

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: TYLENOL
(ACETAMINOPHEN) MARKETING,
SALES PRACTICES, AND
PRODUCTS LIABILITY
LITIGATION**

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**MDL NO. 2436
2:13-md-02436
HON. LAWRENCE F. STENGEL**

This Document Relates to:

Civil Action No. 2:12-cv-07263

Rana Terry, as Personal Representative
and Administrator of the Estate of Denice
Hayes, Deceased,

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Plaintiff,

vs.

McNEIL-PPC, Inc., McNeil Consumer
Healthcare, and Johnson & Johnson, Inc.,

Defendants.

MEMORANDUM

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 over 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 has moved to exclude testimony by defense expert Gordon Sze, M.D. For the reasons explained below, I will deny this Daubert motion.

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:

- (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.

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. Gordon Sze, M.D.

The plaintiff moves to exclude the testimony of Dr. Gordon Sze, a defense expert intending to testify about the decedent's cause of death.⁸ Dr. Sze opines that Ms. Hayes' CT scan shows patterns inconsistent with acetaminophen-induced acute liver failure (ALF), indicating that she died from some other illness or condition. The defendants have the burden of showing by a preponderance of the evidence that Dr. Sze is qualified to offer his opinion and testimony. See FED. R. EVID. 104(a); FED. R. EVID. 702, Adv. Comm. Note (2000 Amendments).

Gordon Sze, M.D. is a neuroradiologist. After reviewing a CT scan of Ms. Hayes' brain taken the day before she died, Dr. Sze compared Ms. Hayes's CT scan results with those found in published in peer-reviewed literature. From this review, he determined that Ms. Hayes' CT scan was inconsistent with the pattern of abnormality for acute liver failure (ALF) attributed to acetaminophen toxicity found in those other published scans.

a. Dr. Sze is Qualified to Offer His Opinion

It is clear that Dr. Sze has the qualifications as an expert on neuroradiology. He has worked as a neuroradiologist since 1985. Dr. Sze is a Professor of Radiology and

⁸ The defendants claim this opinion is not a diagnosis of Ms. Hayes' cause of death but information that could help a jury determine cause of death. They claim that Dr. Sze's findings will then be used to correlate with the clinical findings of other physicians to assist in identifying the precise cause of death. From this, I take it that the defendants will put forth other expert opinions to show a logical sequence for causation for a diagnosis or opinion on specific cause of death. See Banks v. Secretary of the Dept. of Health and Human Services, 2007 WL 2296047, at *14 (Fed. Cl. Ct. 2007)(“As all have agreed, a full diagnosis of ADEM is best arrived at as a joint conclusion made between such a radiologist and a neurologist, the latter of whom can observe clinical indicia of the (admittedly nonspecific) symptoms associated therewith, in reaching that conclusion. However, it is clear that the MRI scan, administered by the radiologist, provides the most effective means of diagnosing ADEM.”). My understanding is that Dr. Sze's opinion is but one piece of their specific causation argument.

Chief of Neuroradiology at Yale University School of Medicine.⁹ As Chief of Neuroradiology, Dr. Sze is responsible for the conduct and interpretation of all neuroradiological studies at Yale. Over the past 30 years, Dr. Sze has personally read approximately 6,000 brain scans annually. Dr. Sze estimates that about 2,000 of these brain scans are CT scans, meaning that he has read approximately 60,000 brain CT scans in his career.

For more than 30 years, Dr. Sze has conducted scientific research in neuroimaging. He authored or co-authored more than 100 published peer-reviewed scientific articles and more than 20 book chapters in this area. He has lectured or spoken at dozens of universities and scientific and medical symposia throughout the world.

The plaintiff argues that the opinion Dr. Sze attempts to render would be one outside his area of expertise. See Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 322 (3d Cir. 2003) (“An expert may be generally qualified but may lack qualifications to testify outside his area of expertise.”). It is true that Dr. Sze has little to no experience offering opinions about brain scans for liver injuries and/or sepsis. At his deposition in this case, Dr. Sze acknowledged that he is not medically qualified to give an opinion on drug-induced liver injury, nor as to whether or not a patient has developed sepsis.¹⁰ He indicated he would need to refer to another physician with more knowledge in these areas

⁹ See Curriculum Vitae of Gordon Sze, M.D. (Doc. No. 158, Def. Ex. A); Dec. of Gordon Sze, M.D. (Doc. No. 158, Def. Ex. B) for all qualifications listed in this paragraph.

¹⁰ See G. Sze Dep., May 11, 2015 at 12-14 (Doc. No. 158, Def. Ex. C) (“Q. You would not consider yourself medically qualified to give an opinion about whether a patient has developed sepsis, correct? A. Correct Q. Wouldn’t feel medically qualified to give an opinion about whether a patient has suffered a drug-induced liver injury, correct? A. Correct Q. Including acetaminophen drug-induced liver injury? A. Correct”).

as to an opinion.¹¹ He also has given no indication—in his report or deposition—that he has been asked to render an opinion in practice or as an expert in another case about whether a patient has suffered acetaminophen-induced liver injury or sepsis.¹²

This argument goes more to the weight a jury should afford Dr. Sze’s opinion rather than to his qualifications.¹³ The defendants do not need to put on the “best qualified” expert to offer an opinion on specific causation, only one who is qualified.¹⁴ The plaintiff is free to explore these areas on cross-examination, but they do not necessarily preclude Dr. Sze’s testimony from being admitted. See U.S. v. Mitchell, 365 F.3d 215, 244-45 (3d Cir. 2004)(“Rule 702 and Daubert put their faith in an adversary system designed to expose flawed expertise.”)(citations omitted).

Dr. Sze is qualified to read the decedent’s CT scan and offer an opinion about what that reading might show in terms of cause of death.

b. Dr. Sze’s Methodology Is Reliable

To be reliable and admissible, an expert’s testimony must be based on the “methods and procedures of science,” not on “subjective belief or unsupported

¹¹ As the defendants themselves point out, he is not making a full diagnosis because a radiologist would need to confer with another physician (typically the treating physician) in order to do so. See Banks v. Secretary of the Dept. of Health and Human Services, 2007 WL 2296047 at *11-14 (Fed. Cl. Ct. 2007)(acknowledging that a “full diagnosis” is “best arrived at” as a joint conclusion made between the radiologist, who determines whether scans are consistent with suspected causes, and a treating physician, who can observe clinical indicia of the symptoms associated therewith in reaching a diagnosis).

¹² See G. Sze Dep., May 11, 2015 at 23-29 (Doc. No. 158, Def. Ex. C)(discussing Sze’s experience as a products liability expert).

¹³ See also Reynolds v. General Motors Corp., No. 2:04-CV-0106-RWS, 2007 WL 2908564, at *5 & n. 3 (N.D. Ga. Sept. 28, 2007)(denying motion to exclude radiologist’s testimony regarding whether injuries reflected on CT Scan were consistent with certain types of forces identified as potential cause of injury).

¹⁴ See Holbrook v. Lykes Bros. S.S. Co., Inc., 80 F.3d 777, 782 (3d Cir. 1995); Keller v. Feasterville Family Health Care, 557 F. Supp. 2d 671, 675 (E.D. Pa. 2008)(Rice, J.).

speculation.”¹⁵ To determine whether an expert’s methodology is “reliable,” i.e., that the expert truly is testifying to “scientific knowledge,” the Supreme Court in Daubert suggested that the trial court consider the following factors: 1) whether a scientific theory or technique has been or can be tested; 2) whether the scientific theory has been published or otherwise subjected to peer review; 3) the known or potential error rate; and 4) whether the theory is generally accepted in the applicable field or has gained little support from the medical or scientific community. See Daubert, 509 U.S. at 592-94. In addition, courts may consider: 1) whether maintenance of standards and controls exist; 2) whether the knowledge upon which an expert bases his opinion is gained from his own research independent of litigation or whether the opinion is derived solely for the purposes of litigation; 3) whether there is too great an analytical gap between the proffered opinion and the raw data; 4) whether the expert accounted for obvious alternative explanations; 5) whether the expert is as careful in his opinion for litigation as he would be in practice; and 6) whether the field in which the opinion is offered is known to reach reliable results. See FED. R. EVID. 702, Adv. Comm. Note (2000 Amendments).

Dr. Sze describes his methodology as comparing patterns of abnormalities in the decedent’s CT scan with published brain scans where the cause of death or diagnosis is known. This is the type of procedure neuroradiologists typically use to determine whether the findings they see on a patient’s brain scan are normal or abnormal.¹⁶

¹⁵ Kannankeril v. Terminix Int’l, Inc., 128 F.3d 802, 806-07 (3d Cir. 1997)(citing In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 (3d Cir. 1994)).

¹⁶ See, e.g., Diagnostic Radiology Malpractice Litigation, 75 Am. Jur. Trials 55, §11 (Originally published in 2000).

The plaintiff argues that Dr. Sze's methodology is unreliable and his opinion only offered for the purposes of litigation. The plaintiff points to Dr. Sze's lack of medical literature to support this argument.

Dr. Sze explained that there are large numbers of published scans that report the pattern of abnormality for common conditions and illnesses. For acetaminophen-induced ALF, however, he recognized that published scans of acetaminophen-induced ALF are rare because neurological findings in acetaminophen-induced ALF are rare. For this reason, he only references three such scans in reaching his opinion.¹⁷ Dr. Sze explained that neuroradiologists typically are not asked for opinions about whether patients have liver injury.¹⁸ He himself has seldom, if ever, rendered an opinion on acetaminophen-induced ALF in practice.¹⁹

¹⁷ His initial report, in rendering an opinion about whether the decedent's CT scan offered indications of acetaminophen-induced ALF, referenced only one article on the subject. See Tharapararaja, Sathes Waran, et al., Acute Fulminant Hepatic Encephalopathy and Early CT Changes, Canadian Journal of Neurological Sciences, Jan. 2013 (Doc. No. 158, Pl. Ex. 3). At his deposition, he referenced two other articles on the topic which he had researched after he submitted his report but before his deposition. See Arnold, S. M., et al., Acute Hepatic Encephalopathy with Diffuse Cortical Lesions, NEURORADIOLOGY (2001) 43:551-554. (Doc. No. 158, Pl. Ex. 4); Fridman, Vera et al., Clinical/Scientific Notes, NEUROLOGY (2009) 72: 2130-2131 (Doc. No. 158, Pl. Ex. 5). See also G. Sze Dep., May 11, 2015 at 89-93 (Doc. No. 158, Def. Ex. C) ("Q. [I]n terms of acetaminophen toxicity and its association to the presence of cerebral edema on CT scan, the only article on which you relied for that opinion in your report was Exhibit? A. That is correct at that time, yes. Q. And the only thing you've added since then are the two articles that you obtained this weekend, correct? A. That is correct. Q. Any other articles that we should be looking at other than those three for support of your opinion in this case? Q. No.").

¹⁸ Compare Banks v. Secretary of the Dept. of Health and Human Services, 2007 WL 2296047, at *11-14 (Fed. Cl. Ct. 2007)(allowing radiologist opinion because "most of the clinical symptoms of ADEM are nonspecific to ADEM, it is apparent from the medical literature filed that the primary diagnostic mechanism for ADEM is neural imaging scans, such as the MRI scan...administered by doctors with special skill and training in doing so: radiologists"); Reynolds v. General Motors Corp., No. 2:04-CV-0106-RWS, 2007 WL 2908564, *5 & n.3 (N.D. Ga. Sept. 28, 2007)(allowing expert testimony by radiologist for injuries caused by motor vehicle accident including injuries to the head); Bartley v. Euclid, 180 F.3d 175, 179 (5th Cir. 1999)(affirming admission of radiologist's expert testimony related to back injuries and review of MRI on back).

¹⁹ See G. Sze Dep., May 11, 2015 at 53-55, 61-65 (Doc. No. 158, Def. Ex. C).

Though Dr. Sze’s methodology is seldom used for acetaminophen-induced ALF, the methodology itself is sound and reliable. The plaintiff’s arguments are better addressed during cross-examination than in a Daubert motion. Her points go more to the strength of Dr. Sze’s opinion than to its admissibility.

I find Dr. Sze’s methods to rest on “good grounds.” See U.S. v. Mitchell, 365 F.3d 215, 244 (3d Cir. 2004)(“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.”)(citations omitted).²⁰

c. Dr. Sze’s Opinion “Fits” This Case

Lastly, the plaintiff argues that Dr. Sze’s opinion would not be helpful to the jury because there is “too great an analytical gap between the data and the opinion proffered.” General Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). The plaintiff points to several differences between the circumstances and conditions of patients to whose scans Dr. Sze compares Ms. Hayes’ CT scan and the conditions under which Ms. Hayes’ scan was taken.²¹

²⁰ See also Pineda, 520 F.3d at 243 (quoting Kannankeril, 128 F.3d at 806)(recognizing the Third Circuit’s “liberal policy of admissibility” regarding Rule 702); United States v. Schiff, 602 F.3d 152, 173 (3d Cir. 2010)(same).

²¹ For example, the second article on which he relies involves a single case study of a young man who had taken 50 grams of acetaminophen, along with alcohol and another drug in a suicide attempt. See Fridman, Vera et al., Clinical/Scientific Notes, Neurology (2009) 72: 2130-2131. (Doc. No. 158, Pl. Ex. 5). The last article upon which he relies offers a CT scan for a single patient with alcoholic cirrhosis and a hereditary defect who suffered from liver injury but had not taken acetaminophen. See G. Sze Dep., May 11, 2015 at 98 (Doc. No. 158, Def. Ex. C).

Dr. Sze's testimony is being offered to help answer a key jury question in this case: did acetaminophen-induced acute liver failure cause Ms. Hayes' death. For this reason, it "fits" the case. The plaintiff should raise her points about potential deficiencies in the articles relied upon by Dr. Sze during cross-examination. The plaintiff's arguments about the articles' deficiencies go to weight, not admissibility.

III. CONCLUSION

For these reasons, I find that Dr. Sze is qualified to offer testimony on the subject he has been designated to address. I will **DENY** the plaintiff's Daubert motion.

An appropriate Order follows.