics later in the course, but right now we'll begin with a description of what is considered a "record".







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**Records and Information Management Training**


### Records and Convenience Information


#### Records

We create records every day.

Records are recorded information, regardless of medium or characteristics, created or received by an organization in meeting legal obligations or in transacting business. That is, records can exist in a paper form, such as a paper calendar book, in electronic form, such as an email message or file on a CD, in film form, such as a video tape, and many other forms.

Company records are considered valuable assets. As an associate, you are accountable for the records you create and receive. If you do not comply with Records and Information Management requirements, you may be subject to disciplinary action including, but not limited to, employment termination and criminal or civil liability.




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**Records and Information Management Training**





### Records and Convenience Information

#### Check Your Understanding

Here are some common pieces of information you may come across during the normal course of business.

Which of the following are considered records? Check the ones that apply.




- ☒ A. Online calendar
- ☒ B. Electronic invoice for vendor services
- ☒ C. "Sticky" notes, or other handwritten notes, attached to a formal document
- ☒ D. Audio recording of a meeting
- ☒ E. Word document containing meeting minutes
- ☒ F. Graphic of the company logo
- ☒ G. Videotape of meeting
- ☒ H. E-mail discussing project spending

Incorrect. All of the items listed are considered to be "records".







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Records and Information Management Training

### Records and Convenience Information

#### Convenience Information

Although the majority of the information we create or use is considered a record, there is a type of information that is not classified as a record. That information is referred to as Convenience Information.

Convenience Information is defined as information that may be used or exists within Johnson & Johnson but which will not further Johnson & Johnson's business.


An example of Convenience Information is a newspaper.

We may receive many newspapers or magazines in our company but they are not considered records and therefore different retention rules apply when determining how long to keep Convenience Information.

While information that is considered a record must be retained according to the Records Retention Schedule and any Document Preservation Notices, Convenience Information can be disposed of after it is no longer of use. However, it must be retained (even after it is no longer of use) if there is a Document Preservation Notice in place related to that Convenience Information.

The following types of information are also considered Convenience Information:

- Magazines, trade journals, catalogs, newspapers
- Transitory correspondence—correspondence used for some internal communications, like mass announcements regarding closures of the cafeteria, or to communicate meeting logistics, etc.
- Duplicate copies of a record—the exact duplicates, with no additional notes attached, are considered Convenience Information
- Personal working files, such as drafts of documents for which a final version of that document exists (however, the final version of the document is considered a record)
- Unused templates or forms that have not been filled out




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### Records and Convenience Information

#### Check Your Understanding

It's important to be able to distinguish between records and Convenience Information. Making this distinction has an impact on how long you need to retain information and when you can discard it. Records must be retained according to the Records Retention Schedule and any Document Preservation Notices. Convenience Information can be disposed of after use, as long as it is NOT the subject of a Document Preservation Notice.

Read the cards carefully. If you think the information is considered a record, then drag and drop the card to the record category. If you think the information is considered Convenience Information, then drag and drop the card to the Convenience Information category.


**Record**


You're conducting a training class for your department. You photocopy a blank sign-in template. After the class, you receive the sign-in sheet signed by all the participants. Is the sign-in sheet a record or Convenience Information?

**Convenience Information**

The Project Manager has made too many hardcopies of the status update she distributed at the team meeting. She has 20 exact copies of the status update left over. Are these copies considered records or Convenience Information?

Nice job! When the participants signed the sign-in sheet, the document became a record. When a form or template is written on or filled out, it becomes a record and is no longer considered Convenience Information.






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## Roles and Responsibilities


### Everyone has a Role

Each of us has a responsibility to manage company records according to Records and Information Management policy and standards. Some of us have specialized roles in addition to our employee responsibilities.


Do you know what your role is? Let's see what these employees have to say about their role in Records and Information Management.




Records Manager



Records Coordinator




J&J Law Department



### Supervisor



Hi, I'm the supervisor for a department that has both employees and contractors. I'm responsible for ensuring my direct reports have the opportunity to learn and practice good records management.

I also ensure that any associates leaving my department have managed and handed off their records according to procedures before they leave the department. If the associate doesn't address his or her records prior to departure, as the supervisor I am responsible for taking on this task. Also, as a sponsor for several contractors, I'm responsible for ensuring that a departing contractor hands off all of their company records to me prior to their departure.



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## Roles and Responsibilities

### Your Role

You've learned the specific roles involved in Records and Information Management (RIM), but remember that YOU also play a very important role.

You create records or receive records during everyday business, and it's your responsibility to:

- Comply with all Records and Information Management (RIM) policy, standards, and procedures
- Review your records at least once a year
- Retain records required for litigation, audit, tax, or regulatory investigation
- Discard records no longer needed for the business in accordance with RIM procedures and local company Records Retention Schedule

When you leave your company, you must transition all paper and electronic records for which you are responsible to your manager or supervisor as instructed by your company's procedures.





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**WWRIM**  
Worldwide Records & Information Management

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### Managing Electronic Records

**Content is Key**

Records Management requirements apply to the content of a record, not to the media on which it resides. This means that regardless of whether a record is paper, electronic, or film-based, it is the content of the record that determines how that record is retained.

For example, an official meeting agenda that is stored electronically as a Word document on your network share drive is retained the same amount of time (and is subject to the same legal requirements) as if the official meeting agenda were printed on paper.

Further, e-mails also have retention times based on their content. So it is a good practice to limit the number of topics you "discuss" on a single e-mail as that will make it easier to determine the content of that e-mail and classify it according to the Records Retention Schedule.





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Worldwide Records & Information Management

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### Managing Electronic Records

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### Managing Electronic Records

#### Retention Time for E-Mails

E-mails that contain content on multiple topics will need to be retained based on the content that has the longest retention time.

For example, an e-mail is used to discuss two different topics: Topic 1 "talks" about the project plan for upgrading to an electronic store ordering system, and Topic 2 "talks" about the tax implications of buying a new building. In this situation, although the retention for the content around Topic 1 (upgrading the system) may be 5 years, the retention for the content in Topic 2 (buying a new building) is at least 10 years; therefore, this e-mail must be retained for at least 10 years to ensure the content with the longest retention time meets its retention requirements.

Also, Document Preservation Notices apply to records on all types of media – electronic, paper, and film-based, etc. – unless otherwise noted on the actual Preservation notice. So using the example above regarding the e-mail containing a discussion of two different topics (project plan for the electronic store ordering system and tax implications of buying a new building), if you received a Document Preservation Notice related to any records pertaining to buying the new building, you would need to retain this entire e-mail according to the instructions listed on the actual Document Preservation Notice.


**From:** Mary Lamb  
**Sent:** Thursday, December 10, 2009 2:49 PM  
**To:** John Doe  
**Subject:** Some news on 2 different topics

**Topic 1**

Here is an update on the Electronic Store Ordering System - we need to have another meeting with the vendor to discuss the timing of the final product.



I also have some news regarding buying the old building on Main Street to house our over stock of widgets. We've analyzed the situation and have decided that it makes sense to buy this building both from a tax perspective and to address an immediate business need to store our overstock of widgets.


*Mary Lamb*



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Records and Information Management Training

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### Document Preservation Notice

#### What is it?

During the course of business your company may be involved in litigation or government inquiries. These cases often require the company to produce records related to the case. In these instances, the J&J Law Department will instruct the company Records Manager to send out a Document Preservation Notice, also called a Document Hold Notice.

The Document Preservation Notice describes specific records that must be kept, even if they would otherwise be destroyed. For example, Convenience Information can't be destroyed if it is relevant to a Document Preservation Notice.

When you receive a Document Preservation Notice, you are required to comply with the request. Be sure to read all sections of the Document Preservation Notice carefully!

It's also important to note that you will receive Document Preservation Notices only from your Records and Information Management (RIM) department. On some rare occasions you may receive the notice directly from the J&J Law Department. However, if you have obtained a Document Preservation Notice from someone other than your company's RIM department or the J&J Law Department, please contact your Records Manager immediately.

In addition, only your RIM department, and on rare occasions the J&J Law Department will notify you when a Document Preservation Notice has been released and is no longer active.

**J&J LAW DEPARTMENT  
DOCUMENT PRESERVATION  
NOTICE  
DO NOT DESTROY  
SPECIFIED DOCUMENTS**

[Note: For a comprehensive list of hold notices that pertain to your company or J&J headquarters department, please visit the following website: <http://documenthold.jnj.com> and select the appropriate operating company or corporate department.]

June 01, 2008


**RE: Hold Notice for XXX v. YYY, Inc. et al.**  
Matter No.: J12008

Company XXX, Inc. has filed a declaratory judgment action seeking to invalidate Company YYY's U.S. Patent No. 3,333,333.

In connection with this matter, it is vital to preserve all documents relating in any way to the below listed subject matters (attached as Exhibit A) until contrary written notice is received from the J&J Law Department. Failure to preserve these materials could result in Court imposed penalties or sanctions on both the company and/or individual employees.



Do not discard, destroy or alter in any way any of the documents (electronic or paper) described below. Please ensure that these instructions are followed.


Please save and preserve all documents in categories described below, including emails and attachments, drafts, letters, memos, notes (handwritten or typed), reports and tables (either printed or on the computer), slides or other graphics, data stored on computer, mobile or other devices, "hardcopies" or other printed matter, notes, memos and



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**Records and Information Management Training**

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### Document Preservation Notice

How to Read a Document Preservation Notice

A Document Preservation (Hold) Notice is composed of three sections:

1. Title and Explanation of Action
2. Compliance Caution and Preservation Instructions
3. Specific Categories or Documents to be Preserved

Click the **Begin** button to explore the Sample Document Preservation Notice.

HEALFAST LAW DEPARTMENT  
DOCUMENT PRESERVATION  
NOTICE  
DO NOT DESTROY  
SPECIFIED DOCUMENTS

January 15, 2007

RE: Hold Notice for *Garsino v. HealFast, Inc.*

HealFast is party to a lawsuit involving HealFast's Cling-Care adhesive bandage. In connection with this matter, it is vital to preserve all documents relating in any way to the below listed subject matter until contrary written notice is received from the HealFast Law Department. Failure to preserve these materials could result in Court imposed penalties or sanctions on both the company and/or individual employees.

Do not discard, destroy or alter in any way any of the documents (electronic or paper) described below. Please ensure that these instructions are followed.

Please save and preserve all documents in categories described below, including e-mails and attachments, drafts, letters, memos, notes (handwritten or typed), reports and tables (either printed or on the computer), slides or other graphics, data stored on computer, audio or video tapes, "working" or other personal files, notes, guidelines and procedures and minutes. Documents must be maintained even if known to be duplicates of documents held by other persons or you, and even if the duplicate has notes or handwritten comments on it.

"Document" includes all written materials, including all drafts as well as finalized documents, all e-mails and other electronic media (computer files), and all other types of recorded information such as audiotapes, video tapes, etc.

Hold all documents, memoranda, notes, files, e-mails, etc. relating to Cling-Care adhesive bandages as follows:

1. Consultants and Advisors: All communications, evaluations, agreements, memos, budgets, payments, other financial information, proposals, notes or other documents pertaining to consultants or advisors involved with Cling-Care, whether or not retained or otherwise compensated by the company.
2. Corporate documents: Organizational charts, document retention protocols, minutes and reports for Board of Directors, other executive and management meetings and employee quarterly meetings in which Cling-Care is addressed.
3. Litigation documents: Hold notices and other instructions pertaining to Cling-Care documents, communications regarding Cling-Care legal actions or claims, all communications regarding same.
4. External Communications: All documents, including drafts, pertaining to Cling-Care press releases, media responses and other statements, Q&As, correspondence, company position papers, and review, analysis, discussion or other communications pertaining to the media or public dissemination of information; shareholder documents regarding Cling-Care.
5. Internal Communications: All documents, including drafts, pertaining to Cling-Care products employee notices, corporate or departmental bulletins, briefings, Q&As, statements, reports, and meetings.
6. Product Communications: All documents pertaining to dear doctor letters, communications with health care professionals or patients including written responses to product inquiries and attachments, telephone logs or other records or communication files dealing with this incident, plaintiff or event including documents pertaining to records of plaintiff's complaint and incident, if known, and the product actually involved, if removed or available. Also included should be bibliographies, abstracts, reprints, literature search requests, search results, product complaints, investigations, correspondence and testing of the product at issue.

Hold all documents, memoranda, notes, files, e-mails, etc. relating to Cling-Care adhesive bandages as follows:

1. Consultants and Advisors: All communications, evaluations, agreements, memos, budgets, payments, other financial information, proposals, notes or other documents pertaining to consultants or advisors involved with Cling-Care, whether or not retained or otherwise compensated by the company.
2. Corporate documents: Organizational charts, document retention protocols, minutes and reports for Board of Directors, other executive and management meetings and employee quarterly meetings in which Cling-Care is addressed.
3. Litigation documents: Hold notices and other instructions pertaining to Cling-Care documents, communications regarding Cling-Care legal actions or claims, all communications regarding same.
4. External Communications: All documents, including drafts, pertaining to Cling-Care press releases, media responses and other statements, Q&As, correspondence, company position papers, and review, analysis, discussion or other communications pertaining to the media or public dissemination of information; shareholder documents regarding Cling-Care.
5. Internal Communications: All documents, including drafts, pertaining to Cling-Care products employee notices, corporate or departmental bulletins, briefings, Q&As, statements, reports, and meetings.
6. Product Communications: All documents pertaining to dear doctor letters, communications with health care professionals or patients including written responses to product inquiries and attachments, telephone logs or other records or communication files dealing with this incident, plaintiff or event including documents pertaining to records of plaintiff's complaint and incident, if known, and the product actually involved, if removed or available. Also included should be bibliographies, abstracts, reprints, literature search requests, search results, product complaints, investigations, correspondence and testing of the product at issue.



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### Document Preservation Notice

Check Your Understanding

Nice job! Even though this document shows other products' sales figures, it does mention HealFast Cling-Care adhesive bandages.



**Retain**




**Sales Report  
(Excel Doc)**




Instructions    Document Preservation Notice

**Destroy**







**Lunch Invite  
(E-mail)**



Click **Next** to continue.

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**Records and Information Management Training**


### Document Preservation Notice

**Summary**


Remember, the records referred to in a Document Preservation Notice must be held and not destroyed. If a record is not related to a Document Preservation Notice, you will follow its normal Records Retention requirements, which you will learn about in the next section of this course. Your RIM department will notify you if a Document Preservation Notice is no longer active.




Remember, only your Operating Company's RIM department or on rare occasions, the J&J Law Department, will notify you if a Document Preservation Notice is in effect or no longer in effect. If you receive notification about Document Preservation Notices from any other source, notify your Record Manager immediately so they can verify it and provide accurate direction.

*Loading, please wait...*


Click **Next** to continue.

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**Records and Information Management Training**

### Records Retention

**Keep or Discard?**


The life cycle of a record is identified by its retention period.


The retention period is the period of time that a record must be maintained by an organization because it is needed for operational, legal, fiscal, historical, or other purposes.

At the end of the retention period, a record can be discarded unless there is a Document Preservation Notice in place related to the record. Courts may view improper destruction of records as a deliberate attempt to obstruct justice or conceal harmful information.

Your company documents the retention period of records using a Records Retention Schedule. In this section, you will learn how to interpret a Records Retention Schedule and use it to correctly maintain your records.

Records retention times often vary by country and jurisdiction due to differing legal requirements. It is important when using your company's Records Retention Schedule to ensure you are referring to the retention times associated with your country.




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### Records Retention

#### Records Retention Schedule

Let's see the description of each heading before looking at the Records Retention Schedule.

Category	Record Title	Record Description	Trigger Event	Required Retention Period	Total Retention
This column indicates the functional category the records reside in.	The Record Title indicates the name of the record. It may define one type of document or a collection of different documents that are related but share a common retention period.	The Record Description further defines the Record Title. It may also list similar records with the same retention period that are covered by the Record Title.	The <u>Trigger Event</u> is an event or situation which, once it has occurred, "triggers" the start of the Required Retention Period.	The Required Retention Period is the amount of time the record needs to be retained after the trigger event occurs or is met. This period is usually displayed in years.	Total Retention indicates the total length of time the company retains the record. It encompasses the time the record is retained up to the trigger event plus the required Retention Period after the trigger event has occurred.
For example Administration	For example Calendars	For example Books and/or calendars (paper and electronic) recording daily activities and appointments	For example CY	For example 2	For example CY+2


Click to view an example of the [Records Retention Schedule](#)



Click each column header. Then click Next.




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### Records Retention


#### Trigger Event Code Legend

Trigger codes are used in a Retention Schedule to abbreviate a specific date, occurrence, or length of time used to calculate a record's retention period.

Once the trigger event has occurred, the identified retention period (in years) begins.

For example, many record types have a Retention Period of CY (Current Year) + a number of years. In this example, the trigger is the Current Year when the record is created or received - after the Current Year has passed, the number of years in the Retention Period begins.


Trigger Event Code	Title of Trigger Event Code	Description of Trigger Event Code
ACT	Active	The retention period does not commence running while the document is active, in force or in use, for example a contract
BA	Batch Expiry	The retention period does not commence running until the date of batch expiry
CY	Current Year	Indicated the year the record was created
FTA	Until Final Tax Audit	Maintain until final tax audit is completed and records are released by the Johnson & Johnson Tax Department.
IND	Indefinitely	The document is kept indefinitely
LAS	Life of Affected System	The retention period does not commence running until the equipment, system or facility to which it relates is taken out of service
LO	Life of Organization	The document is kept for the life of the organization
PL	No Longer in Production	The retention period does not commence running until the product is no longer in production
SUP	Until Superseded	The retention period does not commence running until the document is superseded by a later document or version
TE	Termination of Employment	The retention period does not commence running until the termination of the employee to which it relates



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### Records Retention

**Check your Understanding**

A record can be destroyed on January 1 of the year after the end of its total retention period.  
For example:

You have a record that has a total retention period of CY + 10 (that is Current Year + 10 years).


If the record was created in 2003, then CY (Current Year) = 2003.  
2003 + 10 years = 2013

That means the Total Retention Period for this record ends at midnight, 31 December 2013 (31/12/2013).


You can destroy this record beginning on 01 January 2014 (01/01/2014), providing it is not relevant to a Document Preservation Notice.

Let's try a few examples:  
A record was created in 1999.  
It has a Total Retention Period of CY + 9.


? When is the last year of that record's total retention period? (Note: Enter the year in **YYYY** format)

 Incorrect. CY+9 refers to the year the record was created plus 9 years. So the last year of the record's Total Retention Period is 2008.

? What is the earliest date that the record can be destroyed? (Note: Enter the date in **DD/MM/YYYY** format)


 Incorrect. The earliest you can destroy the record is January 1, 2009 (01/01/2009).

*For example: 01/12/2008 for December 1, 2008*






Click **Next** to continue.

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### Records Retention


**Check Your Understanding**

It's Records Clean-Up Event week. Records Clean-Up is an event designated by your company to provide associates a dedicated time to review and discard any records that no longer need to be maintained.

All associates are responsible for participating in their company's Records Clean-Up Event. You must look through all of the records you're responsible for and decide whether you need to retain them.

Click the **Begin** button. After clicking the Begin button, follow the steps below when determining whether the records should be destroyed or not.

1. Read the Document Preservation Notice by clicking on its icon.
2. Read each item by clicking on it.
3. If you decide that the item should be destroyed because it is not related to a Document Preservation Notice AND because it has met its total retention time, drag the item to the box labeled **Destroy** on the right.
4. If you decide that the item should be retained because it pertains to the Document Preservation Notice, drag the item to the box labeled **Retain**.



Click **Begin** to get started.

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# Records and Information Management Training



## Records Retention

Check Your Understanding

Nice job! You don't have to retain this e-mail because it is considered Convenience Information. You may dispose of these types of e-mails after reading them unless they are subject to a Document Preservation Notice.



### Retain



Staff Meeting Minutes 8-2001  
(Word Doc)

### Destroy



Room Change Notification  
(E-mail)



InstructionsDocument Preservation NoticeRecords Retention Schedule







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**Records and Information Management Training**

### Vital Records, Records Clean-Up, and Compliance Audits

More Records and Information Management Requirements

We've covered most of the key elements you need to know about Records and Information Management at Johnson & Johnson.

However, here are some final topics that are important to know about in order to comply with Records and Information Management (RIM) requirements

*Click the links below to learn more about the final topics.*


- Vital Records
- Records Clean-Up
- Records Compliance Audits

#### Records Compliance Audits


Records Compliance Audits are typically conducted by your Records Management department and serve to measure how well associates are complying with the requirements of the Records and Information Management program.




These audits also help determine the effectiveness of the company's Records and Information Management program, and the results help provide a roadmap of areas of improvement for both the Records Management department as well as the department whose compliance is being audited.

It is your responsibility to participate in Records Compliance Audits if you are designated to do so. Your Records Management department will usually work with your department's Records Coordinator to arrange and conduct the audits.


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**Records and Information Management Training**


### Vital Records, Records Clean-Up, and Compliance Audits

Check Your Understanding

Sorry! You have not matched the options with the descriptions correctly.





Option	Description
Vital Records	Fundamental to the functioning of an organization and necessary to continue operations without delay under abnormal conditions.
Records Clean-Up Events	Opportunity and time allotted to review your records against the Retention Schedule and the Document Preservation Notices and participate in the controlled destruction of eligible records.
Records Compliance Audits	Help gauge how well associates are complying with the requirements of the Records and Information Management program.


Click **Next** to continue.

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**Quiz**  
Introduction

For the final quiz, you will be required to complete exercises similar to those you have already seen, however using different scenarios. Read each item carefully.

A score of 80% (8 correct out of 10) is required to pass the quiz. You will have 3 opportunities to pass the quiz. If you fail the third time, you will need to retake the course from the beginning.

You can review any topic from the **Menu** before getting started.

If you are ready to take the quiz now, click **Next**.

Good luck!

This is the first attempt out of 3. You need 80 percent to pass.



Click **Next** to continue.

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# **Exhibit B**



## COMPANY PROCEDURE FOR TRANSFERRING / TERMINATING EMPLOYEES AND CONTRACTORS

### REVISION HISTORY FOR PR553-003

Revision #	Summary of Change	Change Order #	Originator
12	<p>Added Mentor Santa Barbara to the Section 2: Scope.</p> <p>Updated Employee / Contractor Role in Section 4: Roles and Responsibilities.</p> <p>Changed references to the Ethicon Change Control System (ECCS) to Document Control System.</p> <p>Updated Appendix I references of the Litigation Vault to Litigation Hold folder.</p> <p>Updated Appendix I Items #1 &amp; 18 in order to align with changes released by Johnson &amp; Johnson Corporate Worldwide Records &amp; Information Management to RIMS-5 Inactive Records &amp; Information Storage Standard and RIMS-9 <i>Management of Records and Information of Departing Associates Standard</i>.</p>	CO-0036329	W. Patire-Singer
11	<p>Major re-write to improve clarity to the end users &amp; to better align to the new J&amp;J Corporate Worldwide Records &amp; Information (WWRIM) Management of Records and Information of Departing Associates Standard (RIMS-9). Form &amp; Certification have also been modified to be completed electronically rather than manually.</p>	CO-0029899	W. Patire-Singer
10	<p>Revised to edit the Scope section. Add Guaynabo departments for implementation.</p>	CO-0024320	W. Patire-Singer



## 1. PURPOSE

This procedure describes the process by which all employees or contractors who leave ETHICON are required to review all of their paper and electronic records, prior to their departure. In order to manage the Records and Information, departing employees and/or contractors need to assure that their records and information are reviewed and dispositioned in compliance with the ETHICON Records Retention Schedule (RRS), and active Preservation Hold Notices.

## 2. SCOPE

This process applies to the following ETHICON locations:

- Cornelia, Georgia
- Guaynabo, Puerto Rico
- Juarez, Mexico
- Raleigh, North Carolina
- San Angelo, Texas
- San Lorenzo, Puerto Rico
- Santa Barbara, California
- Somerville, New Jersey

## 3. DEFINITIONS, ACRONYMS AND ABBREVIATIONS

Reference terms used in this document are found in PS-0000971 *Franchise Process Specification for the Records Management Program Glossary*.

## 4. ROLES AND RESPONSIBILITIES

Roles and Responsibilities	Description
<b>Human Resources Vice President</b>	<p>Provide the necessary guidelines and instructions for terminated/transferred employees &amp; contractors via the ETHICON Exit Processes.</p> <p>Transfer HR files to other J&amp;J Human Resources Departments as employee transfer situations occur.</p> <p>Work with ComplianceWire Administrators to facilitate consistent training on this document for Site Records Management staff, Records Coordinators, and Managers/Supervisors and any other site specific relevant targeted training audience.</p> <p>Adjust this procedure and/or provide feedback on any areas of process to respond to changing business needs.</p>





Roles and Responsibilities	Description
<b>Manager/ Supervisor (includes District/ Divisional Managers)</b>	<p>Ensure that:</p> <ol style="list-style-type: none"> <li>1) Records of all departing direct reporting individuals are dispositioned appropriately per established Company Procedures, active Preservation Hold Notices and per the requirements of this Procedure &amp; Certification.</li> <li>2) The terminating or transferring individual fully understands how to review and disposition their records, where to locate the Records Retention Schedule, Preservation Hold Notices and other relevant Record Review and Disposition related Documents.</li> <li>3) Instruct IT that the departing individual's records need to be taken off of the computer and put on a CD or equivalent technology within 30 days when an individual is unable to perform their own records disposition prior to their departure to avoid their files being re-imaged prior to dispositioning the records. Manager/Supervisor then is responsible for performing the records review &amp; disposition.</li> </ol>
<b>Employee / Contractor (Consultant/Contractor Kelly Temp, or other Temporary Workers)</b>	<p>Work with their Manager to complete the Exit Checklist &amp; Certificate of Compliance For Records Disposition (APPENDIX I) prior to exiting ETHICON in order to clean-up and appropriately disposition their records per established Company Procedures and active Preservation Hold Notices.</p> <p>If the temporary worker is unable to do this prior to their departure (e.g. if the departure is short notice), then it is the responsibility of the Manager/Supervisor to whom this person reported to disposition their records and disconnect their system/security authorizations.</p> <p>The departing employee or contractor may take with them upon departure any personal notes provided these documents, in their entirety, were (1) not prepared, used for, or communicated in the course of transacting Ethicon business, and (2) not subject to an active Preservation Hold Notice for any reason.</p>
<b>ITS Representatives</b>	<p>Obtaining the terminating/transferring employee's or contractor's /consultant's computer files and provide a CD of the individual's files if required by their Manager/Supervisor.</p> <p>Ensuring that computer Accounts are disabled within 30 days and that files are removed within 90 days.</p>

## 5. MINIMUM REQUIREMENTS

The Manager and Employee / Contractor must follow & complete the process outlined in **Appendix I.**



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## 6. APPENDICES

Appendix	Appendix Name
Appendix I	Transferring/ Terminating Employee / Contractor Checklist & "Certificate of Compliance for Records & Information Disposition"



## APPENDIX I: TRANSFERRING / TERMINATING EMPLOYEE / CONTRACTOR CHECKLIST & "CERTIFICATE OF COMPLIANCE FOR RECORDS & INFORMATION DISPOSITION"

### Management's Responsibility PRIOR to the Employee/Contractor leaving the company:

☐ 1. Instruct employee/contractor to review his or her paper and electronic files against approved records retention schedules, and any Preservation Notices in effect in order to be sure they understand where and how to find and follow the Records Retention Schedule and Preservation Hold Notices in order to perform their records review. **The 4 types of Litigation are: Employment, Product, Patent and General Litigation.** The link to the Johnson & Johnson Legal Hold Notice Site is available on the ETHICON Records Management Intranet Portal and on the ETHICON Somerville Human Resources Exit Process Portal. Any records, paper or electronic, that are under litigation, must be labeled (Case name of Litigation) and forwarded to their manager.

All electronic Outlook Software records (Word, Excel, PowerPoint, Access, etc.) must be moved to the Litigation Hold folder on your desktop per the instructions in the respective, relevant Preservation Hold Notices. Move electronic files subject to Preservation Hold Notices to the Litigation Hold as follows:

❖ **Paper Records-**

All paper records that are under litigation should be flagged and forwarded to your immediate manager.

❖ **Electronic Records-**

All electronic email records must be moved to the Litigation Hold folder in your Microsoft Outlook Inbox per the instructions in the respective relevant Preservation Hold Notices.

All electronic Outlook Software records (Word, Excel, PowerPoint, Access, etc.) must be moved to the Litigation Hold folder on your desktop per the instructions in the respective, relevant Preservation Hold Notices.

- Ensure employee/contractor references PS-0000117 – *Process Specification for Onsite Paper/Electronic Records Clean-up*. Follow all instructions in PS-0000117 including completion of the electronic records clean-up tracker. These can be found in the Document Control System or on the Records Management Intranet portal.
- Records and information determined to be eligible for destruction or deletion after this review process shall be:
  - Destroyed at that time in accordance with ETHICON Procedures OR
  - Transferred to the Supervisor to retain until ETHICON's annually scheduled Records Clean-up event, at which point those records will be re-reviewed, re-dispositioned and destroyed, as appropriate. OR
  - Destroyed/deleted at that time with written approval by the supervisor.
- Once the employee/contractor has completed their paper and electronic review of all records, then instruct the individual to transfer the remaining records to management or their management representative.

**NOTE: Do not move email and files from C, H, and other drives to department shared drives for permanent storage.**

- ☐ 2. If the employee/contractor has staff reporting to them, then instruct that all department staff's personnel files are transferred to the newly appointed manager.



- ☐ 3. The individual's supervisor will ensure, commensurate with the risk, that all appropriate passwords are changed immediately. If a resigning/ transferring/ terminated employee or contractor is responsible for the system (application) administration of ANY ETHICON System (application), then the individual's supervisor is responsible for ensuring the individual's:
- System Administrator Rights need to be deleted immediately for each system to which they have System Administrator rights.
  - Password(s) is/are changed immediately.
- ☐ 4. If the employee/contractor has access to Document Control System, then instruct the individual to transfer all pending document change packages to another permanent individual with the required Document Control System role or request that they cancel the change packages. Contact WW Quality Systems or your local Quality System associate for assistance if required.
- If the employee is identified as a Document Owner, then a new document owner must be identified and the required forms be completed. Refer to PR-0000001, Company Procedure for the ETHICON Document Management Process, for details. Complete FM-0000001, Document Control System Document Ownership Transfer Form, and process per instructions.
  - If the employee is a Document Control System Approver, then they must ensure that an alternate approver is identified for them. If the employee functions in the role of Document Control System Implementer, they must ensure the Implementer role is transferred to an appropriate associate within their functional group.
- ☐ 5. If the employee/contractor has access to the Corrective and Preventative Action (CAPA) System, then instruct the individual to take the necessary steps to transfer the CAPA ownership of all **pending** CAPA's to another individual to be identified by the Manager.
- If the employee is in the Approver role in CAPA, they must ensure that all pending approvals are executed prior to termination or take steps to transfer the approval responsibility to another appropriate approver in the CAPA System.
- ☐ 6. If the employee/contractor has access to the Non-Conformance Report (NCR) System, then instruct the individual to work with the NCR Site Leader to transfer all pending NCR's under his/her name as an NCR Owner and/or Product Control Owner to another individual with the required NCR role.
- If the employee is identified as having an Approver Role in the NCR System, then ensure all the NCR's pending his/her approval are identified and reassigned by the NCR Site Leader.
- ☐ 7. **For Field Sales Management Only:** If your field based employee did not complete the records clean-up and did not sign the Certificate of Compliance prior to departure, then the Field Service Equipment Vendor will copy the electronic records on to a CD and send a copy to the District Manager or Management Representative for review and disposition in accordance with this policy. Utilize the Field Sales Equipment vendor to obtain the terminated/ transferred field sales employee's laptop or any other company assets that were issued to the individual back to C3I.
- ☐ 8. **For United States Based Human Resources Employees / Contractors Only:** No Human Resources related records can be deleted or discarded. Manager needs to send the computers to the **Global Site Services Lead** so a copy of the hard drives can be made before the computer can be re-imaged. This process step is required in order to support the Gutierrez, Morgan, Brown & Marshall v. Johnson & Johnson Employment Litigation Case.
- ☐ 9. Forward the employee's personnel file to the Human Resource Department if the employee is leaving or transferring to another J&J Company. If the employee is transferring to another department within ETHICON, forward the personnel file to the new manager.
- All Contractor department files remain in the department and should **not** be sent to Human Resources. These files are to be retained per the "Consultant/Contractor Contract & Supportive Documentation" Record Title on the Administrative Records Retention Schedule.



- **UNTIL FURTHER NOTICE, ALL PERSONNEL FILES, INCLUDING COMPENSATION INFORMATION ARE UNDER PRESERVATION HOLD - DO NOT DESTROY OR REMOVE DOCUMENTS FROM THE FILE.**
- ☐ 10. The employee/contractor is required to return all ETHICON owned software, and equipment upon the end of employment.
- ☐ 11. If any records were password protected, then the passwords should be communicated to their Manager before leaving.
- ☐ 12. Manager is to identify if the employee/contractor is an authorized user for a contracted offsite Records Storage Vendor for the retrieval of offsite records such as Iron Mountain, Angelo Archives, etc. If yes, then the manager must notify Site Records Manager that the individual is leaving the company and must be removed from the Contracted Offsite Records Storage Vendor authorization list. Has the employee/contractor retrieved any records from the offsite facility? If yes, then instruct the individual to identify & document the location of those records (boxes).
- ☐ 13. Instruct employee/contractor to return laboratory notebooks to Managers.
- ☐ 14. Instruct employee/contractor to identify any company paid services that they subscribe to. The Manager must remove the individual from the respective subscription(s).
- ☐ 15. Remove employee's/contractor's name from any distribution lists.
- ☐ 16. A (Service Request Management) SRM Form must be completed to request the following:
- Delete inactive accounts such as NT id, Mailbox and specific applications with user access.
  - Identify if the employee/contractor has access to any other SharePoint Sites, shared drive systems, etc. If so, manager should request removal from those respective lists and group shares.
  - Coordinate the pick-up all ETHICON equipment such as laptop, blackberry, printer, etc. that is in the possession of the departing or transferring individual.
- ☐ 17. Manager/Supervisor of terminated/transferring employee/contractor must complete the Certificate of Compliance Form for Records Disposition to certify that the individual's records have been reviewed and that proper disposition has been determined within 30 day. (**Appendix I**). Submit or retain the completed Certificate of Compliance Form for Records Disposition as it instructs based upon whether the individual is an employee or a contractor.
- **For the Employee:** The original Certificate of Compliance must be filed in the Employee's Personnel File along with the Exit Checklist and forwarded to Human Resources.
  - **For the Temporary Assignment Employee transferring back to their original J&J Operating Company location:** The original completed Certificate of Compliance is retained in the Human Resources file of the ETHICON site where the Associate worked on temporary assignment.
  - **For the Consultant:** The completed Certificate of Compliance is retained in the consultant/contractor Department file. This will remain in the department for the applicable Retention Period on the current approved Records Retention Schedule.
- ☐ 18. In the event the employee/contractor does not complete these steps before leaving, their management or their management representative must, within 30 days after the individual has left the company:
- Assume responsibility for this review, transfer and disposition procedure.
  - Request that IT create a copy of the Associate's electronic records on to a CD-Rom via an SRM request for the CD-Rom to be forwarded to them promptly for disposition.



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☐ 19. If the departing employee / contractor served as a Records Coordinator or a Department Head, then notify the Site Records Manager of this individual's departure and who their replacement will be who will assume these responsibilities for the Department moving forward.



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## ETHICON TRANSFERRING / TERMINATING EMPLOYEE / CONTRACTOR CERTIFICATE OF COMPLIANCE FORM FOR RECORDS DISPOSITION

NAME OF EMPLOYEE OR CONTRACTOR: \_\_\_\_\_  
(PRINT Name)

**Employment Status:** (Check One) ☐ Employee ☐ Contractor

**Division Worked In:** \_\_\_\_\_  
(Check One)

- ☐ Non-Human Resources Employee  
☐ Human Resources Employee (None of their files can be destroyed or dispositioned.)

**Departure Reason:** (Check One)

- ☐ Transfer to another Johnson & Johnson Operating Company  
☐ Transfer to another ETHICON Site/Division  
☐ Employment Termination  
☐ Contract Expiration  
☐ Contract Termination

**Termination Circumstance:** (Check One)

- ☐ Voluntary Departure  
☐ Non-Voluntary Departure

### **CERTIFICATION:**

I hereby confirm that, to the best of my knowledge, all paper & electronic records owned by  
 \_\_\_\_\_ have been reviewed and subsequently either dispersed and/or  
 (Name of Employee / Contractor)  
 disposed of per the requirements of:

- PS-0000117 ETHICON Onsite Paper / Electronic Records Clean-up
- PR-0000018 ETHICON Records Retention Schedule
- Active Preservation Hold Notices for Product, General, Employment and Patent related litigations

\_\_\_\_\_  
PRINT MANAGER'S NAME

\_\_\_\_\_  
MANAGER'S SIGNATURE

\_\_\_\_\_  
DATE

### **ROUTING INSTRUCTIONS:**

- For Terminating Employees: Include this completed & signed document in the Employee's Personnel File and forward with the completed Exit Checklist to Human Resources.
- For Transferring Employees: The individual's personnel file transfers to either the new department or to the HR Department on behalf of the terminating or transferring employee.
- For Contractors: Retain this completed & signed document in the Contractor's Department file. This will remain in the department for the applicable Retention Period per the requirement listed on the approved Company Records Retention Schedule.

# **Exhibit C**



**From:** Meek, Andrew [ETHUS] <AMeek@ETHUS.JNJ.com>  
**Sent:** Fri, 31 Aug 2007 15:13:14 GMT  
DL-ETHUSSO EWHU DMs <DL-ETHUSSOSLSPECIALTYDMs@ETHUS.JNJ.com>;  
Pattyson, Bart [ETHUS] <BPATTYSON@ETHUS.JNJ.com>; Gatewood, Jim [ETHUS]  
<JGatewoo2@ETHUS.JNJ.com>; Zipfel, Robert [ETHUS] <RZipfel@ETHUS.JNJ.com>;  
**To:** Yu, Kyung [ETHUS] <KYu@ETHUS.JNJ.com>; Parisi, Paul [ETHUS]  
<PParisi@ETHUS.JNJ.com>; St. Hilaire, Price [ETHUS] <PSTHILAI@ETHUS.JNJ.com>;  
Barendse, Stevan [ETHUS] <SBarends@ETHUS.JNJ.com>; Meek, Andrew [ETHUS]  
<AMeek@ETHUS.JNJ.com>  
**Subject:** Nov 3 Cadaver Lab - Dallas, TX

---

DMs/RSDs,  
Please forward to you teams.

I am excited to announce the debut of a new course on November 3 in Dallas, TX - Advanced Pelvic Floor Course - Level 1. The surgeon targets for this course are plicators, biologic users, flat mesh users with little experience, etc.

The goal for this lab is to train these doctors to prepare them for using mesh for pelvic floor repairs. The content that will be covered is as follows:

1. Pelvic Floor Anatomy, to include anatomic dissection
2. Diagnosis of pelvic floor defects, levels of support, staging
3. Graft selection criteria for augmented repairs
4. Graft implantation techniques
5. Handling complications

The cadaver lab will focus on anatomy, dissection, and placement of GYNEMESH.

Again, the targets for this course are surgeons with little or no experience using mesh with pelvic floor repairs. The experience gained at this level 1 course will prepare these doctors to possibly take a level 2 course in the future, which will feature Prolift.

This course is fully funded and will not impact region/division PE budgets. It is open to all regions. The course is posted on-line and the brochure is attached. Good luck!

Andy

Andy Meek  
Professional Education Manager  
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# **Exhibit D**

**From:** Luscombe, Brian [ETHUS] <BLuscomb@ITS.JNJ.com>  
**Sent:** Fri, 06 Apr 2012 14:52:05 GMT  
**To:** Chahal, Ricky [ETHUS] <rchahal@ITS.JNJ.com>; Garbarino, Stefanie [ETHUS] <sgarbari@ITS.JNJ.com>; Stewart, Edward [ETHUS] <EStewar9@its.jnj.com>; Affeld, Tom [ETHUS] <TAffeld1@its.jnj.com>; Bouterie, Benjamin [ETHUS] <BBouteri@its.jnj.com>; Boldish, Walter [ETHUS] <WBoldish@its.jnj.com>; Tan, Daryl [ETHUS] <DTAN2@ITS.JNJ.com>; Courts, Paul [ETHUS] <PCourts@its.jnj.com>; Frost, Kevin [ETHUS] <KFrost88@ITS.JNJ.com>; Kajy, Mark [ETHUS] <Mkajy@its.jnj.com>; Lynch, Edward [ETHUS] <ELynch3@its.jnj.com>; Jones, Scott [ETHUS] <SJones34@its.jnj.com>; Jackson, David [ETHUS] <DJacks18@its.jnj.com>; Sovereign, John [ETHUS] <jsoverei@ITS.JNJ.com>; Clements, Charles [ETHUS] <CClemen4@its.jnj.com>; Mohler, Troy J. [ETHUS] <TMohler@its.jnj.com>; Syndram, Curtis [ETHUS] <csyndram@ITS.JNJ.com>; Toth, Janet [ETHUS] <JToth2@its.jnj.com>; Rose, Garrin [ETHUS] <grose1@ITS.JNJ.com>; Calabrese, Frank [ETHUS] <FCalabre@its.jnj.com>; Durand, Rosemarie [ETHUS] <RDurand2@its.jnj.com>  
**CC:** Horton, Ronald [ETHUS] <RHorton9@its.jnj.com>; McCabe, Barbara [OCDUS Non J&J] <BMccabe@its.jnj.com>; DL-ETHUSSO EWHU DMs <DL-ETHUSSOSLSPECIALTYDMs@ETHUS.JNJ.com>; Jones, Scott [ETHUS] <SJones34@its.jnj.com>; Salyer, Jon [ETHUS] <jsalyer@its.jnj.com>; Crawford, Tiffany [ETHUS] <TCrawfo1@its.jnj.com>  
**Subject:** POP/INC BRAND TEAM CALL - Minutes from 4/5/2012

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INCONTINENCE & PELVIC ORGAN PROLAPSE BRAND TEAM,

Thank you to those of you who were able to make yesterday's call, including: Troy Mohler, Ed Stewart, Garrin Rose, JD Sovereign, Stephanie Garbarino, and the marketing team. I realize that there was a last minute change to when this call was being held and that people had trouble with the dial-in number...

For those of you who were not able to make the call we covered three topics:

1) EARL-

- a) Likes – The team is generally happy with the content that is available on EARL and are finding it useful in their selling efforts
- b) Improvements - The team had a few recommendations for improvements to the content including:
  - i) Update all Price Quotes (currently on the Portal) to 2012 pricing and make available on EARL
  - ii) Enable the animated TVT procedure videos to be emailable to customers (last 3 video assets under TVT ABBREVO)
  - iii) Add an emailable letter to the POP brands that provides customers with an update on the FDA and regulatory issues (currently only available as an Internal FAQ)
  - iv) Add all Patient marketing materials to EARL (vs having on portal)

2) Sales and Marketing Portal

- a) The team felt that the Portal was out of date and only used it 1 time / month on average
  - i) e.g. Price Quotes currently on the portal are for 2011 in some cases...
- b) The Portal is currently being redesigned to focus primarily on INTERNAL Only materials while EARL will be our primary venue for materials that are customer facing.
- c) It was noted that any presentation or document on the Portal can be uploaded to EARL by first saving it as a PDF, then emailing it to yourself, then opening on your iPad and storing it under iBOOKS, however it

would be nice if we could simplify this and just make certain documents (like Price Quotes) available on the Ipad.

c) Now that reps have EARL, they often will call on customers without their laptops so having everything they need on the ipad makes them more efficient

3) Y-mesh Launch

a) We are getting close to being able to share specific launch information with the organization!

b) In the meantime, we discussed some recommended actions that ALL reps can do NOW, in order to prepare for and maximize the launch:

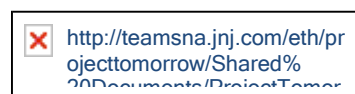
i) We discussed how familiar most reps are with the sacrocolpopexy procedure. Most people thought that reps could benefit now by being in a few cases and asking questions and really understanding the procedures. Given that GYNECARE TVT and GYNECARE MORCELLEX are sometimes used in the same patients (concomitantly) as a Y-mesh this is something every rep can do now without detracting from the focus.

ii) Although not discussed on the call, here is some additional information that comes from one of the reps on our Y-mesh launch team:

Recommendation is to talk with the GYN/URO who sits on the Value Analysis Committees in your Key Accounts. Make sure you understand the procedure for introducing new products in these facilities. Understand and get copies of the forms are required to be completed, so that when you speak to your competitive y-mesh surgeons for the first time you have the new product request form in hand. Sometimes the surgeons will be willing to sign and fill out the forms right on the spot. **The rep will not speak about the Y mesh at all at this time.** They just need to understand the process and get the appropriate forms. The process should be the same for any product.

*Brian Luscombe*

US Product Director, Pelvic Reconstructive Surgery



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# **EXHIBIT 3**

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON

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

**Master File No. 2:12-MD-02327  
MDL No. 2327**

**THIS DOCUMENT RELATES TO ALL  
CASES**

**JOSEPH R. GOODWIN  
U.S. DISTRICT JUDGE**

**DECLARATION OF LISA KAISER**

Lisa Kaiser declares and says:

**Background**

1. My name is Lisa Kaiser. I am over twenty-one years of age and of sound mind. I am competent to affirm all of the matters set out in this Declaration.

2. I am currently employed as Director, Worldwide Quality Systems at Ethicon Inc. ("Ethicon"), a position I have held for the past two years. Previously, from 2002 through 2006, I held other positions in Quality Systems and Supplier Quality at Ethicon. From 2006 through the end of 2009, I worked at Ortho Clinical Diagnostics (another Johnson & Johnson company) in quality affairs and quality systems positions. Between 2010 and 2011, I was employed by International Technidyne Corporation as a senior director of quality systems and compliance.

**Ethicon's Records Management Policies, Procedures and Training**

3. In my current position in Ethicon's Quality Systems group, I have oversight and accountability for Ethicon's records management policies, procedures and practices.

4. Ethicon operates in the highly regulated field of medical device manufacturing. United States Food & Drug Administration (FDA) regulations require Ethicon to manage and

maintain certain quality records related to Ethicon's business, which is among the reasons records management is within my area of responsibility. (Various standards published by the International Standards Organization (ISO) also cover quality records requirements.)

5. To comply with regulatory requirements or adhere to accepted standards, Ethicon has established policies, procedures and training programs regarding records retention in the ordinary course of its business.

6. Ethicon has a written records management policy – Ethicon's Franchise Policy for Records Management (PL 553-005), which is attached. As stated in the policy, its purpose is to enable Ethicon to "effectively create, use, value, manage, protect and dispose of" its records and information in accordance with applicable laws and regulations, business considerations, and other Ethicon and Johnson & Johnson policies and standards, including those regarding legal holds.

7. The policy also outlines its scope, providing that it applies to all associates (that is, employees, contractors, consultants and temporary staff) of Ethicon and records and information in any form or medium (e.g., paper, electronic, microfilm, microfiche, photograph, map, magnetic or optical disk or tape, software, video or other records information).

8. In addition, the policy details the roles and responsibilities of the management with executive responsibility, the corporate records manager, site records manager(s), department head(s), the records coordinator, and Information Technology.

9. To promote this policy, Ethicon has published various training documents and other written materials that further describe record retention procedures, and established programs to train its associates on these procedures.

10. For example, Ethicon has published an extensive record retention schedule that provides associates with guidance as to the retention of various categories and specific types of records and information, regardless of form (e.g., paper, electronic, etc.). This schedule provides that many types of records related to its products (including but not limited to pelvic mesh products) must be maintained for at least the “life of production” or the “life of the organization” (Ethicon). Examples of records that must be retained for at least the life of the product or organization include, among others, design history files (DHF), laboratory notebooks, technical reports, labeling content, and FDA submissions.

11. Ethicon has in place training programs and protocols to educate its associates as to record retention. New associates at Ethicon receive Records and Information Management (RIM) training.

12. Ethicon’s training is interactive, requiring associates to “check their understanding” of issues as they move through the program.

13. In its substance, this training provides an overview of the records and information management program, including its benefits and the risks of non-compliance. It provides detailed information regarding other issues such as (i) the lifecycle of records and information; (ii) the distinction between a record and convenience information; (iii) roles and responsibilities with respect to records and information management; (iv) managing electronic records in particular; and (v) legal holds.

14. As to the last component, the training explains what a document preservation or legal hold notice is and how to read it. It then tests the associate’s understanding of compliance through an exercise. Finally, the training includes a summary discussion of the legal hold requirements.



15. Ethicon associates are required to complete this training, including the portion on legal holds, on an annual basis. Associates receive reminder emails if they have not completed the training. Further, executive management receive emails regarding overdue training of any associates that fall under their supervision.

How Documents Are Maintained at Ethicon

16. Due to the regulations under which Ethicon operates as well as technology employed by Ethicon, an increasing number of records are created and managed in central or shared locations, such as SharePoint, group shares, and databases.

17. Indeed, most “files of record” (many of which are required to be maintained and preserved by Ethicon under the Quality Systems Regulations, 21 CFR part 820) are maintained in group or central sources, rather than in any one individual’s custody. For example, the Design History File, or DHF, which defines the design and development of a given product, is a collection of materials that Ethicon maintains centrally. Likewise, Ethicon’s Regulatory Affairs group maintains in central files applications for regulatory clearance for Ethicon’s products (including pelvic mesh products), which include applications, supporting materials, follow-up communications between Ethicon and FDA, and documentation regarding FDA’s clearance determination. In addition, reports of complaints or adverse events associated with Ethicon’s products are maintained by Ethicon on an electronic database, rather than by any one individual.

18. I represent that the foregoing statements are true under the penalties of perjury.

Dated: January 9, 2014

  
Lisa Kaiser

# **EXHIBIT 4**

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

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO ALL CASES</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**DECLARATION OF PAMELA DOWNS**

Pamela Downs declares and says:

1. My name is Pamela Downs. I am over twenty-one years of age and of sound mind. I am competent to affirm all of the matters set out in this Declaration.
2. I am employed as a Senior Director at Epiq Systems, Inc., eDiscovery and Litigation Solutions. During my 26 year career supporting the legal services industry, I have developed extensive experience in the assessment, collection and production of hard copy and electronically stored information in litigated matters.
3. In 2013, on behalf of Ethicon, Inc. ("Ethicon"), I was retained to examine the nature and scope of documents outside of the United States ("ex-US documents") maintained by Ethicon, including documents provided to Ethicon by MedScand Medical ("MedScand"), the original manufacturer of TVT based in Sweden.
4. In connection with my examination of MedScand related issues, I have interviewed over 25 Ethicon employees and reviewed numerous documents.

5. It is my understanding that in November of 1999, Ethicon purchased from MedScand the rights to manufacture and sell TVT. It is my understanding that in 2005, CooperSurgical purchased MedScand and sought to determine the disposition of a pallet of 12 cases, weighing approximately 600 pounds, which were believed to contain TVT-related MedScand materials.

6. It is my understanding that in November 2005, CooperSurgical sent the pallet of 12 cases to the Johnson & Johnson International Shared Services Distribution Center Site in Sweden.

7. In 2006, seven of these cases -- which contained product retains -- were disposed of as they no longer served any business purpose.

8. As to the MedScand manufactured product retains, I have confirmed that the shelf life for the original TVT product was five years. In 2000, Ethicon began manufacturing TVT and maintaining its own product retains. Therefore, by 2006, any MedScand manufactured product retains from prior to 2000 would have been past the product's shelf life.

9. Colin Yuill, the current Quality Manager in Neuchatel, confirmed that a product retain past its shelf life would not have been retained as it no longer served a business function.

10. Four of the 12 cases contained lot documentation from the period during which MedScand manufactured TVT. While the continuing business purpose of these materials to Ethicon in 2005 or 2006 is unclear, it appears that Ethicon decided that this lot documentation should be sent to Ethicon SARL in Neuchatel, Switzerland. I have been unable to determine whether these records were actually sent; however, I understand that Ethicon has been unable to locate these records.

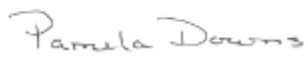
11. It is my understanding that in February 2006, the 12<sup>th</sup> case, which contained boxes that included documents regarding clinical studies, was shipped from the Johnson & Johnson International Shared Services Distribution Center Site in Sweden to Ethicon SARL in Neuchatel, Switzerland and stored at an offsite facility maintained by Secur'Archiv, a third party vendor.

12. On or around September 24, 2009, a fire occurred inside the Secur'Archiv offsite facility destroying thousands of boxes including all but one of the boxes from the 12<sup>th</sup> case. This box, along with other surviving boxes, were reassigned to other offsite storage facilities in Switzerland. It is my understanding that this box contained only a single binder of patient data from the Scandinavian Multicenter Study, which Ethicon has produced to Plaintiffs in this litigation.

13. It is also my understanding that Ethicon has produced documents related to Ulmsten's clinical studies aside from the binder including Ulmsten's published articles and the October 17, 1997 report of Margareta Eriksson on the Scandinavian Multicenter Study.

14. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 9th day of January, 2014.



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PAMELA DOWNS

# **EXHIBIT 5**

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

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO ALL CASES</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**DECLARATION OF PHU DAO**

Phu Dao declares and says:

1. My name is Phu Dao. I am over twenty-one years of age and of sound mind. I am competent to affirm all of the matters set out in this Declaration.

2. I have been employed by Johnson & Johnson Shared Services, Inc. ("ITSS"), since 2006. I am currently Director, End User Services for North America and Latin America. Between approximately 2008 and 2010, I provided support to Ethicon at its Somerville, New Jersey location. During that period, ITSS had a contract with International Business Machines ("IBM") under which IBM provided end-user company issued desktop and laptop computer ("PC Device") support to all levels of Ethicon employees including upper management, contractors, consultants, and temporary staff (collectively referred to below as "Associates").

3. As described further below, the IBM contractors acted as representatives of ITSS. I had overall responsibility for oversight of the IBM contract which outlined the responsibilities of these ITSS representatives.

4. I am submitting this declaration to describe the roles and responsibilities of ITSS representatives and to clarify that I am unaware of circumstances in which data known to be

relevant to pelvic mesh litigation was intentionally deleted or destroyed. I also submit this declaration to explain one of several steps that have been taken since mid-2012 to minimize the risk of loss of data in the future.

5. ITSS representatives have and have had responsibility for retrieving an Associate's PC Device upon his or her departure.

6. During the period prior to mid-2012, upon retrieving the departed Associate's hardware, ITSS representatives retained the hard drive for 14 days. If within that 14-day period, ITSS received a request to facilitate a manager's access to or preservation of the departed Associate's data, ITSS accommodated the request by providing the departed Associate's manager with access to the data. Only after any such requests to facilitate access to or preservation of the departed Associate's data were satisfied, or, if no requests were submitted, at the end of the 14-day period, the PC Device would either be (a) recycled, if it was at the end of its lifecycle, or (b) re-imaged and re-deployed in the ordinary course of business.

7. I am not aware of anyone employed by ITSS or IBM having intentionally deleted or destroyed any data that was known at that time to be relevant to the Ethicon pelvic mesh litigation.

8. Indeed, in June 2012, in order to minimize the risk of loss of departing Associates' data, I understand that Ethicon's Somerville, New Jersey site adopted the practice of indefinitely preserving the data from departing Associates' PC Device(s), which remains Ethicon's practice today and now includes all Ethicon locations within the United States.



I represent that the foregoing statements are true under penalties of perjury.

  
Phu Dao

Dated: January 8, 2014