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 27, 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 defendants move to exclude part of the testimony by plaintiff's regulatory expert Gerald M. Rachanow, Esq. For the reasons below, I will grant this Daubert 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;
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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.

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.

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

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).[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. Gerald Rachanow's Opinions About GRASE

The defendants move to exclude testimony by plaintiff's regulatory expert Gerald M. Rachanow, Esq. that acetaminophen—the active ingredient in Extra Strength Tylenol®—is not "generally recognized as safe and effective" (GRASE) by the Food and Drug Administration (FDA). They claim this is a legal conclusion which invades the province of the court and that this conclusion contradicts the FDA's stance that acetaminophen is GRASE.

The District Court has the discretion to decide whether expert testimony should be admitted in order to assist the trier of fact. Berckeley Inv. Group, Ltd. v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006). "In utilizing that discretion, however, the District Court must ensure that an expert does not testify as to the governing law of the case." Id. While an expert witness may testify about "an ultimate issue to be decided by the trier of fact," an expert witness cannot render a legal opinion "because it would usurp the District Court's pivotal role in explaining the law to the jury." Id. (citing United States v. Leo, 941 F.2d 181, 195–96 (3d Cir. 1991); First National State Bank v. Reliance Elec. Co., 668 F.2d 725, 731 (3d Cir. 1981)).[8] Nonetheless, an expert may offer testimony about business or trade customs and practices without invading the province of the court. See, e.g., United

[8] See, e.g., Carswell v. Borough of Homestead, 381 F.3d 235, 243-44 (3d Cir. 2004)("In any event, this is a question of law to be decided by the court as a matter of law…than by expert opinion."(citation omitted)); Knopick v. Downey, No. 09-1287, 2013 WL 1882983, at *14 (M.D. Pa. May 6, 2013)("Because the jury does not decide questions of law, legally conclusive statements are not helpful to the jury, and thus, inadmissible at trial or at summary judgment."); In re Wellbutrin SR Antitrust Litig., No. 04-5525, 2010 WL 8425189, at *2 (E.D. Pa. Mar. 31, 2010)("In other words, district courts have discretion to allow expert legal testimony where it would be helpful for the trier of fact to 'understand the evidence,' Federal Rule of Evidence 702, but they cannot allow experts to explain the law, Berckeley, 455 F.3d at 217."); McCrink v. Peoples Benefit Life Ins. Co., No. 04-01068, 2005 WL 730688, at *4 (E.D. Pa. Mar. 29, 2005)("An expert witness is not permitted to express legal conclusions.").

States v. Leo, 941 F.2d 181, 196–97 (3d Cir. 1991); In re Wellbutrin SR Antitrust Litig., No. 04-5525, 2010 WL 8425189, at *2 (E.D. Pa. Mar. 31, 2010).

Mr. Rachanow is an attorney who has over thirty years of experience with the FDA working on drug product regulations.[9] He is expected to offer testimony about the monograph system—the regulatory framework governing acetaminophen products like Extra Strength Tylenol.[10] As part of this testimony, he plans to offer an opinion about whether acetaminophen would be considered Generally Recognized as Safe and Effective, or GRASE, under 21 C.F.R. § 330.10. This opinion would require a legal interpretation of the meaning of GRASE. While Mr. Rachanow is qualified to make such an interpretation given his education and experience, it is not within the scope of his role as an expert. It is for the court to make this legal determination about whether acetaminophen is considered GRASE under the regulatory scheme. In this regard, I agree with the defendants that he cannot render a legal opinion about whether or not acetaminophen is GRASE.[11]

However, I agree with Mr. Rachanow's legal determination that acetaminophen has not been approved as GRASE by the FDA. The regulations which outline the monograph process are titled "Procedures for classifying OTC drugs as generally

[9] See Affidavit of Gerald M. Rachanow, Esq. (Pl. Ex. 1). In fact, Mr. Rachanow was one of the drafters of the TFM. He is most certainly qualified to render an expert opinion on the appropriate regulations. His job was to explain the monograph regulatory system to manufacturers and consumers.

[10] For an explanation of the history of this regulatory framework, see Memorandum Denying Motion for Summary Judgment on Plaintiff's Failure-to-Warn Claim, Nov. 13, 2015 at 10-15 (Doc. No. 181).

[11] The plaintiff's argument that this is a "regulatory fact" and not a legal determination is unpersuasive. In order to reach the conclusion which both the court and Mr. Rachanow have reached about acetaminophen's status under the regulations, one would need to interpret the regulations in accordance with administrative and general law principles. This requires a legal process, not a factual one.

recognized as safe and effective and not misbranded, and for establishing monographs." 21 C.F.R. § 330.10. The monograph process itself is intended to determine under what conditions OTC drugs are GRASE. 21 C.F.R. § 330.10(a)(8). ("[T]he Commissioner shall publish in the Federal Register a final order containing a monograph establishing conditions under which a category of OTC drugs or a specific or specific OTC drugs are generally recognized as safe and effective and not misbranded."). During the initial step of the monograph process, the available OTC drug ingredients were recommended by the panel of experts to be a Category I: GRASE, Category II: not GRASE, or Category III: unclear if GRASE or not.[12] This categorization appears to be nothing more than that—a way to organize the available drug ingredients. Those ingredients found to not be GRASE were not permitted to continue through the monograph process.[13]

Acetaminophen remains stagnated at the second step of the monograph process. It is currently governed by a Tentative Final Monograph (TFM), not a Final Monograph (the third and final step in the approval process). Because the TFM is a proposed rule—not a final regulation—the categorization of acetaminophen in the TFM as GRASE would not be binding until a Final Monograph/Rule was promulgated. [14]

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[12] See http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ucm118349.pdf; http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ucm317137.htm.

[13] See 58 Fed. Reg. 27636 ("Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients")(May 10, 1993)("As mentioned, no substantive comments or new data were submitted to support reclassification of any of these active ingredients to monograph status. Therefore, before a final rule on each respective drug category is published, the Commissioner has determined that these ingredients are not generally recognized as safe and effective and that any OTC drug product containing any of these active ingredients not be allowed to continue to be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application.").

[14] See TFM, 21 C.F.R. 343 at 35346 ("Based upon the conclusions and recommendations of the Panel, the Commissioner *proposes, upon publication of the final regulation*…" (emphasis added)); 53 C.F.R. 46204 ("In order

The defendants point to statements by the FDA over the years which indicate that acetaminophen is generally considered "safe" and "effective." These statements, however, cannot be viewed as approving acetaminophen as GRASE, a legal term and title which carries with it different legal duties and responsibilities.[15] As laid out in the regulatory provisions governing the monograph process, a drug cannot be afforded that title unless and until a Final Monograph has been issued for it.[16]

III. CONCLUSION

For these reasons, I will **GRANT** the defendants' motion **in part and DENY it in part**.[17] Mr. Rachanow may not offer a legal conclusion about whether acetaminophen

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to conform to terminology used in the OTC drug review regulations (21 CFR 330.10), the present document is designated as a 'tentative final monograph.' Its legal status, however, is that of a proposed rule."); FDA/CDER, Guidance for FDA Staff and Industry, Marketed Unapproved Drugs—Compliance Policy Guide, Sec. 440.100 Marketed New Drugs Without Approved NDAs or ANDAs, Sep. 19, 2011, at 13 ("Drugs marketed in accordance with a final monograph are considered to be generally recognized as safe and effective (GRAS/GRAE) and do not require FDA approval of a marketing application.")(Doc. 49-20)(Ex. C attached to J. Jones Report, Def. Ex. S).

[15] The defendants support this argument by pointing to Judge Johnson's ruling in Lyles v. McNEIL-PPC, et al., Superior Court of New Jersey, Law Division, Docket No. ATL-L-8655-11, Order Re: N.J.S.A. 2A:59C-5(c) (Aug. 28, 2014). Judge Johnson found acetaminophen to be GRASE. This divergence relates to the way New Jersey courts have interpreted "GRASE." Alabama, not New Jersey, law governs this case.

Whether acetaminophen is considered GRASE affects whether a plaintiff can bring a punitive damages claim in a drug products liability action under New Jersey law. See N.J.S.A. 2A:58C-5 (1995). There is no similar provision under Alabama law, which applies in this case. For this reason, whether acetaminophen is or is not considered GRASE is less important to the outcome of this case. Here, what is important is that a Final Monograph was never issued for acetaminophen. Acetaminophen is only regulated under a Tentative Final Monograph, which is simply a proposed rule. The defendants do not disagree with this point. Without a Final Monograph, the defendants are not *required* to adhere to what is outlined within the TFM. Their compliance or noncompliance with the TFM may offer a showing of state of mind or intent. But the TFM in itself does not create a legal duty nor does non-compliance with it create *per se* negligence.

[16] I note that just as Mr. Rachanow cannot offer a legal conclusion about whether acetaminophen is GRASE so too will defendants' regulatory expert(s) be prohibited from rendering a legal conclusion about whether acetaminophen is GRASE.

[17] The defendants also argue his opinion is based on insufficient or improper methodology because he "simply reads the federal regulations." Under the circumstances, it would seem that reviewing applicable regulations and their historical content would be the appropriate methods for a regulatory expert like Mr. Rachanow. He would not simply be "reading" the regulations but instead would be interpreting and analyzing those regulations based on his knowledge and experience. From this standpoint, his methodology is reliable. See, e.g., Betterbox Commcns. Ltd. v,

has been approved as GRASE. However, Mr. Rachanow may testify as a regulatory expert on the statutory framework, explaining the history of the monograph system and acetaminophen's place within that framework.[18]

An appropriate Order follows.

BB Techs., Inc., 300 F.3d 325, 329 (3d Cir. 2002)("[I]n cases not involving scientific testimony, '[t]he factors identified in Daubert may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.' In such cases…'the relevant reliability concerns may focus upon personal knowledge or experience.'")(quoting Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999)); U.S. v. Davis, 397 F.3d 173, 178–79 (3d Cir. 2005)(explaining that "years of experience" was a reliable basis for rendering a non-scientific opinion).

[18] See, e.g., In re Wellbutrin SR Antitrust Litig., No. 04-5525, 2010 WL 8425189, at *3 (E.D. Pa. Mar. 31, 2010) (Stengel, J.)("District courts in this Circuit have applied Rule 702 to allow the testimony of experts concerning both broad and narrow areas of law, but have been careful to prevent experts from offering conclusions of law…[C]ourts recognize that where expert testimony concerns the interpretation or explanation of complex areas of law difficult for a layperson to understand, expert testimony may be proper." (citations omitted)); United States v. Universal Rehab. Serv., Inc., No. CRIM 94-147, 1996 WL 297575 at *10 (E.D. Pa. May 31, 1996)("Olshin also provided qualified expert testimony regarding the Medicare reimbursement system and how it functioned, and such testimony assisted the jury in understanding the rules and regulations under which Universal submitted its claims for reimbursement. Evidence that the defendants acted contrary to these dictates is relevant evidence of intent. Furthermore, expert testimony is viewed as helpful in cases, like this one, involving complex statutes or issues outside of the general knowledge of the jury." (citation omitted)).