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. **August 31, 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" case scheduled for trial.[2] The plaintiff moves to exclude the testimony of Dr. Judith Jones, the defense's regulatory expert, under Daubert. For the reasons stated below, I will grant their motion in part and deny it in part.

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.[3] 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).[4]

"[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

[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).

[3] 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.

[4] 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).

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.[5] 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., 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

[5] 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;
>
> (b) the testimony is based on sufficient facts or data;
>
> (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.

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).[6] "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 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

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

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).[7]

"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. "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

[7] 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)).

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. Judith Jones, M.D., Ph.D.

The plaintiff offers many reasons why Dr. Judith Jones should not be permitted to testify as an expert under Daubert. In her expert report, Dr. Jones offers a wide range of opinions about this case: 1) she opines that the defendants' actions in terms of pharmacovigilance were appropriate based on regulations and industry standards, 2) she offers expert testimony about the regulatory structure governing Tylenol and acetaminophen, 3) she opines about whether acetaminophen is "generally recognized as safe and effective" (GRASE) under Food and Drug Administration (FDA) regulations, and 4) she claims that the Extra Strength Tylenol label was adequate.

a. Dr. Jones is Qualified to Offer Some Opinions But Not All

Dr. Judith Jones has professional experience in medicine and pharmaceutical consulting. Dr. Jones is a board-certified doctor of internal medicine with a Ph.D. in pharmacology and a specialty in geriatrics.[8] She has held a variety of teaching positions at several medical schools and universities, including Tufts, Michigan, and Georgetown and in the areas of public health, pharmacology, and medicine.[9] Dr. Jones continues to be licensed in Virginia, but she has not practiced medicine since 1989.[10]

Dr. Jones has experience working for and with the Food and Drug Administration (FDA). From 1973 through 1978, Dr. Jones worked as a consultant for the FDA. In that

[8] Curriculum Vitae of Judith Jones (Doc. No. 157, Ex. 1); J. Jones Expert Report at 1 (Doc. No. 157, Ex. 1); J. Jones Dep., May 5, 2015 at 47-49 (Doc. No. 157, Ex. B).

[9] See J. Jones Expert Report at 1-2 (Doc. No. 157, Ex. 1); Curriculum Vitae of Judith Jones (Doc. No. 157, Ex. 1); J. Jones Dep., May 5, 2015 at 50-52 (Doc. No. 157, Ex. B). I note, however, that most of these courses were typically only one week long. Curriculum Vitae of Judith Jones (Doc. No. 157, Ex. 1); J. Jones Dep., May 5, 2015 at 50-52 (Doc. No. 157, Ex. B).

[10] J. Jones Dep., May 5, 2015 at 47, 289 (Doc. No. 157, Ex. B).

role, she served on an advisory panel reviewing the safety of hemorrhoidal products at the first level of the monograph process.[11] From 1978 to 1983, Dr. Jones became the Director of the Division of Drug Experience (later known as the Division of Drug and Biological Experience) of the FDA.[12] In this role, Dr. Jones drafted definitions, guidelines, and procedures to expand the FDA's adverse event reports (AER) system and to instruct manufacturers on how to appropriately submit voluntary AERs.[13] Her work helped shape reporting procedures to identify "signals" from medical product adverse events in order to determine of the marketed products continued to be safe as labeled.[14]

In 1983, Dr. Jones decided to work half-time; she stepped down from her role as Director.[15] From 1983 to 1985, she served as a part-time special assistant to the Director of the Office of Biometrics and Epidemiology in the Bureau of Drugs.[16] In 1985, she left the FDA to pursue other opportunities.

In 1988, Dr. Jones founded a consulting and education company called The Degge Group.[17] Her company specializes in epidemiological studies and regulatory evaluation

[11] J. Jones Expert Report at 1 (Doc. No. 157, Ex. 1); Curriculum Vitae of Judith Jones (Doc. No. 157, Ex. 1); J. Jones Dep., May 5, 2015 at 17, 21, 23 (Doc. No. 157, Ex. B).

[12] J. Jones Expert Report at 1 (Doc. No. 157, Ex. 1); Curriculum Vitae of Judith Jones (Doc. No. 157, Ex. 1); J. Jones Dep., May 5, 2015 at 17-19 (Doc. No. 157, Ex. B).

[13] J. Jones Expert Report at 1 (Doc. No. 157, Ex. 1); J. Jones Dep., May 5, 2015 at 27 (Doc. No. 157, Ex. B).

[14] J. Jones Expert Report at 1 (Doc. No. 157, Ex. 1); J. Jones Dep., May 5, 2015 at 18 (Doc. No. 157, Ex. B).

[15] J. Jones Dep., May 5, 2015 at 18 (Doc. No. 157, Ex. B).

[16] J. Jones Expert Report at 1 (Doc. No. 157, Ex. 1); Curriculum Vitae of Judith Jones (Doc. No. 157, Ex. 1); J. Jones Dep., May 5, 2015 at 18 (Doc. No. 157, Ex. B).

[17] J. Jones Dep., May 5, 2015 at 47-48 (Doc. No. 157, Ex. B).

of medical product safety.[18] The Degge Group advises manufacturers on the appropriate management of safety issues of their products including regulatory actions and product labeling.[19] Dr. Jones also heads a nonprofit organization called Pharmaceutical Education and Research Institute (PERI), which was founded in 1989. PERI educates scientists and other personnel in the pharmaceutical industry about the regulatory issues.[20]

Dr. Jones' experience qualifies her to offer testimony about pharmaceutical industry standards and AERs.[21] She has been consulting on these topics for close to thirty years and had prior experience working for the FDA. She is especially qualified to offer testimony about AERs and what significance they may have in informing drug manufacturers of risks to consumers.

Dr. Jones does not appear to be qualified to offer opinions about the regulatory structure or duties of drug manufacturers under the monograph system. Dr. Jones' only experience working with the monograph regulatory system was her time as a consultant on a recommendation panel over forty years ago.[22] Her understanding of the monograph system is based on guidance general counsel for the FDA gave her panel at that time.[23] Dr. Jones has never worked in the FDA offices responsible for New Drug Application

[18] J. Jones Expert Report at 1 (Doc. No. 157, Ex. 1).

[19] J. Jones Expert Report at 1 (Doc. No. 157, Ex. 1).

[20] J. Jones Expert Report at 1-2 (Doc. No. 157, Ex. 1).

[21] The plaintiff argues that Dr. Jones is not qualified to offer an opinion about the defendants' pharmacovigilance practices because she does not have expertise in this area nor has she reviewed the appropriate pharmacovigilance documents of the defendants to render an accurate opinion. In response, the defendants indicated Dr. Jones will not offer an opinion on the subject of pharmacovigilance at trial. The plaintiff's argument is moot.

[22] J. Jones Dep., May 5, 2015 at 186 (Doc. No. 157, Ex. B).

[23] J. Jones Dep., May 5, 2015 at 186 (Doc. No. 157, Ex. B).

(NDA) or monograph compliance.[24] She has never reviewed or drafted a tentative final monograph or a final monograph.[25] Her consulting company has never advised a client on how to change the label on a monograph-regulated drug.[26] For these reasons, Dr. Jones is precluded from offering an opinion about whether the defendants complied with their regulatory duties under the NDA or monograph systems.[27] She is not qualified to offer an opinion in this area.[28]

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[24] J. Jones Dep., May 5, 2015 at 20, 22, 23-25, 142 (Doc. No. 157, Ex. B); id. at 23 ("Other than your work as a consultant to FDA on the hemorrhoidal panel from 1973 to 1978, have you ever been employed with FDA in any capacity responsible for regulating monograph drugs? A. Not, not other than that, that panel."). Dr. Jones was involved in issues related to Reye's syndrome's link to aspirin, a monograph-regulated OTC drug. Beyond that, she was not involved in drafting or enforcing monograph regulations. Id. at 24.

[25] J. Jones Dep., May 5, 2015 at 24, 46 (Doc. No. 157, Ex. B).

[26] J. Jones Dep., May 5, 2015 at 70 (Doc. No. 157, Ex. B)("Q. Have you ever advised a company or assisted them in drafting an NDA deviation [a method for amending a Final Monograph]? A. No. Q. Have you ever advised a company or offered any advice to a company on how to change, and the steps to change a final monograph? A. No. Q. Have you ever advised a company or assisted a company or offered, as it relates to changing a label or altering a label of an OTC product that is governed solely by a tentative final monograph? A. No.").

During her deposition, Dr. Jones was not aware of what the dosing regimen was for Extra Strength Tylenol under the Tentative Final Monograph (TFM). See J. Jones Dep., May 5, 2015 at 118, 280-81 (Doc. No. 157, Ex. B). See also Acetaminophen Panel Report, Jul. 8, 1977 (Pl. Ex. 10, filed under seal); TFM, Nov. 16, 1988 (Pl. Ex. 4, filed under seal). This information is a key part of this case. Her inability to speak to this issue raises concerns about her expertise on this subject.

[27] See also In Re Gadolinium-based Contrast Agents Products Liability Litig., No. 1:08 GD 50000, MDL No. 1909, 2010 WL 1796334, at *30-31 (N.D. Ohio May 4, 2010)(excluding defense expert opining about labeling process when expert only worked at FDA for three years as a medical officer).

[28] Dr. Jones is also of the opinion that acetaminophen is safe when taken at recommended doses. The plaintiff argues that she is not qualified to offer an opinion about the hepatic effect of acetaminophen at the recommended dose. Though she is board certified in internal medicine and has a Ph.D. in pharmacology, Dr. Jones has not practiced as a physician in over twenty years. Instead, her focus has been on regulatory and consulting work. Curriculum Vitae of Judith Jones (Doc. No. 157, Ex. 1); J. Jones Dep., May 5, 2015 at 47-48 (Doc. No. 157, Ex. B). Though she has a "special interest in effects of drugs on hepatic function," Dr. Jones admits that she is not an expert on liver failure. J. Jones Expert Report at 2 (Doc. No. 157, Ex. 1); J. Jones Dep., May 5, 2015 at 85 (Doc. No. 157, Ex. B)(A: "I'm not an expert on liver failure."). She also has not conducted academic studies in this research area. Dr. Jones has not reviewed the available data on this topic (or if she did, could not speak about it in her deposition). See J. Jones Dep., May 5, 2015 at 270-71 (Doc. No. 157, Ex. B)("Q. What is the data from the American Association of the Study of the Liver, from the AIRS database, the FDA's own database show? A. I can't say. …Q. Have you looked at the, provided in the course of your review for this case a document called the Acetaminophen Working Group's document that was presented to Janet Woodcock on February 2nd, 2008?... A: I don't recall.").

Her methodology is this respect is also questionable. Dr. Jones admits that she has not reviewed all the relevant literature about this issue—from McNeil's internal documents and from outside sources; at most, she read

b. Questions Regarding Dr. Jones' Methodology Go to Weight, not Admissibility

The plaintiff questions whether Dr. Jones' methodology is appropriate. She points out that Dr. Jones did not review all available documents in developing her opinions. Dr. Jones is qualified to offer opinions about industry standards and offer an opinion about whether the defendants' actions fell below what a "reasonable drug manufacturer" would do. However, Dr. Jones admited during her deposition that she has not reviewed many internal documents of the defendants related to actions they have taken in reaching her opinion.[29]

In rendering her opinions about the defendants' handling of spontaneous reports and/or adverse event reports, she admits that she only reviewed five to six years of annual summaries of the reports prepared by the defendants.[30] She did not review the reports themselves to indicate whether they appropriately complied with regulatory and/or

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summaries of the information provided in McNeil's annual reports. See J. Jones Dep., May 5, 2015 at 82-83, 103, 112-13, 143, 159, 194-96, 217-18, 223-25, 238-40, 243-44 (Doc. No. 157, Ex. B). Dr. Jones testified that she only read summaries of trials for Extra Strength Tylenol's NDA that took place prior to 1975 (when the NDA was approved), as well as summary material of the discussions held at the 2002 and 2009 advisory committee meetings. She also bases her opinion on medical literature from forty years ago. See J. Jones Dep., May 5, 2015 at 115-16 (Doc. No. 157, Ex. B).

The defendants claim that Dr. Jones will not be testifying about general or specific causation or about pharmacovigilance. Any opinion Dr. Jones offers about the safety of acetaminophen at recommended doses will be excluded. She would not be qualified to offer this opinion based on her credentials and/or this opinion would not be helpful to the jury for the purposes she is being called to testify.

[29] See J. Jones Dep., May 5, 2015 at 82-83, 103, 112-13, 143, 159, 194-96, 217-18, 223-25, 238-40, 243-44 (Doc. No. 157, Ex. B). Dr. Jones testified that she only read summaries of trials for Extra Strength Tylenol's NDA that took place prior to 1975 (when the NDA was approved), as well as summary material of the discussions held at the 2002 and 2009 advisory committee meetings.

[30] See J. Jones Dep., May 5, 2015 at 237-38 (Doc. No. 157, Ex. B)("Q. So how many spontaneous reports did you review? A. I reviewed the summaries of the reports. I didn't review, I, I did review some of the case reports of liver effects, but I didn't review all of the spontaneous reports. Just the summaries. Q. Well, where did you get the summaries from? A. They were in the annual reports….And about how many years of annual reports did you read? A. I don't recall precisely, five or six.").

industry standards. Dr. Jones did not read the depositions of Dr. Ed Kuffner, who was previously in charge of drug safety and surveillance at McNeil.[31] She said that she does not usually review the "opinions of the company" before rendering her own opinion, since it is meant to be independent.[32]

Dr. Jones admitted that she was not provided and did not review McNeil's surveys indicating that up to 40% of consumers take more than the recommended dose of over-the-counter (OTC) pain relievers, including Tylenol, because the medication is marketed as "safe."[33]

While the plaintiff's arguments raise questions about the accuracy of Dr. Jones' opinions, these questions are best addressed on cross-examination and answered by the jury. Whether Dr. Jones' opinion is based on all available information or the best information available is an issue that goes to weight, not admissibility.

By all accounts, Dr. Jones' actual methods—reviewing and deciphering the information contained in documents provided her based on her professional experience—are reliable ways of reaching opinions about industry standards and the use of AERs. For these reasons, I find that Dr. Jones' opinions on these two topics are reliable.

c. Dr. Jones' Opinions Regarding a Manufacturer's Duties Are Misleading and not Helpful

[31] See J. Jones Dep., May 5, 2015 at 35-36 (Doc. No. 157, Ex. B).

[32] J. Jones Dep., May 5, 2015 at 36 (Doc. No. 157, Ex. B).

[33] Dr. Jones also claims that changing a label under the Tentative Final Monograph cannot be done without a company first having "a dialogue" with the FDA. Yet, she has not reviewed McNeil's own documents about how McNeil did just that in the past— voluntarily adding an alcohol warning before it was mandated or reducing the maximum daily dose before it was mandated. I agree with the plaintiff that her opinions about the defendants' duties under the monograph system should be excluded, but more so because she is not qualified as an expert in this area and her opinions, which contradict Wyeth v. Levine (explained below), are not helpful to the jury.

Lastly, the plaintiff points out that Dr. Jones' opinions are contrary to the law governing this case. Throughout her expert report, Dr. Jones opines that the FDA, and not the manufacturer, is ultimately responsible for the content of the label on an OTC product such as Tylenol.[34] She also indicates that it is very difficult for a company like McNeil to change the label or increase warnings on an OTC product such as Tylenol under the monograph system.[35]

In Wyeth v. Levine, the Supreme Court unambiguously rejected this interpretation of law:

> [The drug manufacturer] suggests that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling. Yet through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.

Wyeth v. Levine, 555 U.S. 555, 570-71 (2009).

Dr. Jones contends that the defendants are precluded from changing their label to include a fasting warning because the FDA considered and rejected such a warning when promulgating the 2009 Final Rule. This opinion is not legally correct. It contradicts my ruling on the defendants' motion for summary judgment on the plaintiff's failure-to-warn

[34] See J. Jones Expert Report at 4, 13, 14, 15 (Doc. No. 157, Ex. 1) and J. Jones Dep., May 5, 2015 at 245-46 (Doc. No. 157, Ex. B)("Q. And that is noted on Page 27 of your report. And it is the obligation of the pharmaceutical company, that we have already discussed, that if they begin to see information, scientific data, and information that may suggest that acetaminophen may cause hepatotoxicity other than at massive overdoses or at lower doses, to assess that and alert the regulators, true?...
A. If they find that, of course. FDA is receiving, sometimes, the same information. Q. I'm not talking about the FDA. I'm just talking about the duty of the manufacturer. That is the duty of the manufacturer, true? A. It is also the duty of the FDA, that is part of their surveillance activities as well.").

[35] I note that Dr. Jones was also not given the FOIA letter from the FDA which explains what legal duties the defendants have under the Tentative Final Monograph. See J. Jones Dep., May 5, 2015 at 110-11, 125-26 (Doc. No. 157, Ex. B). See also FOIA Letter to Gainer, Nov. 17, 2011 (Pl. Ex. 3, filed under seal).

claim and could mislead the jury as to the duties required of the defendants (i.e., if the defendants found evidence that a fasting warning was needed, they were required to act on this knowledge to prevent injury to consumers).[36] Dr. Jones will be precluded from offering such an opinion.

Dr. Jones admits that her opinion—that the FDA, not the manufacturer, is ultimately responsible for the content of an OTC label—is not supported by Supreme Court precedent and is, in fact, inconsistent with it.[37] She also was unable to point to regulations which supported her opinion.[38] Dr. Jones' opinions to this effect would be misleading and not helpful to the jury. See In Re Gadolinium-based Contrast Agents Products Liability Litig., No. 1:08 GD 50000, MDL No. 1909, 2010 WL 1796334, at *30-31 (N.D. Ohio May 4, 2010)("The Court will not permit Dr. Waymack to offer his expert opinion on either of these topics because, as evidenced by both his expert report and deposition testimony, Dr. Waymack intends to offer opinions that are contrary to the Supreme Court's recent opinion in Wyeth v. Levine, 555 U.S. 555, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009)").[39]

[36] See Memorandum Denying Motion for Summary Judgment on Plaintiff's Failure-to-Warn Claim, November 15, 2015 at 41-43 (Doc. No. 181).

[37] See J. Jones Dep., May 5, 2015 at 105-06 (Doc. No. 157, Ex. B)("Q. When you say that the final decision on labelling changes belongs to the FDA, is that consistent or inconsistent with what the United States Supreme Court says? A: It is not supported by a decision of that particular court at that time. Q. Well that is our highest court, isn't it? A. Yes. Q. Okay. So your position here in bold, at the bottom of Page 4 is, differs from what the United States Supreme Court says, true? A: That's correct.") and id. at 134 (reiterating same).

[38] See J. Jones Dep., May 5, 2015 at 204-05 (Doc. No. 157, Ex. B).

[39] See also In re Levaquin Products Liability Litigation, MDL No. 08–1943 (JRT), 2010 WL 8399949, at *4-6 (D. Minn. Nov. 9, 2010)(excluding opinions of Paul Waymack which contradicted Wyeth v. Levine); In re Trasylol Products Liability Litigation, No. 08–MD–01928, 2010 WL 4259332, at *3-7 (S.D. Fla. Oct. 21, 2010)(excluding Dr. Waymack's expert testimony "that, under the FDA regulatory scheme, it would have been inappropriate for [the

The defendants argue that Dr. Jones' opinions are not contradictory to Wyeth because Wyeth involved a prescription drug and not an OTC product. The defendants also claim that Wyeth's discussion of the Changes Being Effected procedure for making label changes only applies to products covered by a New Drug Application (NDA). Because Extra Strength Tylenol is no longer covered by an NDA and is only regulated under the monograph system, they claim Wyeth is not entirely on point with this case.

This argument wholly ignores the defendants' own actions in changing their labels in the past. As I explained in my decision denying the defendants motion for summary judgment on the plaintiff's failure-to-warn claim, the defendants have, in fact, used the CBE procedures previously for one Tylenol product covered by an NDA to change the label for all Tylenol products (those covered by the NDA and those covered by the monograph system). This label change was done voluntarily and without prior FDA approval. See Memorandum Denying Motion for Summary Judgment on Plaintiff's Failure-to-Warn Claim, November 15, 2015 at 44-48 (Doc. No. 181).

Even if Wyeth leaves room for interpretation, Dr. Jones' opinions could still be misleading or could contradict my rulings in this case. See In Re Gadolinium-based Contrast Agents Products Liability Litig., No. 1:08 GD 50000, MDL No. 1909, 2010 WL 1796334, at *30-31 (N.D. Ohio May 4, 2010)("Technically, Dr. Waymack's observations in his report that the FDA possesses an advantage in evaluating safety data for particular classes of drugs and has ultimate authority over labeling may not wholly contradict

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drug manufacturer] to unilaterally update the label for Trasylol" because this opinion contradicts Wyeth and/or would mislead jurors).

Wyeth. However, Dr. Waymack's opinions are misleading because they attempt to minimize the manufacturer's role in the labeling process and therefore should not be presented to the trier of fact. Given that Dr. Waymack's probable testimony is at best misleading and at worst directly contrary to the Supreme Court's holdings in Wyeth, the Court, pursuant to Rule 702, precludes Dr. Waymack from testifying."). See also Memorandum Denying Motion for Summary Judgment on Plaintiff's Failure-to-Warn Claim, November 15, 2015 at 44 (Doc. No. 181)("As Wyeth made clear, the onus has always been on McNeil to ensure its label accurately reflects the risks of Extra Strength Tylenol.").

The defendants are correct in pointing out that they could not unilaterally change the language of the liver warning. It is not "incorrect" for Dr. Jones to opine that in practice, pharmaceutical companies do not unilaterally change the labeling for a product subject to a tentative final monograph. The liver warning only (not all of the conditions which would make acetaminophen GRASE under the final monograph) is covered by a final rule. Under that final rule, the defendants are required to at least have that warning on their label.

However, the question of whether the defendants can strengthen that warning is an entirely different one. If Dr. Jones had accurately explained the duties required by the defendants for the final liver warning rule and those required by the Tentative Final Monograph, the defendants may have a point. However, Dr. Jones does not make this distinction and instead confuses the duties imposed by the final liver warning rule with

those imposed by the final monograph, which is non-existent. To allow her to offer testimony to this effect to the jury would be confusing or misleading.

For these reasons, the following opinions of Dr. Jones will be precluded: that the defendants were unable to change their label without prior FDA approval and that the FDA—not the defendants—was responsible for the contents of the Tylenol label.[40]

d. Scope of Dr. Jones' Opinion

The plaintiff argues that Dr. Jones' recitation of the regulatory history of Tylenol products is simply a regurgitation of known facts without any additional insight into how those facts pertain to this case. "[A]n expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence." See In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009)(citations omitted). Narrative testimony only for this purpose would invade the province of the jury.[41] A narrative may be admissible, however, if an expert's explanation of complicated facts can help a jury better understand them.[42]

[40] The plaintiff also argues that Dr. Jones is not qualified to testify as an expert because she does not know that FDA regulation 21 C.F.R. § 201.80 offers the standard for when a manufacturer is required to change a drug label. In supplemental briefing ordered by the court, the plaintiff admitted that this regulation does not apply in this case. This argument is moot.

[41] See Wolfe v. McNeil-PPC, Inc., No. 07–348, 2011 WL 1673805, at *8 (E.D. Pa. May 4, 2011)("It will be the role of the jury, not Dr. Goldberg, to determine if McNeil acted negligently."); Brill v. Marandola, 540 F. Supp. 2d 563, 570 (E.D. Pa. 2008)("Mr. Newman's extensive interpretation of the relevant legal documents and suggested credibility determinations as presently included in his written report are not admissible because they usurp the fact-finding role of the jury and distract more than they aid."); Gallatin Fuels, Inc. v. Westchester Fire Ins. Co., 410 F. Supp. 2d 417, 423 (W.D. Pa. 2006)("An expert simply is not in any better position than the jury to assess another's subjective intent.").

[42] See In re Welding Fume Prod. Liab. Litig., No. 1:03–CV–17000, 2005 WL 1868046, at *17 (N.D. Ohio Aug. 8, 2005)("Thus, a 'narrative' by an expert is not automatically inadmissible; it is only when, as in In re Rezulin, the narrative is purely 'a repetition of the factual allegations in plaintiffs' complaint,' involving 'nothing technical or scientific,' that a court might find the expert testimony unhelpful, because the expert is providing only 'simple inferences drawn from uncomplicated facts.'… In this case, the great majority of the documents and articles that Dr. Levy is reviewing and comparing are complicated, and the inferences those documents may or may not support are

Dr. Jones' report goes through the legislative history of the FDA. Dr. Jones may offer information about FDA regulations as they pertain to adverse event reporting (her area of regulatory expertise). She may not, however, offer opinions about the regulatory framework of the NDA or monograph system because she is not an expert in this area.

e. Opinions About Whether Tylenol is GRASE

Dr. Jones also offers an opinion about whether Tylenol is "generally recognized as safe and effective" or GRASE by the FDA. She claims that the FDA considers it to be GRASE. As I explained in a previous Daubert ruling regarding the plaintiff's regulatory expert, whether acetaminophen is considered GRASE by the FDA involves legal interpretation of federal regulations.[43] This legal determination is the job of the court, not an expert or the jury. The FDA has not fully approved acetaminophen as GRASE because a final monograph for acetaminophen has not been issued. Dr. Jones' opinions about the status of acetaminophen as GRASE will be excluded.

Dr. Jones' opinion that acetaminophen has been approved by the FDA as GRASE by implication is also legally and factually incorrect. See J. Jones Dep., May 5, 2015 at 184 (Doc. No. 157, Ex. B)("So, by implication, if nothing, if not specifically, it is generally recognized as safe and effective."); id. at 214 ("[I]n essence what has happened is that a tentative final monograph product, acetaminophen, has been treated as if a final

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not at all simple. It is through the application of his expertise that Dr. Levy may allow the trier of fact to better understand what the documents do (and don't) mean, and, thus, what the defendants did (or didn't) know.")(citation omitted). See also In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Products Liab. Litig., 3:09-MD-02100-DRH, 2011 WL 6302287, at *8 (S.D. Ill. Dec. 16, 2011)("As to defendant's argument regarding narrative testimony, the Court has broad discretion over the mode and order of examining witnesses and presenting evidence and may allow testimony in narrative form at trial if the Court finds that it would helpful to the jury."(citing FED.R.EVID. 611; United States v. Pless, 982 F.2d 1118, 1123 (7th Cir. 1992)).

[43] See Memorandum Granting in Part and Denying in Part Motion to Exclude Gerald Rachanow's testimony, Jul. 27, 2016 (Doc. No. 241).

monograph in the sense of modifying the label by providing public notice, and so the, the regulatory process has just been speeded up."); and id. at 319-20 (same). This opinion contradicts basic administrative law principles. See, e.g., the Administrative Procedures Act, 5 U.S.C. § 553; 21 CFR § 330.10. She also bases this opinion on that fact that Extra Strength Tylenol was previously approved for an NDA; however, that NDA was withdrawn by McNeil about twenty years ago. See J. Jones Dep., May 5, 2015 at 192 (Doc. No. 157, Ex. B)("You have a tentative final monograph, and the acetaminophen is marketed under that monograph as well as an NDA. And that is why, that is the basis of my saying it is generally recognized as safe and effective."); id. at 193. Her opinion to this extent would be irrelevant and/or misleading.

III. CONCLUSION

For the foregoing reasons, I will **GRANT** the plaintiff's motion **in part and DENY it without prejudice in part**. Dr. Jones is qualified to offer testimony about AERs—how they are regulated, what purpose they serve in the industry, their advantages/deficiencies, etc. She also may offer general testimony about industry standards related to label changes (i.e., how drug manufacturers typically interact with the FDA when seeking label changes).[44] This information may help the jury understand what a "reasonable drug manufacturer" would have done and whether the defendants' actions fell below this standard of care.

[44] For this reason, she may offer an opinion about plaintiff's expert opinions in these areas (case reports/AERs) but is precluded from opining about areas outside her expertise (i.e., their qualifications as experts or legal conclusions for the court to make).

However, she is precluded from offering testimony about the monograph or NDA regulatory systems and the defendants' legal duties under those regulatory systems. Dr. Jones may explain the history of label changes for Tylenol products; however, her opinions to this extent should not contradict my rulings in this action or Supreme Court precedent Wyeth v. Levine.

An appropriate Order follows.