UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: TYLENOL (ACETAMINOPHEN) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	§ § § § § §	**MDL NO. 2436** **2:13-md-02436** **HON. LAWRENCE F. STENGEL**
This Document Relates to: Rana Terry, as Personal Representative and Administrator of the Estate of Denice Hayes, Deceased, Plaintiff, vs. McNEIL-PPC, Inc., McNeil Consumer Healthcare, and Johnson & Johnson, Inc., Defendants.	§ § § § § § § § § § § § § § §	Civil Action No. 2:12-cv-07263

M E M O R A N D U M

Stengel, J. **April 19, 2016**

This case is part of a Multidistrict Litigation (MDL) involving claims of liver damage from the use of Tylenol at or just above the recommended dosage.[1] This is the

[1] See Master Compl., 13-md-2436, Doc. No. 32. There are close to two hundred other cases included in this MDL, along with several similar cases in New Jersey state court.

first "bellwether" scheduled for trial.[2] The defendants have filed eighteen motions in limine. My rulings on each motion are explained below.

I. Evidentiary Standards

Several of the defendants' motions in limine involve arguments about the relevancy or prejudicial effect of certain evidence under Federal Rules of Evidence 401 and 403. "A district court is accorded a wide discretion in determining the admissibility of evidence under the Federal Rules." Sprint v. Mendelsohn, 552 U.S. 379, 384 (2008)(quoting U.S. v. Abel, 469 U.S. 45, 54 (1984)). See also Moyer v. United Dominion Indus., 473 F.3d 532, 542 (3d Cir. 2007)(citation omitted). "Assessing the probative value of [the proffered evidence], and weighing any factors counseling against admissibility is a matter first for the district court's sound judgment under Rules 401 and 403...." Id.

Context is important to questions involving Rules 401 and 403. Luce v. U.S., 469 U.S. 38, 41 (1984)("A reviewing court is handicapped in any effort to rule on subtle evidentiary questions outside a factual context."). To be admissible, evidence must be relevant. FED. R. EVID. 402. Relevant evidence is evidence having any tendency to make a fact of consequence in determining the action more or less probable than it would be without the evidence. FED. R. EVID. 401.

[2] A "bellwether" case is a test case. "Bellwether" trials should produce representative verdicts and settlements. The parties can use these verdicts and settlements to gauge the strength of the common MDL claims to determine if a global resolution of the MDL is possible. See FEDERAL JUDICIAL CENTER, MANUAL FOR COMPLEX LITIGATION, FOURTH EDITION 360 (2004); DUKE LAW CENTER FOR JUDICIAL STUDIES, MDL STANDARDS AND BEST PRACTICES 16-21 (2014).

Under Rule 403, relevant evidence may be excluded "if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." FED. R. EVID. 403.

1. Defendants' Motion In Limine to Exclude Evidence of, or Reference to, Adverse Event Reports (MIL 1)

The defendants move to exclude evidence of, or reference to, adverse event reports (AERs). The defendants claim they are "irrelevant, unreliable, and unsubstantiated anecdotes."

Under FDA regulations, manufacturers are required to create an AER in their safety surveillance database whenever they receive information that a person taking their drug has experienced an adverse event. 21 C.F.R. § 314.80. AERs are created on a standard form and may be submitted alone or accompanied by few or dozens of pages of supporting medical records. See Office of Epidemiology and Biostatistics, Food and Drug Administration, Annual Adverse Drug Experience Report: 1996 (Oct. 30, 1997), at 2 (Doc. No. 61, Ex. A). AERs are prepared by an employee of a pharmaceutical manufacturer based either on telephone conversations with a third party or other correspondence received by the manufacturer. AERs are drawn from a variety of sources: patients, their family members, physicians, or even civil complaints. See, e.g., In re Carter-Wallace, Inc. Sec. Litig., 220 F.3d 36, 40 (2d Cir. 2000)("Drug manufacturers receive these reports from several sources, including treating physicians.").

Both parties recognize that AERs have limitations in terms of their reliability. Because AERs are based on self-reported complaints of adverse events, they may not contain information which can make them a reliable source.[3] AERs are not considered to "necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse effect." 21 C.F.R. § 314.80(l).

a. Hearsay

First, the defendants argue that AERs would be inadmissible as hearsay: out-of-court statements offered to prove the truth of the matter asserted. See FED. R. EVID. 801. The defendants claim that they are not admissible under any of the hearsay exceptions or exemptions. The plaintiff counters that they would fall within the public records exception or the business records exception to hearsay. See FED. R. EVID. 803(c)(8)(A); FED. R. EVID. 803(c)(6). Whether an AER falls within an exception to the hearsay rule will require a more specific inquiry as to each document. It's entirely likely that an AER could be offered for a non-hearsay purpose. If offered for knowledge, or state of mind,

[3] See 71 Fed. Reg. 77314, 77321 (Dec. 26, 2006)("FDA noted that there are limitations to interpreting the AERS data. Dosing information may be unreliable. Acetaminophen products are generally taken on an as-needed basis, so the actual dose ingested can be difficult to ascertain. There is no certainty that all of the adult cases included in this analysis were unintentional. Stigma may be associated with reporting suicide, so cases may be reported as unintentional when they were intentional overdoses. In addition, spontaneous reporting systems cannot provide certainty that acetaminophen was the cause of any of the reported adverse event. Furthermore, incidence rates cannot be determined, because the numerator or denominator descriptors for the entire population are not available. Overall, spontaneous reports may be subject to significant underreporting.").

and not for its inherent truth, the AER would not be hearsay as to each document. For this reason, I will defer any ruling on the hearsay objection to the AERs.[4]

b. Notice

Even if the AERs are hearsay, the plaintiff argues they are relevant to showing notice. The defendants argue that these AERs are not admissible to show "notice" because they are unreliable. This argument misses the point. An AER is notice of some event or problem. The "reliability" issue is more one of weight than of relevance. Reliable or not, they are notice of some event of significance to this case and that likely takes them out of the hearsay rule.

The purpose of recording AERs is to serve as a warning system or signaling system for drug manufacturers. See Soldo v. Sandoz Pharms. Corp., 244 F. Supp. 2d 434, 463-64 (W.D. Pa. 2003)(quoting Brief Description with Caveats of System, Surveillance and Data Processing Branch of the Division of Epidemiology and Surveillance, Division of Epidemiology & Surveillance, Dec. 1988, at p. 1). Drug manufacturers are expected to report AERs to the FDA, which compiles them into a database. See http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082193.htm. AERs are often reviewed by the FDA and its subcommittees to determine if changes to a drug composition or its label need to be made.[5]

[4] The plaintiff also argues that the AERs could be considered party admissions. I will need to see the context and content of the AERs in order to make a ruling on this point.

[5] The 2002 Advisory Committee reviewed AERs to determine what risk of injury recommended dosing posed. See FDA Safety Analysis Power Point, Sept. 19, 2002 (Doc. No. 96, Ex. 7); FDA Memorandum Aug. 15, 2002 (Doc.

Drug manufacturers are expected to take certain steps to ensure their products are safe for consumers. These steps are known as "pharmacovigilance." See Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemioliogic Assessment (2005)(Doc. No. 96, Ex. 3). Reporting AERs to regulatory authorities is at the heart of pharmacovigilance. See E. Kuffner Dep., Mar. 5, 2014 at 8 (Doc. No. 90, Ex. 3)("Reporting – reporting adverse event reports to the regulatory authorities would be my description of pharmacovigilance. I believe that's accurate."); E. Nelson Dep., Nov. 21, 2013 at 62-65, 98-101 (Doc. No. 96, Ex. 4)(confirming how AERs are used in the context of pharmacovigilance). Whether the defendants undertook the appropriate steps to carry out their duty of pharmacovigilance is important to the plaintiff's failure-to-warn and design defect claims.

With all this in mind, AERs would be admissible to show notice. See, e.g., Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378, 1385-86 (4th Cir. 1995)("[T]he district court did not abuse its discretion in admitting the DERs and case summaries, because the plaintiff offered the evidence solely to prove notice."); In re Gadolinium-Based Contrast Agents Products Liability, 956 F.Supp.2d 809, 815 (N.D. Ohio Jul. 25, 2013), *affirmed by* Decker v. GE Healthcare Inc., 770 F.3d 378 (6th Cir. 2014)(citations omitted); In re Fosamax Prods. Liab. Litig., No. 06 MD 1789(JFK), 2013 WL 174416, at *4 (S.D.N.Y. Jan. 15, 2013)("Adverse event reports received by Merck until the time of Plaintiff's

No. 95, Ex. 17). The Acetaminophen Working Group of the FDA relied on AERs in making its recommendation to reduce the single caplet strength from 500 mg to 325 mg. See CDER Working Group Executive Summary and Recommendations, Feb. 26, 2008 (Doc. No. 96, Ex. 1). Other Committees Groups of the FDA use AERs as data for understanding further regulatory needs. See Characterization of Acetaminophen Overdose and Related Hepatotoxic Events, Joint Meeting of the Drug Safety and Risk Management, Nonprescription and Anesthetic and Life Support Drugs Advisory Committees of the FDA, Powerpoint, Jun. 29, 2009 (Doc. No. 95, Ex. 21).

injury are admissible if used as evidence that Merck was on notice of potentially serious jaw injuries."); Wolfe v. McNeil–PPC, Inc., No. 07–348, 2012 WL 38694, at *2 (E.D.Pa. Jan. 9, 2012)("However, reports submitted to the FDA before plaintiff's alleged injury occurred would not be hearsay if offered on the issue of defendants' notice of potential safety risks from the use of Children's Motrin."); Schedin v. Ortho–McNeil–Janssen Pharm., Inc., 808 F.Supp.2d 1125, 1139 (D. Minn. 2011)("The Court had denied its previously filed motion in limine regarding AERs, finding that the evidence was admissible to show notice and could also support a finding of causation."), *reversed in part on other grounds*, In re Levaquin Products Liability Litigation, 700 F.3d 1161 (8th Cir. 2012); Hogan v. Novartis Pharm. Corp., No. 06–civ–0260, 2011 WL 1533467, at *13 (E.D.N.Y. Apr. 24, 2011)("The motion to preclude admission of adverse drug experience reports is denied. Individual reports and the total number of ONJ reports before June, 2005 can establish notice regardless of whether Hogan's jaw condition was not similar to any of the patients described in the reports."); In re Fosamax Prods. Liab. Litig., No. 1:06–MD–1789–JFK, 2010 WL 4242708, at *3 (S.D.N.Y. Oct. 27, 2010)("[A]dverse event reports are admissible only to prove when Merck had notice of the adverse events alleged therein."); Bartlett v. Mutual Pharmaceutical Co., Inc., No. 08–cv–358–JL, 2010 WL 3092649, at *1 (D. N.H. Aug. 2, 2010)("The [adverse event] reports are not hearsay, though, if offered to prove that the FDA was on notice of Sulindac's safety risks, or that Mutual should have been on notice of such risks.").

If they are admitted for the purposes of "notice," the defendants ask that the AERs admitted be limited only to those involving similar circumstances to those surrounding

the decedent's death. I agree that the AERs presented for the purpose of notice should be ones that would be similar to the circumstances of this case (i.e., persons who developed acute liver failure/damage at or just above 4 g, persons who were fasting/malnourished). Other AERs would likely be irrelevant to the case.

The defendants claim that the admission of only one AER which is substantially similar is necessary; admission of other AERs would be redundant. I disagree. The extent to which the defendants were on notice of the potentially adverse effects of Tylenol would be relevant to showing how intentional their behavior was in not addressing a potential problem or safety signal. The number of AERs will not necessarily be limited. However, the defendants can raise objections to relevance and prejudicial effect at the time of trial for specific AERs.

c. Design Defect

The defendants claim the AERs cannot serve as substantially similar prior incidents to show a design defect. "In the appropriate circumstances, evidence of prior occurrences and accidents involving a product which is identical or substantially similar to the product which has allegedly caused an injury has generally been held to be admissible at trial." Barker v. Deere & Co., 60 F.3d 158, 162 (3d Cir. 1995)(quoting 2A Louis Frumer & Melvin Friedman, Products Liability § 18.02[1], at 18–14 to 18–17 (1995)). In order to be considered "substantially similar," a district court "must be apprised of the specific facts of previous accidents." Barker, 60 F.3d at 163. "Absent such a foundation, it is impossible for the district court in the first instance, and for this court on appeal, to review the facts in order to make a determination as to similarity." Id. In

order to determine whether AERs are substantially similar enough to serve as evidence of a design defect, I will need factual context. I decline to make a ruling on this point until trial. The parties can raise their arguments at that time.

d. Reliance by Experts

The defendants claim that because AERs are unreliable sources of data, experts cannot use them in forming their opinions. The plaintiff recognizes that AERs may have limitations but argues that they may be used by experts to corroborate other information or research.

"If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted." FED. R. EVID. 703. Though AERs do not have the same controls as other sources of data, courts have found that they can be relied upon by experts, along with other data or research, in forming opinions about causation.[6] See Wolfe v. McNeil-PPC, Inc., No. 07–348, 2011 WL 1673805, at *5 (E.D. Pa. May 4, 2011)("In this case, the three doctors did not solely rely on case reports in forming their opinions on causation but used them to supplement their extensive review of plaintiff's medical records and deposition testimony of plaintiff's treating physicians. As with defendants' other objections, the three doctors' use of case studies in reaching their conclusion affects only the weight to be given their testimony, not its admissibility. Thus, the proposed testimony of the three doctors is based on sufficiently reliable methods."); Deutsch v. Novartis

[6] See Reference Manual on Scientific Evidence (2d Edition, Federal Judicial Center, 2000), at 469.

Pharmaceuticals Corp., 768 F.Supp.2d 420, 431 (E.D.N.Y. 2011)("Accordingly, the fact that a particular opinion is not based on a randomized controlled clinical trial, while certainly an area for cross-examination, will not affect its admissibility.").[7] In addition, an expert opining about a drug companies' pharmacovigilance duties may need to rely on AERs to explain what tasks drug companies may need to take to monitor the safety of their products. See Decker v. GE Healthcare Inc., 770 F.3d 378, 394 (6th Cir. 2014)("[Plaintiff's expert] was qualified to reliably testify as to the significance of the AERs.").

For these reasons, an expert's reliance on AERs may, in and of itself, be appropriate. Whether the expert used those AERs in a reliable manner is a different question, best addressed by a Daubert motion.[8]

[7] See also Tyler v. Sterling Drug, Inc., 19 F. Supp. 2d 1239, 1241 (N.D. Okla. 1998)("[A]necdotal reports may be relevant to the issue of causation to the extent that plaintiffs rely on the reports to show the evolution of the scientific literature.")(citations omitted); Schedin v. Ortho–McNeil–Janssen Pharm., Inc., 808 F.Supp.2d 1125, 1139 (D.Minn. 2011)(explaining that AERs are admissible because are commonly used by experts to determine causation in conjunction with other evidence), *rev'd in part on other grounds*, In re Levaquin Prods. Liab. Litig., 700 F.3d 1161 (8th Cir. 2012); In re Neurontin Marketing, Sales Practices, and Prods. Liab. Litig., 612 F. Supp. 2d 116, 153 (D. Mass. 2009)("Courts may, and often do, rely on other lines of causation evidence such as adverse event data."); id. at 157 ("In sum, Plaintiffs' experts point to the adverse event and case report data as real-world evidence to back up their theory that Neurontin increases the risk of suicidality in its patients."); In re Phenylpropanolamine (PPA) Prods. Liab. Litig., 289 F. Supp. 2d 1230, 1242 (W.D. Wash. 2003)("Non-epidemiological sources [such as AERs] are frequently utilized by experts in rendering scientific opinions…."); Crawford v. Muscletech Research & Dev., Inc., No. Civ.–01–1298–C, 2002 WL 31852828, at *1 (W.D. Okla. 2002)(holding that expert opinion testimony based in part on AERs and case reports were admissible under Daubert).

But see Soldo v. Sandoz Pharms. Corp., 244 F. Supp. 2d 434, 537-44 (W.D. Pa. 2003)(finding case reports to be unreliable and "unscientific" sources that plaintiff's experts could not rely on for causation); McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1250 (11th Cir. 2005)(AERs "reflect complaints called in by product consumers without any medical controls or scientific assessment."); Hollander v. Sandoz Pharms. Corp., 289 F.3d 1193, 1211 (10th Cir. 2002)("[I]t was not unreasonable for the district court to characterize the reports as unreliable evidence of causation."); Rhodes v. Bayer Healthcare Pharms., Inc., No. 10–1695, 2013 WL 1289050, at *5 (W.D. La. Mar. 26, 2013)("Dr. Hamilton's reliance on adverse event reports is also unimpressive, as such reports do not demonstrate the requisite degree of reliability demanded by Daubert.").

[8] Daubert motions filed by the parties on this issue are still pending.

e. Rule 401 and Rule 403 Arguments

Lastly, the defendants argue that AERs are not relevant under Rule 401 and/or any probative value they may have would be substantially outweighed by the risk of prejudice under Rule 403. AERs may be relevant to this case. Whether Rule 403 would bar their admission is better determined at trial.

For these reasons, I will **DENY** this motion **without prejudice**. The plaintiff may offer AERs to show notice. The question of whether an expert opinion appropriately relies on AERs will be discussed in rulings on the parties' Daubert motions. If the plaintiff plans to introduce specific AERs for any reason other than notice (i.e., causation or to show design defect), the defendants may object as appropriate at trial.

2. Defendants' Motion In Limine to Exclude Evidence or Argument Relating to Fraud on the FDA (MIL 2)

The defendants move to exclude all evidence meant to show that the defendants committed a "fraud on the FDA." Specifically, they claim the following evidence is inadmissible: evidence showing that the defendants misled the Food and Drug Administration (FDA), withheld information from the FDA, violated FDA disclosure requirements, otherwise violated the Food, Drug, and Cosmetic Act (FDCA), or did not cooperate with the FDA regarding Extra Strength Tylenol. They argue this evidence is preempted by the United States Supreme Court's decision in Buckman Co. v. Plaintiffs' Legal Committee, which held that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law." 531 U.S. 341, 348 (2001).

In Buckman, the liability for fraud was based solely on alleged non-disclosure of information to the FDA. Id. at 353. The Court held that fraud-on-the-FDA claims were impliedly preempted because these types of state law tort claims conflicted with the FDCA. Id. at 348. "The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the [FDA], and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." Id. Allowing fraud-on-the-FDA claims, the Court reasoned, could skew that balance. Id. See also Farina v. Nokia Inc., 625 F.3d 97, 123 (3d Cir. 2010).

I previously found that the plaintiff's fraud and fraudulent concealment claims were not impliedly preempted by Buckman. See Memorandum Denying Motion for Summary Judgment on Plaintiff's Short Form Complaint Claims, Nov. 13, 2015 at 14-17 (Doc. No. 177). I did not view them as fraud-on-the-FDA claims, which are preempted under Buckman. Id. at 15. If the evidence in question were being used to establish the defendants' liability solely based on concealment of information to the FDA or violations of FDA regulations, that evidence would not be permitted under Buckman.[9] See Buckman, 531 U.S. at 352-53 ("[T]he Medtronic claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. In the present case, however, the fraud claims exist

[9] To support their motion, the defendants cite cases where courts found that claims were impliedly preempted under Buckman. See, e.g., Farina v. Nokia Inc., 625 F.3d 97, 123 (3d Cir. 2010); In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II), 751 F.3d 150, 164 (3d Cir. 2014); Henderson v. Merck & Co., No. 04-CV-05987-LDD, 2005 WL 2600220, at *11 (E.D. Pa. Oct. 11, 2005). These cases are not helpful. Whether the plaintiff's claims were preempted was an issue discussed in the defendants' motion for summary judgment. At issue here is whether the evidence related to the defendants' interactions with the FDA is admissible for purposes other than establishing liability or breach of duty. That is a different inquiry than whether the plaintiff's claims are preempted.

solely by virtue of the FDCA disclosure requirements."). The defendants' breach of duty cannot be premised solely on their interactions with the FDA.

However, evidence that the defendants attempted to manipulate the regulatory process, failed to comply with regulatory duties, or adhere to guidance provided by the FDA can be used to show other elements of the plaintiff's claims. See Eve v. Sandoz Pharmaceutical Corp., No. IP 98–1429–C–Y/S, 2002 WL 181972, at *3 (S.D. Ind. Jan. 28, 2002)("Thus, evidence of NPC/SPC's interaction with the FDA may be pertinent to proving the Eves' claim, but it is not the basis for the claim itself.").[10] For example, how the defendants responded to FDA requests for information, what they did to comply with FDA regulations, and what information they presented to the FDA is all relevant to plaintiff's failure-to-warn and design defect claims.[11] See In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Products Liab. Litig., 3:09-MD-02100-DRH, 2011 WL 6302287, at *11 (S.D. Ill. Dec. 16, 2011)("Buckman does not pre-empt evidence of when Bayer informed the FDA of information relating to Yasmin and YAZ. Buckman is a claim preemption case focusing on fraud-on-the-FDA claims, not an evidence preemption case….The Supreme Court made clear in Wyeth that federal law

[10] See also In re Vioxx Products Liab. Litig., MDL No. 1657, 132005 WL 3164254, at *1 (E.D. La. Nov. 21, 2005)(denying similar motion in limine based on Buckman preemption); In re Medtronic, Inc., Implantable Defibrillators Litigation, 465 F.Supp.2d 886, 900 (D. Minn. 2006)("Thus, plaintiffs may use evidence—if they are able to produce it—of Medtronic's efforts to manipulate the regulatory process in order to prove their negligence and strict liability claims, but they may not bring an independent claim for relief based on fraud-on-the-FDA.").

[11] The plaintiff argues that this evidence also may be relevant if the defendants "open the door" and claim they are absolved from liability by complying with FDA regulations. These sorts of arguments will likely be precluded under Wyeth v. Levine, 555 U.S. 555 (2008). The defendants also cannot argue that the use of Extra Strength Tylenol in all circumstances was fully "approved" by the FDA because no Final Monograph has ever been issued. However, if the defendants offer such an affirmative defense, and I find it is permissible, evidence of their non-compliance with FDA regulations will be relevant to rebutting their defense.

does not prevent judges and juries in failure to warn cases from considering a drug companies compliance with FDA regulations. Wyeth, 555 U.S. at 568–73."). This evidence would be highly probative of the defendants' state of mind, motive, or knowledge of a defect.[12]

It also would be relevant to the plaintiff's fraud claims if the information the defendants sent to or received from the FDA was different from what the defendants were communicating to consumers, such as the decedent. See Globetti v. Sandoz Pharms. Corp., No. CV98-TMP-2649-S, 2001 WL 419160, at *2 (N.D. Ala. Mar. 5, 2001)("Notwithstanding that information may have been misrepresented to or concealed from the FDA, once defendant undertook to misrepresent those facts *to plaintiff*, or to conceal *from plaintiff* facts it was bound to disclose, the plaintiff's claim no longer rests simply on the assertion that the agency was defrauded but on the additional fact that *she* was defrauded.")(emphasis in original).

[12] See In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & PMF Products Liab. Litig., 3:09-CV-10012-DRH, 2011 WL 6740391, at *2 (S.D. Ill. Dec. 22, 2011)("The Court finds, as it has in the past, that Buckman is inapposite and Bayer's reliance thereon is misplaced (as it has been throughout this litigation). Wyeth v. Levine, 555 U.S. 555 129 S.Ct. 1187 (2009) is a far better guidepost for this Court and for this litigation. Bayer's knowledge and notice of the adverse effects of the subject drugs are of paramount relevance in this litigation. It will ultimately be an intertwined decision of the jury on the issue of proper warning whether Bayer complied with the FDAs [sic] policies. But, it is clear that the FDA is, for all practical purposes, wholly dependent upon the honesty of the pharmaceutical proponent of a drug when engaged in the approval process. In a case such as this, the jury must be fully informed of any information withheld from the FDA that could have effected decisions regarding the label."); Globetti v. Sandoz Pharms. Corp., No. CV98-TMP-2649-S, 2001 WL 419160, at *3 (N.D. Ala. Mar. 5, 2001)("The defendant's motion in *limine* based on Buckman is due to be and hereby DENIED. While plaintiff may not offer evidence simply to show misrepresentations to or concealment from the FDA, such evidence may be relevant to showing the defendant's knowledge relating to the adequacy of the warning or the truth of information represented to or concealed from plaintiff or her physician. FRE 403 may dictate that some such evidence be excluded to avoid confusing the jury about the exact nature of plaintiff's claims. Defendant remains free to raise appropriate objections during the course of trial.").

For these reasons, I will **DENY** the defendants' motion.[13]

3. Defendants' Motion In Limine to Exclude Evidence and Argument Relating to the September 2002 and June 2009 Advisory Committee Meeting (MIL 3)

The defendants move to exclude certain evidence and argument concerning the September 2002 and the June 2009 Advisory Committee Meetings of the FDA discussing acetaminophen-related liver issues. In September 2002, an Advisory Committee of the FDA met to discuss ways to prevent liver injury caused by unintentional acetaminophen overdose.[14] During the Committee Meeting, the FDA presented findings from medical literature: 1) that hepatotoxicity may occur "at recommended doses of APAP [or acetaminophen]," 2) that such cases were linked to risk factors such as alcohol use and/or fasting, and 3) that some cases of unintentional overdose led to death.[15] The Committee noted findings of hepatotoxicity (i.e., liver damage) in persons who have ingested less than 4 grams/day of acetaminophen and/or had risk factors like "poor nutritional status."[16]

[13] The defendants only argued that this evidence should be precluded under Buckman. They did not argue that that it should be precluded under other Federal Rules of the Evidence (i.e., Rule 403, etc.). Any objections or arguments regarding admissibility for other reasons may still be raised at trial.

[14] See FDA Safety Analysis Power Point, Sept. 19, 2002 (Doc. No. 95, Ex. 11); FDA Memorandum, Aug. 15, 2002 (Doc. No. 95, Ex. 17).

[15] See FDA Safety Analysis (Doc. No. 95, Ex. 11). See also Larson, et al., Acetaminophen-Induced Acute Liver Failure: Results of a United States Multicenter, Prospective Study, Hepatology 2005; 42(6):1364-1372 (Doc. No. 95, Ex. 7)(explaining how fasting may enhance toxicity and how unintentional "overdose" seemed possible at recommended dosing levels).

[16] See FDA Safety Analysis at Slide 44 (Doc. No. 95, Ex. 11). This data was later published in the Federal Register as part of FDA's Proposed Rule for the 2009 Label Change, discussed below. See 71 Fed. Reg. 77314 (Dec. 26, 2006)(Doc. No. 95, Ex. 10).

In June 2009, several advisory committees within the FDA held a joint meeting to discuss the issue of liver injury related to acetaminophen use.[17] McNeil representatives were present at the meeting and offered presentations to the committee members.[18] At that meeting, the committee members voted to recommend that the current maximum single dose of OTC acetaminophen (i.e., 2 x 500 mg) be made available only by prescription.[19] If that recommendation were put into effect, Extra Strength Tylenol could only be sold by prescription according to its current dosing. The majority of committee members recommended that the maximum single dose of acetaminophen be lowered to 650 mg (i.e., two tablets of Regular Strength Tylenol).[20]

The FDA has over thirty advisory committees which focus on different aspects of its mission. See FDA website, About Advisory Committees, http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/default.htm. As one might deduce from their title, these committees are meant to be advisory in nature. Their decisions or discussions are not considered binding actions by the FDA. The materials prepared by committees are meant to be recommendations which the FDA can adopt or reject.[21]

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[17] See FDA, CDER, Joint Meeting of the Drug Safety and Risk Management Advisory Committee, NDAC, and the Anesthetic and Life Support Drugs Advisory Committee, Questionnaire (Doc. No. 90, Ex. 14).

[18] See McNeil Briefing packet for June 2009 Meeting (Pl. Ex. 9 attached to Response for MIL 3, filed under seal).

[19] See FDA, CDER, Joint Meeting of the Drug Safety and Risk Management Advisory Committee, NDAC, and the Anesthetic and Life Support Drugs Advisory Committee, Questionnaire (Doc. No. 90, Ex. 14).

[20] See FDA, CDER, Joint Meeting of the Drug Safety and Risk Management Advisory Committee, NDAC, and the Anesthetic and Life Support Drugs Advisory Committee, Questionnaire (Doc. No. 90, Ex. 14).

[21] As I've explained in earlier decisions, the fact that the FDA does not adopt a recommendation by the advisory committee does not necessarily absolve the defendants of their duty to warn or design a safe product. FDA

a. Hearsay

The defendants argue that materials from these two meetings would be inadmissible hearsay. The plaintiff argues that the documents would be considered a "public record" which would not be hearsay. "A record or statement of a public office" is not excluded as hearsay "if…it sets out…the office's activities [or] a matter observed while under a legal duty to report…or…in a civil case…factual findings from a legally authorized investigation" and "the opponent does not show that the source of information or other circumstances indicate a lack of trustworthiness." FED. R. EVID. 803(8)(2014). "Public records have justifiably carried a presumption of reliability…" FED. R. EVID. 803(8), 2014 Amendment Advisory Committee Notes. The party wishing to admit evidence under this exception simply needs to meet the definition of a "public record" under the Rule. Id. The burden then shifts to the opposing party to show that "the source of information or other circumstances indicate a lack of trustworthiness." Id.; FED. R. EVID. 803(8). Both facts and opinions contained in documents meeting the requirements of the public records exception are considered to be admissible.[22]

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regulations are a floor and not a ceiling. For a further explanation, see Memorandum Denying Defendants' Motion for Summary Judgment on Failure-to-Warn Claim, Nov. 13, 2015 (Doc. No. 182); Memorandum Denying Defendants' Motion for Summary Judgment on Design Defect Claim, Nov. 13, 2015 (Doc. No. 184). See also Wyeth v. Levine, 555 U.S. 806 (2008).

[22] Beech Aircraft Corp. v. Rainey, 4 88 U.S. 153, 170 (1988)("We hold, therefore, that portions of investigatory reports otherwise admissible under Rule 803(8)(C) are not inadmissible merely because they state a conclusion or opinion. As long as the conclusion is based on a factual investigation and satisfies the Rule's trustworthiness requirement, it should be admissible along with other portions of the report.").

The plaintiff also argues that documents related to these meetings are "business records," which are not precluded as hearsay. A record of an act, event, condition, opinion, or diagnosis if:

> (A) the record was made at or near the time by--or from information transmitted by--someone with knowledge;
>
> (B) the record was kept in the course of a regularly conducted activity of a business, organization, occupation, or calling, whether or not for profit;
>
> (C) making the record was a regular practice of that activity;
>
> (D) all these conditions are shown by the testimony of the custodian or another qualified witness, or by a certification that complies with Rule 902(11) or (12) or with a statute permitting certification; and
>
> (E) the opponent does not show that the source of information or the method or circumstances of preparation indicate a lack of trustworthiness.

FED. R. EVID. 803(6)(2015).

To determine whether specific advisory committee documents related to these meetings are "public records" or "business records," I will need to see the context and content of each document. I will defer ruling on whether specific documents are admissible until trial. At that time, the parties may raise their hearsay arguments with a focus on specific documents.

b. Notice or Knowledge

If offered to prove notice to the defendants of certain risks or to prove the state of mind of the defendants, these documents would not be hearsay. It may not be necessary to determine if these documents are public records or business records. The defendants were involved in these meetings and were well-aware of the information shared at these

meetings. This information would be important to showing whether they had notice or knowledge of the potential link between Extra Strength Tylenol and acute liver failure at or just above recommended doses.[23] What was discussed at these meetings may show defendants' state of mind. There is evidence that the defendants took specific actions in preparation for the meetings and as a result of what happened at them.[24] The jury is entitled to hear this evidence and draw appropriate inferences about why the defendants acted as they did before and after these meetings.[25]

c. Rule 403

The defendants also argue that this evidence should be excluded under Federal Rule of Evidence 403 as confusing to the jury, unfairly prejudicial to the defendants, and/or a waste of time. The fact that the Advisory Committee was not a final rulemaking body of the FDA, the defendants claim, could make the materials confusing to a jury. There is nothing inherently confusing about the Advisory Committee process. With an adequate foundation, there should be minimal risk of jury confusion.

[23] The documents at issue were ones produced by the defendants, indicating they were in their possession.

[24] See, e.g., E. Kuffner Dep., Mar. 31, 2011at 92 (Pl. Ex. 17 to Response for MIL 3, filed under seal); E. Kuffner Dep., Apr. 30, 2014 at 32, 201 (Pl. Ex. 13 to Response for MIL 3, filed under seal); L. Pawelski Dep., Feb. 28, 2014 at 85-86 (Pl. Ex. 14 to Response for MIL 3, filed under seal); A. Temple Dep., Mar. 20, 2014 at 158 (Pl. Ex. 15 to Response for MIL 3, filed under seal); Email to C. Goggins re: meeting recommendations, May 27, 2009 (Pl. Ex. 7 to Response for MIL 3, filed under seal); Letter to the FDA about "Risk Mitigation Plan," Jul. 29, 2009 (Pl. Ex. 11 to Response for MIL 3, filed under seal).

[25] The defendants argue that the information presented at these meetings still has to be "substantially similar" to the injuries presented in this case. It is clear that the purpose of these meetings was to address the very concern at issue in this case—what risk was there to consumers of liver injury from taking Extra Strength Tylenol for therapeutic reasons. These meetings were on point with the issues presented in this case. This argument is not helpful.

For these reasons, I will **DENY** MIL 3 **without prejudice**. The plaintiff will, in the least, be permitted to offer information about the 2002 and 2009 meetings as evidence of notice, knowledge, and/or motive of the defendants.

4. Defendants' Motion In Limine to Exclude Evidence or Argument Relating to Employee Compensation (MIL 4)

The defendants move to exclude any evidence or argument relating to employee compensation under Rule 401 or 403. The plaintiff argues that this information is relevant to show bias or conflict of interest. I agree.[26]

If employee compensation evidence is admitted to show bias, the defendants argue that proof of employment alone is enough to show bias. I disagree. For example, an employee's bonus structure may further implicate a particular bias towards a profit motive. The various ways in which an employee was compensated may be relevant.

The defendants contend that evidence of compensation should only apply to current employees of the defendants. There is no good reason to narrow the focus of this evidence. A witness's possible bias created by certain compensation structures would relate to actions taken while the witness was employed with the defendants. While his or her current compensation at a different job may not be relevant, previous compensation while working for the defendants may be relevant to their motivation for making certain decisions on behalf of the defendant corporations. This information appears relevant.

[26] I made a previous ruling in this regard during the deposition of Ashley McEvoy. The parties could not agree about whether the evidence of employee compensation was relevant. They contacted me during the deposition to decide the issue. I ruled that the financial stake or interest in the corporation was relevant to bias. I confirmed this ruling in an Order dated February 26, 2014. See 13-md-2436, Doc. No. 123. While this Order pertained to the ability of the MDL plaintiffs to discover evidence related to employee compensation, the parameters set out in that Order offer good guidance on what types of employee compensation evidence would be relevant to show bias.

At this time, I see no reason why all employee compensation evidence should be precluded based on "unfair prejudice" under Rule 403.

For these reasons, I will **DENY** the defendants' motion.

5. Defendants' Motion In Limine to Exclude Expert Testimony Regarding Corporate State of Mind (MIL 5)

The defendants move to exclude expert testimony about the defendants' "corporate state of mind." They argue that this sort of testimony invades the province of the jury and/or offers inappropriate legal conclusions. Juries can draw inferences from the evidence without the benefit of expert testimony. See In re Viagra Prods. Liab. Litig., 658 F. Supp. 2d 950, 964-965 (D. Minn. 2009)("There is no indication in the record that the jury here would require special assistance to interpret the documents on which [the expert] bases her opinion that Pfizer was more worried about bad publicity than safety. Because the jury is equally capable of evaluating this particular evidence, Dr. Blume's opinion on this matter must be excluded.").

Expert testimony, which draws a legal conclusion about corporate state of mind, is not admissible. See, e.g., Berckeley Inv. Grp., Ltd.v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006)("[T]he District Court must ensure that an expert does not testify as to the governing law of the case. Although Federal Rule of Evidence 704 permits an expert witness to give expert testimony that 'embraces an ultimate issue to be decided by the trier of fact,' an expert witness is prohibited from rendering a legal opinion. United States v. Leo, 941 F.2d 181, 195–96 (3d Cir.1991). Such testimony is prohibited because it

would usurp the District Court's pivotal role in explaining the law to the jury. First National State Bank v. Reliance Elec. Co., 668 F.2d 725, 731 (3d Cir.1981)(per curiam).").[27]

The plaintiff argues that this motion is overly broad.[28] While I agree that every context in which an expert might discuss information about corporate state of mind may not overstep boundaries into the jury's role, it is clear that experts cannot render opinions

[27] See also Wolfe v. McNeil-PPC, Inc., No. 07–348, 2011 WL 1673805, at *8 (E.D. Pa. May 4, 2011)("[T]he extent Dr. Goldberg plans to testify that McNeil behaved negligently in the conduct of its business, such testimony constitutes an improper legal opinion….It will be the role of the jury, not Dr. Goldberg, to determine if McNeil acted negligently." (citing Berckeley, 455 F.3d at 217)); Wolfe v. McNeil-PPC, Inc., 881 F. Supp. 2d 650, 662 (E.D. Pa. 2012)(citing its prior ruling and reiterating that plaintiff's experts "will not be permitted to testify at trial with respect to the state of mind of defendants or the FDA") and at 661 ("The Court rules that expert testimony regarding the state of mind of defendants and the FDA, and expert testimony that constitutes a legal opinion, is inadmissible."); Heineman v. American Home Products Corp., No. 13–cv–02070–MSK–CBS, 2015 WL 1186777, at *12 (D. Colo. Mar. 12, 2015)(excluding opinions about defendants' state of mind)("[I]t may be necessary for [expert] to explain the meaning or significance of certain words or concepts that might appear in such records—she may have to explain what a safety surveillance employee does, the hierarchy that oversees such employees, or the typical consequences of the event the record reflects—but the Plaintiffs have not shown that, armed with such records and [the expert's] explanations thereof, the trier of fact would be unable to reach a conclusion about the Defendants' knowledge of any labeling deficiencies without [the expert's] say-so."); Chandler v. Greenstone Ltd., No. C04–1300RSL, 2012 WL 882756, at *1 (W.D.Wash. Mar. 14, 2012)(excluding expert's opinions on defendants' state of mind, intent, or knowledge); Johnson v. Wyeth LLC, No. CV 10–02690–PHX–FJM, 2012 WL 1204081, at *3 (D.Ariz. Apr. 11, 2012)(excluding expert's opinions on defendants' motive, intent, knowledge, or other state of mind); In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d 531, 547 (S.D. N.Y. 2004)("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony. As the Diet Drugs court stated in excluding testimony that the pharmaceutical defendant's conduct with respect to labeling was motivated by its desire to increase profits, '[t]he question of intent is a classic jury question and not one for the experts.'")(quoting In re Diet Drugs, No. MDL 1203, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000)); In re: Trasylol Prods. Liab. Litig., No. 08–MD–01928, 2010 WL 1489793, at * 8 (S.D. Fla. Feb. 22, 2010)(quoting/citing Rezulin ruling on issue); In re Baycol Prods. Litig., 532 F. Supp. 2d 1029, 1067 (D. Minn. 2007)("The Court finds that Dr. Smith's opinion criticizing Bayer for inadequately evaluating the potential toxicity of Baycol, and asserting that Bayer ignored warnings is legal argument that does not qualify as expert testimony under Rule 702."); In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 192 (S.D. N.Y. 2009)(precluding testimony as to "the knowledge, motivations, intent, state of mind, or purposes of" a company and its employees because it "is not a proper subject for expert or even lay testimony"); Tyree v. Boston Scientific Corp., 54 F. Supp. 3d 501, 564 (S.D.W.Va. 2014)("[T]he defendant's 'knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.'…The reasonableness of conduct and a party's then-existing state of mind 'are the sort of questions that lay jurors have been answering without expert assistance from time immemorial.'…While internal corporate documents and executives' testimony are certainly relevant in this case, such evidence 'should be presented directly to the jury, not through an expert.'" (quoting In re C.R. Bard, Inc., 948 F.Supp.2d 589, 628 (S.D.W.Va. 2013)).

[28] Much of the plaintiff's response revolves around their expert testimony for Dr. Marvin Goldberg. Whether his testimony is appropriate has been addressed in my ruling on the Daubert motion challenging his expert testimony. See Doc. No. 315 (Mar. 2, 2016).

on the defendants' corporate state of mind. See Berckeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 217-18 (3d Cir. 2006)(explaining how expert testimony on industry standards and customs is appropriate but expert conclusions about whether a defendant fell below those standards or complied with federal regulations was inadmissible). That is for the jury.

For these reasons, I will **GRANT** the defendants' motion **without prejudice**. Experts cannot opine about the defendants' corporate state of mind.[29]

6. Defendants' Motion In Limine to Exclude Evidence and Argument Regarding Defendants' Draft Company Documents and Internal Reports that were not Disseminated (MIL 6)

The defendants move to exclude draft company documents and internal reports because the plaintiff cannot show that decedent, plaintiff, decedent's physicians, or any other "relevant" person ever saw and relied on the internal drafts and non-disseminated materials. For this reason, the defendants argue that these documents are irrelevant as they have no probative value. The plaintiff counters that these documents are relevant to what the defendants knew or should have known about risks of liver damage caused by acetaminophen and to the defendants' state of mind, motive, and intent.[30]

[29] This does not mean, however, that the plaintiff's experts cannot offer evidence that could allow a jury to infer what the defendants' corporate state of mind would be. That is entirely appropriate. The specifics of what evidence experts can discuss (as opposed to opinions they may render) is better addressed in the context of Daubert motions, deposition designations, and/or at trial. My ruling on Motion in Limine #5 is meant to be narrow.

[30] The plaintiff's response centers on the expert report of Dr. Marvin Goldberg, the plaintiff's marketing expert. Whether these documents can be used by Dr. Goldberg is a different question. I addressed what testimony Dr. Goldberg could offer in my Daubert ruling. See Doc. No. 315 (Mar. 2, 2016).

Even if the plaintiff, decedent, or decedent's physician did not see the defendants' draft or internal documents at issue, these documents may still be relevant to show the defendants' knowledge, state of mind, motive, and/or intent.

The defendants make an argument based on Rule 403 that any probative value would be substantially outweighed by prejudice to them. I cannot make a determination under Rule 403 without context.

For these reasons, I will **DENY** the defendants' motion **without prejudice**.

7. Defendants' Motion In Limine to Exclude Evidence of Manufacturing, Quality Control, and Production Matters Involving McNeil's Facilities; Related Government Investigations; Regulatory Matters, Including FDA Form 483s and CAPAs; Recalls; Testimony Before Congress; the 2011 Consent Decree; and the 2015 Plea Agreement (MIL 7)

The defendants move to exclude evidence of or references to the following, as irrelevant, impermissible character evidence, and/or unduly prejudicial under Rule 403: manufacturing, quality control, or production issues at McNeil's facilities, along with all related government investigations, regulatory matters (including Form 483s and corrective actions plans or CAPAs), product recalls, testimony before Congress by William Weldon and Colleen Goggins, the 2011 Consent Decree, and any evidence regarding the 2015 Plea Agreement. The plaintiff counters that the evidence is relevant to the defendants' motive, state of mind, and/or knowledge, to show the defendants' character for untruthfulness, or for impeachment purposes. The plaintiff argues that evidence showing the defendants acted contrary to their marketing message of "trust" and

"safety" would be probative of the reasonableness of their conduct. They claim the evidence at issue is illustrative of the defendants' motive to maximize profits at the expense of consumer safety.

i. The 483 Forms

The FDA regularly conducts on-site inspections of the facilities of manufacturers of products subject to FDA regulation.[31] At the end of the inspection, the FDA issues a Form 483, outlining observations of any conditions the FDA investigator believes constitute violations of relevant laws and regulations.[32] "Companies are encouraged to respond to the FDA Form 483 in writing with their corrective action plan and then implement that corrective action plan expeditiously."[33] The Form 483 is not considered a final corrective action by the agency but instead is meant to alert the company to harmful conditions.[34]

One area that FDA investigates when it makes its site visits is whether the company had in place appropriate reporting systems of adverse events. On October 19, 1999, the FDA issued a 483 Form for a period of inspection for October 5, 6, 13, and 19, 1999 for a McNeil facility.[35] One noted violation was a failure to establish an audit trail to track changes or deletions made to the Consumer Response System (CRS) containing

[31] See Investigations Operations Manual, 5.5, *available at* http://www.fda.gov/ICECI/Inspections/IOM/ucm122533.htm.

[32] Id. See also K. Kwong Dep. at 24-25 (Pl. Ex. 11)(calling a 483 Form a "[c]itation of significant finding").

[33] See Investigations Operations Manual, 5.5, *available at* http://www.fda.gov/ICECI/Inspections/IOM/ucm122533.htm.

[34] Id.

[35] See FDA Form 483, Oct. 19, 1999 (Pl. Ex. 12); K. Kwong Dep. at 269 (Pl. Ex. 11).

15 day and periodic adverse events reports.[36] The Form 483 noted that the Medical Affairs department personnel were allowed to make changes to information entered on MedWatch Forms.[37] The second violation reported a failure of McNeil/J&J's legal department to report two recent adverse drug events they received through litigation.[38]

On December 9, 2010, the FDA issued a second 483 Form for a period of inspection from October 27, 2010 through December 9, 2010.[39] Again, the defendants were cited for having inadequate procedures in handling written and oral complaints.[40]

On April 14, 2011, a third 483 Form was issued for an inspection period of March 21, 2011 to April 14, 2011.[41] The form noted two violations: 1) that procedures for handling written and oral complaints related to drug products were again deficiently written/followed and were not appropriately followed up on; and 2) a failure to report adverse drug experience information to the FDA.[42]

While information in the 483 forms about the actual quality control of the defendants' products would not be relevant to the plaintiff's claims, the reports of

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[36] FDA Form 483, Oct. 19, 1999 (Pl. Ex. 12).

[37] FDA Form 483, Oct. 19, 1999 (Pl. Ex. 12).

[38] FDA Form 483, Oct. 19, 1999 (Pl. Ex. 12). During the same timeframe, the defendants also conducted internal audits showing similar deficiencies about adverse event reporting. See Quintiles Memorandum, May 2, 2003 (Pl. Ex. 13). I do not consider those internal audits to be at issue in this motion.

[39] FDA Form 483, Dec. 9, 2010 (Pl. Ex. 14).

[40] FDA Form 483, Dec. 9, 2010 (Pl. Ex. 14). The Form specifically noted deficiencies in how the defendants' pharmacovigilance department inappropriately handled complaints of stomach pain, diarrhea, and vomiting. This information may be relevant to notice, given that the reported conditions not appropriately handled were those experienced by the decedent.

[41] FDA Form 483, Apr. 14, 2011 (Pl. Ex. 15).

[42] Id.

pharmacovigilance deficiencies would definitely be relevant to show defendants' breach of duty.[43] From this evidence, a jury may infer that the defendants were careless about and/or willfully blind to potential risks of consumer safety.

Additionally, this information may be relevant to rebut any argument by the defendants that they have been in compliance with FDA regulations. In the same way, it would be appropriate for impeachment purposes.

ii. Recall Evidence

In 2007, the defendants voluntarily withdrew liquid Infant Tylenol products from the market. The recall was presented in internal memos as a way to remove the risk of overdose from foreseeable misuse.[44] The plaintiff claims that Infant Tylenol, compared to Extra Strength Tylenol, was a small share of profits. This evidence would most certainly be relevant to the defendants' state of mind and/or knowledge of a design defect in this case.

In 2008, the defendants discovered that certain lots of Motrin were not in compliance with FDA regulations. Instead of issuing a formal recall of the product, the defendants allegedly retained a contractor to go to all retail stores where Motrin was sold nationwide, act as regular customers, and buy all of the product on the shelves. The defendants then indicated to the FDA that a formal recall was not necessary because the product was no longer available on the shelves.

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[43] Even if the information about deficiencies in manufacturing were relevant, its probative value would be substantially outweighed by the risk of unfair prejudice. See FED. R. EVID. 403. That evidence will be excluded.

[44] See C. Goggins Email with Internal Memo, Oct. 10, 2007 (Pl. Ex. 5). See also 2003 Consumer OTC Medication Use Survey, Executive Summary (Pl. Ex. 6).

The plaintiff argues that this evidence points to the defendants' character for untruthfulness because the corporate character is imputed to the defendants' witnesses, acting on behalf of the company. Testimony given at a formal hearing of the House Committee on Oversight and Government Reform raised questions about how forthright the defendants were during the above "recall." See Transcript of Hearing of the House Committee on Oversight and Government Reform, 09/30/10, at 33-34, 37, 39, 43 (Pl. Ex. 7).

The plaintiff claims that this motion may encompass evidence showing that the defendants' were not cooperative with the FDA during the investigations into their manufacturing concerns and were, at times, trying to "influence" the FDA.[45] They claim this evidence can be used as impeachment material, to attack the defendants' reputation for truthfulness. See FED. R. EVID. 608(a). I agree that this information may be used for impeachment purposes. However, the information would not necessarily be used as character evidence if the defendants don't open the door to it.

iii. The 2011 Consent Decree, 2015 Plea Agreement, and Related Congressional testimony

From 2008 through 2015, McNeil was involved in several matters related to the contamination of some of its over-the-counter drug products. Some of these issues regarding production were noted in the above-mentioned 483 Forms and "phantom recalls." In 2010, Johnson & Johnson executives Colleen Goggins and William Weldon appeared before Congress to discuss ongoing manufacturing, quality control, and

[45] See C. Goggins Email, Jul. 3, 2009, "Stakeholder plans" (Pl. Ex. 1); McNeil Powerpoint, Jul. 20, 2009 (Pl. Ex. 4).

production issues at McNeil facilities. In 2011, McNeil entered a Consent Decree of Permanent Injunction with the U.S. Department of Justice (DOJ), without admission of fault, in relation to those manufacturing, quality control, and production issues.[46] In 2015, McNeil entered into a Plea Agreement on the same issues with the DOJ because they were not rectified.[47]

The plaintiff asserts a design defect claim, not a manufacturing defect claim. Her claims do not involve injury from a contaminated Tylenol product. For this reason, I see little to no relevance in admitting evidence regarding manufacturing defects. Any probative value this evidence might have would be substantially outweighed by the risk of unfair prejudice or confusion by the jury.[48] See FED. R. EVID. 403. However, if the defendants "open the door" to such evidence (i.e., offering compliance with FDA regulations, etc.), I may reconsider this ruling. Congressional testimony, of course, will be available for impeachment purposes if the defendants' witnesses provide inconsistent testimony at trial. This testimony also may include discussions of the defendants' treatment of AERs and other pharmacovigilance actions, which I've noted would be relevant to the plaintiff's claims.

[46] See 2011 Consent Decree (Doc. No. 69, Ex. B).

[47] See 2015 Plea Agreement (Doc. No. 69, Ex. A).

[48] The plaintiff argues that these are "prior bad acts" which can show "proof of motive, opportunity, intent, preparation, plan, knowledge, identity, or absence of mistake." See FED. R. EVID. 404(b). If the plaintiff had a manufacturing defect claim, this argument would have merit. However, I do not see this act as being similar enough to count as "prior bad acts" under Rule 404.

The plaintiff also claims this evidence is relevant to the punitive damages claim, because it reflects "a pattern and practice of evading federal marketing regulations and federal obligations." I disagree. Again, the Consent Decree and Plea Agreement involved manufacturing defect issues. This is not a manufacturing defect case.

iv. Character Evidence

The defendants also argue that this evidence should be excluded under Rule 404, as impermissible character evidence. Rule 404(a)(1) provides that, "Evidence of a person's character or character trait is not admissible to prove that on a particular occasion the person acted in accordance with the character or trait." Rule 404(a)(2) provides exceptions to this rule but only in criminal proceedings. Under Rule 404(a), evidence showing the defendants' character for "untruthfulness" would be excluded to prove the plaintiff's claims.

Rule 404(b)(1) states that: "Evidence of a crime, wrong, or other act is not admissible to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character." However, Rule 404(b)(2) provides that evidence of crimes or "prior bad acts" "may be admissible for another purpose, such as proving motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident." Given that the plaintiff may be offering this evidence to show motive/state of mind or knowledge, I cannot exclude this evidence outright. This evidence has the potential to be very prejudicial. A specific offer of proof is necessary for each item of possible 404(b) evidence.

The plaintiff also argues that the evidence of the Congressional testimony, Plea Agreement, and Consent Decree also show the defendants' character for being untruthful. This likely will not come in during the plaintiff's case-in-chief. However, if the defendants claim they have been forthright with the FDA and the Government, this information may be allowed for impeachment.

v. Hearsay Argument

Lastly, the defendants argue that regulatory documents and communications, including recall announcements, Forms 483s, are inadmissible hearsay under Rule 801 because they are out-of-court statements offered for the truth of the matter. The defendants do not address whether any of these documents are exempted or excepted under hearsay rules. If these documents are being used to show motive, state of mind, or knowledge, they would not be hearsay. If they are being used for the truth of the matter, I will determine at trial whether they are hearsay or whether they fall within an exception or exemption.[49]

For these reasons, I will **GRANT** MIL 7 **in part** and **DENY** it **in part without prejudice**. The 2011 Consent Decree and 2015 Plea Agreement shall be excluded. 483 Form evidence will be limited to deficiencies regarding pharmacovigilance (i.e., AERs, complaint reporting, etc.). The admissibility of all other evidence will be considered at trial, in context.

8. Defendants' Motion In Limine to Exclude Evidence of Other Lawsuits, Settlements, Government Investigations, and Unrelated Actions (MIL 8)

The defendants move to exclude evidence of or references to any other pending or former lawsuits, claims, or settlements of non-parties who allegedly experienced adverse

[49] The plaintiff also argues that this evidence may be considered party admissions, which would not be hearsay. See FED. R. EVID. 801(d). This also may be a reason the evidence would not be considered hearsay. Context, again, is important to determine this.

reactions from ingesting any Tylenol product.[50] They argue such evidence is inadmissible as irrelevant under Rules 401 and 402 and/or unduly prejudicial under Rule 403. The defendants also argue this information would be inadmissible hearsay and/or character evidence.

It is unclear what evidence to this effect might be presented or how it might be used. Evidence of past settlements is highly disfavored under Rule 408. However, evidence of past lawsuits may be probative of notice/knowledge of a possible defect and/or of the motive of the defendants. Information related to past lawsuits also may be relevant for impeachment purposes. Without more information about the content and context of the evidence at issue, I cannot make a blanket ruling on its exclusion. See Luce v. U.S., 469 U.S. 38, 41 (1984)("A reviewing court is handicapped in any effort to rule on subtle evidentiary questions outside a factual context.").

For this reason, I will **DENY** MIL 8 **without prejudice**.

9. Defendants' Motion In Limine to Exclude Evidence or Argument Regarding Any Documents, Events, or Labeling that Post-Date Decedent's August 2010 Acute Liver Failure (MIL 9)

The defendants move to exclude evidence or argument regarding documents, events, and/or labeling changes that post-date Ms. Hayes's August 2010 acute liver failure.[51] The defendants argue, generally, that this evidence is inadmissible under Rule

[50] I do not consider a 2011 Consent Decree (i.e., settlement) or 2015 Plea Agreement with the federal government to be included in this evidence. Arguments about the admissibility of that evidence were raised in MIL 7 and are addressed in my ruling on that motion.

[51] Specifically, the defendants would like to exclude:

401 or Rule 403. Without the context of this evidence, I cannot make such a ruling. For example, communications by the defendants' employees may have occurred after the decedent's death but may discuss what the defendants' knew about the risk of acute liver failure at the recommended dose *before* she died. That evidence would be highly relevant to this case.[52]

The defendants argue that changes to prescription acetaminophen labels are irrelevant. Unlike other OTC drugs, acetaminophen's maximum total daily limit is the same for both OTC and prescription products. Because one of the key issues in this case is whether the defendants should have recommended different dosing or warnings for Extra Strength Tylenol, there may be instances when changes to a prescription acetaminophen label may be relevant. Without more of a context, I cannot say for certain that this evidence would not have probative value.

- Post-injury changes to the labeling for over-the-counter Extra Strength Tylenol® labeling (e.g., McNeil's voluntary reduction of the listed maximum daily dose on its OTC acetaminophen products that was made in conjunction with FDA input–namely a reduction from 4,000 mg to 3,000 mg in a 24 hour period);
- Post-injury changes to prescription acetaminophen labeling (see, 76 Fed. Reg. 2691 (Jan. 14, 2011));
- Post-injury FDA statements/pronouncements or regulations concerning prescription acetaminophen (see, e.g., FDA safety communications regarding limiting prescription acetaminophen products to 325 mg per dosage, and recommendations to health care professionals to stop dispensing prescription combination drug products with more than 325 mg of acetaminophen, http://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm165107.htm; and notice of public hearing on Over-The-Counter Drug Monograph System –Past Present, and Future, 79 Fed. Reg. 10168 (Feb. 24, 2014));
- Post-injury MedWatch 3500 forms, including that of Ms. Hayes, or other adverse event reports; and
- The notice of proposed rulemaking for acetaminophen currently on the unified agenda with a projected completion date of December 2015 (79 Fed. Reg. 76718-01 (Dec. 22, 2014)).

This is not an exhaustive list, however, of the types of evidence that might be covered by this motion.

[52] The plaintiff offers another example: evidence that the defendants neglected to follow up on adverse events after the decedent's death. This information will likely not be relevant. Punitive damages cannot be imposed on the defendants for conduct that occurred after the injury asserted. I note this example but decline to rule definitely on it until trial.

They also argue the change of the dosing on Extra Strength Tylenol's label, after the decedent's death, would be inadmissible as a subsequent remedial measure under Rule 407. Rule 407 prohibits the introduction of evidence of post-injury measures which "would have made an earlier injury or harm less likely to occur" (i.e., "subsequent remedial measures") to show negligence, a defendants' culpable conduct, a defect in a product or its design, or a need for a warning or instruction. However, "the court may admit this evidence for another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures." The defendants have already claimed that their making a label change prior to the decedent's death was not possible. Under Rule 407, the plaintiff would be allowed to rebut this argument offering the post-death label changes.[53] The post-injury label changes are also available for impeachment purposes. I see no reason, at this time, to exclude this evidence pre-trial.[54]

[53] See, e.g., Kenny v. Southeastern Pennsylvania Transp., 581 F.2d 351, 356 (3d Cir.1978)("As a general rule, evidence of remedial measures taken after the event is not admissible to prove culpable conduct. Fed.R.Evid. 407. The reason for the exclusion is to encourage post-accident repairs or safety precautions in the interest of public safety. See Saltzburg & Redden, Federal Rules of Evidence Manual 162 (2d ed. 1977). But when the defendant opens up the issue by claiming that all reasonable care was being exercised at the time, then the plaintiff may attack that contention by showing later repairs which are inconsistent with it. See 2 J. Weinstein & N. Berger, Weinstein's Evidence PP 407(03), (04) (1977).").

[54] The plaintiff also argues that the subsequent remedial measures were not voluntary and are, therefore, not covered by Rule 407. In January 2011, the FDA asked manufacturers of combination drugs containing acetaminophen, sold globally under trade names such as Tylenol and Panadol, to limit acetaminophen doses to no more than 325 mg in each tablet or capsule by January 14, 2014. For this reason, the plaintiff argues, the changes were not voluntary. The majority of Circuits agree that a subsequent remedial measure is not "voluntary" if it is not done by the defendants. See Steele, Texas Emp. Ins. Ass'n, Intervenor v. Wiedemann Mach. Co., 280 F.2d 380, 382 (3d Cir. 1960)(holding the rule excluding evidence of repairs made after an accident is not applicable where the person who made the repairs is not a party to the suit); TLT–Babcock, Inc. v. Emerson Elec. Co., 33 F.3d 397, 400 (4th Cir.1994)("In the case at bar, the remedial measures were not taken by defendant Emerson but rather were initiated by a third party, the Maryland Transit Authority. Under our reading of Rule 407, we conclude that the district court correctly admitted the disputed evidence."); Lolie v. Ohio Brass Co., 502 F.2d 741, 744 (7th Cir. 1974)(Rule 407 has no applicability "when the evidence is offered against a party…which did not make the changes."); O'Dell v. Hercules, Inc., 904 F.2d 1194, 1204 (8th Cir. 1990)("An exception to Rule 407 is recognized for evidence of remedial action mandated by superior governmental authority or undertaken by a third party because the policy goal of encouraging remediation would not necessarily be furthered by exclusion of such evidence."); In re Aircrash in Bali, Indonesia,

More context will be needed to determine if this evidence is admissible.[55]

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871 F.2d 812, 817 (9th Cir. 1989)(per curiam)("The purpose of Rule 407 is not implicated in cases involving subsequent measures in which the defendant did not voluntarily participate."); Mehojah v. Drummond, 56 F.3d 1213, 1215 (10th Cir.1995)("'[R]ule 407 only applies to a *defendant's* voluntary actions;' it does not apply to subsequent remedial measures by non-defendants." (citation omitted)(emphasis in original)); Millennium Partners, L.P. v. Colmar Storage, LLC, 494 F.3d 1293, 1302 (11th Cir. 2007)("Rule 407 does not apply to a remedial measure that was taken without the voluntary participation of the defendant.").

The more specific question presented here is whether a subsequent remedial measure is "voluntary" if it was undertaken at the request or authority of a regulatory agency, like the FDA. Several Circuits have held that a subsequent remedial change made at the bequest on a "superior authority" is not "voluntary" and, therefore, is not to be covered by Rule 407. See O'Dell v. Hercules, Inc., 904 F.2d 1194, 1204 (8th Cir. 1990)("An exception to Rule 407 is recognized for evidence of remedial action mandated by superior governmental authority or undertaken by a third party because the policy goal of encouraging remediation would not necessarily be furthered by exclusion of such evidence."); Herndon v. Seven Bar Flying Service, Inc., 716 F.2d 1322, 1331 (10th Cir. 1983)("Where a superior authority requires a tort feasor to make post-accident repairs, the policy of encouraging voluntary repairs which underlies Rule 407 has no force—a tort feasor cannot be discouraged from voluntarily making repairs if he *must* make repairs in any case." (emphasis in original)); Rozier v. Ford Motor Co., 573 F.2d 1332, 1343 (5th Cir. 1978)("Invoking this policy [of Rule 407] to justify exclusion here is particularly inappropriate since the estimate was prepared not out of a sense of social responsibility but because the remedial measure was to be required in any event by a superior authority, the National Highway Traffic Safety Administration."); In re Aircrash in Bali, Indonesia, 871 F.2d 812, 817 (9th Cir. 1989)(per curiam)("Where the defendant has not voluntarily participated in the subsequent measure at issue, the admission of that measure into evidence does not 'punish' the defendant for his efforts to remedy his safety problems. In this case, Pan Am's management, although to be commended for its cooperation, nonetheless was legally obligated to cooperate with the FAA's investigation. See 14 C.F.R. § 13.3. Thus, the admission of the Hudson report did not penalize Pan Am for its voluntary participation in safety measures."). See generally Annot., Subsequent Remedial Measures, 158 A.L.R. Fed. 609 at § 5[a] (1999).

The Third Circuit has not ruled on this issue. See Stecyk v. Bell Helicopter Textron, Inc., No. CIV. A. 94–CV–1818, 1998 WL 744087, at *12 (E.D. Pa. Oct. 23, 1998)("There is a conflict within the federal courts regarding the court's authority to admit certain government-ordered remedial measures under the 'superior authority' exception to Fed.R.Evid. 407 cited by plaintiffs. See generally, E. Lee Reichert, Note, The Superior Authority Exception" to Federal Rule of Evidence 407: the Remedial Measure Required to Clarify a Confused State of Evidence, 1991 U. Ill. Rev. 843 (1991). In O'Dell v. Hercules, 904 F.2d 1194 (8th Cir. 1990), the Eighth Circuit became the first to explicitly adopt an exception to Rule 407 for evidence of remedial action mandated by a superior authority. Conversely, the Fourth Circuit explicitly rejected a superior authority exception to Rule 407 in Werner v. Upjohn, 628 F.2d 848 (4th Cir.1980), *cert denied*, 449 U.S. 1080, 101 S.Ct. 862, 66 L.Ed.2d 804 (1981). To date, the Third Circuit has not ruled on whether to recognize a superior authority exception to Rule 407.").

There is not enough evidence before the court to determine even if the possibly admissible subsequent remedial measure was "voluntary" or whether it was done at the behest of the FDA. For this reason, I will decline to make a ruling based on this "theory" of admissibility. When the plaintiff seeks to admit evidence of a post-death label change, the parties can then address the issue of whether Rule 407 applies based on the "voluntariness" of the subsequent change.

[55] See, e.g., Whitehead v. St. Joe Lead Co., Inc., 729 F.2d 238, 247 n. 6 (3d Cir. 1984)(subsequent remedial measure of label change admissible under Rule to show the feasibility of providing warnings); Siegle v. Sears, Roebuck and Co., 1990 WL 250527, at *3-4 (E.D. Pa. Dec. 28, 1990)(subsequent remedial change to a radial saw arm admissible because defendants disputed feasibility prior to injury), *judgment aff'd without opinion*, 941 F.2d 1203 (3d Cir. 1991); Bowman v. General Motors Corp., 64 F.R.D. 62, 70 (E.D. Pa. 1974)("Evidence of subsequent design modifications and indeed even post-accident precautions are admissible: (1) to refute the position that the existing condition was incapable of improvement, or to demonstrate that precautions were feasible before the injury; or (2) to show that the defendant knew or should have known of a reasonably foreseeable danger yet failed to give notice

For these reasons, I will **DENY** the defendants' MIL 9 **without prejudice**. The parties may raise their arguments under Rules 401, 403, and 407 at trial.

10. Defendants' Motion In Limine to Exclude Evidence or Argument Regarding What the FDA May Do in the Future (MIL 10)

The defendants have indicated they are withdrawing this motion and that any rulings on this point can be made at trial. For this reason, I will **DENY** this motion **without prejudice**.

11. Defendants' Motion In Limine to Exclude Evidence or Argument Relating to the Alleged Inadequacy of the FDA's Regulatory Process (MIL 11)

The defendants move to exclude evidence and arguments related to the alleged inadequacy of the FDA's regulatory process. They claim this evidence and argument is preempted by Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001). I previously found that Buckman did not preempt the plaintiff's claims. I see no reason

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thereof." (citations omitted)); Sterner v. U.S. Plywood-Champion Paper, Inc., 519 F.2d 1352, 1354 (8th Cir. 1975)("Evidence of such changes are, however, admissible for some purposes such as demonstration of knowledge of dangerous properties prior to the accident or the availability of better design or the feasibility of a more adequate warning of the risk involved.").

See also Standridge v. Alabama Power Co., 418 So.2d 84, 87 (Ala. 1982)("[Under Alabama law,] [t]here are several exceptions to the general rule of inadmissibility of evidence of subsequent repairs or remedial measures. A party may introduce such evidence to show the existence of a condition at the time of an accident; Dixie Electric Co. v. Maggio, 294 Ala. 411, 318 So.2d 274 (1975); to show the feasibility of the use of safeguards or precautionary measures; Werner v. Upjohn Co., 628 F.2d 848 (4th Cir. 1980); to impeach a witness, Norwood Clinic, Inc. v. Spann, 240 Ala. 427, 199 So. 840 (1941); or to give testimony which is part of the res gestae.") and id. at 88 (acknowledging that proof of ownership is an additional exception to the rule).

why Buckman would preempt the admission of evidence about alleged flaws in the FDA's regulatory process.[56]

The defendants also argue that this evidence would be prejudicial, confusing, or a waste of time and should be excluded under Rule 403. Without more information, I cannot determine whether this will be the case. This information may be irrelevant or confusing to a jury if the plaintiff raises criticism of the FDA process in her case-in-chief. However, if the defendants claim they were compliant with their duties under FDA regulations and were not required to do more, the plaintiff could potentially offer evidence of the criticism of the FDA regulatory process to rebut these assertions.

For these reasons, I will **DENY** the defendants' motion **without prejudice**.

12. Defendants' Motion In Limine to Exclude Evidence and Argument Based on Defendants' Exercise of their Constitutionally Protected Right to Petition the Government (MIL 12)

The defendants move to exclude any evidence or argument regarding their lobbying efforts towards Congress or the FDA. They argue that this evidence is barred by the Noerr-Pennington doctrine and is violative of their First Amendment rights to petition the government.

[56] The defendants support this argument with Horn v. Thoratec Corp., 376 F.3d 163, 178 (3d Cir. 2004). Horn did quote part of the FDA's amicus brief stating: "[I]t is inappropriate for a jury to second-guess FDA's scientific judgment on such a matter that is within FDA's particular expertise." The FDA has not offered any opinion on the outcome of this motion or case. That case also involved a medical device and different regulations than this one. Horn discussed whether preemption was appropriate, not whether evidence was admissible. I have already ruled that the plaintiff's claims are not preempted by Buckman. For these reasons, Horn is not helpful.

I also note that the FDA itself has questioned the efficacy of the monograph process. See FDA Is Seeking Ideas for a "New and Improved" Process for Regulating OTC Drugs under the OTC Drug Review, available at http://blogs.fda.gov/fdavoice/index.php/2014/04/fda-is-seeking-ideas-for-a-new-and-improved-processfor-regulating-otc-drugs-under-the-otc-drug-review/.

The First Amendment provides the right to petition the government without fear of retribution or penalty. See U.S. Const. amend. I ("Congress shall make no law . . . abridging . . . the right of the people to petition the government for a redress of grievances."); see also U.S. Const. amend. XIV. "Under the Noerr–Pennington doctrine—established by Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961), and United Mine Workers v. Pennington, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965)—defendants are immune from antitrust liability for engaging in conduct (including litigation) aimed at influencing decisionmaking by the government." Octane Fitness, LLC v. ICON Health & Fitness, Inc., 134 S.Ct. 1749, 1757 (2014)(citation omitted).[57] Essentially, businesses can't be held liable for antitrust violations for petitioning the government because their First Amendment rights supersede antitrust laws.

The defendants argue that Noerr-Pennington is applicable beyond just the anti-trust context. While that is true, the Noerr-Pennington doctrine has no place here.[58] The

[57] The doctrine also includes a "sham exception" which provides that "activity 'ostensibly directed toward influencing governmental action' does not qualify for Noerr immunity if it 'is a mere sham to cover...an attempt to interfere directly with the business relationships of a competitor.' " Octane Fitness, LLC v. ICON Health & Fitness, Inc., 134 S.Ct. 1749, 1757 (2014)(citation omitted). Since the Noerr-Pennington doctrine does not apply here, I see no reason to consider argument about whether the sham exception applies to prevent immunity.

[58] See, e.g., We, Inc. v. City of Philadelphia, 174 F.3d 322, 327 (3d Cir. 1999)("Thus, the purpose of Noerr–Pennington as applied in areas outside the antitrust field is the protection of the right to petition. Immunity from liability is necessary so as not to chill the exercise of that right."); Congregation Anshei Roosevelt v. Planning and Zoning Bd. of the Borough of Roosevelt, No. 07–4109(GEB), 2008 WL 4003483, at *6-9 (D. N.J. Aug. 21, 2008)("The Supreme Court as well as the Third Circuit Court of Appeals have since extended the Noerr–Pennington doctrine beyond the scope of antitrust to areas such as civil conspiracy and cases arising under § 1983 as well as other civil rights statutes.")(citations omitted); Falise v. Am. Tobacco Co., 94 F. Supp. 2d 316, 350-53 (E.D. N.Y. 2000); Video Intern. Production v. Warner-Amex Cable Com., 885 F.2d 1075, 1084 (5th Cir. 1998)("Although the Noerr–Pennington doctrine initially arose in the antitrust field, other circuits have expanded it to protect first amendment petitioning of the government from claims brought under federal and state laws, including section 1983 and common-law tortious interference with contractual relations. See, e.g., Evers v. County of Custer, 745 F.2d 1196, 1204 (9th Cir. 1984); Gorman Towers, Inc. v. Bogoslavsky, 626 F.2d 607, 614 (8th Cir.1980), and cases cited

plaintiff is not trying to restrain the defendants' speech or enjoin the defendants' conduct towards the government. See NAACP v. Claiborne Hardware Co., 458 U.S. 886, 913-15 (1982)(recognizing Noerr-Pennington protects right to boycott businesses for civil rights violations; reversing state court's issuance of an injunction and damages for lost profits). The plaintiff is not seeking civil liability for the defendants' petitioning efforts, based on a theory of conspiracy. See In re Asbestos School Litigation, 46 F.3d 1284, 1286, 1294 (3d Cir. 1994)(finding that a civil conspiracy claim could not withstand summary judgment when it was based primarily on evidence that the defendant company joined a lobbying organization that may have offered misleading information to governmental officials); Int'l Bhd of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc., 196 F.3d 818, 826 (7th Cir. 1999)("To the extent the manufacturers' statements were designed to influence Congress—to get favorable laws and ward off unfavorable ones—they cannot be a source of liability directly under the Noerr–Pennington doctrine."); Evers v. County of Custer, 745 F.2d 1196, 1204 (9th Cir. 1984)(finding conspiracy claim unfounded based on petitioning activities).[59] Nor is the plaintiff trying to base her cause of action on the defendants' petitioning activities. See

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therein. We find it easy to agree that the same rationale under antitrust law that supports WAX's petitions to the City also serves to protect WAX from the tort claim. There is simply no reason that a common-law tort doctrine can any more permissibly abridge or chill the constitutional right of petition than can a statutory claim such as antitrust.").

[59] The Third Circuit in In re Asbestos School Litigation, 46 F.3d 1284 (3d Cir. 1994), relied on NAACP v. Claiborne Hardware Co., 458 U.S. 886, 913-15 (1982), in making its decision. However, the court's focus was more on a violation of Pfizer's First Amendment right to associate with a lobbying organization than it was Pfizer's right to petition the government. Id. at 1289-94. See also id. at 1294 ("In sum, then, the district court's decision was clearly wrong. Worse, it has implications that broadly threaten First Amendment rights. The district court's holding suggests that Pfizer-based solely on its limited and (as far as the record reflects) innocent association with the SBA-could be held liable, as the plaintiffs have urged, for all of the allegedly tortious acts committed by all of the defendants, whether before or after the SBA was formed. The implications of such a holding are far-reaching. Joining organizations that participate in public debate, making contributions to them, and attending their meetings are

Brownsville Golden Age Nursing Home, Inc. v. Wells, 839 F.2d 155, 160 (3d Cir. 1988)("In numerous cases, the courts have rejected claims seeking damages for injuries allegedly caused by the defendants' actions directed to influencing government action."); Structure Building Corp. v. Abella, 377 N.J. Super. 467, 471-73 (N.J. Super. 2005) (applying Noerr-Pennington doctrine to bar malicious abuse of process, malicious use of process, and tortious interference with prospective economic advantage suit against homeowners who opposed zoning applications that affected their properties); Caixa Geral De Depositos, S.A. v. Rodrigues, No. COV/A/03-746 MLC, 2005 WL 1541055, at *10-11 (D.N.J. June 30, 2005)(Noerr-Pennington doctrine barred defamation and injurious falsehood claims against defendants who had sent letters to federal regulators).

Instead, the plaintiff seeks to offer evidence about how the defendants attempted to influence, petition, or communicate with Congress and/or the FDA to show their knowledge, state of mind, or intent. It would be a stretch to say that Noerr-Pennington bars any use of any evidence of the defendants' petitioning of the government, and its agencies, or evidence of any communications with the FDA. See Wolfe v. McNeil-PPC, Inc., No. 07–348, 2012 WL 38694, at * 6 (E.D. Pa. Jan. 9, 2012)(rejecting that argument that Noerr-Pennington allows exclusion of evidence to show state of mind/knowledge); In re Brand Name Prescription Drugs Antitrust Litig., 186 F.3d 781, 789 (7th

activities that enjoy substantial First Amendment protection….But the district court's holding, if generally accepted, would make these activities unjustifiably risky and would undoubtedly have an unwarranted inhibiting effect upon them." (citations omitted)). While the lobbying organization's communications with Congress would be protected, the Court noted that misleading communications by the lobbying organization to plaintiffs and potential members of the class may not be protected and could be evidence of fraudulent concealment. See id. at 1290 and 1290, n. 4.

Cir.1999)(finding that district judge "erred in treating the [Noerr–Pennington] doctrine as a rule of evidence").[60]

They also argue this evidence should be precluded under Rule 401 and 403. The context of this evidence is important to understanding its relevance and/or risk of undue prejudice. I will decline to rule based on Rule 401 or 403 at this time.

For these reasons, I will **DENY** the defendants' motion **without prejudice**.

13. Defendants' Motion In Limine to Exclude Evidence and Argument Related to Foreign Labeling and Foreign Regulatory Actions (MIL 13)

The defendants argue that evidence related to labeling or regulatory actions taken in countries outside the U.S. should be excluded under Rules 401, 402, or 403. The defendants argue that foreign regulatory processes regarding labeling of OTC products are so different from the FDA's processes that information about foreign regulatory actions would be irrelevant.[61] The plaintiff counters that foreign labels on the defendants'

[60] See also In re Cardizem CD Antitrust Litigation, 105 F.Supp.2d 618, 645 (E.D. Mich. 2000)(finding that district judge "erred in treating the [Noerr–Pennington] doctrine as a rule of evidence")(citing In re Brand Name Prescription Drugs); Mason v. Texaco, Inc., 741 F.Supp. 1472, 1500-01 (D. Kan. 1990)(explaining how Noerr-Pennington only bars cause of action based on solely on petitioning activities, not evidence of petitioning activities for other claims).

[61] The defendants cite In re Vioxx Litig., 2006 WL 2950622, at *5 (N.J. Super., Law Div. Oct. 2, 2006), and 395 N.J. Super. 358, 377 (App. Div. 2007), *cert. denied*, 193 N.J. 221 (2007), as support for this argument. These decisions focused on whether New Jersey was an appropriate forum, not whether foreign labels would be admissible evidence. I do not find these cases to be helpful.

They also cite to Meridia Prods. Liab. Litig. v. Abbot Labs., 447 F.3d 861 (6th Cir. 2006). In Meridia, the Sixth Circuit reviewed whether the district court's grant of summary judgment was appropriate. Id. at 863. The court considered whether a foreign label with different instructions created a "triable issue of fact," not whether admission of a foreign label was permissible. See id. at 867. This case is not helpful.

The other cases offered by the defendants to support their relevance argument are also not on point or are not persuasive. See Hurt v. Coyne Cylinder Co., 956 F.2d 1319, 1327 (6th Cir. 1991)(discussing the use of foreign labels in the context of whether a jury instruction about alternative designs was appropriate); Deviner v. Electrolux Motor, AB, 844 F.2d 769, 771 n.2 (11th Cir. 1988)(noting simply that the district court excluded foreign instructions

products, warning of the risk of "severe or possibly fatal liver damage" before the decedent's death are evidence of the defendants' knowledge of potential risks related to their products. See Pl. Ex. 1, Canadian Label (filed under seal). I agree. I recognize that the admission of foreign labels may require context of a foreign country's regulatory system in order to present them accurately, leading to a trial within a trial and undue delay. However, I believe it's possible for the plaintiff to offer evidence that foreign regulatory agencies raised concerns about acetaminophen dosing years before the decedent's death, to show notice and/or knowledge. A jury instruction can be given to ensure that jurors understand the limited nature of this evidence.

The plaintiff also argues that defendants' foreign labeling can be offered to show how the defendants fell below their standard of care. Here, I agree with the defendants. It would be unfair to allow evidence of foreign labeling in countries requiring different regulatory and/or statutory duties to show that the defendants breached their duties under United States laws. Use of foreign regulatory activities in this way would be inappropriate.

The plaintiff claims this evidence could also be used to show causation. It is unclear to me how this evidence would be probative of causation. I would need to see

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on a saw based on relevance, without offering much explanation of the rationale of that decision); In re Trasylol Prods. Liab. Litig., 709 F. Supp. 2d 1323, 1336 (S.D. Fla. 2010)(excluding expert testimony on foreign regulatory matters in a Daubert motion because expert was not qualified in this area of expertise, testimony included improper opinions, and/or information about foreign regulations should be excluded under Rule 403); In re Seroquel Prods. Liab. Litig., 601 F. Supp. 2d 1313, 1318 (M.D. Fla. 2009)(affirming exclusion of evidence of foreign regulatory activities under Rule 403); In re Baycol Prods. Litig., 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007)(excluding evidence about foreign label based on Rule 403 and the risk of confusion to the jury).

how it was used in context to determine whether its admission for this purpose would be appropriate.

In addition, I will decline to make rulings as to the admissibility of this evidence based on Rule 403. The context and content of the evidence regarding foreign labels and foreign regulatory actions will be important to my determining its probative value and any risk of prejudice, undue delay, or confusion to the jury.

The defendants also argue that foreign labels are inadmissible hearsay that do not fall within an exception.[62] The plaintiff counters that they are not hearsay because they are not being offered for the truth.[63] In order to address this argument, I would need more information about the labels and how the plaintiff plans to use them in order to rule on this point.

Lastly, the defendants claim that the plaintiff cannot authenticate foreign labeling evidence. The plaintiff argues that the evidence is self-authenticating under Rule 902(3). Argument on this point is better addressed at trial.

For the foregoing reasons, I will **DENY** the defendants' MIL 13 **without prejudice**.[64]

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[62] The plaintiff counters that these labels are adoptive admissions under Rule 801(d)(2)(A), (B). I would need to see more information about the content and context of the labels in order to rule appropriately on this point.

[63] The plaintiff also argues that her experts may rely on the foreign labels and regulatory actions in rendering an opinion. This may be true. See FED. R. EVID. 703. However, this argument is better addressed in the context of pending Daubert motions.

[64] See, e.g., Tobin v. SmithKline Beecham Pharms., No. 00-CV-0025, 2001 WL 36102165, at *1 (D. Wyo. May 18, 2001)(denying motion in limine to exclude foreign labels because they may be relevant to knowledge or adequacy of warning); In re: Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and PMF Prods. Liab. Litig., 3:09-md-2100-DRH, MDL 2100, 2011 U.S. Dist. LEXIS 147935, at *5-6, 2011 WL 6740391, at *2 (S.D. Ill. Dec. 22, 2011)(denied motion to exclude foreign regulatory action and labeling evidence on grounds it would assist jury in finding out what defendant knew and when); In re Levaquin Prods. Liab. Litig., No. 08-5743, 2010 U.S. Dist.

14. Defendants' Motion In Limine to Exclude Marketing and Promotional Materials (MIL 14)

The defendants move for the exclusion of any evidence related to marketing, public relations, and/or promotional materials for Tylenol products. They argue the information is irrelevant, would confuse the jury, or cause undue delay in the trial. The plaintiff argues that evidence regarding marketing and advertising decisions made by the defendants should be allowed to show knowledge, state of mind, and/or conscious disregard and is relevant to the plaintiff's failure-to-warn, design defect, and wrongful death claims.[65]

First, the defendants argue that the information is irrelevant because the plaintiff cannot assert a deceptive marketing claim under Alabama law.[66] The plaintiff concedes this point.[67] This argument is moot.

Next, the defendants claim that advertising is irrelevant because the plaintiff admits that the decedent read the label. The plaintiff notes that advertising, marketing, and public relations are other ways the defendants use to communicate with the public and physicians about Tylenol products and their risks; all of the varied ways the

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LEXIS 145282, at *13, 2010 WL 4676973, at *4-5 (D. Minn. Nov. 9, 2010)(denied motion to exclude foreign regulatory action evidence on grounds it speaks to notice and motive).

[65] See A. McEvoy Dep., Feb. 12, 2014 at 332-339 (Pl. Ex. 2)(discussing how negative press about liver damage side effects was shown to hurt sales of Tylenol); A. Vernon Dep., Aug. 5, 2014 at 128-129, 132 (Pl. Ex. 3)(discussing the lack of warning about serious side effects in advertising).

[66] The parties also discuss the relevant regulatory standards for over-the-counter drug marketing, as enforced by the Federal Trade Commission (FTC). Because there is no deceptive marketing claim, I do not see this information as relevant or helpful to the motion at hand.

[67] See McClain v. Metabolife Int'l, Inc., 193 F.Supp.2d 1252, 1257 (N.D. Ala. 2002).

defendants communicated with consumers should be considered because Tylenol is an over-the-counter product.[68]

There is a question—to be answered by the jury—about whether the decedent took the recommended dose or accidentally took an overdose. The plaintiff argues that marketing and advertising affected consumers' perceptions of how strictly to adhere to the warnings, giving consumers the impression that Tylenol was "safe." Given that the jury will have to decide whether the decedent overdosed or misused the product and whether this misuse was foreseeable, marketing and advertising may be relevant to the plaintiff's theory that the defendants' branding of Extra Strength Tylenol "blunted" the warnings provided.

Third, the defendants argue that any advertising not actually seen or relied upon by the decedent should be excluded as irrelevant.[69] For example, the defendants argue that

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[68] See A. McEvoy Dep., Feb. 12, 2014 at 282-89 (Pl. Ex. 2).

[69] To support this point, the defendants point to other cases which have excluded marketing evidence: Zundel v. Johnson & Johnson, No. MID-L-6854-05, Hrg. Tr., at 60-62 (N.J. Super. Ct., Middlesex Cty. Jan. 13, 2009)(Doc. No. 76, Ex. E); In re Norplant Contraceptive Prods. Liab. Litig., 165 F.3d 374, 379 (5th Cir. 1999); and Appleby v. Glaxo Wellcome, Inc., 2005 WL 3440440, at *4 n. 5 (D. N.J. Dec. 13, 2005). These cases are not helpful.

In Zundel, the judge excluded marketing evidence because it was not relevant to the plaintiff's failure-to-warn claim. See No. MID-L-6854-05, Hrg. Tr., at 60-62 (N.J. Super. Ct., Middlesex Cty. Jan. 13, 2009)(Doc. No. 76, Ex. E). However, it is not clear from that decision whether the plaintiff also had asserted a punitive damages claim. In this case, the marketing evidence may be relevant to state of mind, which is especially important to the plaintiff's punitive damages claim. For this reason, I cannot say that Zundel is helpful.

In re Norplant Contraceptive Prods. Liab. Litig., 165 F.3d 374, 379 (5th Cir. 1999), was an appeal of a summary judgment decision. The Fifth Circuit briefly discussed the appellant's argument that evidence of "aggressive" marketing should negate adequate warnings. The court found that this argument was "critically weakened by the absence of any evidence on the record that any of the five plaintiffs actually saw, let alone relied, on any marketing materials issued to them by [the defendant]." Id. The court went on to explain that even if there was evidence of the plaintiff relying on marketing, the learned-intermediary doctrine would make summary judgment appropriate. Id. Norplant, unlike this case, involved a prescription drug. Given Norplant's procedural and factual differences, it is distinguishable and not persuasive.

certain promotional materials involving Tylenol Cool Burst Caplets has no bearing on Ms. Hayes' case. They claim that the only evidence the plaintiff can offer on this topic comes from "vague and conclusory testimony" by Rebecca Hayes, the decedent's sister. This, the defendants argue, should not be enough to permit any and all advertising of about Tylenol into evidence at trial.[70]

It may very well be true that Ms. Hayes did not see all the advertising the plaintiff purports to put forth. It may also be true that information regarding these promotional materials could be relevant to show the defendants' state of mind. Decisions on whether specific pieces of evidence are relevant or irrelevant are best made in context, at trial, when the use of such materials is clearer.

Lastly, the defendants argue that financial information related to marketing should be excluded under Rule 403 because it would be unfairly prejudicial or would cause undue delay in the trial. The defendants have filed a separate motion (MIL 17) seeking to exclude all financial information. I will address the admissibility of financial information in discussing that motion.

Appleby v. Glaxo Wellcome, Inc., 2005 WL 3440440 (D. N.J. Dec. 13, 2005), also involved a prescription drug. In discussing whether a direct marketing exception of the learned intermediary doctrine existed, the court found that liability premised on this theory could not stand because the plaintiff had not presented evidence she was affected by marketing. Id. at *4-5. This case is distinguishable.

[70] To support this theory, the defendants cite decisions in Wolfe v. McNeil-PPC, Inc., 2011 WL 1673805, at *8-9 (E.D. Pa. May 4, 2011), and Lyles v. McNeil-PPC, Inc., No. ATL-L-8655-11 (N.J. Super. Ct.). These decisions are not helpful. Both of those decisions discussed whether the expert testimony of Dr. Marvin Goldberg, the plaintiff's marketing expert, should be excluded under Daubert. The defendants filed a separate Daubert motion to exclude Dr. Goldberg's testimony. The plaintiff also makes arguments in this motion in limine about the admissibility of Dr. Goldberg's testimony. The extent to which Dr. Goldberg's testimony is admissible has been addressed in my decision on his Daubert motion. See Doc. No. 315 (Mar. 2, 2016).

The plaintiff counters that sales of Tylenol were influenced by the defendants' branding of Tylenol products as safe and recommended most by doctors and hospitals. She also claims marketing evidence may show the defendants' breach of their pharmacovigilance duties. One of the plaintiff's main theories of the case is that the defendants put profits over safety. The plaintiff has offered evidence about how expenditures on marketing far exceeded those budgeted for research and development. This information would, in the least, be relevant to the plaintiff's theory about the defendants' state of mind and/or motive.[71]

The plaintiff argues that evidence related to marketing and advertising would be relevant to the plaintiff's failure-to-warn claim—to show that the danger of liver failure was not known and obvious under the circumstances, thereby imposing a duty to warn of such risks on the defendants. The marketing and promotional materials could establish the context in which the decedent perceived the risks associated with Extra Strength Tylenol.[72] Evidence explaining the backdrop of the product's marketing may be helpful in providing the details the jury would need to determine whether the risk of acute liver

[71] See Forst v. Smithkline Beecham Corp., No. 07-CV-612, 2008 WL 4951155, at *2 (E.D. Wis. Nov. 18, 2008)("The more efforts and resources GSK expended to encourage use of its product, the more culpable its behavior in knowingly exposing users to an increased suicide risk without proper warnings.").

[72] See, e.g., Strickland v. Royal Lubricant Co., 911 F.Supp. 1460, 1468 (M.D. Ala. 1995)(explaining that warnings are "adequate" if it is "reasonable under the circumstances" and that the duty to warn is for non-obvious risks)(quoting Gurley v. American Honda Motor Co., 505 So.2d 358, 361 (Ala. 1987)); Reynolds v. Bridgestone/Firestone, Inc., 989 F.2d 465, 471 (11th Cir. 1993)("There is 'a duty to warn of those dangers which the user would not be aware of under the particular circumstances of his use of the product.'...The purpose in placing a duty to warn on the manufacturer is to familiarize the user with dangers of which he may be unaware.…So if the user is aware of the dangers associated with the product, the manufacturer has no duty to warn.")(quoting and citing Gurley, 505 So.2d at 361).

failure was really one that was known and obvious to consumers of Extra Strength Tylenol.[73]

The plaintiff claims marketing evidence may also be relevant to the plaintiff's design defect claim by showing Extra Strength Tylenol was an "unreasonably dangerous product." Under Alabama law, "a defective product is one that is unreasonably dangerous, i.e., one that is not fit for its intended purpose or that does not meet the reasonable expectations of the ordinary consumer." Beam v. Tramco, Inc., 655 So.2d 979, 981 (Ala.1995)(citing Casrell v. Altec Industries, Inc., 335 So.2d 128, 133 (Ala.1976); Entrekin v. Atlantic Richfield Co., 519 So.2d 447 (Ala.1987)). The plaintiff argues that marketing evidence would be relevant to showing "the reasonable

[73] See Hon v. Stroh Brewery Co., 835 F.2d 510, 512, 514-15 & n. 4 (3d Cir. 1987)("In addition, we conclude that the story boards of Stroh's commercials provide additional evidence from which a jury could conclude that the general public is unaware of the hazard that allegedly led to Mr. Hon's death. If a jury finds that Stroh's marketing of its product has effectively taught the consuming public that consumption of beer on the order of eight to twelve cans of beer per week can be a part of the 'good life' and is properly associated with healthy, robust activities, this conclusion would be an important consideration for the jury in determining whether an express warning was necessary to make Old Milwaukee beer safe for its intended purpose. Cf. Baldino v. Castagna, 505 Pa. 239, 478 A.2d 807, 810 (1984)(jury may consider whether a manufacturer has nullified warning that has been given by its promotion of the product); Incollingo v. Ewing, 444 Pa. 263, 282 A.2d 206, 220 (1971)("Action designed to stimulate the use of a potentially dangerous product must be considered in testing the adequacy of a warning as to when and how the product should not be used....")); Salmon v. Parke, Davis & Co., 520 F.2d 1359, 1360, 1363 (4th Cir. 1975)(explaining how advertising "with emphasis that was [not] commensurate with the risk [of injury]" may allow a jury to determine that a warning was not adequate in context). See also McDarby v. Merck & Co., Inc., 949 A.2d 223, 266-267 (N.J. Super. 2008)(upholding admission of Vioxx marketing evidence–including identification of doctors to be neutralized by sales staff, video training sales staff to allay fears, and other risk-minimizing materials–because it bore on failure to adequately warn of known dangers and conduct in obscuring risk evidence); Incollingo v. Ewing, 282 A.2d 206, 220 (Pa. 1971)("[W]hether or not the printed words of warning were in effect cancelled out and rendered meaningless in the light of the sales effort made by the detail men, were questions properly for the jury. Action designed to stimulate the use of a potentially dangerous product must be considered in testing the adequacy of a warning as to when and how the product should Not be used; if detail men are an effective means of selling a product and explaining its nature, a jury could find that they also afforded an effective medium of conveying a warning.")(citation omitted), *overruled on other grounds by*, Kaczkowski v. Bolubasz, 491 Pa. 561 (1980); Bullock v. Philip Morris USA, Inc., 71 Cal. Rptr. 3d 775, 791 (2008)("Philip Morris contends the dangers of smoking cigarettes were known to the ordinary consumer before July 1, 1969, and thereafter, and the jury's finding to the contrary was not supported by substantial evidence. We disagree. The evidence of Philip Morris's extensive efforts, through various means, to mislead the public about the adverse health effects of smoking cigarettes and create a false controversy as to whether smoking caused lung cancer and other diseases, and evidence that smokers are particularly vulnerable to such manipulation, is sufficient to support the finding that the ordinary consumer was mislead and was unaware of the dangers of cigarette smoking.").

expectations of the ordinary consumer."[74] I agree that marketing evidence may be relevant evidence in this respect.

Furthermore, the Tylenol label itself included the defendants' marketing message of "How Tylenol® Products are Different." This message, on the box of Tylenol products, stated how Tylenol is "[r]ecommended the most by doctors and used the most by hospitals" and is "[u]nlikely to cause the gastric irritation often associated with aspirin, naproxen sodium or even ibuprofen." This information most certainly would be relevant, given Rebecca Hayes' testimony that her sister took Extra Strength Tylenol—as opposed to another pain reliever—because she thought it was gentler on her stomach and was a safer product. A jury could conclude from this information that the decedent expected it to be a safe product—not one which might cause her irreparable harm and death.

The evidence may also help the plaintiff make out her fraud claims, by showing that the information communicated to the public through marketing, advertising, public relations, and the products' label did not fully inform the decedent of Extra Strength Tylenol's risks. The drug product in this case is sold over-the-counter (OTC). A consumer does not need the advice of a doctor to take it. From that vantage point, the label and any other information, i.e., marketing, advertising, and public relations, would

[74] See Wilson Sporting Goods Co. v. Hickox, 59 A.3d 1267, 1276 (D.C. 2013)("There was evidence that Wilson's representative told Mr. Hickox that the mask would disperse energy and protect against concussion, and that the mask was the best and safest technology. Mr. Hickox also testified that he believed that companies like Wilson tested new products and did not sell them unless they were safe to use. Jurors could consider such testimony in combination with their own reasonable inferences to determine an ordinary consumer's expectations.").

be the primary means by which consumers learn about the product.[75] In this context especially, marketing and advertising may be more relevant because there is no "learned intermediary" who can educate consumers about an OTC product.[76] The plaintiff has offered evidence that Rebecca Hayes and the decedent relied upon the defendants' marketing and advertising messages for Tylenol in making their decisions to purchase/consume Extra Strength Tylenol. Marketing evidence would, therefore, be relevant to the plaintiff's fraud claims.

In the least, the plaintiff argues that marketing and sales documents should be admissible for impeachment purposes. I agree.

For these reasons, I will **DENY** the defendants' MIL 14 **without prejudice**. The parties may raise arguments regarding relevance and unfair prejudice at trial.

[75] See Torsiello v. Whitehall Labs., Div. of Home Prods. Corp., 165 N.J. Super. 311, 326 (App. Div. 1979)("A consumer of over-the-counter drugs is, as it were, self-prescribing and is intended, expected, and indeed encouraged by the drug industry to do so. He must, therefore, also be given such information by the manufacturer as will permit him to self-prescribe with a minimum of risk.").

[76] See id. at 322-23 ("It was clearly for the jury to determine whether in fact that danger is, in Restatement verbiage, as 'generally known and understood' among lay consumers as it apparently is in medical and pharmaceutical circles. In our view, the duty of the manufacturer explicitly to warn consumers of the specific risks of over-the-counter drug use derives from the basic marketing predicate of the over-the-counter drug industry, namely, that nonprescription drugs are purchased by consumers for the purpose of self-medication typically without any intended or actual intervention by a physician. The consuming public may well appreciate that an inherent risk of self-medication is delay or failure in obtaining professional attention for an ailment requiring more than simple symptomatic relief. But it has also been led to believe that while the over-the-counter product may not prove ultimately helpful, neither will it harm if taken as directed. Indeed, a jury would be justified in concluding that the advertising and mass marketing techniques involved in selling aspirin to the consumer are calculated to assure the public of its essential innocuousness and inherent safety. It is indeed this actual and intended direct relationship between the manufacturer and the consumer of over-the-counter drugs, in contradistinction to the interposition between them of the physician where prescription drugs are involved, which accounts for what has become a well-recognized dichotomy in respect of the required recipient of the manufacturer's warning, namely, that while it is the consumer who is entitled to the warning in respect of nonprescription drugs, only the prescribing physician need be warned as to the risks involved in a prescription drug.").

15. Defendants' Motion In Limine to Exclude Media Reports Relating to Tylenol (MIL 15)

The defendants move to preclude the plaintiff from introducing into evidence media reports concerning Tylenol "that are unrelated to Plaintiff's claims in this case." Specifically, the defendants take issue with admission of an April 1995 television program "Prime Time Live," a series of print and audio reports by ProPublica including a September 2013 program on the National Public Radio (NPR) podcast "This American Life," and a 2015 article published online at thebmj.com on the efficacy of acetaminophen for the treatment of spinal pain and related media coverage of that article. They argue this evidence is hearsay, is irrelevant, and is highly prejudicial under Rule 403.

The plaintiff counters that the defendants' motion is vague and overly broad. Further, she argues that media reports may be relevant because the defendants used aggressive public relations tactics as part of their marketing of Tylenol as safe. The plaintiff "acknowledges that, in general, media video and/or publications may fall under the hearsay rule." However, the plaintiff claims media reports may fall into hearsay exceptions or may be appropriate impeachment material. Media reports, the plaintiff claims, also may be offered for a purpose other than the truth of their content (i.e., notice, breach of duty, knowledge, state of mind, etc.).

The defendants have not provided these specific pieces of evidence. It is not entirely clear what they discuss or include. The lack of information about this evidence makes it difficult for me to assess their admissibility. See Luce v. U.S., 469 U.S. 38, 41

(1984)("A reviewing court is handicapped in any effort to rule on subtle evidentiary questions outside a factual context."). Without the context of this evidence or any other media reports the plaintiff might introduce, I cannot rule on this motion based on the defendants' Rule 401, 402, and 403 arguments. In addition, the purpose for which these materials may be offered will help determine whether they are hearsay.

For these reasons, I will **DENY** the defendants' MIL 15 **without prejudice**.

16. Defendants' Motion In Limine to Exclude Evidence or Argument Related to Statements Submitted to the American Association for the Study of Liver Diseases to the FDA and the 2006 Press Release Issued by the American Liver Foundation (MIL 16)

The defendants move to exclude evidence and argument concerning two related pieces of evidence created by third-parties: 1) the July 2006 press release issued by the American Liver Foundation (ALF) regarding the dangers of "excess acetaminophen," and 2) the April 27, 2007 memorandum prepared by the American Association for the Study of Liver Diseases (AASLD) that was submitted to the FDA. See Doc. No. 79, Ex. C and D. They argue that this evidence is inadmissible hearsay or is barred by Rule 403.

a. AASLD and ALF

The AASLD "was founded in 1950 by a small group of leading liver specialists... to bring together those who had contributed to the field of hepatology." See http://www.aasld.org/aboutus/Pages/default.aspx; see also Doc. No. 79, Ex. A: "About Us," from http://www.aasld.org/aboutus/Pages/default.aspx. The AASLD's stated mission is "[t]o advance and disseminate the science and practice of hepatology, and to

promote liver health and quality patient care." Id. The American Liver Foundation is a non-profit organization created by the AASLD in 1976 with a mission of "facilitat[ing], advocat[ing], and promot[ing] education, support and research for the prevention, treatment and cure of liver disease." See http://www.liverfoundation.org/about/; see also Doc. No. 79, Ex. B: "About Us," from http://www.liverfoundation.org/about/.

b. July 2006 ALF Press Release

In July 2006, the American Liver Foundation (ALF) issued a press release to warn of the "dangers of excess acetaminophen." See ALF press release, Jul. 18, 2006 (Doc. No. 79, Ex. C). The press release discussed a recently published study in the Journal of the American Medical Association (JAMA) that "showed that healthy adults who took the maximum recommended dose of acetaminophen for two weeks had drastically increased liver enzyme levels which could lead to liver damage." Id.[77]

In response to the article, the ALF recommended "that people not exceed three grams of acetaminophen a day for any prolonged period of time." Id. The press release explained that the recommendation concerned persons taking "the equivalent of six 'extra-strength' tablets a day for several weeks" not those taking acetaminophen for "[r]egular, short-term use." Id.

c. The AASLD's Public Comment on FDA's December 2006 Rulemaking

In December 2006, the FDA proposed certain amendments to its OTC labeling regulations and the tentative final monograph for OTC internal analgesic, antipyretic, and

[77] The article in question was Paul B. Watkins, Aminotransferase Elevations in Healthy Adults Receiving 4 Grams of Acetaminophen Daily, 296 JAMA 87, 91 (Jul. 5, 2006)("An association between therapeutic dosing of acetaminophen and elevations in ALT has not been previously reported.").

antirheumatic (IAAA) drug products to include new warnings and other labeling requirements. See 71 Fed. Reg. 77314-01 (Dec. 26, 2006). Proposed changes included removing the prior-enacted alcohol warning and adding a new liver warning that also included an alcohol warning. See id. at 77333. The FDA requested comments and data from interested persons. See id. at 77346.

The AASLD submitted a public comment in April 2007, which recommended, *inter alia*, that the FDA add: 1) a warning that using acetaminophen at the maximum recommended dose (4 grams/day) for 5 or more consecutive days increases the chance for severe or fatal injury; and 2) a warning that using acetaminophen at the maximum recommended dose (4 grams/day) when food intake is restricted or prohibited increases the chance for severe or fatal injury. See Doc. No. 79, Ex. D. The FDA did not adopt these recommendations because the FDA did not have sufficient data to support the warnings. See 74 Fed. Reg. 19385-01, 19391, 19397 (Apr. 29, 2009).[78]

d. Hearsay

The defendants argue that the press release and public comment are inadmissible hearsay. The plaintiff counters that she plans to use the evidence not for its truth, but instead to show notice, knowledge, standard of care, or state of mind.[79] This would not be for a hearsay purpose.

[78] I explained in a previous decision that the FDA's decision to not adopt these recommendations based on insufficient data did not preempt the plaintiff's claims under Wyeth v. Levine. See Memorandum Denying Motion for Summary Judgment regarding Failure-to-Warn Claim, Doc. No. 181 at 41-44.

[79] The plaintiff also plans to have their experts use these documents in forming opinions about post-marketing reporting and labeling. Evidence relied upon by experts need not be admissible so long "experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject." FED. R. EVID. 703.

e. Notice, Knowledge, State of Mind

The defendants argue that these documents cannot be admitted to show "notice" because the risks they discuss are not substantially similar to those experienced by the decedent.

"In products liability cases evidence of prior accidents involving the same product under similar circumstances is admissible to show notice to the defendant of the danger, to show existence of the danger, and to show the cause of the accident." Gumbs v. International Harvester, Inc., 718 F.2d 88, 97 (3d Cir. 1983). The idea that prior incidents be "substantially similar" is especially important in cases "where the evidence is proffered to show the existence of a design defect." Barker v. Deere and Co., 60 F.3d 158, 162-63 (3d Cir. 1995). In determining whether the prior incidents are "substantially similar," a court must look to the facts and circumstances of the prior incidents in weighing their potential relevance and potential prejudice. See Tait v. Armor Elevator Co., 958 F.2d 563, 568-69 (3d Cir. 1992)(explaining how district courts should use Rules 402 and 403 to determine similarity of prior accidents); Stecyk v. Bell Helicopter Textron, Inc., No. CIV. A. 94–CV–1818, 1998 WL 744087, at *4 (E.D. Pa. Oct. 23, 1998)(same).

From the information provided, the ALF press release and the AASLD public comment offer information that is highly probative of the risks later experienced by the decedent (i.e., plaintiff was fasting and/or taking recommended daily dose of Extra

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Whether the press release or public comment can be relied upon by experts in rendering an opinion is a question more appropriately answered in Daubert motions pending before the court.

Strength Tylenol for more than five days). The evidence in question involves risks related to taking acetaminophen for long periods and/or while fasting. The information is similar enough that I do not see a substantial risk of undue prejudice in admitting it for the purpose of notice.[80] The defendants may explore any dissimilarity between this evidence and the circumstances of the decedent's death at trial; the jury can then determine how much weight to give them. See, e.g., Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378, 1386 (4th Cir. 1995)("McNeil explored these dissimilarities at length. Whether the dissimilarities were significant was for the jury to determine."); Kehm v. Procter & Gamble Mfg. Co., 724 F.2d 613, 626 (8th Cir. 1983)("It was up to the jury to decide what weight to give the complaints from other consumers.").

As the plaintiff argues, the press release, together with other evidence showing the defendants' reaction to this press release, can also be offered to show the defendants' knowledge of potential risks and state of mind. Additionally, the documents could be relevant to show how reasonable the defendants' conduct was or was not by comparing it to the actions other members of the scientific community took regarding information about potential risks.

f. **Rule 403 Generally**

The defendants argue the evidence would be unduly prejudicial, confusing, or misleading as compared to their probative value. From what has been provided, I cannot say for certain. Context is key to rulings regarding Rule 403.

[80] See Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378, 1386 (4th Cir. 1995)("When prior incidents are admitted to prove notice, the required similarity of the prior incidents to the case at hand is more relaxed than when prior incidents are admitted to prove negligence. The incidents need only be sufficiently similar to make the defendant aware of the dangerous situation.").

For these reasons, I will **DENY** the defendants' motion **without prejudice**.

17. Defendants' Motion In Limine To Exclude Evidence Or Argument Relating To Defendants' Profit Margins, Wealth, And Other Financial Information (MIL 17)

The defendants move to exclude any evidence or argument relating to the defendants' profit margins, wealth, or other financial information. They argue this information is irrelevant or considered "highly prejudicial" under Alabama law. The plaintiff counters that this motion is overly broad and vague.

Both sides agree that the defendants' net worth is not admissible under Alabama law because it would be highly prejudicial. See Southern Life Health Ins. Co. v. Whitman, 358 So.2d 1025, 1026-1027 (Ala. 1978)("Our cases have long held that evidence of the defendant's wealth is highly prejudicial and, therefore, inadmissible."); Industrial Chemical & Fiberglass Corp. v. Chandler, 547 So.2d 812, 835-836 (Ala. 1989)("Our cases have long held that evidence of the defendant's wealth, or lack of wealth, is highly prejudicial and, therefore, inadmissible (and our cases recognize no distinction between situations involving compensatory damages and those involving punitive damages)…"); Pacific Mut. Life Ins. Co. v. Haslip, 499 U.S. 1, 19 (1991)("Any evidence of Pacific Mutual's wealth was excluded from the trial in accord with Alabama law.").[81] However, the plaintiff argues that certain financial evidence, such as the

[81] See also Ex parte Hsu, 707 So.2d 223, 225 (Ala. 1997)("Accordingly, we turn to long-standing Alabama law on the issue of admissibility of evidence of a defendant's wealth. Under that law, 'evidence of a defendant's wealth is highly prejudicial and, therefore, inadmissible [during trial].' Southern Life & Health Ins. Co. v. Whitman, 358 So.2d 1025, 1026 (Ala. 1978), citing Alabama Fuel & Iron Co. v. Williams, 207 Ala. 99, 91 So. 879 (1921); Long v. Seigel, 177 Ala. 338, 58 So. 380 (1912); Southern Car & Foundry Co. v. Adams, 131 Ala. 147, 32 So. 503 (1902);

defendants' substantially higher spending on marketing as compared to spending on research and development, is relevant to show motive.[82] I agree that this information would be relevant to the defendants' state of mind.

The plaintiff further argues that other monetary numbers, beyond the defendants' net worth, may be admissible to show the defendants' level of culpability: the amount of money spent on marketing and advertising to influence consumers to purchase Tylenol;

Ware v. Cartledge, 24 Ala. 622, 60 Am. Dec.489 (1854). See Pacific Mut. Life Ins. Co. v. Haslip, 499 U.S. 1, 111 S.Ct. 1032, 113 L.Ed.2d 1 (1991). However, evidence of a defendant's wealth is considered relevant and admissible in a post-verdict hearing on alleged excessiveness of a punitive damages award, held before the trial judge pursuant to the procedure this Court adopted in Hammond v. City of Gadsden, supra.").

This rule of exclusion has been considered substantive and not procedural by other federal courts. See Wilson v. Gillis Adver. Co., 145 F.R.D. 578, 580 (N.D. Ala. 1993)("Although an argument can be made that this is simply an Alabama rule of evidence, and is thus procedural rather than substantive, it is so fundamental to the resolution of the issue of punitive damages under the Alabama law theories as to be effectively substantive and as a practical matter binding on a federal trial court when it tries an Alabama tort claim seeking punitive damages."); Carr v. City of Florence, 729 F. Supp. 783, 786 (N.D. Ala. 1990)(applying wealth exclusionary rule), *aff'd*, 934 F.2d 1264 (11th Cir. 1991).

The Alabama Supreme Court has indicated that arguments about what awards may be sufficient to punish the defendants are not proper, but such improper comments may not cause reversible errors if a curative instruction is offered. See Daniel Construction Co. V. Pierce, 120 So.2d 381, 386-387 (Ala. 1960)(discussing whether attorney arguing "if the jury brings out a verdict less than $50,000 it wouldn't be any more than a mosquito bite to this defendant" was reversible error; finding it was improper but cured by jury instruction); Blount Bros. Construction Co. v. Rose, 149 So.2d 821, 831-833 (1963)(explaining that argument "Why, a $25,000 verdict against Blount Brothers would not be a slap on the leg to them" was cured by jury instruction, citing Daniel Construction). But see Young v. Bryan, 445 So.2d 234, 237-239 (Ala. 1984)(plaintiff's counsel's argument in closing statement regarding size and contents of defendant deceased's estate held to be improper/highly prejudicial and warranted remand for new trial and reversal).

[82] The plaintiff also argues that financial wealth information may be admissible if the defendants "open the door" to such evidence. There is caselaw in Alabama supporting this point. See Mutual Sav. Life Ins. Co. v. Smith, 765 So. 2d 652, 655-56 (Ala. Civ. App. 1998)("The rule under discussion does not operate to exclude evidence of wealth or poverty if such is relevant to some issue, other than damages, properly in the case. One way for such an issue to be properly in a case is for one's opponent to have opened the door by commenting upon or asking questions concerning a party's financial standing. Whenever one addresses a particular subject, even if impermissibly so, this then permits the opponent to rebut such evidence under the doctrine of 'curative admissibility.' Some writers and courts have referred to this as 'retaliatory admissibility.'")(quoting 1 Charles W. Gamble, McElroy's Alabama Evidence, § 189.05(1)(5th ed. 1996)); City of Gulf Shores v. Harbert Int'l, 608 So. 2d 348, 353 (Ala. 1992)("We acknowledge this Court's long-standing rule that evidence of a party's wealth, be it plaintiff's or defendant's, is inadmissible generally.…However, we also recognize that an opposing party may inquire into the other party's wealth on cross-examination or in rebuttal if the other party 'opens the door.'")(citations omitted). However, the parties are expected to abide by Alabama's rule of precluding evidence of a party's wealth because unintentional admission of such evidence could result in a mistrial.

the amount the defendants earned "as a result of that misleading marketing and advertising;" the amount the defendants saved because they did not conduct clinical trials and testing; the amount of revenue preserved because a warning was not added; and the amount donated to "influence" the American Liver Foundation to change its position on acute liver failure. Admission of these numbers might implicitly allow the jury to draw conclusions about the defendants' wealth. Implicit references to the defendants' net worth may also not be appropriate under Alabama law.[83] See, e.g., Otis Elevator Co. v. Stallworth, 474 So. 2d 82, 84 (Ala. 1985)("The language used by plaintiff's attorney implies that if Otis Elevator Company could afford to hire an expensive expert from New York to testify in over one hundred cases, then that same company could afford to pay a judgment in favor of the plaintiff. While the argument that Mr. McAuley had testified in over one hundred cases for Otis Elevator might have been proper to show his bias, the direct reference to the company's ability to hire that expert was an improper reference to the wealth or the supposed wealth of the defendant."); Bennett v. Brewer, 682 So. 2d 448 (Ala. 1996)(statements by plaintiff's counsel that defendant lived in a certain area, could afford a certain expert's fees, made "tremendous money," and drove a Mercedes-Benz automobile were improper comments on defendant's wealth warranting a new trial); Estis Trucking Co. v. Hammond, 387 So. 2d 768 (Ala. 1980)(comments made by plaintiffs'

[83] The defendants are also precluded from implying that their net worth is the reason the plaintiff has brought suit against them. See Baptist Med. Ctr. Montclair v. Whitfield, 950 So. 2d 1121, 1128 (Ala. 2006)(finding arguments by defense counsel that plaintiff dismissed individual doctor so that she could "focus on recovering from BMC, a corporation, which had more money than Dr. Pennington's practice group" was improper argument; grant of a new trial was warranted); Allison v. Acton-Etheridge Coal Co., Inc., 289 Ala. 443, 446-49 (1972)(finding that defense counsel's argument "It's a great thing, folks, to be a very wealthy man and to be able to go out here and hire two law firms with four lawyers" was improper and warranted a reversal).

attorney that defendant "could have afforded" and that defense counsel was not surprised by the amount of damages requested because "[h]e deals in these figures everyday. He tries lawsuits all over the State of Alabama" were improper). Argument or references to wealth which imply that the jury award damages simply because the defendant has the means to pay damages are not appropriate.[84] Whether the use of a financial number is prejudicial depends upon the context in which it is used. In order to determine whether other financial numbers are highly prejudicial, in line with Alabama's "exclusion of wealth rule," I will need to see them used in context.

The defendants also argue, with little explanation, that Johnson & Johnson cannot be liable because it is a holding company of McNeil and does not design, manufacture, market, or sell Extra Strength Tylenol. For this reason, they claim, no liability can attach to Johnson & Johnson. The plaintiff has offered evidence that Johnson & Johnson executives were involved in decision making about the day-to-day operations regarding

[84] See Southern Life and Health Ins. Co. v. Smith, 518 So.2d 77, 80-82 (Ala. 1987)(finding that argument "'A corporation, like I said, is a legal entity..., but it's not a human being. It has no conscience. 'The only way you can punish a corporation is through monetary damages'" was improper); Taylor v. Brownell–O'Hear Pontiac Co., 91 So.2d 828, 828-29 (Ala. 1957)(finding plaintiff's counsel's comment "We have also dismissed as to Mr. Ritchie. We don't want to penalize Mr. Ritchie. We are after somebody that can pay" was highly prejudicial); American Ry. Express Co. v. Reid, 113 So. 507, 510 (Ala. 1927)(plaintiff's argument "We are asking simply for justice which this boy is entitled to. And we are going to insist that he is entitled to some good round sum. It doesn't make any difference to the American Express Company, this defendant. What difference does it make to them what your verdict in this case is?" was improper because they "were an appeal for a large verdict upon the assumed ability of the corporate defendant to pay").

Tylenol.[85] From what the defendants have provided, I do not find this argument to be persuasive.[86]

Lastly, the defendants argue that all financial information is unfairly prejudicial, can cause juror confusion, or cause undue delay. Under Alabama law, I agree that there is a risk of unfair prejudice in presenting financial information to the jury that could implicate defendants' net worth. However, I am not convinced that all financially-related evidence should be excluded. As the plaintiff argues, some of this information would be relevant to the plaintiff's theory that the defendants' decisions regarding Extra Strength Tylenol were driven by profits and not consumer safety. There are ways that this sort of information can be presented to the jury (i.e., graphs without numbers, use of percentages, jury instructions on appropriate use of information, etc.), which can reduce the risk of unfair prejudice.

For these reasons, I will **GRANT** the defendants' motion **in part** and **DENY** it in part **without prejudice**. Evidence of the defendants' net worth will be excluded. Argument about the admissibility of all other financial information will be reserved for trial.

18. Defendants' Motion In Limine to Exclude Testimony Regarding Inapplicable "Risk Factors" (MIL 18)

The parties have agreed that any rulings on this motion should be deferred

[85] See Pl. Brief Opposing MIL 17 at 4-13 (outlining evidence that high-level J & J executives were involved in decisions regarding the marketing and sales of Tylenol products)(filed under seal) and attached exhibits.

[86] I note, as the plaintiff has, that Johnson & Johnson remains a named defendant in this case. No summary judgment motion or other motion has been filed asserting the theory stated above. If the defendants disagree with my ruling on this point, they may file a motion for reconsideration.

until trial. For this reason, I will **DENY** MIL 18 **without prejudice**.

II. Conclusion

For the foregoing reasons, I make the following rulings:

- MIL 1 is DENIED without prejudice;
- MIL 2 is DENIED;
- MIL 3 is DENIED without prejudice;
- MIL 4 is DENIED;
- MIL 5 is GRANTED without prejudice;
- MIL 6 is DENIED without prejudice;
- MIL 7 is GRANTED in part and DENIED in part;
- MIL 8 is DENIED without prejudice;
- MIL 9 is DENIED without prejudice;
- MIL 10 is DENIED without prejudice;
- MIL 11 is DENIED without prejudice;
- MIL 12 is DENIED without prejudice;
- MIL 13 is DENIED without prejudice;
- MIL 14 is DENIED without prejudice;
- MIL 15 is DENIED without prejudice;
- MIL 16 is DENIED without prejudice;
- MIL 17 is GRANTED in part and DENIED in part; and

- MIL 18 is DENIED without prejudice.

An appropriate Order follows.