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. **July 28, 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 first "bellwether" case scheduled for trial.[2] The plaintiff plans to offer Dr. Cheryl Blume

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

[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

as a pharmacovigilance and regulatory expert. The defendants move to exclude parts of her testimony under Daubert. For the reasons stated below, I will grant their motion in part and deny it in part.[3]

I. LEGAL STANDARD

The admissibility of expert testimony is governed by Federal Rules of Evidence 702 and 703 as well as by Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), and its progeny.[4] See In re Paoli RR Yard PCB Litigation (Paoli II), 35 F.3d 717, 735 (3d Cir. 1994). "Under the Federal Rules of Evidence, a trial judge acts as a 'gatekeeper' to ensure that 'any and all expert testimony or evidence is not only relevant, but also reliable.'" Pineda v. Ford Motor Co., 520 F.3d 237, 243 (3d Cir. 2008)(quoting Kannankeril v. Terminix Int'l, Inc., 128 F.3d 802, 806 (3d Cir. 1997)). The Third Circuit recognizes a "liberal policy of admissibility" regarding Rule 702. Pineda, 520 F.3d at 243 (quoting Kannankeril, 128 F.3d at 806); United States v. Schiff, 602 F.3d 152, 173 (3d Cir. 2010).[5]

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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).

[3] In making my decision, I have reviewed all of the materials submitted as attachments to the parties' briefs, including those submitted during oral argument.

[4] Daubert held that the Federal Rules of Evidence, specifically Rule 702, controlled the issue of when experts were qualified. Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 587-88 (1993). It found that Rule 702 superseded the Court's prior precedent on the subject found in Frye v. United States, 54 App.D.C. 46, 47, 293 F. 1013, 1014 (1923). Id. at 587. Daubert went on to clarify what was required under Rule 702, as compared to Frye. See id. at 589-598.

[5] See also Holbrook v. Lykes Brothers Steamship Company, Inc., 80 F.3d 777, 780 (3d Cir. 1996); Zaprala v. USI Servs. Gp., Inc., No. 09–1238, 2013 WL 1148335, at *6 (E.D. Pa. Mar. 20, 2013)(quoting Pineda, 520 F.3d at 243).

"[B]ecause expert evidence is often more misleading than other evidence, Rule 403 gives a judge more power over experts than over lay witnesses." In re Paoli RR Yard PCB Litigation (Paoli II), 35 F.3d 717, 747 (3d Cir. 1994). However, "in order for a district court to exclude scientific evidence, there must be something particularly confusing about the scientific evidence at issue—something other than the general complexity of scientific evidence." Id.

a. Rule 702

Federal Rule of Evidence 702 has three major requirements: 1) the expert must be qualified; 2) the expert must testify about matters requiring scientific, technical, or specialized knowledge; and 3) the testimony must assist the trier of fact.[6] Pineda, 520 F.3d at 243 (citing Kannankeril, 128 F.3d at 806). 702's inquiry should be a "flexible one." Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 594 (1993).

i. Expert Must Be Qualified

An expert's qualifications may include education, provided it is in a field related to the one in which the expert intends to testify. Fedor v. Freightliner, Inc.,

[6] Federal Rule of Evidence 702 states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702.

193 F. Supp. 2d 820, 827 (E.D. Pa. 2002). Overall, the court will consider both academic training and practical experience to determine if the expert has "more knowledge than the average lay person" on the subject. Id. at 827-28 (citing Waldorf v. Shuta, 142 F.3d 601, 627 (3d Cir. 1998)). "An expert may be generally qualified but may lack qualifications to testify outside his area of expertise." Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 322 (3d Cir. 2003).

However, this does not mean that the "best qualified" expert must testify. "[W]itnesses may be competent to testify as experts even though they may not, in the court's eyes, be the 'best' qualified." Holbrook v. Lykes Bros. S.S. Co., Inc., 80 F.3d 777, 782 (3d Cir. 1995).[7] "Rule 702 and Daubert put their faith in an adversary system designed to expose flawed expertise." U.S. v. Mitchell, 365 F.3d 215, 244-45 (3d Cir. 2004)(citations omitted). "As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process—competing expert testimony and active cross–examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies." Id. at 244 (citations omitted).

ii. Expert's Methods Must be Reliable

This Circuit interprets the second factor as one of "reliability," i.e., the testimony is admissible so long as the process or technique the expert used in formulating the

[7] See also Keller v. Feasterville Family Health Care, 557 F. Supp. 2d 671, 675 (E.D. Pa. 2008)(Rice, J.).

opinion is reliable. Pineda, 520 F.3d at 244. An expert's opinion need not be correct, only reliable. See In re Paoli RR Yard PCB Litigation (Paoli II), 35 F.3d 717, 744 (3d Cir. 1994)("This does not mean that plaintiffs have to prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*, they only have to demonstrate by a preponderance of evidence that their opinions are reliable." (emphasis in original)). "[A]n expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation." Daubert, 509 U.S. at 592. "[I]t is the burden of the party offering the expert scientific testimony to demonstrate reliability by a preponderance of the evidence." In re TMI Litig., 193 F.3d 613, 705 (3d Cir. 1999)(citing Paoli II, 35 F.3d at 744).[8]

"Rule 702 grants the district judge the discretionary authority, reviewable for its abuse, to determine reliability in light of the particular facts and circumstances of the particular case." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 158 (1999). Judges considering this factor should look to whether a theory, technique, or opinion can be tested or has been subject to peer review or publication. Daubert, 509 U.S. at 593. "The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised." Id. at 594. A court should also consider the known or potential rate of error involved in a scientific method. Id.

[8] See also FED. R. EVID. 702, Advisory Committee Note (2000 Amendments)("Under that Rule, the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence." (citing Bourjaily v. United States, 483 U.S. 171 (1987)).

"Reliability" does not require that a technique or methodology be generally accepted by a scientific community. Id. See also id. at 597-98. However, "[w]idespread acceptance can be an important factor in ruling particular evidence admissible" while a minimally supported technique "may properly be viewed with skepticism." Id.

iii. Expert Must be Helpful

The third factor "is typically understood in terms of whether there is a sufficient 'fit' between the expert's testimony and the facts that the jury is being asked to consider." United States v. Schiff, 602 F.3d 152, 172-73 (3d Cir. 2010)(citing Daubert, 509 U.S. at 591). See also In re: TMI Litigation, 193 F.3d 613, 670 (3d Cir. 1999). This factor is about relevance. "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." Daubert, 509 U.S. at 591 (quoting 3 Weinstein & Berger ¶ 702[02], p. 702–18). "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." Id. at 591-92.

b. Rule 703

Under Federal Rule of Evidence 703, the data underlying the expert's opinion is the central focus. Rule 703 states:

> An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. 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. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.

FED. R. EVID. 703. The trial court must evaluate whether the data used by an expert is reasonably relied upon by experts in the field. See In re Paoli RR Yard PCB Litigation (Paoli II), 35 F.3d 717, 747-49 (3d Cir. 1994).

II. Dr. Blume's Proffered Opinions

The plaintiff plans to offer Dr. Blume as an expert in pharmacovigilance and risk reduction, including drug labeling. "Pharmacovigilance principally involves the identification and evaluation of safety signals." FDA, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemioliogic Assessment, at 4 (2005)(Pl. Ex. 7, filed under seal).[9] The term "safety signal" "refers to a concern about an excess of adverse events compared to what would be expected to be associated with a product's use." Id. Safety signals can be found in a variety of sources, including post-marketing data, preclinical data, or case reports offering adverse effects of the drug. See id.[10] A single well-documented adverse event report (AER) may be a safety signal, depending on the circumstances of the adverse event (i.e., the only explanation for the event would be the drug itself). See id. at 4-5.[11] Signals do not establish causation, per se; instead, they simply indicate that further investigation into the drug's effects is needed. See id. at 4, 12-16. Investigation of a signal may include both randomized trials and "carefully

[9] See also Wu, J., et al., Postmarketing Drug Safety Surveillance: An Overview of Regulatory Issues, Pharm. Dev. Regul., 2003:1(4), pp. 221-44 (Pl. Ex. 11, filed under seal)(article co-authored by Kenneth Kwong, McNeil's Director of Pharmacovigilance, explaining pharmacovigilance).

[10] See also E. Nelson Dep., Nov. 21, 2013 at 100-101 (Pl. Ex. 25, filed under seal)(McNeil's Vice President for Scientific Affairs explaining that information, including AERs, may lead to a label change as part of pharmacovigilance).

[11] See also K. Kwong Dep., Jan. 25, 2014 at 166 (Pl. Ex. 6, filed under seal).

designed nonrandomized observational studies of the product's use in the 'real world,'" such as registries and surveys. Id. at 12-17.

"After a signal is identified, it should be further assessed to determine whether it represents a potential safety risk and whether other action should be taken." Id. See also id. at 17-18. If the investigation finds that the signal poses a risk to consumer safety, the drug label's warnings may need to be altered or the company may need to withdraw the drug from the market. See K. Kwong Dep., Jan. 25, 2014 at 163, 219-20 (Pl. Ex. 6, filed under seal).[12] A drug company does not have to establish that the drug actually caused the adverse effects being investigated before taking a risk reduction action.[13]

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[12] See also Wu, J., et al., Postmarketing Drug Safety Surveillance: An Overview of Regulatory Issues, Pharm. Dev. Regul., 2003:1(4), pp. 221-44 (Pl. Ex. 11, filed under seal)(article co-authored by Kenneth Kwong, McNeil's Director of Pharmacovigilance); E. Nelson Dep., Nov. 21, 2013 at 100-101 (Pl. Ex. 25, filed under seal)(McNeil's Vice President for Scientific Affairs explaining that information, including AERs, may lead to a label change as part of pharmacovigilance).

Kenneth Kwong, McNeil's Director of Pharmacovigilance, identified four distinct levels of risk mitigation increasing in intensity: Level 1 (labeling), Level 2 (labeling, education and outreach), Level 3 (labeling, education and outreach, and systems that provide guidance), and Level 4 (labeling, education and outreach, systems that provide guidance, and restricted access). See K. Kwong Dep, Jan. 25, 2014 at 219-20 (Pl. Ex. 6, filed under seal); Wu, J., et al., Postmarketing Drug Safety Surveillance: An Overview of Regulatory Issues, Pharm. Dev. Regul., 2003:1(4), pp. 221-44 (Pl. Ex. 11, filed under seal)(article co-authored by Kwong).

In the 1990s, McNeil voluntarily relabeled Tylenol to include alcohol warnings after finding that the literature and other sources indicated a risk of liver damage. See E. Nelson Dep., Nov. 21, 2013 at 100-101 (Pl. Ex. 25, filed under seal).

[13] See In Re: Gadolinium-Based Contrast Products Liab. Litig., No. 1:08 GD 50000, 2010 WL 5173568 at *7 (N.D. Ohio Jun. 18, 2010)("The question of whether these AERs constituted a safety signal requires someone with expertise in pharmacovigilance. The expert must determine whether, given all the information available to GEHC at the time, the AERs gave rise to a safety signal alerting GEHC to the risks associated with administering Omniscan, particularly to the renally impaired. Hence, whether the four AERs supported a clinical diagnosis of NSF is irrelevant to the question of whether the AERs constituted a safety signal.").

This is especially true in this case, since Extra Strength Tylenol was governed by a Tentative Final Monograph, not a Final Monograph. See Letter from FDA re: FOIA request, Nov. 17, 2011 (Pl. Ex. 17, filed under seal); L. Pawelski Dep., Fe. 28, 2014 at 112-17 (Pl. Ex. 20, filed under seal). See also Memorandum Denying Motion for Summary Judgment on Failure-to-Warn Claim at 10-15 (Doc. No. 181); Memorandum Denying Motion for Summary Judgment on Design Defect Claim at 12-18 (Doc. No. 183).

Dr. Blume plans to offer an opinion that McNeil should have identified safety signals showing that hepatotoxicity was possible at or near 4 grams of acetaminophen—the active ingredient in Tylenol—as early as the early 2000s and that the defendants failed to take appropriate risk mitigation steps.[14] In her opinion, the labeling on Extra Strength Tylenol did not fully inform consumers of hepatotoxicity risk. In short, Dr. Blume's opinion offers a standard for an appropriate label for Extra Strength Tylenol, under all the known and available circumstances.

To reach her conclusions, Dr. Blume independently reviewed several sources of information: toxicology studies, clinical trial data, case reports, case series, and the results of adverse event databases, along with depositions and related internal documents.[15] She also reviewed third-party assessments of the risk, including independent audits of the defendants' pharmacovigilance practices.[16]

III. Dr. Blume is a Qualified Pharmacovigilance Expert

Dr. Cheryl Blume is the President of Pharmaceutical Development Group, Inc. (PDG), a multi-disciplinary pharmaceutical services firm that specializes in the development, registration, and monitoring of drugs and drug company activity for

[14] See C. Blume Expert Report, May 5, 2014 at ¶¶ 100, 120 (Doc. No. 124, Ex. A).

[15] See C. Blume Expert Report, May 5, 2014 at ¶ 17, Sec. 3 (Doc. No. 124, Ex. A).

Among these references, Dr. Blume cites Larson, A.M., et al., Acetaminophen-induced acute liver failure: results of a United States multicenter, prospective study, Hepatology, 2005 Dec.: 42(6): 1364-1372 (Doc. No. 154, Ex. 22). The defendants filed a separate motion to exclude the use of this article. See Motion to Exclude Opinion Testimony of Cheryl Blume based on Supplemental Data, Jan. 29, 2016 (Doc. No. 193). I denied that motion. See Memorandum and Order Denying Defendants' Motion to Exclude Plaintiff's Expert Testimony Based on Larson Article/ALFSG Data, Jul. 14, 2016 (Doc. No. 224, 225). I see nothing improper with how Dr. Blume has used the Larson article (which she only cites once in her report)—along with other evidence—in rendering her opinion.

[16] See C. Blume Expert Report, May 5, 2014 at ¶ 13 (Doc. No. 124, Ex. A).

pharmaceutical companies.[17] She received a Ph.D. in Pharmacology and Toxicology from The West Virginia University Medical Center. Dr. Blume's graduate study and research was funded by a National Institutes of Health (NIH) fellowship.

After completing her graduate fellowship, Dr. Blume joined Mylan Laboratories, one of the world's largest pharmaceutical companies. During her 18-year career with Mylan, Dr. Blume served in several senior scientific, management, and regulatory positions, including Corporate Vice President, Technical Director, Director of Pharmacology, and Assistant Director of Regulatory Affairs. Additionally, she spent five years as an Executive Vice President, Chief Operations Officer, and Board Member of Somerset Pharmaceuticals, Inc. She started PDG in 1999. During her career, she has worked with generic drugs, brand-name drugs, and drugs regulated by both the New Drug Application (NDA) system and the monograph system.

Over the course of her professional career, Dr. Blume has written, consulted on, or been responsible for the labeling and/or promotional materials for more than 100 different pharmaceutical products. She is also an Affiliate Associate Professor to the Voluntary Faculty of the Department of Molecular Pharmacology and Physiology at the University of South Florida's College of Medicine in Tampa, Florida.

[17] See http://www.pharmdevgroup.com/about-pdg/.

The information about Dr. Blume's qualifications can be found in her expert report (Doc. No. 124, Ex. A), in her Curriculum Vitae (Doc. No. 124, Ex. A at Ex. 1), and her deposition (Doc. No. 124, Ex. B). The defendants do not challenge Dr. Plunkett's qualifications, per se; however, an overview of her credentials is helpful in explaining my rulings.

Dr. Blume has been qualified as a pharmacovigilance expert in numerous drug products liability actions.[18] From all that has been provided, she is well-qualified to serve as a pharmacovigilance and regulatory expert in this case.

IV. The Defendants' Daubert Challenge to Dr. Blume's Testimony

The defendants move to exclude Dr. Blume's opinions on:

1) The cause or mechanism of acetaminophen-induced hepatotoxicity;
2) Risk factors for acetaminophen-induced hepatotoxicity;
3) Case reports or adverse events reports (AERs);
4) Alleged deficiencies in McNeil's pharmacovigilance process;
5) Actions that have been considered by the FDA;
6) Johnson & Johnson's Credo; and
7) Marketing materials of the defendants.

They claim that she cannot testify because she is not qualified or prepared to offer an opinion about causation in this case. They also claim that her methodology does not pass muster under Daubert or the Federal Rules of Evidence.

[18] See, e.g., In Re: Gadolinium-Based Contrast Products Liab. Litig., No. 1:08 GD 50000, 2010 WL 1796334, at *15-17 (N.D. Ohio May 4, 2010); Wright v. American Home Products Corp., 557 F. Supp. 2d 1032, 1037-38 (W.D. Mo. 2008)("Blume is clearly qualified to testify about the risks and benefits of Pondimin as it relates to general industry practice and she is qualified as to any general industry standards Wyeth followed or failed to follow prior to marketing and distributing Pondimin."); Fraser v. Wyeth, No. 3:04cv1373, 2014 WL 129172, at *5 (D. Conn. Jan. 14, 2014)("Dr. Blume, based on her extensive experience, testified as to the industry standard of pharmacovigilance. . . and opined that Wyeth had violated that standard with respect to the Prempro label."); In Re Yasmin & Yaz Mktg., Sales Practices & Prod. Liab. Litig., No. 3:09-md-02100, MDL No. 2100, 2011 WL 6302287, at *23 (S.D. Ill. Dec. 16, 2011)(qualifying Blume as a pharmacovigilance an regulatory expert); In re: Neurontin Mtkg Sales Practice & Prod Liab. Litig., 612 F. Supp. 2d 116, 158 (D. Mass. 2009)("Dr. Blume is amply qualified at least to evaluate the adverse event data and other sources of information regularly used by the FDA and industry professionals."). See also Decker v. GE Healthcare Inc., 770 F.3d 378, 393 (6th Cir. 2014)(discussing Dr. Blume's qualifications as pharmacovigilance expert).

a. Testimony on Medical Causation and Risk Factors

First, the defendants argue that the "Acetaminophen-related Hepatotoxicity events" section of Dr. Blume's report (p. 22-36) includes information she cannot offer as an expert because she is not a medical doctor.

The plaintiff counters that Dr. Blume is a regulatory expert, offering an opinion about general causation from a pharmacovigilance perspective (i.e., whether the available information signals a risk that liver damage can occur at or near 4 grams of acetaminophen). She intends to discuss the processes required of companies carrying out pharmacovigilance. Pharmacovigilance is essentially the methods pharmaceutical companies use to assess risk to consumers.[19] The plaintiff argues that, as a pharmacovigilance expert, Dr. Blume does not necessarily need to be a medical doctor. I agree.[20]

Dr. Blume is qualified as a pharmacovigilance expert and developed her opinion as such an expert would. She approached her analysis by conducting research in the way

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[19] See In Re: Gadolinium-Based Contrast Products Liab. Litig., No. 1:08 GD 50000, 2010 WL 1796334, at *15 (N.D. Ohio May 4, 2010)(discussing FDA's Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (Mar. 2005)).

[20] See Decker v. GE Healthcare Inc., 770 F.3d 378, 394 (6th Cir. 2014)("The district court concluded that because Blume was a pharmacovigilance expert, irrespective of whether she was a medical doctor, she was qualified to reliably testify as to the significance of the AERs. Conversely, the district court concluded that because Gaspari was not a pharmacovigilance expert, even though he was a medical doctor, he was not qualified to testify reliably regarding the significance of the AERs. The district court did not abuse its discretion in reaching either conclusion.").

Even McNeil's own Director of Pharmacovigilance Kenneth Kwong, M.D., Ph.D. noted the distinction between what a pharmacovigilance professional does and medical professional does. See K. Kwong Dep., Jan. 25, 2014, at 62 ("Even hepatologists might not be necessarily the best person to look at it because someone who practice medicine is quite different from someone who look at pharmacovigilance") and at 58 ("Both of them have years of drug safety experience. They might not necessarily be hepatologists. In drug safety we deal with different drug safety issue, there's not one particular type of area. With their years experience [sic] they're well qualified to be physician to deal with liver toxicity.")(Pl. Ex. 6, filed under seal).

the FDA would: reviewing the available information about the risk of liver damage at or close to the recommended dose of 4 grams to see if this information raises "safety signals" requiring the defendants to act.[21] Her testimony about the risk of liver damage at recommended doses will be permitted.[22]

The defendants also argue Dr. Blume cannot testify about risk factors for acetaminophen-induced liver damage—such as alcohol use, preexisting liver diseases, etc.—because they do not "fit" this case. They claim this information is outside the scope of Dr. Blume's area of expertise.

Dr. Blume offers an opinion about when certain "vulnerable populations" may be at risk to develop liver damage at recommended doses from a pharmacovigilance perspective. As she explains in her deposition, she reviewed available information about whether, when, and how acetaminophen posed a risk of liver damage. This discussion provides background for her analysis of whether the defendants acted appropriately in light of this information. Her discussion of risk factors, as they pertain to the defendants' pharmacovigilance duties, passes muster under Daubert.

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[21] See In Re: Gadolinium-Based Contrast Products Liab. Litig., No. 1:08 GD 50000, 2010 WL 1796334, at *15 (N.D. Ohio May 4, 2010)("[T]he Court finds that Dr. Blume's background in pharmacology, toxicology and risk assessment qualify her to opine on NSF causation, the stability of Omniscan, and the free gadolinium theory. Dr. Blume is also qualified to interpret the results of any of GEHC's toxicology, pharmacology or pharmacokinetic studies and to opine on the significance of the results. The Court finds that Dr. Blume may testify, based on the facts adduced at trial (including GEHC internal studies and documents), on the accuracy and adequacy of the toxicology, pharmacology and pharmacokinetics data appearing on the Omniscan label at the time a given plaintiff was administered Omniscan."); In re: Neurontin Mtkg Sales Practice & Prod Liab. Litig., 12 F. Supp. 2d 116, 158 (D. Mass. 2009)("In performing this review, Dr. Blume states that she used the same methods that she employs when preparing a drug development for submission to the FDA.")(qualifying Blume as a regulatory expert who can provide an opinion on general causation).

[22] See, e.g., Daniel v. Wyeth, Inc., 15 A.3d 909, 926 (Pa. Super. 2011)(explaining and Dr. Blume was qualified as an expert on causation even though she was not a medical doctor); Decker v. GE Healthcare Inc., 770 F.3d 378, 393-95 (6th Cir. 2014)(same).

b. Reliance on AERs or Case Reports[23]

The defendants argue that Dr. Blume's opinion should not be based on case reports or adverse event reports (AERs) because they are unreliable.[24] Using AERs to evaluate the risk of safety concerns to consumers is a methodology often used in pharmacovigilance by the FDA and others in the field.[25] FDA advisory committees and working groups have relied on AERs to evaluate risks to consumers regarding acetaminophen toxicity at the recommended dose.[26] AERs are especially important to the

[23] Dr. Blume does not rely solely on AERs in rendering her opinions. She considers many other sources typically used by pharmacovigilance experts (i.e., FDA documents, internal documents, etc.), in rendering her opinions. Her sources all appear to be appropriate under Rule 702 and 703. Any weaknesses in her sources can be explored during cross-examination.

[24] In a related motion in limine, I ruled that AERs were admissible, in the least, to show "notice." I also found that it may be appropriate for experts to rely on AERs so long as they did so in a reliable manner. See Memorandum on Defendants' Motions in Limine (MIL 1), Apr. 19, 2016 at 3-11 (Doc. No. 336)(denying defendants' motion to exclude AERs).

[25] See FDA, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemioliogic Assessment, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm ("The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products…. FAERS is a useful tool for FDA for activities such as looking for new safety concerns that might be related to a marketed product, evaluating a manufacturer's compliance to reporting regulations and responding to outside requests for information. The reports in FAERS are evaluated by clinical reviewers in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) to monitor the safety of products after they are approved by FDA. If a potential safety concern is identified in FAERS, further evaluation is performed."); Decker v. GE Healthcare Inc., 770 F.3d 378, 394 (6th Cir. 2014)("The district court concluded that because Blume was a pharmacovigilance expert, irrespective of whether she was a medical doctor, she was qualified to reliably testify as to the significance of the AERs. Conversely, the district court concluded that because Gaspari was not a pharmacovigilance expert, even though he was a medical doctor, he was not qualified to testify reliably regarding the significance of the AERs. The district court did not abuse its discretion in reaching either conclusion.").

[26] See, e.g., FDA Working Group, Recommendations for FDA Interventions to Decrease the Occurrence of Acetaminophen Hepatotoxicity, Feb. 26, 2008, at 11 (Pl. Ex. 8, filed under seal).

field of pharmacovigilance in evaluating risk.[27] A single well-documented adverse event report (AER) may be a safety signal, depending on the circumstances of the adverse event (i.e., the only explanation for the event would be the drug itself).[28] Given that AERs are sources of information commonly relied upon by pharmacovigilance experts, Dr. Blume's use of AERs in formulating her opinions would be appropriate in this case.[29] See FED. R. EVID. 703 ("An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. 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. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to

[27] The defendants question Dr. Blume's reliance on specific AERs and whether they are relevant to her opinions in this case. They argue that a number of these AERs are not substantially similar to the plaintiff's case. From what I see, the AERs relied on by Dr. Blume have some relation to this case (i.e., they involve fasting, acetaminophen at recommended doses, etc.). Any dissimilarities in these cases, as compared to the plaintiff's medical history, are appropriately explored on cross-examination. If Dr. Blume discusses AERs that do not involve acetaminophen at or near recommended doses, fasting/malnutrition, liver injury, or other conditions similar to the plaintiff's case, the defendants may raise an objection at trial. See In re Viagra Prods. Liab. Litig., 658 F. Supp. 2d 950, 964 (D. Minn. 2009)(excluding as irrelevant Dr. Blume's testimony regarding adverse event reports addressing Viagra and eye conditions other than non-arteritic anterior is chemic optic neuropathy (NAION), the eye condition at issue in the case).

[28] See FDA, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemioliogic Assessment, at 4-5 (2005)(Pl. Ex. 7, filed under seal). See also Wu, J., et al., Postmarketing Drug Safety Surveillance: An Overview of Regulatory Issues, Pharm. Dev. Regul., 2003:1(4), pp. 221-44 (Pl. Ex. 11, filed under seal) (article co-authored by Kenneth Kwong, McNeil's Director of Pharmacovigilance, explaining pharmacovigilance); K. Kwong Dep., Jan. 25, 2014 at 166 (Pl. Ex. 6, filed under seal).

[29] See, e.g., In Re: Gadolinium-Based Contrast Products Liab. Litig., No. 1:08 GD 50000, 2010 WL 1796334, at *11 (N.D. Ohio May 4, 2010)(explaining how AERs are often one of several sources relied on by experts like Blume); In re: Neurontin Mtkg. Sales Practice & Prod. Liab. Litig., 12 F. Supp. 2d 116, 153, 157 (D. Mass. 2009)(explaining how AERs may be used to support general causation theories by pharmacovigilance experts); In re Phenylpropanolamine (PPA) Prods. Liab. Litig., 289 F. Supp. 2d 1230, 1242 (W.D. Wash. 2003)(observing that "[n]on-epidemiological sources [such as AERs] are frequently utilized by experts in rendering scientific opinions[.]").

the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.").[30]

c. Pharmacovigilance Deficiencies[31]

The defendants claim that Dr. Blume should not be permitted to testify about McNeil's pharmacovigilance deficiencies. First, they claim this testimony does not "fit" the case. I disagree. Whether the defendants took the proper steps to recognize potential problems or "safety signals" related to Extra Strength Tylenol is entirely relevant to notice, knowledge, and defendants' state of mind. The defendants are required to monitor potential safety concerns with their products (i.e., pharmacovigilance). If they were not doing so, a jury could find they placed an unreasonably dangerous product on the market.

The defendants also argue that their prior "bad acts" before 2010 are not admissible and would be confusing to the jury. They claim only those deficiencies in adverse event reporting around the time of the decedent's death are the only deficiencies that are relevant. I again disagree. A pattern of deficiencies in pharmacovigilance could be relevant to the plaintiff's failure-to-warn and punitive damages claims. The deficiencies in the defendants' adverse event reporting in the years prior to the decedent's

[30] Whether the AERs themselves are admissible at trial is a different question, which I will resolve when I see how they will be used at trial.

[31] The defendants claim Dr. Blume's methodology regarding deficiencies in their adverse event reporting is not reliable because she does not review the AERs herself to determine if the defendants missed a safety signal during the relevant time frame. They also argue that her testimony about AERs should be excluded because she did not review the AERs herself, only a summary of them. Dr. Blume is considering whether the information found in the AERs raised a "safety signal" and whether the defendants appropriately addressed adverse events known to them. Dr. Blume's use of summaries of AERs and reports of AERs procedural deficiencies would be appropriate for the purpose of opining that the defendants' pharmacovigilance duties had been triggered by such information.

death are highly probative evidence of notice, intent, and knowledge of the defendants.[32] This information is relevant to Dr. Blume's pharmacovigilance opinion about the adequacy of the defendants' risk reduction measures prior to the decedent's death.

d. Testimony about Corporate State of Mind

The defendants argue that Dr. Blume's testimony that the defendants "behaved negligently in conducting its business" would be an improper legal opinion. See Berckeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006). See also Wolfe v. McNeil-PPC, Inc., No. CIV.A. 07-348, 2011 WL 1673805, at *8 (E.D. Pa. May 4, 2011) (citing Berckeley, 455 F.3d at 217); Wolfe v. McNeil-PPC, Inc., 881 F. Supp. 2d 650, 662 (E.D. Pa. 2012). The defendants claim that the jury, not the plaintiff's expert, is to decide whether the defendants acted negligently.

An expert cannot usurp the role of the judge or jury. See, e.g., Berckeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006). "Notwithstanding this admonition, the line between admissible and inadmissible expert testimony as to the customs and practices of a particular industry often becomes blurred when the testimony concerns a party's compliance with customs and practices that implicate legal duties." Id. at 218. I agree that Dr. Blume cannot opine that the defendants breached their legal duties, offer an opinion about what the defendants' intent was, or offer testimony about internal documents which the jury themselves can easily interpret on their own.[33]

[32] See also Memorandum on Defendants' Motions in Limine (MIL 7), Apr. 19, 2016 at 24-27 (Doc. No. 336)(denying defendants' MIL to exclude forms noting deficiencies in adverse event reporting).

[33] See 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

Dr. Blume can, however, offer testimony on what certain technical regulatory documents mean and how they exemplify compliance with industry standards/customs.[34] "The FDA drug approval process, FDA regulations, and protocols of drug labeling are topics that are likely unfamiliar to a layperson, and expert testimony on these topics will be helpful to the jury's understanding of the complex issues in this case." Johnson v. Wyeth LLC, No. CV 10–02690–PHX–FJM, 2012 WL 1204081, at *3 (D. Ariz. Apr. 11, 2012). This testimony will aid the jury in determining whether the defendants fell below

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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. Jun. 20, 2000)); Heineman v. American Home Products Corp., No. 13–cv–02070–MSK–CBS, 2015 WL 1186777, at *12 (D. Colo. Mar. 12, 2015)(excluding Dr. Blume's opinions about defendants' state of mind); 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 Dr. Blume 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."); Chandler v. Greenstone Ltd., No. C04–1300RSL, 2012 WL 882756, at *1 (W.D.Wash. Mar. 14, 2012)(excluding Dr. Blume'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 Dr. Blume's opinions on defendants' motive, intent, knowledge, or other state of mind); 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."); Tyree v. Boston Scientific Corp., 54 F. Supp. 3d 501, 564 (S.D. W.Va. 2014)("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.V. 2013)).

[34] See Heineman v. American Home Products Corp., No. 13–cv–02070–MSK–CBS, 2015 WL 1186777, at *12 (D. Colo. Mar. 12, 2015)("[I]t may be necessary for Dr. Blume 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 Dr. Blume's explanations thereof, the trier of fact would be unable to reach a conclusion about the Defendants' knowledge of any labeling deficiencies without Dr. Blume's say-so."); In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 192 (S.D. N.Y. 2009)("Dr. Parisian's commentary on any documents and exhibits in evidence will be limited to explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge. She will not be permitted to merely read, selectively quote from, or 'regurgitate' the evidence."); Wright v. American Home Products Corp., 557 F. Supp. 2d 1032, 1038 (W.D. Mo. 2008)("Blume is clearly qualified to testify about the risks and benefits of Pondimin as it relates to general industry practice and she is qualified as to any general industry standards Wyeth followed or failed to follow prior to marketing and distributing Pondimin."); Fraser v. Wyeth, No. 3:04cv1373, 2014 WL 129172, *5 (D. Conn. Jan. 4, 2014)("Dr. Blume, based on her extensive experience, testified as to the industry standard of pharmacovigilance (see Trial Tr. Vol. II at 202–03), and opined that Wyeth had violated that standard with respect to the Prempro label (see, e.g., id. at 737–38 (testifying that the failure to include information regarding the risk of dying from breast cancer in the Prempro label violated the duties of pharmacovigilance and the FDA regulations)).").

the industry standard for labelling, warning, or dose levels and to what extent the defendants knew or should have known about the risk of liver damage.

e. Actions Considered by the FDA but Not Yet Taken

The defendants argue that Dr. Blume's testimony about actions that FDA has considered but not yet taken is irrelevant, misleading, a waste of judicial resources, and/or unfairly prejudicial. Specifically, the defendants take issue with FDA Working Group recommendations or proposals that were not adopted by the FDA. If a pharmaceutical company would typically take those FDA recommendations or working group proposals into consideration in determining how to act in terms of pharmacovigilance goals, this information would be relevant. Whether it is unfairly prejudicial under Rule 403—the argument the defendants really appear to be making, which is addressed in a separate motion in limine—would be a determination I would need to make in context. I will defer a ruling based on Rule 403 until trial.

f. Testimony about Johnson & Johnson's Credo

The defendants argue that Dr. Blume should not be permitted to opine about Johnson & Johnson's Credo or mission statement. They claim that their own internal standard of care should not be presented as a legal standard of care; such information could mislead a jury. I agree. The defendants' own Credo should not be held out as the legal standard by which it should conduct its affairs. See Johnson v. Mountainside Hospital, 239 N.J. Super. 312, 323 (App. Div. 1990)("It was potentially misleading

because it attempted to exalt an exhortatory statement in the by-laws of the Hospital into the legal standard for determining whether or not the defendant physicians committed malpractice. The relevant legal standard is defined by law."). Additionally, any probative value the Credo may serve would be substantially outweighed by potential prejudice of the jury confusing this standard what was legally required.[35] See In re Paoli RR Yard PCB Litigation (Paoli II), 35 F.3d 717, 747 (3d Cir. 1994)(explaining how "Rule 403 gives a judge more power over experts than over lay witnesses" but this exclusion of evidence should only happen when they is "something particularly confusing about the scientific evidence at issue—something other than the general complexity of scientific evidence").

Testimony by Dr. Blume about Johnson & Johnson's Credo will be excluded.

g. Testimony about Marketing Materials

Lastly, the defendants argue that Dr. Blume's opinions concerning marketing materials are irrelevant and/or not helpful to the jury because it is unclear what advertisements the decedent saw. The plaintiff counters that Dr. Blume is qualified to offer a marketing opinion and the information is relevant to what the decedent and her sister were led to believe about the drug.

[35] The plaintiff argues that the defendants' Credo simply serves as an acknowledgement of the standard of care to which they must adhere. Johnson & Johnson's Credo requires more of its employees than the legal standard of care (i.e., putting consumers first and shareholders last). Allowing the company to be judged on this standard could discourage companies to create internal policies that go beyond what the law asks. See Cast Art Indus., LLC v. KPMG LLP, 416 N.J. Super. 76, 106-07 (2010)(explaining how applying company's internal procedures with a higher standard of care than common-law standard could discourage companies from creating procedures that exceed common law duties), rev'd on other grounds, Cast Art Indus., LLC v. KPMG LLP, 209 N.J. 208 (2012); Branham v. Loews Orpheum Cinemas, Inc., 819 N.Y.S.2d 250, 255 (App. Div. 2006)("While a defendant's internal rules may be admissible as evidence of whether reasonable care was exercised, such rules must be excluded, as a matter of law, if they require a standard of care which transcends the traditional common-law standard of reasonable care under the circumstances." (citations omitted)).

Pharmacovigilance involves several levels of risk reduction, as shown by this diagram from an article co-authored by Dr. Kwong, McNeil's Director of Pharmacovigilance.[36]

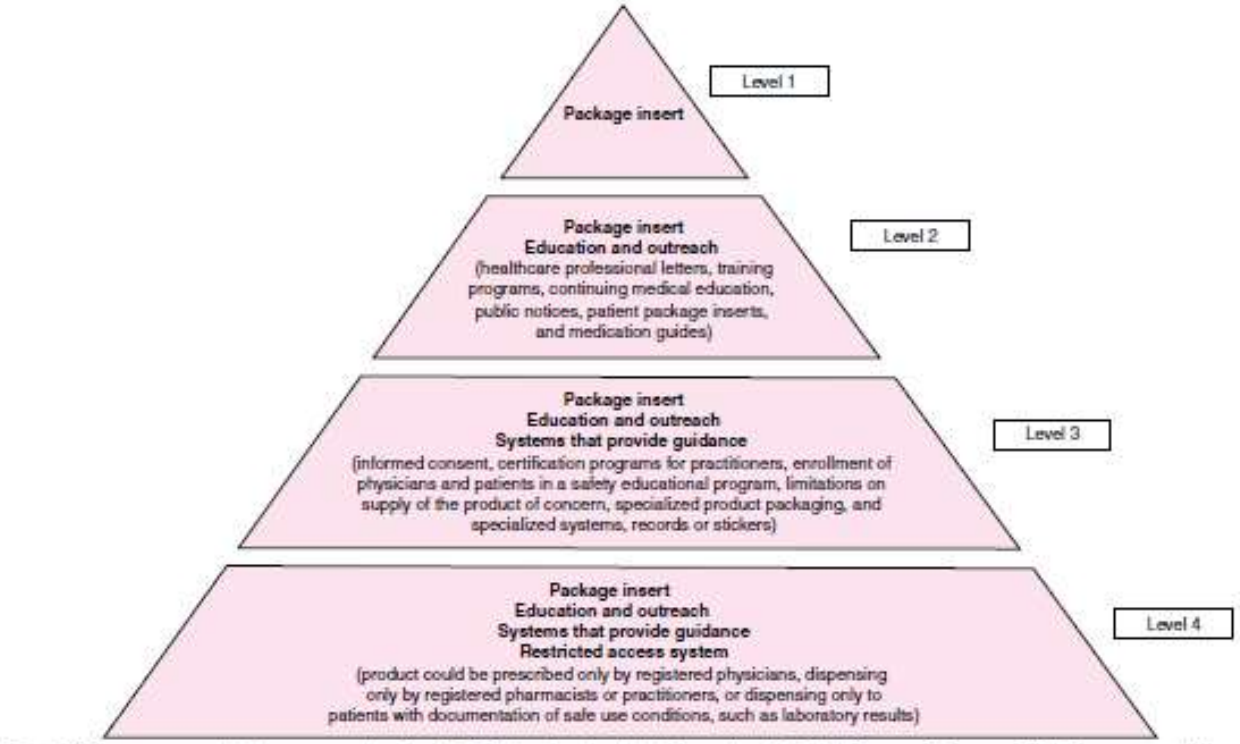

Fig. 1. Risk management tools proposed by the US FDA (contents adopted from the *2003 FDA Concept Paper on Risk Management*).[20]

Several of those levels involve communicating with consumers about known risks. For an over-the-counter product, like Tylenol, marketing and advertising is an important way of communicating with consumers. For this reason, marketing would be relevant to pharmacovigilance and Dr. Blume's testimony. Dr. Blume may offer an opinion about marketing materials as they relate to pharmacovigilance**.**

[36] See Wu, J., et al., Postmarketing Drug Safety Surveillance: An Overview of Regulatory Issues, Pharm. Dev. Regul., 2003:1(4), pp. 221-44 (Pl. Ex. 11, filed under seal)(article co-authored by Kenneth Kwong, McNeil's Director of Pharmacovigilance, explaining pharmacovigilance).

V. CONCLUSION

For the foregoing reasons, I will **GRANT** the defendants' motion in part and **DENY** it in part. Dr. Blume's testimony about the Johnson & Johnson Credo will be excluded, as explained above. All other testimony will be permitted, in accordance with the above.[37]

An appropriate Order follows.

[37] The defendants make several other cursory arguments about Dr. Blume's opinions. Those arguments not specifically addressed in this memorandum go to the weight of the evidence, not to its admissibility.