IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER # 100
(Plaintiffs' Motion for a Finding of Spoliation and for Sanctions)

Currently pending in this multidistrict litigation is Plaintiffs' Motion for a Finding of Spoliation and for Sanctions. (ECF No. 952). Plaintiffs claim that after a duty to preserve evidence had been triggered, defendant Ethicon, Inc. ("Ethicon") lost or destroyed tens of thousands of documents that likely contained information relevant to Plaintiffs' claims. Plaintiffs seek a default judgment against Ethicon in three bellwether cases, the striking of defenses in other cases, an adverse instruction in all cases, and attorneys' fees and costs. Ethicon has responded in opposition to the motion, and Plaintiffs have replied. (ECF Nos. 1022, 1041). The undersigned heard oral argument from the parties on January 23, 2014. Therefore, the matter is fully briefed and ready for disposition.

Having now thoroughly considered the matter, the court finds that Ethicon did destroy or otherwise lose documents that should have been preserved in anticipation of this litigation. However, the court further finds that Ethicon's loss of evidence was negligent, not willful or deliberate, and Plaintiffs have failed to establish a resulting

prejudice sufficient to support the severe sanctions of default judgment, striking of defenses, and the offering of an adverse instruction in every case.

On the other hand, the court finds that Plaintiffs are entitled to monetary sanctions to compensate them for the additional time spent by their counsel piecing together missing custodial files and preparing for depositions of key employees for whom scant information was provided by Ethicon. In addition, the undersigned recommends to the presiding District Judge that Plaintiffs be permitted on a case-by-case basis to introduce evidence of spoliation at trial, when appropriate, and seek an adverse instruction in specific cases.[1] Thus, for the reasons that follow, the court **GRANTS**, in part, and **DENIES**, in part, Plaintiffs' motion.

I. RELEVANT FACTS

A. History of Litigation and Document Preservation Notices

This multidistrict litigation ("MDL") was opened in February 2012 to address claims involving surgical mesh products designed, manufactured, marketed, and sold by Ethicon to treat pelvic organ prolapse and stress urinary incontinence. (ECF No. 1). At its inception, the MDL included thirty-seven cases pending in federal courts across the country, most of which were filed in 2011. (*Id.* at 12-14). Since that time, thousands of additional cases have been joined in the Ethicon MDL. For the most part, plaintiffs in these actions complain about two product lines, TVT and Prolift,[2] and allege design defects, manufacturing defects, negligence, failure to warn, and breach of express and implied warranties.

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[1] For example, in a case in which a Plaintiff establishes a *prima facie* claim of failure to warn, Plaintiffs may be permitted to introduce evidence that Ethicon destroyed the call notes of the sales representative who provided information to Plaintiff's implanting physician.

[2] The TVT line includes the following products: TVT (Original and Blue), TVT-Secur, TVT-Obturator, TVT-Exact, and TVT-Abbrevo. The Prolift line includes Prolift and Prolift+M. (ECF No. 953 at 3).

Prior to the MDL, other suits involving products in Ethicon's TVT and Prolift lines were filed in various state and federal courts. This first suit was filed in Oregon in March 2003 and involved TVT. (ECF No. 1022-1 at 3). In response to the complaint, Ethicon's in-house counsel issued a "document preservation notice" specific to the Oregon case. (ECF No. 953-39). The May 22, 2003 notice instructed employees to "save and preserve" documents pertaining to TVT, "either printed or on the computer," and was accompanied by instructions to "[i]dentify any documents in your possession which may be related to this notice ... [a]ppropriately segregate such documents and/or otherwise mark them so that they are preserved from any destruction ... [k]eep such documents in a safe place," and to contact the risk manager or legal department if the employee was not sure whether the documents in his possession were "subject to" the notice. (*Id.*). Finally, the notice advised employees to preserve the materials until "contrary written notice is received from the J&J Law Department." (*Id.*). The notice was somewhat ambiguous as to whether documents prepared *after* May 22, 2003 were subject to a litigation hold and did not specify the nature of the claims or the injuries alleged in the civil action. The case was settled in January 2004, but the document preservation notice was not explicitly withdrawn. (ECF No. 1022-1 at 3).

The next case, filed in Florida in April 2006, also involved TVT. (ECF No. 1022-1 at 3; *see Keeton v. Gynecare Worldwide, et al,* United States District Court for the Southern District of Florida, Case No.: 1:06-cv-21116-UU at ECF No. 1), and again resulted in the issuance of a document preservation notice specific to that complaint and covering documents related to "TVT Device." (ECF No. 953-40). The April 27, 2006 notice essentially covered the same type and category of documents outlined in the 2003 notice, but included a new section entitled 'Instructions for Handling Electronic

Materials." Specifically, the notice instructed employees to create an e-mail folder on their desktop computer titled "TVT Litigation" and place into that folder all relevant e-mails and attachments. The instructions made clear that future e-mails were to be copied into the folder "within three working days of the e-mails being opened or created by you." (*Id.*). The documents were to be held until further notice. There is no indication that this document hold was ever withdrawn.

While the Florida case was still pending, a third complaint was filed in California on February 21, 2007, involving a TVT device. (ECF No. 1022-1 at 3-4). On April 30, 2007, a new document preservation notice was issued by Ethicon's in-house counsel, again covering TVT-related documents.[3] The Florida case was dismissed by summary judgment in August 2007, and the California case was voluntarily dismissed in August 2008. (*Id.*).

In 2008, five cases involving transvaginal mesh were filed against Ethicon in New Jersey state court. (*Id.* at 4). The first case involved a Prolift device and resulted in another document preservation notice specific to the complaint and applicable to all documents involving Gynecare Prolift. (ECF No. 953-41). This particular notice, issued on April 21, 2008, included information on how to create a case specific electronic folder on each employee's desktop computer for relevant e-mails and attachments. The notice instructed employees to move into the designated folder all existing e-mails and attachments, including those in the "deleted items" folder, and to copy and place in the folder all relevant documents stored on their hard drives. Later that year, in October 2008, the U.S. Food and Drug Administration ("FDA") issued a public health

[3] For some reason, the court was not provided with a copy of this document preservation notice. However, the parties indicate that this notice was essentially the same as the first two notices.

notification discussing rare, but serious complications experienced by nine manufacturers of surgical mesh products associated with the transvaginal placement of mesh products to treat pelvic organ prolapse and stress urinary incontinence. (ECF No. 953-4).

According to Ethicon, over the next two years, additional cases began to "trickle" in, with forty-five cases filed in 2009. (ECF No. 1022-1 at 4). In February 2010, plaintiffs' counsel sought centralized management of approximately 60 cases that were pending in New Jersey; a request that was granted in October 2010. (*Id.*). Thereafter, on February 18 2011, Ethicon's in-house counsel issued a "Consolidated Hold Notice for *Pelvic Mesh/Gynecare Product Liability Litigation*," directing employees to preserve all documents pertaining to the TVT and Prolift product lines, as well as other products involved in ongoing litigation.[4] (ECF No. 953-42). Significantly, in this consolidated document preservation notice, counsel listed the original dates on which "company-wide" hold notices had been issued for various products involved in litigation, including the following:

TVT	April 30, 2007
Prolift	April 21, 2008
Prolift Master Notice	November 12, 2008
TVT Obturator	October 7, 2009
TVT Secur	January 28, 2010

(*Id.*)

B. Documents Allegedly Lost or Destroyed

In their motion and supplement to the motion, (ECF Nos. 952, 996), Plaintiffs identify 22 current or former employees of Ethicon for whom productions of custodial

[4] By February 23, 2011, the notice included the following products: Prolift, Prolift+M, Prosima, Gynemesh PS, TVT Retropubic (Original and Blue), TVT Obturator, TVT Secur, TVT Exact, TVT Abbrevo, Prolene Mesh, Prolene Soft Mesh, and successor mesh products for pelvic floor repair and in the TVT family of products.

files contained few, if any, documents. The employees included corporate executives, regulatory and medical affairs personnel, marketing staff, and sales representatives. Thirteen of the employees left the company before 2008; five left between 2008 and 2010. One left in 2011, one in 2012, and two are still employed by Ethicon. In particular, Plaintiffs identify the following:

1. **Renee Selman**, worldwide president, 2005-2010. Accordingly to Plaintiffs, Ms. Selman was president during critical periods in the development of the TVT and Prolift product lines, as well as in 2008, when the FDA published its initial public health notification regarding the transvaginal placement of mesh. As president of the company, Ms. Selman had "responsibility for setting certain key policies, defining strategy, direction, overall responsibility for some of the company's actions." (ECF No. 953 at 3). Ms. Selman testified that she was aware of the preservation notices, believed they applied to the entire TVT family of products, and placed relevant electronic documents in the proper litigation folders. The parties agree that Ms. Selman's custodial file contained only 25 documents, and her hard drive was wiped clean and recycled after she left Ethicon in 2010.

2. **Ramy Mahmoud**, chief medical officer and worldwide president of evidence-based medicine, August 2007-July 2010. Dr. Mahmoud supervised four departments at Ethicon and testified that he fully complied with all litigation holds. However, Dr. Mahmoud's custodial file contained only 27 documents. (*Id.* at 4).

3. **Charlotte Owens,** global medical director, Gynecare, September 2003-August 2005. Dr. Owens worked in product development, and on marketing and regulatory matters. She also assisted in drafting the "instructions for use" for the Prolift product, and she monitored adverse events. According to Plaintiffs, only six documents

were produced in Dr. Owen's custodial file. However, when Plaintiffs searched all documents produced by Ethicon using the term "Owens," they located 14,000 documents. (ECF No. 953 at 4-5).

4. **Sean O'Bryan,** senior project manager in regulatory affairs, November 2001-April 2005. Mr. O'Bryan was the regulatory lead on the TVT-Blue and TVT-Obturator projects. Nevertheless, his custodial filed contained only 54 documents. (*Id.* at 5).

5. **Laura Angelini**, vice president of global strategic marketing for Ethicon Surgical Care. Ms. Angelini worked on the TVT product between 1997 and 2005. She left the company in 2005, but returned to her original position shortly thereafter. According to Plaintiffs, Ms. Angelini's computer files were purged in the interim; thus, destroying all relevant documents that pre-dated her departure. (*Id.* at 5-6).

6. **Jennifer Paine**, worldwide director of regulatory affairs, June 2004-December 2009. Ms. Paine worked on the TVT product line from June 2007 through December 2009 and, Plaintiffs postulate, would have had significant interaction with the FDA. However, Ethicon produced only 71 documents in Ms. Paine's custodial file, none of which were e-mail communications. (*Id.* at 6).

7. **Price St. Hillaire,** sales and marketing positions, 1999-November 2008. Mr. St. Hillaire testified that he did not recall any document preservation notices, but nonetheless left intact his physical files and all electronic documents on his laptop computer when he ended his relationship with Ethicon. Ethicon produced no custodial file for Mr. St. Hillaire. (*Id.* at 6).

8. **Cheryl Bogardus,** various marketing positions including worldwide marketing director, January 2001-May 2007. Although Ms. Bogardus testified that she

left all of her paper and electronic documents behind when she left Ethicon, no custodial file was attributed to her. (ECF No. 953 at 6-7).

9. **Gregory Jones,** various regulatory positions, including worldwide director of regulatory affairs, 1989-2003. Mr. Jones maintained electronic copies of documents involving regulatory matters. He testified that he was unaware of any efforts made by Ethicon to preserve his documents when he left. His custodial file included approximately 20 documents. (*Id.* at 7).

10. **Rick Isenberg,** worldwide director of medical affairs, 1999-2002. No custodial file or personnel file was located and produced for Mr. Isenberg. (*Id.* at 7).

11. **Patricia Hojnoski,** project manager and contractor in regulatory affairs, 2002-2009.[5] Ms. Hojnoski testified that she retained all documents and handwritten notes required by Ethicon's retention policies and preservation notices. Her custodial file included only six documents. (*Id.* at 7-8).

12. **Jill Schiaparelli,** project director for strategic growth, 2000-2007. Ms. Schiaparelli worked with Dr. Heniford, Ethicon's expert and an advocate of light mesh materials. Ethicon has no custodial file for Ms. Schiaparelli. (*Id.* at 8).

13. **Paul Courts, Troy Mohler**, sales representatives. Although both witnesses believed that they had hardcopy materials, such as visual aids, CDs, and call notes, none of these documents were produced as part of their custodial files. (ECF No. 953 at 8-9).

14. **Allison London Brown,** marketing director for women's health and urology, 2004-2007. Ms. Brown was responsible for developing marketing strategy for

[5] According to Ethicon, Ms. Hojnoski left Ethicon's employ in 2006 and returned as a contract employee with limited responsibilities for one year in 2008.

pelvic floor and incontinence markets; however, Ethicon produced no custodial file for Ms. Brown. (*Id.* at 9).

15. **John Clay,** manager, regulatory affairs. Mr. Clay was the primary regulatory affairs associate with responsibility for the TVT line of products in 2006-2007. He was also Ethicon's 30(b)(6) witness for regulatory matters. Ethicon indicated that it has no custodial file for Mr. Clay. (ECF No. 996 at 1-2).

16. **Kendra Munchel,** global marketing manager, 2005-2007. Ms. Munchel was a member of the "core team" for professional education related to the TVT-O and Prolift launches. Ethicon has no custodial file for Ms. Munchel. (*Id.* at 2).

17. **Tom Divilio**, Director of Medical Affairs, 1997 through December 2009. E-mails recovered from other custodial files indicate that Dr. Divilio was involved in TVT projects, yet Ethicon produced no custodial file for Mr. Divilio. (*Id.*).

18. **Amy Godwin,** clinical development, 2000-recent years.[6] Plaintiffs indicate that Ms. Godwin had involvement in the "clinical affairs" of the TVT line, and her name appears in 4,000 e-mails recovered from other employees' custodial files. (*Id.* at 2-3).

19. **Susan Landgrebe**, research and development, 2004-present. Plaintiffs contend that Ms. Landgrebe is named on the patent for TVT-Secur, yet only 75 documents, consisting of 543 pages, were contained in her custodial file. (*Id.* at 3).

20. **Zenobia Walji**, worldwide director of strategic planning, 2009-2012.[7] Ms. Walji worked at Johnson & Johnson since 1988 and in 2000-2004 oversaw Ethicon's marketing of its pelvic floor products. From 2004-2005, Ms. Walji was heavily

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[6] Ethicon claims that Ms. Godwin left its employ in 2004.

[7] According to Ethicon, Ms. Walji left the company in 2005.

involved in the global launch of Prolift. Ethicon produced 100 documents in Ms. Walji's custodial file, although Plaintiffs believe that specific documents are missing, including versions of her global launch plan and her operational and strategic plans for pelvic floor products. (ECF No. 996 at 3-4).

21. **Nancy Leclair,** director of marketing services, 2000-2011. Despite Ms. Leclair's longevity with Ethicon, only 189 documents, totaling 1,633 pages were produced as her custodial file. (*Id.* at 4).

In addition, Plaintiffs complain that in 2006 Ethicon destroyed 600 pounds of documents provided to it from Medscand, the company that originally manufactured TVT, (ECF No. 953 at 10-11), and lost a critical videotape supplied by its expert, Dr. Heniford. (*Id.* at 10).

II. DISCUSSION

Spoliation of evidence refers to "the destruction or material alteration of evidence or to the failure to preserve property for another's use as evidence in pending or reasonably foreseeable litigation." *Silvestri v. General Motors Corp.,* 271 F.3d 583, 590 (4th Cir. 2001) (citing *West v. Goodyear Tire & Rubber Co.,* 167 F.3d 776, 779 (2d Cir. 1999)). The duty to preserve evidence arises "not only during litigation but extends to that period before the litigation when a party reasonably should know that the evidence may be relevant to anticipated litigation." *Silvestri,* 271 F.3d 591 (citing *Kronisch v. United States,* 150 F.3d 112, 126 (2d Cir. 1998)). Once the duty is triggered, the party should "identify, locate, and maintain information that is relevant to specific, predictable, and identifiable litigation" and "notify the opposing party of evidence in the hands of third parties." *Victor Stanley, Inc. v. Creative Pipe, Inc.,* 269 F.R.D. 497, 522-23 (D.Md. 2010).

The failure of a party in a federal proceeding to preserve material evidence may result in the imposition of sanctions under Fed. R. Civ. P. 37, or through the court's inherent authority "to control the judicial process and litigation." *Id.* at 517 (quoting *Goodman v. Praxair Servs. Inc.,* 632 F.Supp.2d 494, 505-06 (D.Md. 2009)). Generally, conduct that occurred prior to commencement of the litigation is addressed through the court's inherent authority. *In Re Actos (Pioglitazone) Products Liability Litigation,* Case No. 6:11-md-2299, 2014 WL 308909, at *12 (W.D.La. Jan. 27, 2014). Sanctions may be imposed to preserve "the orderly administration of justice," *Victor Stanley,* 269 F.R.D. at 517 (quoting *United States v. Shaffer Equip. Co.,* 11 F.3d 450, 462 (4th Cir. 1993)), and to redress conduct which abuses or undermines the integrity of the judicial process. *Id.* at 517. In the Fourth Circuit, sanctions for spoliation are appropriate when the moving party establishes 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.

Goodman v. Praxair Services, Inc., 632 F.Supp.2d 494, 509 (D.Md. 2009) (quoting *Thompson v. U.S. Dept. of Housing & Urban Dev.,* 219 F.R.D. 93, 101 (D.Md. 2003)). The district court has broad discretion when selecting a sanction for spoliation; however, "the applicable sanction should be molded to serve the prophylactic, punitive, and remedial rationales underlying the spoliation doctrine." *Silvestri,* 271 F.3d at 590 (quoting *West,* 167 F.3d at 779). "Because the [court's] inherent power is not regulated by Congress or the people and is particularly subject to abuse, it must be exercised with the greatest restraint and caution, and then only to the extent necessary." *Shaffer Equip. Co.,* 11 F.3d at 461.

Thus, the sanction chosen should employ "the least possible power adequate to the end proposed." *Spallone v. United States,* 493 U.S. 265, 280, 110 S.Ct. 625, 107 L.Ed.2d 644 (1990) (quoting *Anderson v. Dunn,* 19 U.S. (6 Wheat) 204, 231, 5 L.Ed. 242 (1821)).

A. Duty to Preserve

The duty to preserve evidence contains two distinct components. The first component is the event that triggers the duty. In other words, when should the party *reasonably* have anticipated litigation? It is well established that the duty is triggered, at the latest, when the defendant is served with the complaint. *Victor Stanley,* 269 F.R.D. at 522 (citing *Nucor Corp. v. Bell,* 251 F.R.D. 191, 197 (D.S.C. 2008)). Before litigation begins, courts agree that the receipt of a demand letter, a request for evidence preservation, a threat of litigation, or a decision to pursue a claim will all trigger the duty to preserve evidence. *See Turner v. United States,* 736 F.3d 274, 282 (4th Cir. 2013) (A document preservation letter or letter threatening litigation triggers a duty to preserve evidence); *Sampson v. City of Cambridge, Md.,* 251 F.R.D. 171, 181 (D.Md. 2008) (Defendant's duty to preserve arose when plaintiff's counsel made a written request to preserve evidence); *Silvestri,* 271 F.3d at 592 (Duty arose when plaintiff retained experts to examine evidence for potential litigation).

However, it is less clear what other occurrences should alert a party to preserve evidence for future litigation. Consequently, in those instances, the analysis is highly case specific and fact dependent. *Rimkus Consulting Group, Inc. v. Cammarata,* 688 F.Supp.2d 598, 613 (S.D.Tex. 2010) "These general rules are not controversial. But applying them to determine when a duty to preserve arises in a particular case and the extent of that duty requires careful analysis of the specific facts and circumstances. It can be difficult to draw bright-line distinctions between acceptable and unacceptable conduct

in preserving information and in conducting discovery, either prospectively or with the benefit (and distortion) of hindsight." *Id.*

In this case, Ethicon clearly understood in March 2003 that it had an obligation to preserve evidence for pending litigation involving TVT. In keeping with its obligation, Ethicon issued a document preservation notice that identified the specific litigation and listed categories of documents relating to TVT that needed to be segregated and preserved. There is no dispute that this lawsuit involved a single recipient of a TVT device, did not involve any of the Plaintiffs in the MDL, and was resolved in January 2004, eight years before the MDL was created. There also is no dispute that the litigation hold was never officially withdrawn even after dismissal of the case that gave rise to its issuance.

According to Plaintiffs, the filing of that first lawsuit in 2003, and the corresponding document preservation notice, triggered an ongoing duty on Ethicon's part to preserve documents, including all documents relevant to the claims in this MDL. In Plaintiffs' view, the 2004 resolution of the lawsuit did not alter that obligation. Plaintiffs argue that Ethicon appreciated its duty to preserve evidence by issuing a broad litigation hold notice that instructed employees to retain every document pertaining to TVT, and Plaintiffs further point out that Ethicon has admitted through the testimony of James Mittenthal, its 30(b)(6) representative, that the 2003 litigation hold notice continues to be in effect to this day. [8]

[8] Plaintiffs also argue that the duty to preserve must coincide with the period of time for which Ethicon claims work product protection. Plaintiffs point to several entries on Ethicon's privilege log for documents that are dated in 2003 and argue that if Ethicon is claiming a work product protection, it must have been anticipating litigation as early as 2003. The undersigned does not find this argument persuasive given that Ethicon was involved in other unrelated litigation in 2003. Therefore, the document may have been created in anticipation of litigation, *but not* this litigation.

Not surprisingly, Ethicon disagrees with these assertions, arguing that a single case involving one product simply does not create a reasonable anticipation of future litigation. Ethicon contends that the few isolated cases filed before 2008 were insufficient to place it on notice of the widespread litigation that would follow in 2010. Ethicon concedes that the 2003 litigation hold notice required it to preserve relevant evidence for that specific case, but denies that it had "a general and widespread duty to preserve and collect documents from a wide range of custodians with respect to a wide range of products" 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." (ECF No. 1022 at 5).

Unfortunately, minimal guidance exists as to the effect that an isolated product liability action has on a manufacturer's duty to preserve evidence that may be relevant to different plaintiffs in future litigation based on the same or similar product. The issue becomes murkier in today's world of class actions and multidistrict litigation and is further complicated by the continuous evolution of computer technology, making it easier and less expensive for companies to save large volumes of information. Even less guidance exists on whether a corporate litigation hold notice that is never expressly withdrawn requires the company to continue preserving evidence even after resolution of the legal action that triggered it. Those are the preliminary issues in this case.

Plaintiffs' position that the first TVT case was an unmistakable harbinger of lawsuits to come begs some important questions relating to the duty to preserve. Does the phrase "reasonably anticipate litigation" mean that once a manufacturer has been accused in a legal complaint of making a defective product, it should assume that others will lodge the same complaint in the future? And is it reasonable to find, in retrospect, that a widespread

duty to preserve evidence for use in a MDL arose when the first similar, but unrelated claim was filed? A few courts have answered these questions in the negative, finding that the duty to preserve evidence runs to a specific plaintiff. *See, e.g., Delta/Airtran Baggage Fee Antitrust Litigation,* 770 F.Supp.2d 1299 (N.D.Ga. 2011); *Point Blank Solutions, Inc. v. Toyobo America, Inc.,* Case No. 09-61166-CIV, 2011 WL 1456029 (S.D.Fla. Apr. 5, 2011); *Brigham Young Univ. v. Pfizer, Inc.,* 282 F.R.D. 566, 572 (D.Utah 2012). Others have found the duty to be triggered by industry-wide events, regardless of the status of individual litigation. *See Livingston v. Isuzu Motors, Ltd.,* 910 F.Supp. 1473, 1494 (D. Mont. 1995). And at least one court found that the duty to preserve evidence for the benefit of subsequent plaintiffs was triggered by the broad and sweeping language of a litigation hold notice. (*See* ECF No. 1056). *In Re Actos,* 2014 WL 308909.[9] The undersigned has considered each of these positions and briefly discusses them below.

In *Delta/Airtran Baggage Fee Antitrust Litigation,* the United States District Court for the Northern District of Georgia considered whether a Civil Investigative Demand ("CID") issued by the Department of Justice Antitrust Division ("DOJ") triggered a duty on the part of Delta Airlines to preserve evidence for use in subsequent multidistrict litigation filed by passengers who were allegedly charged illegal first-bag fees. *Id.,* 770 F.Supp.2d at 1307-08 (N.D.Ga. 2011). On February 2, 2009, the DOJ issued a CID requiring Delta to produce a variety of records relating to fees charged for checked baggage. The following day, Delta's assistant general counsel e-mailed a document preservation and litigation hold notice to twenty-two individuals identified as being potential document custodians. Over the course of the next few days, Delta collected relevant documents from the custodians

[9] This opinion was amended and superseded on January 30, 2014; however, the text was not available at the time of this opinion.

and produced them to the DOJ. In May 2009, after a conversation with the DOJ regarding Delta's e-mail system, Delta's in-house counsel instructed its technology department to copy the hard drives of the custodians and place them on a separate server in order to prevent the automatic deletion of relevant e-mails. In addition, Delta instructed a third-party vendor to suspend its overwriting of Delta's back-up tapes, although the vendor did not implement this instruction until sometime after June 6, 2009.

On May 22, 2009, the first case was filed in the multidistrict litigation. After conducting discovery, plaintiffs filed a motion seeking sanctions for spoliation of evidence. In particular, they claimed that Delta's improper three-month delay in suspending its standard electronic document destruction policy after receiving the CID resulted in the automatic deletion of relevant e-mails and documents dating back to July 2008. The court was not persuaded by plaintiffs' argument, as the court fundamentally disagreed with plaintiffs' premise that the issuance of the CID gave rise to a general duty on the part of Delta to preserve evidence related to baggage fees. The court explicitly rejected plaintiffs' argument that "the duty to preserve documents is a duty that does not attach to any party," finding instead that such an argument "flies in the face of the legal definition of the word duty, which defines duty as a 'legal obligation that is owed or due to *another*.'" *Id.* at 1308 (quoting Black's Law Dictionary 580 (9th ed. 2009)). Instead, the court found that the DOJ-issued CID triggered a duty to preserve evidence that ran only to the DOJ, and not to the plaintiffs.

In that same vein, the District Court for the Southern District of Florida concluded that neither a government investigation, nor a prior lawsuit, triggered the duty to preserve evidence for use in a later proceeding. *Point Blank Solutions, Inc.*, 2011 WL 1456029, at *24. In *Point Blank Solutions,* plaintiff, a manufacturer of body armor, contracted with

defendant, Toyobo America, Inc. ("Toyobo") to supply Zylon, a fiber used in making bullet-proof vests. In June 2003, an officer was shot while wearing a Zylon vest and was injured by bullets that penetrated the fiber. In October 2003, Toyobo hired a public relations firm to provide assistance in connection with "possible litigation concerning Zylon," although no litigation had commenced at that time. *Id.* at *13. However, beginning in November 2003, numerous cases were filed across the country involving the Zylon-containing vests, and the United States Department of Justice launched its own investigation into the matter. That same month, Toyobo collected information in connection with the pending litigation, including documents relating to all manufacturers working with Toyobo. It also allegedly issued an oral litigation hold on documents pertaining to Second Chance, a manufacturer that had filed suit.

In April 2004, a class action was filed against Toyobo America and another vest manufacturer, Armor Holdings. *Id.* at *17. Additionally, in August 2005, the National Institute of Justice issued a Body Armor Standard Advisory Notice, indicating that Zylon was a material that "appears to create a risk of death or serious injury as a result of degraded ballistic performance when used in body armor." The Institute subsequently decertified all Zylon-containing vests. *Id.* at 18.

Point Blank filed suit against Toyobo in 2009. In the course of conducting discovery, Point Blank learned that Toyobo had an ineffectual document preservation system and had apparently lost or destroyed a large portion of electronic data and other records prepared between 2003 and 2005. Accordingly, Point Blank sought spoliation sanctions, arguing that Toyobo was under a duty to preserve evidence that began in November 2003 with the first round of litigation and the government investigation. In addition, Point Blank contended that "a general duty to preserve is created when a party is aware that industry-

wide litigation is reasonably foreseeable." *Id* at *22. Finally, Point Blank argued that privilege logs submitted by Toyobo, which included work product documents dated as early as December 2003, established that the duty to preserve arose in 2003. In Point Blank's view, work product only applied when a document was prepared in anticipation of litigation. Thus, the logs proved that Toyobo was anticipating litigation in December 2003. In response, Toyobo argued that its only duty to preserve evidence in 2003 ran to Second Chance, and because it had no inkling until December 2006 that Point Blank intended to file suit, the duty to preserve evidence relevant to Point Blank's claim did not arise until December 2006.

The court addressed Point Blank's argument that the 2003 investigation and litigation created a duty to preserve evidence that "shifted" from the government and Second Chance to Point Blank when it filed suit. Rejecting that contention, the court found the concept of a shifting duty to be "incompatible with the basic rule that a duty is owed to a specific party," adding that, "[i]t is well-settled that the duty to preserve potentially relevant evidence 'arises when the party in possession of the evidence knows that litigation **by the party seeking the evidence** is pending or probable.'" *Id.* at *24 (quoting *Kounelis v. Sherrer,* 529 F.Supp.2d 503, 518 (D.N.J. 2008)) (emphasis in original); *see also, Brigham Young Univ.,* 282 F.R.D. at 572 ("It is difficult for the Court to imagine how a party could ever dispose of information under such a broad [shifting] duty because of the potential for some distantly related litigation that may arise years into the future.").

The court also considered the "industry-wide" theory, conceding that Point Blank's argument was logical, but ultimately declined to apply the theory, as the trigger date of the duty was determined not to be crucial to resolution of the motion. However, in another case, the United States District Court for the District of Montana briefly addressed the

"industry wide" theory. *Livingston,* 910 F.Supp. at 1494. In *Livingston,* the plaintiff sued Isuzu Motors after suffering personal injuries in a rollover accident involving an Isuzu Trooper. After a jury verdict in favor of the plaintiff, Isuzu filed a motion for a new trial and argued, *inter alia,* that the court erred by improperly allowing the jury to hear evidence regarding Isuzu's destruction of raw data underlying a report on the Trooper. Isuzu claimed that the jury was thus permitted to presume that Isuzu had destroyed the evidence in bad faith, even though Isuzu had no duty to preserve evidence at the time it disposed of the data. The court rejected this argument, stating "[g]iven Isuzu's knowledge of the Jeep CJ rollover problem in the U.S., as well as other information known industry wide involving the rollover factor in narrow track utility vehicles, Isuzu had notice of potential relevance to this and other litigation involving their product." *Id.* It merits mention that the court did not consider the "industry-wide" concept in the context of a spoliation motion, and this theory has not been universally accepted, nor specifically addressed by the Fourth Circuit.

Recently, in *In Re Actos,* the United States District Court for the Western District of Louisiana found that a pharmaceutical company's duty to preserve evidence relevant to a MDL was triggered in 2002 by a general "product liability" litigation hold issued by the manufacturer of the diabetic drug, Actos©. *In Re Actos,* 2014 WL 308909. Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. ("Takeda") introduced Actos© to the market in 1999. According to the record before the Louisiana District Court, beginning in 2002, several lawsuits were filed against Takeda claiming personal injuries involving the liver and cardiovascular system of patients taking the drug. As a result of the lawsuits, Takeda issued a litigation hold notice that instructed employees "to preserve any and all documents and electronic data which discuss, mention,

or relate to Actos." The notice also advised that it was to be interpreted "in its broadest sense to prevent the deletion or destruction of any recorded information and data relating in any way to Actos." According to testimony in the case, this litigation hold notice was "refreshed" several times, including in 2003, 2006, 2007, 2008, and 2011. Apparently, despite the existence of the litigation hold and its "refreshers," the electronic files of 46 employees, including some key personnel, were deleted or discarded. The e-mail folder of one key executive was destroyed just days before the first MDL lawsuit was filed.

The MDL, which was created in late 2011, involved individuals who claimed to have developed bladder cancer from taking Actos©. In the course of discovery, Plaintiffs learned of the missing electronic files and moved for an award of sanctions. Plaintiffs argued that the litigation hold notice generated in 2002, and refreshed on multiple occasions, triggered Takeda's ongoing and unabated duty to preserve all information relating to Actos©. In response, Takeda maintained that the 2002 litigation hold was not applicable to the MDL, because it applied only to claims involving the liver and cardiovascular system, and not claims related to bladder cancer.

Based largely upon the "broad and sweeping" language of the litigation hold notice, and Takeda's concession that the notice had been "refreshed" in the years that followed, the court concluded that the duty to preserve evidence for use in the MDL arose in 2002. Rejecting Takeda's argument that the court was improperly shifting the duty to preserve from the plaintiffs in the original cases to plaintiffs in the MDL, the court again pointed to the language of the notice.[10] Emphasizing that the original hold notice was prompted by the filing of a lawsuit alleging personal injury or wrongful death resulting from the use of

[10] Unfortunately, the spoliation motion and related memoranda and exhibits filed by the parties in this multidistrict litigation have been sealed and, therefore, some of the factual underpinnings and rationale of the parties' arguments are unavailable.

Actos©, and the MDL plaintiffs were likewise alleging personal injury or wrongful death resulting from the use of Actos©, the court found there was no "shifting duty." Thus, the court concluded that the broad and sweeping "general products liability hold," made applicable to the drug Actos©, which had been in Takeda's own words "refreshed" over a period of twelve years, was sufficient to trigger a duty to preserve evidence for the MDL plaintiffs. (*Id.* at *23).

In this circuit, the duty to preserve evidence arises when "litigation is reasonably anticipated." *Victor Stanley,* 269 F.R.D. at 521 (citing *Silvestri,* 271 F.3d at 591). The undersigned is not persuaded by Plaintiffs' argument that Ethicon's duty to preserve evidence relevant to this MDL began with the 2003 document preservation notice. That notice was specifically tied to a civil action filed in 2003, which was dismissed in January 2004. Although Ethicon's legal department did not expressly withdraw the notice, key personnel in the company would have known that the lawsuit was resolved, which then eliminated the duty to segregate and preserve such things as e-mails and other informal documents related to TVT. Nothing before this court suggests that Ethicon had any reason in 2003 to anticipate additional litigation relating to its transvaginal mesh products. Indeed, it was two years after the 2003 complaint was dismissed before another lawsuit was filed. Moreover, an isolated lawsuit, or even two, would not reasonably lead Ethicon to believe that large scale nationwide products liability litigation was down the road.

Having concluded that the duty to preserve was not triggered in 2003, the court considered when it was reasonable for Ethicon to anticipate a future of ongoing litigation that would culminate in the MDL. The undersigned contemplated the importance of the October 20, 2008 FDA publication and the status of pending and evolving litigation against Ethicon in answering this question. In *In re Pradaxa,* the United States District

Court for the Southern District of Illinois noted that circumstances surrounding a few pending products liability actions may give rise to a duty to preserve evidence for future widespread litigation. *Id.* In this case, the court found that the manufacturer of Pradaxa© was "acutely aware that nationwide litigation involving hundreds of case (if not more) was imminent," when a plaintiff in one of thirty pending cases moved the panel on multidistrict litigation to consolidate the cases in one district. *In re Pradaxa (Dabigatran Etexilate) Products Liability Litigation,* Case No. 3:12-md-02385-DRH-SCW, 2013 WL 6486921, at *7 (S.D. Ill. Dec. 9, 2013). Plaintiff's counsel anticipated that 500 additional actions would be filed in the near future, and this prediction was communicated to the manufacturer. Accordingly, the court found that the manufacturer should have appreciated at that time its obligation to replace a limited litigation hold issued in the pending cases with a broad hold commensurate with the size of the impending litigation.[11]

Applying the logic in *In re Pradaxa,* one could argue that given the 2008 FDA publication, coupled with the fact that (1) a smattering of personal injury cases based on the TVT and Prolift devices were pending and (2) the number of lawsuits was steadily increasing, Ethicon should reasonably have anticipated large scale future litigation over its pelvic mesh products in 2009, and should have begun efforts to preserve evidence for that purpose. Therefore, while the filing of one or two cases may not have given Ethicon good cause to implement ongoing, large scale document preservation measures, the circumstance in 2009 certainly suggested the looming prospect of substantial product

[11] Plaintiffs rely on this decision for their position that a single case gives rise to a widespread duty to preserve evidence. However, *In re Pradaxa* can be distinguished from this litigation in two ways. First, the issue in *In re Pradaxa* was whether a case filed before the launch of Pradaxa© triggered a preservation duty for post-launch cases. The manufacturer argued that it did not, but agreed that the duty to preserve arose with the first post-launch claim. Ethicon makes no similar concession. Second, the amount of time between the first post-launch Pradaxa© claim and the thirty lawsuits filed nationwide was minimal. In this case, it was more than two years after resolution of the first TVT case that a second case, which was filed *pro se,* was served on Ethicon.

liability litigation.

Nonetheless, having thoroughly considered the relevant law on this issue and the particular facts before the court, the undersigned finds that Ethicon's earliest duty to preserve evidence for use in this MDL regarding the TVT device arose on April 30, 2007, and regarding the Prolift device arose on April 21, 2008. To the extent that component parts of the TVT and Prolift devices are the same as those used in other pelvic mesh products at issue in this MDL, April 30, 2007 (or April 21, 2008 in the case of components found in Prolift and not in TVT) would be the earliest date that evidence should have been preserved related to those component parts. Conversely, to the extent that issues related to the other devices are unique to the device, the duty to preserve may not have been triggered until later.[12]

The undersigned determines the April 30, 2007 (TVT) and April 21, 2008 (Prolift) dates to be appropriate in this case given that those were the triggering dates identified in a "Consolidated Hold Notice for Pelvic Mesh/Gynecare Product Liability Litigation" issued on February 18, 2011. (ECF No. 953-42). The consolidated notice was prepared by Ethicon's in-house counsel, the corporate individual most knowledgeable about the corporation's litigation exposures, and the one responsible for preparing and disseminating document preservation notices. As previously stated, in the Consolidated Notice, counsel described litigation as "ongoing" and reminded employees that "[h]old notices relating to the individual products previously have been distributed company-wide on the following dates:" TVT April 30, 2007; Prolift April 21, 2008. *Id.* Considering that this notice was issued at a time when sixty cases were being consolidated by the Supreme Court of New Jersey for centralized management, the only reasonable interpretation of the

[12] Some of the products were not on the market until after 2008.

notice is that counsel for Ethicon believed that documents relating to TVT and Prolift were already being preserved company-wide for the purpose of large scale litigation. Accordingly, the February 2011 hold notice was intended to "refresh" the 2007 and 2008 document preservation notices.

Turning to the second component of the preservation duty, the question is what must be preserved? It is uniformly agreed that a corporation under a duty to preserve is not required to keep "every shred of paper, every e-mail or electronic document, and every backup tape." *Zubulake v. UBS Warburg, LLC ("Zubulake IV"),* 220 F.R.D. 212, 217 (S.D.N.Y. 2003). As the court points out in *Zubulake IV,* such a requirement "would cripple large corporations." *Id.* In addition, "[a]s a general rule ... a party need not preserve all backup tapes even when it reasonably anticipates litigation."). In essence, the duty to preserve evidence "extends to those employees likely to have relevant information—the 'key players' in the case," and applies to "unique, relevant evidence that might be useful to the adversary." *Id.* at 217-18. Proper analysis of this component "requires the Court to determine reasonableness under the circumstances ... 'and that in turn depends on whether what was done—or not done—was *proportional* to that case and consistent with clearly established applicable standards.'" *Victor Stanley,* 269 F.R.D. at 522 (quoting *Rimkus Consulting Group, Inc.,* 688 F.Supp.2d at 613.

Ethicon argues that the cases filed before 2009 involved the production of only "general source materials." (ECF No. 1022-1 at 3-4). Therefore, Ethicon's preservation of all formal documentation, such as regulatory submissions and adverse event reports, was proportional to the litigation. To the contrary, Ethicon contends that it had no reason to keep the e-mails of every employee, the drafts found on their hard drives, and other incidental records before the case consolidation in 2010. While this position could

potentially have merit, the undersigned need not address it because the scope of the preservation was established by Ethicon's in-house counsel in the document preservation notices. In each case, counsel instructed employees to segregate and hold "all documents, memoranda, notes, files, emails, etc." relating to the device at issue and pertaining to labeling; pharmacovigilence; regulatory; discovery, research and development; product communications; marketing and sales; manufacturing; and distribution.

B. Breach of Duty

"A party breaches its duty to preserve evidence if it fails to act reasonably by taking 'positive action to preserve material evidence' ... The action must be 'reasonably calculated to ensure that relevant materials will be preserved,' such as giving out specific criteria on what should or should not be saved for litigation." *Victor Stanley,* 269 F.R.D. at 525 (quoting *Jones v. Bremen High Sch. Dist. 228*, No. 08-C-3548, 2010 WL 2106640, at *7 (N.D.Ill. May 25, 2010)). Generally, the party "must suspend its routine document retention/destruction policy and put in place a 'litigation hold' to ensure the preservation of relevant documents." *Zubulake IV,* 220 F.R.D. at 218. Once the duty to preserve attaches, any destruction of material evidence within the party's control is a breach of the duty. *Id.* at 220.

Plaintiffs claim that the custodial files of 22 former and current employees of Ethicon have been destroyed in whole or in part. However, ten of these employees left the company before the duty to preserve arose, and their records were either discarded or passed on to other employees in keeping with Ethicon's standard practice. Another employee, Cheryl Bogardus, left within days of the April 30, 2007 document preservation notice, and the record is not clear as to whether she even received it. Allison London Brown also left the company in 2007, and was apparently working in plastic surgery sales

and marketing at the time of her separation. Therefore, it is unclear whether she would have possessed relevant documents. (ECF No. 953-30). One additional employee, John Clay, left Ethicon in 2007; however, his date of departure is not in the record. Consequently, the court cannot presume that Ethicon breached a duty to preserve Mr. Clay's materials.

As to the remaining nine employees, Plaintiffs have demonstrated the likelihood that some relevant records possessed by these employees were lost or destroyed. Of particular note, Ethicon produced only twenty-five documents in the custodial file of Renee Selman, its worldwide president from 2005-2010, and only twenty-seven documents for Dr. Ramy Mahmoud, Ethicon's chief medical officer and worldwide president of evidence-based medicine from August 2007 through July 2010. Therefore, Ethicon has breached its duty to preserve evidence in regard to these employees' custodial files.

Plaintiffs also complain that Ethicon disposed of product samples and documents provided to it by Medscand, the company that manufactured TVT before Ethicon acquired the product. Plaintiffs argue that much of Medscand's information formed the basis of Ethicon's representations regarding the safety of TVT; therefore, destruction of this material severely prejudiced Plaintiffs' ability to impeach the product. Nonetheless, the parties agree that the Medscand materials were lost or discarded in 2006, before Ethicon had a duty to preserve evidence relevant to this MDL. Accordingly, the missing Medscand documents do not support a finding of spoliation.

Lastly, Plaintiffs contend that a videotape regarding small pore mesh, which was prepared by Ethicon's expert, Dr. Heniford, was destroyed; thereby, limiting Plaintiffs' ability to cross-examine him. However, Ethicon indicates that it provided such a videotape to Plaintiffs and disputes that another tape on small pore mesh exists. Given that Plaintiffs

have not established the existence of a second videotape, the court cannot find that Ethicon breached a duty to preserve in regard to a videotape.

C. Culpability

Having determined that Ethicon had a duty to preserve documents pertaining to TVT as early as April 30, 2007, and Prolift as early as April 21, 2008, and that Ethicon breached that duty, the undersigned must now examine Ethicon's culpability. Circuits vary as to what level of culpability makes spoliation sanction-worthy. "In the Fourth Circuit, for a court to impose some form of sanctions for spoliation, any fault—be it bad faith, willfulness, gross negligence, or ordinary negligence—is a sufficiently culpable mindset." *Victor Stanley,* 269 F.R.D. at 529 (citing *Goodman,* 632 F.Supp.2d at 518, 520). "Under existing case law, the nuanced, fact-specific differences among these states of mind become significant in determining what sanctions are appropriate." *Id.; see also E.I.Dupont de Nemours v. Kolon Industries,* 803 F.Supp.2d 469, 498 (E.D.Va. 2011) ("Assessing the quantum of fault becomes appropriate when determining the appropriate sanction, not in deciding whether spoliation has taken place.").

Negligence is a lack of due care, the failure to exercise the level of care expected of a reasonably prudent person acting under like circumstances. Negligent spoliation "has been found in cases where a party failed to properly preserve, collect, and review evidence, resulting in the destruction of relevant materials." *Felman Production, Inc. v. Industrial Risk Insurers,* Case. No. 3:09-cv-0481, 2011 WL 4547012, *12 (S.D.W.Va. Sept. 29, 2011) (citing *Victor Stanley,* 269 F.R.D. at 529). Gross negligence is the same as ordinary negligence, except in degree. *Id.* In contrast, willfulness and bad faith require "intentional, purposeful, or deliberate conduct." *Victor Stanley,* 269 F.R.D. at 530 (citing *Buckley v. Mukasey,* 538 F.3d 306, 323 (4th Cir. 2008)). "The fundamental element of bad faith

spoliation is advantage-seeking behavior by the party with superior access to information necessary for the proper administration of justice." *Micron Technology, Inc. v. Rambus, Inc.,* 645 F.3d 1311, 1326 (Fed. Cir. 2011). "While bad faith requires 'destruction for the purpose of depriving the adversary of the evidence,' for willfulness, it is sufficient that the actor intended to destroy the evidence." *Victor Stanley,* 269 F.R.D. at 530 (citations omitted).

Here, Plaintiffs argue that Ethicon's destruction of documents ranged from negligence to bad faith. For example, they argue that Ethicon's wiping of Renee Selman's hard drive constitutes bad faith, while Ethicon's complete failure to implement an effective retention policy and monitor compliance with the litigation holds was, at a minimum, grossly negligent. They also contend that Ethicon made a conscious choice not to preserve back-up tapes from which deleted e-mails could be retrieved. In response, Ethicon contends that its document preservation notices and exit checklist for departing employees demonstrate its good faith efforts to properly segregate and store relevant evidence. Ethicon further argues that Plaintiffs have presented no proof that Ethicon, or any of its employees, ever intentionally lost or destroyed evidence. Finally, Ethicon's expert testified that Ethicon had only disaster recovery tapes, which were not considered a part of the operational function of the business systems, and would not have been subject to litigation holds. As explained below, the undersigned agrees with Plaintiffs that Ethicon negligently lost or destroyed relevant evidence after a duty to preserve was triggered; however, the undersigned is not persuaded that Ethicon acted willfully or in bad faith.

First, Plaintiffs attack Ethicon's records management program in general. Plaintiffs point to a 2007 Corrective and Preventative Action ("CAPA") summary report produced by Ethicon during discovery. This internally-created report addressed Ethicon's lack of

compliance with Johnson & Johnson's corporate records management requirements; specifically, Ethicon's inability to appropriately provide all relevant documents in case of litigation or inspection. (ECF No. 1041-6). According to Plaintiffs, the CAPA grew out of a 2002 internal audit and a 2006 consultant's audit, which found that Ethicon's "current paper-based method of document management and retention has become untenable." (ECF No. 1041 at 12). Plaintiffs' interpret these materials to show that Ethicon "had no formal document management program ... and it took *Plaintiffs* complaining about the lack of documents" for Ethicon to take corrective action. (*Id.* at 13).

Another way of looking at the audit results is that Ethicon, in fact, had a practice and procedure related to record retention and management, but that process was burdensome and unwieldy because it relied too heavily on paper. Therefore, Johnson & Johnson took the initiative to drag Ethicon into the modern world. The audits and reports do not indicate any deliberate intent on the part of Ethicon to cling to its hard-copy format in order thwart litigation and inspection. They merely suggest that Ethicon preferred paper over electronics, while Johnson & Johnson wanted all of its subsidiaries to use consistent record-keeping procedures. Moreover, while the CAPA corroborates that Ethicon was not maintaining its records in accordance with the policies of its parent corporation, it also demonstrates concerted effort on the part of Ethicon to become compliant with Johnson & Johnson's directives by December 2007. Interestingly, the CAPA additionally reflects that a scheduled "Records Cleanout (Administrative and Full)" was cancelled "due to legal restriction;" thus substantiating an affirmative measure on Ethicon's part to preserve evidence. (ECF No. 1041-6 at 10-11). Accordingly, the CAPA does not establish willful or bad faith acts on the part of Ethicon.

Second, Plaintiffs impugn the system used by Ethicon to implement and monitor litigation holds. The record reflects that document preservation notices were sent from the legal department/risk management to district managers. The managers were then given broad discretion to determine which employees should receive the holds and what documents should be preserved. In addition, the managers were responsible for insuring that departing employees had segregated and preserved documents subject to a litigation hold. Unfortunately, the process was riddled with holes, starting with the discretion given to the district managers and ending with in-house counsel's apparent failure to evaluate the efficacy of the system. Evidence supplied by Plaintiffs in the form of testimony by James Mittenthal, Ethicon's Rule 30(b)(6) representative,[13] confirms the following:

> Not all employees understood their obligations under the litigation holds. Some may not have received the holds at all.
>
> Ethicon did not insist on consistency in the preservation of documents. Although Ethicon instructed employees on how to create a litigation hold folder for electronic documents, it allowed employees to decide their own method of segregating and storing relevant documents.
>
> Ethicon failed to take routine measures designed to ensure document preservation; such as, keeping back-up tapes and retaining hard drives.
>
> Disconnect between employees, managers, and the information technology department likely resulted in the loss of relevant evidence. Employees were under the impression that documents preserved for litigation, if left in their office or on their computer at the time they left Ethicon's employ, would be retained. Managers were under the impression that employees would report at the time of the exit interview if they had relevant documents that needed to be removed from their desktop or office and retained. The information technology department was under the impression that computer hard drives

[13] Plaintiffs argue that the court should not consider the affidavits authored by Mr. Mittenthal and Pamela Downs, another technology consultant hired by Ethicon, for two reasons. First, the affidavits are comprised of hearsay and hearsay within hearsay. Second, Ethicon's use of outside experts to explain its document retention failures is, itself, evidence of bad faith. Relying on the court's observations in *In Re Actos,* Plaintiffs assert that Ethicon offers witnesses with no personal knowledge of its record management procedures in order to create a buffer and obfuscate on its behalf. Plaintiffs may rest assured that the undersigned gave little weight to the affidavits and instead focused on the testimony of Mr. Mittenthal. Having reviewed the testimony, however, the undersigned sees no basis upon which to conclude that Ethicon's retention of experts to investigate document losses and to testify regarding the reasons for the losses were acts of bad faith.

> could be wiped and either recycled or repurposed once an employee left the company unless a specific request was made to remove and preserve information.

Ethicon concedes that its process failed miserably in certain instances, but assures the court that it has implemented additional retention measures "to secure its ability to meet legal hold obligations going forward." (ECF No. 1022 at 12). For example, in June 2012, Ethicon began saving all hard drives of departing employees. In December 2012 Ethicon's third-party vendor managing the hardware of sales representatives began permanently retaining hard drive images when sales staff separated from the company or received replacement equipment. In early 2013, Ethicon joined an "IT Safe" program that images the hard drives of all departing employees for preservation, and also in 2013 launched Ethicon Outlook Exchange, which stores e-mails permanently in a central location. (*Id.*)

Of course, these efforts, while laudable, do nothing to restore the information that was already lost. A party's obligations "do not end with the implementation of a 'litigation hold' ... [c]ounsel must oversee compliance with the litigation hold, monitoring the party's efforts to retain and produce the relevant documents." *Zubulake v. UBS Warburg, LLC ("Zubulake V"),* 229 F.R.D. 422, 432 (S.D.N.Y. 2004). Certainly, at a minimum, Ethicon's in-house counsel should have educated employees on what measures were expected of them to collect and preserve material evidence. In light of the technology that was available to Ethicon between 2007 and 2012 to protect electronic records, the undersigned concludes that Ethicon's failure to better implement and monitor its litigation holds was negligent, and perhaps grossly negligent in some cases.

On the other hand, the record does not support a finding that Ethicon, or any employee of Ethicon, acted willfully or intentionally to delete, discard, or hide evidence, and certainly there is no proof that Ethicon destroyed evidence specifically for the purpose

of preventing its disclosure in this litigation. In the case of missing custodial files, the record indicates that employees aware of litigation holds took steps to collect, segregate, and save relevant information. Many of the employees confirmed under oath that they never deleted or discarded any materials subject to preservation notices. The record further demonstrates that when evidence was destroyed, it usually occurred when an employee left Ethicon, and generally was deleted by a technician in the information technology department who had no knowledge that he or she was destroying material evidence.[14]

D. Relevance

The next consideration for the court is whether the information that was lost was relevant. "The test for relevance for the purposes of establishing the third element is somewhat more stringent than merely meeting the standard provided in Federal Rule of Evidence 401" *Sampson,* 251 F.R.D. at 179. In the context of spoliation, lost evidence is relevant if "a reasonable factfinder could conclude that the lost evidence would have supported the claims or defenses of the party that sought it." *Goodman,* 632 F.Supp.2d at 509.

Plaintiffs identified nine custodial files that likely contained documents that were lost or destroyed after the duty to preserve was in place. To determine the relevance of the evidence, the undersigned considered the involvement of the employees with the TVT and Prolift devices. Mr. Price St. Hillaire was heavily involved in the marketing of Ethicon's incontinence line; therefore, the undersigned presumes that some of the missing evidence

[14] Plaintiffs contend that Ethicon encouraged its employees to have "careful communications" and to stop putting opinions in e-mail exchanges, suggesting an effort by Ethicon to prevent discovery of embarrassing or detrimental documents. (ECF No. 1041 at 16-17). Even if true, the undersigned fails to see how this argument supports Plaintiffs' claim of spoliation. To the contrary, if Ethicon insisted that delicate matters be handled in a format other than electronic, it is less likely that the inadequate custodial files contained information useful to Plaintiffs' cases.

from his file would have been relevant. Similarly, Jennifer Paine's work in regulatory affairs would have involved contact with the FDA and other regulatory agencies. Ms. Paine worked on the TVT line of products from July 2007 through December 2009. Accordingly, her documents likely included relevant evidence. Tom Divillio and Dr. Ramy Mahmoud held key positions in medical affairs. Dr. Mahmoud was world-wide president of evidence-based medicine between August 2007 through July 2010. E-mail communications recovered from other custodians confirm that both individuals had considerable involvement in Ethicon's product lines for stress urinary incontinence and pelvic organ prolapse. Obviously, documents in their possession would be relevant to this MDL. Renee Selman was Ethicon's worldwide president and would no doubt have been notified and consulted about important developments, concerns, or modifications related to all of Ethicon's products, including its transvaginal and pelvic mesh. Consequently, relevant documents would have been contained in her custodial file. Troy Mohler and Paul Courts were sales representatives, who would have imparted information regarding the relevant products to customers, including physicians and health care administrators. At a minimum, the files of sales representatives would probably contain information relevant to Plaintiffs' failure to warn claims. Susan Landgrebe, an employee in research and development at Ethicon, had considerable involvement in the TVT-Secur product. Accordingly, her custodial file would have included documents of relevance to the MDL. Finally, Nancy Leclair was director of marketing until her departure in 2011. Therefore, her custodial file would also be expected to contain relevant documents.

Accordingly, Plaintiffs have carried their initial burden of demonstrating that the lost materials likely contained ***some*** relevant evidence (evidence supporting their claims), and Ethicon has not shown otherwise. *See E.I. Dupont de Nemours and Comp.,* 803

F.Supp.2d at 498-99 ("Once the moving party shows that the spoliated material [is relevant], the burden to show otherwise falls on the party charged with spoliation."). Therefore, the undersigned concludes that Plaintiffs have established all three of the criteria necessary to establish Ethicon's spoliation of evidence.

E. Prejudice and Sanctions

Although Plaintiffs have shown the elements to support a finding of spoliation, the analysis does not end there. The concept of relevance includes a second prong; that being, the prejudice flowing from the loss of evidence. The extent of the resulting prejudice to the innocent party and the spoliator's degree of culpability are key factors in determining the appropriate sanction to impose for spoliation of evidence. *E.I. Dupont de Nemours and Comp.,* 803 F.Supp.2d at 499-500 (citing *Samsung Elect. Co., Ltd v. Rambus Inc.,* 439 F.Supp.2d 524, 541 (E.D.Va. 2006). When making this assessment, the court "should take pains neither to use an elephant gun to slay a mouse nor to wield a cardboard sword if a dragon looms. Whether deterrence or compensation is the goal, the punishment should be reasonably suited to the crime." *Anderson v. Beatrice Foods Co.,* 900 F.2d 388, 395 (1st Cir.1990). "A measure of the appropriateness of a sanction is whether it 'restore[s] the prejudiced party to the same position he would have been in absent the wrongful destruction of evidence by the opposing party.'" *Rimkus Consulting Group, Inc.,* 688 F.Supp.2d at 618 (cquoting *West v. Goodyear Tire & Rubber Co.,* 167 F.3d 776, 779 (2d Cir.1999)).

"Spoliation of evidence causes prejudice when, as a result of the spoliation, the party claiming spoliation cannot present 'evidence essential to its underlying claim.'" *Victor Stanley,* 269 F.R.D. at 532 (quoting *Krumwiede v. Brighton Assoc. LLC,* Case No. 05-c-3003, 2006 WL 1308629, at *10 (N.D.Ill. May 8, 2006)). The party moving for

sanctions bears the burden of demonstrating prejudice, although "[t]he burden placed on the moving party to show that lost evidence would have been favorable to it ought not to be too onerous, lest the spoliator be permitted to profit from its destruction." *Rimkus Consulting Group, Inc.*, 688 F.Supp.2d at 616 (citing *Chan v. Triple 8 Palace, Inc.* 2005 WL 1925579, at *7 (S.D.N.Y. Aug. 11, 2005)).

Determining the extent of the prejudice to Plaintiffs in this case is difficult. Plaintiffs rightfully and logically argue that they have no way of knowing precisely what evidence was destroyed or lost, and they urge the court to assume prejudice based on two factors—the "the sheer volume of information that was lost or destroyed," and the key positions held by the employees whose documents are missing. Certainly, these are important factors to consider. Nonetheless, to support an award of sanctions, especially the extreme sanctions demanded by Plaintiffs, they must demonstrate to the court with some precision that unique and relevant evidence has been lost, and this loss creates an evidentiary hurdle to them in presenting the essentials of their cases. "[S]peculative or generalized assertions that the missing evidence would have been favorable to the party seeking sanctions are insufficient." *Id.* at 616-17. Moreover, prejudice is less acute when "there are sources from which at least some of the allegedly spoliated evidence can be obtained ... [and] when the party seeking discovery can obtain extrinsic evidence of the content of at least some of the deleted information from other documents, deposition testimony, or circumstantial evidence." *Id.* at 616.

Ethicon argues that it has produced voluminous documents and communications involving all of the relevant custodians, much of which has been obtained from other sources within the corporation. According to Ethicon, a "custodial file" is nothing more than the hard copy documents found in the employee's possession and the electronic

documents directly collected from his or her computer. Considering that most employees store their documents in "common source" locations, or transfer documents to shared areas, the alleged "missing" documents actually exist and have been produced to Plaintiffs. Ethicon further emphasizes that its employees work in teams; therefore, most e-mail communications are exchanged between multiple senders and recipients. Consequently, relevant e-mails can be retrieved from the files of other participants in the exchange. In addition, Ethicon's Rule 30(b)(6) expert testified that some of the custodians who left the corporation simply gave their material documents to employees remaining at Ethicon. He indicated that in the course of interviewing managers, he learned that some employees burned relevant information located on their computers onto CD's to give to their replacements; some forwarded e-mails; and others handed over hard-copies of documents. He explained that Ethicon's preservation notices were subject-matter related, not custodial. Therefore, employees preserved documents by product, rather than by the custodian who originally possessed the documents. As such, repurposing an employee's hard drive upon his or her separation from the company does not mean that relevant materials in the employee's possession were permanently destroyed. Finally, Ethicon contends that all of the documents necessary for Plaintiffs to present their cases have been produced, because all crucial documents were centrally maintained at Ethicon, including materials relating to product design, regulatory affairs, marketing, adverse events and complaints, and post-market surveillance.

Plaintiffs rely heavily on the court's decision in *In Re Actos,* when arguing that this court should not accept Ethicon's position that much of the missing information has been captured in the custodial files of other employees, in shared server areas, and in written documentation preserved, but not attributed to a particular custodian. While it is true that

the court in *In Re Actos* was not overly impressed that defendant Takeda was able to supply some of the missing information through the custodial files of other employees, Plaintiffs place too much emphasis on that point. Unlike the current situation, in which no specific loss has been identified, the plaintiffs in *In Re Actos* located documents from outside sources that demonstrated the likelihood of prejudice from Takeda's destruction of evidence. Of particular relevance, the plaintiffs located, through third-party discovery, highly damaging documents that should have been preserved in the custodial file of a high-level Takeda executive. Plaintiffs discovered a letter from Upjohn to Takeda in which Upjohn expressed its intention to withdraw from a collaboration involving Actos© due to concerns about the drug's "margin of safety." *In Re Actos,* 2014 WL 308909, at *34. In response to this letter, Takeda's Managing Director, Board Member, and General Manager of Strategic Product Planning Department wrote to Upjohn's Project Manager, requesting that Upjohn omit its safety concerns when explaining the reason for its decision to abandon the collaboration. After reviewing the letter, the court concluded that it was not unreasonable to assume that the request to omit safety concerns made by a high level executive at Takeda reflected the company's corporate position and culture. The court added: "That the missing files could evidence a corporate culture embracing attempts to remove mention of or an attempt to conceal or underplay expressed safety concerns surrounding the development of Actos is strongly suggested, if not fully established by this interchange." *Id.* Here, Plaintiffs simply have not articulated circumstances demonstrating the same probability of severe prejudice.

At the hearing, Plaintiffs were asked to elucidate the effect of the missing evidence on their ability to prosecute their claims. Plaintiffs described the difficulties they had encountered in fleshing out the events of 2006-2009, indicating that critical witnesses,

such as Renee Selman, had no memory of important meetings and discussions, and also had no e-mail communications to refresh her memory. (ECF No. 1054 at 19-48). However, the vast majority of Plaintiffs' frustration involved the witnesses' lack of memory regarding the details of conversations. Nothing before the court suggests that missing e-mail communications would actually remedy that problem. Particularly, in view of Ethicon's instructions to its employees that sensitive issues and opinions should not be expressed in e-mails.

To further support their argument of severe prejudice, Plaintiffs focus on nine e-mail communications produced by Ethicon. According to Plaintiffs, they reviewed the entirety of Ethicon's document production and deduplication logs to determine if multiple copies of the nine e-mails could be found in other custodial files; thus, substantiating Ethicon's position that the "missing" evidence actually was not "lost." (*See* ECF No. 1041-1). In the case of five of the e-mails, only a single copy existed, and in another four e-mails, only partial duplicates could be located. Plaintiffs contend that this result corroborates that (1) Ethicon has not restored all of the missing evidence through production of other files, and (2) highly relevant evidence was destroyed when the custodial files were lost. The undersigned has carefully considered Plaintiffs' position and acknowledges the possibility that certain relevant e-mail communications were permanently lost; however, Plaintiffs have not provided the court with any concrete evidence of prejudice to their cases, as a whole; particularly, not the extent of prejudice that would justify across-the-board sanctions such as default judgments, striking of defenses, and the offering an adverse instruction in every case.

A district court has broad discretion to impose sanctions for the spoliation of relevant evidence, although the sanction imposed should be no harsher than that necessary

"to serve the prophylactic, punitive, and remedial rationales underlying the spoliation doctrine." *Silvestri,* 271 F.3d at 590 (quoting *West,* 167 F.3d at 779). "Put another way, appropriate sanctions should '(1) deter parties from engaging in spoliation; (2) place the risk of an erroneous judgment on the party who wrongfully created the risk; and (3) restore the prejudiced party to the same position he would have been in absent the wrongful destruction of evidence by the opposing party.'" *Victor Stanley,* 269 F.R.D. at 533-34 (quoting *Jones*, 2010 WL 2106640, at *5). Extreme sanctions, such as default judgment or dismissal, "should be avoided if a lesser sanction will perform the necessary function." *Sivestri,* 271 F.3d at 590.

"Determining whether sanctions are warranted and, if so, what they should include, requires a court to consider both the spoliating party's culpability and the level of prejudice to the party seeking discovery." *Rimkus,* 598 F.Supp.2d 598, 613. Both culpability and prejudice can range along a continuum. "A court's response to the loss of evidence depends on both the degree of culpability and the degree of prejudice." *Id.*

> Even if there is intentional destruction of potentially relevant evidence, if there is no prejudice to the opposing party, that influences the sanctions consequence. And even if there is an inadvertent loss of evidence but severe prejudice to the opposing party, that too will influence the appropriate response, recognizing that sanctions (as opposed to other remedial steps) require some degree of culpability.

Id.

Plaintiffs ask the court to enter a default judgment against Ethicon in three bellwether cases and to strike its statute of limitations and learned intermediary defenses in all cases. (ECF No. 952 at 1). Clearly, these are two of the most severe sanctions available to the court. In this circuit, to justify entry of a default judgment, the court must be able to conclude either (1) that Ethicon's behavior was so egregious that it amounts to a forfeiture

of its defense, or (2) that the effect of Ethicon's conduct was so prejudicial that it substantially denies Plaintiffs the ability to make their case. *Goodman,* 632 F.Supp.2d at 519; *see also, Sivestri,* 271 F.3d at 593 (Usually, a default judgment is only be justified in circumstances of bad faith or "like action;" although, less culpable conduct may require such a sanction "if the prejudice to the [plaintiff] is extraordinary."). The court must also give particular consideration to the broader policy of deciding cases on the merits. *Shaffer,* 11 F.3d at 463.

Similarly, to justify the striking of defenses in every MDL case, Plaintiffs must demonstrate some focused intent on the part of Ethicon to destroy evidence related to the defenses. Even then, such a severe sanction is rarely awarded unless the moving party can show a significant resulting handicap in rebutting a defense. *Victor Stanley,* 269 F.R.D. at 515 ("Faced with bad conduct, but minimal prejudice, courts are understandably reluctant to impose the most severe sanctions, especially case-dispositive ones."); *see also E.I.Dupont de Nemours,* 803 F.Supp.2d at 508. In the *Dupont* case, notwithstanding the court's finding that defendant's key employees and executives intentionally and in bad faith deleted numerous e-mails ***after*** the litigation had been instituted and hold orders were issued, the court did not strike defenses or enter a default judgment. The court emphasized that even though some communications were permanently lost, plaintiff was still able to present its case; consequently, the prejudice suffered by plaintiff did not rise to the level necessary to enter a default judgment or strike defenses. As explained *supra,* Plaintiffs plainly have not established that Ethicon acted willfully or in bad faith in its loss of evidence, nor have Plaintiffs' demonstrated prejudice so substantial that their cases are irreparably damaged. Therefore, extreme sanctions like default judgment and striking of

defenses are not justified. Accordingly, the court **DENIES** Plaintiffs' request for these forms of relief.

Next, Plaintiffs ask the court to order an adverse inference instruction in all cases, which would allow a jury to infer that Ethicon lost or destroyed evidence because it was detrimental to its defense. *Vodusek v. Bayliner Marine Corp.,* 71 F.3d 148, 156 (4th Cir. 1995). An adverse inference instruction is also an extreme sanction that "should not be given lightly." *Zubulake IV,* 220 F.R.D. at 220. "In practice, an adverse instruction often ends litigation—it is too difficult of a hurdle for the spoliator to overcome." *Id.* at 219. While a party moving for an adverse inference instruction in this circuit need not demonstrate bad faith on the part of the spoliator, courts granting the request often emphasize the presence of bad faith as the basis for the sanction. *Vodusek,* 71 F.3d at 156 ("An adverse inference about a party's consciousness of the weakness of his case, however, cannot be drawn merely from his negligent loss or destruction of evidence; the 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."). In *Victor Stanley,* the court explained that "certain sanctions make no sense when applied to particular breaches of the duty to preserve." *Id.,* 269 F.R.D. at 526. In the case of an adverse inference instruction, some comprehension by the spoliator of the importance of the evidence should be shown.

> [A]n adverse inference instruction makes little logical sense if given as a sanction for negligent breach of the duty to preserve, because the inference that a party failed to preserve evidence because it believed that the evidence was harmful to its case does not flow from mere negligence—particularly, if the destruction was of ESI and was caused by the automatic deletion function of a program that the party negligently failed to disable once the duty to preserve was triggered. The more logical inference is that the party was disorganized, or distracted, or technically challenged, or overextended, not that it failed to preserve evidence because of an awareness that it was harmful.

Id. And even if the requisite comprehension is shown, a plaintiff must still be able to demonstrate that the missing evidence would have been favorable to her case. *Zubulake IV,* 220 F.R.D. at 221. 'This corroboration requirement is even more necessary where the destruction was merely negligent, since in those cases it cannot be inferred from the conduct of the spoliator that the evidence would even have been harmful to him." *Turner v. Hudson Transit Lines, Inc.,* 142 F.R.D. 68, 77 (S.D.N.Y 1991) (citing *Stanojev v. Ebasco Services, Inc.,* 643 F.2d 914, 924 n. 7 (2d Cir.1981)).

Once again, Plaintiffs have not identified for the court specific gaps or weaknesses in their cases that exist *because* critical evidence was lost or destroyed. Most of the information that was lost were e-mail communications and other incidental records. Certainly, this type of evidence can be quite useful in enhancing a case, but is generally not necessary to prove most product liability claims. In addition, Plaintiffs have failed to identify any individual at Ethicon who destroyed documents or other materials with knowledge that the material were evidence relevant to pending or anticipated litigation. For those reasons, Plaintiffs do not provide sufficient support to justify the offering of an adverse instruction in every case. Having said that, the undersigned appreciates that, in certain cases, missing evidence from a custodian's file may provide the factual basis for an adverse inference instruction. For example, Plaintiffs may be able to demonstrate prejudice in a case involving a claim of failure to warn if the record demonstrates that the sales representative's call records were destroyed, and the implanting physician relied on the information supplied by the sales representative. However, this factual basis for an adverse inference instruction does not exist in every case. Accordingly, the undersigned **DENIES** Plaintiffs' motion for an order offering an adverse inference instruction in every case, but recommends that the Presiding District Judge allow Plaintiffs the opportunity to introduce

evidence regarding Ethicon's loss of relevant documents on a case-by-case basis, and, when appropriate, to tender an adverse inference instruction.

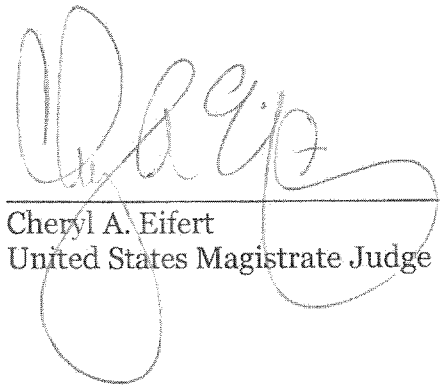
Finally, Plaintiffs request monetary sanctions and reasonable costs incurred in the bringing of this motion. Plaintiffs have demonstrated to the court's satisfaction that Ethicon's negligent loss of relevant evidence has unduly complicated the Plaintiffs' discovery and case preparation, and has unnecessarily increased for Plaintiffs the costs of litigation. Plaintiffs describe the difficulty they have encountered when having to piece together information relevant to a witness whose custodial documents are missing. Plaintiffs' counsel clearly has had to dig deeper and work harder to reconcile testimony with documents and close evidentiary loops. Moreover, the undersigned finds that Plaintiffs have substantially succeeded on their motion for a finding of spoliation.

Therefore, the court **GRANTS** Plaintiffs' request for monetary sanctions and reasonable costs. Plaintiffs are hereby **ORDERED** to submit to the court within **thirty (30) days** of the date of this Order affidavits and other supporting documentation to establish the amount of sanctions, fees and costs that should be awarded to Plaintiffs. Ethicon shall have twenty **(20) days** thereafter to respond, and Plaintiffs shall have an additional **ten (10) days** to reply. After the information has been submitted, the court will determine whether a hearing is necessary.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2327, and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:14-cv-07300. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this

court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at http://www.wvsd.uscourts.gov.

ENTERED: February 4, 2014.



Cheryl A. Eifert
United States Magistrate Judge