

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PAUL ENGLEHARD,)	
)	
)	
Plaintiff,)	
v.)	11 C 5162
)	
WYETH CONSUMER HEALTHCARE, LTD,)	Judge Virginia M. Kendall
and R.P. SCHERER CORPORATION,)	
)	
Defendants.)	

MEMORANDUM OPINION AND ORDER

The Defendants have moved to exclude the testimony of Plaintiff Paul Englehard’s experts David Wingate and Dr. Mark Blitstein. This Court bases all factual findings in this opinion on testimony and other evidence received during the hearing held on September 25, 2013, and makes these findings solely for resolving these motions. The purpose of the hearing was to determine whether David Wingate could testify as an expert about an alleged failure to warn and whether Dr. Mark Blitstein could testify as an expert about the interaction between non-steroidal anti-inflammatory drugs (“NSAIDs”) and stomach ulcers. This Court grants the Defendants’ motion with respect to Mr. Wingate because he did not base his opinions on sufficient facts or data and did not identify any reliable principles or methods that produced his opinions. This Court denies the Defendants’ motion with respect to Dr. Blitstein because he is qualified to offer his opinions that he based on reliable reasoning and that will assist the trier of fact.

A. Legal Standard

Federal Rule of Evidence 702 governs the admissibility of expert testimony. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 588 (1993). Rule 702 permits an expert to offer

opinions that will assist the trier of fact provided sufficient facts or data support the expert's opinions and reliable principle and methods applied to the facts of the case produced those opinions. Fed. R. Evid. 702; *Ortiz v. City of Chicago*, 656 F.3d 523, 526 (7th Cir. 2011). When assessing whether to allow an expert to offer his opinions, courts consider: (1) whether the expert is qualified to offer his opinions; (2) whether the reasoning or methodology underlying the expert's opinions is reliable; and (3) whether the expert's opinions will assist the trier of fact. *Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010).

B. David Wingate

David Wingate is a licensed pharmacist who graduated from Drake University in 1975. He then worked as a retail pharmacist for approximately fifteen years. He has since worked in hospital pharmacy and did pharmaceutical research in the private sector. He currently works at the Rehabilitation Institute of Chicago as a research pharmacist. Mr. Wingate has more than thirty-five years of experience as a pharmacist and is current with his continuing education requirements.

As a pharmacist, Mr. Wingate has administered various medications to patients. In doing so, Mr. Wingate reviewed health information to ensure that prescriptions were appropriate for patients and advised patients as to the proper methods for taking their medication. For example, Mr. Wingate has advised patients to take certain medications with food to mitigate side effects. Mr. Wingate is familiar with ibuprofen in tablet and gelatin capsule ("gel cap") formulations, its indications, and its administration. He recommends that one take the appropriate dose with eight ounces of water and remain upright to ensure that the dose properly moves through his or her body.

After reviewing Dr. Blitstein's assessment of Englehard's injury, a gastric ulcer in the upper end of the stomach, Mr. Wingate did research on his own to determine what could have

caused Englehard's ulcer. He concluded that the quick dissolution, the potential of gel caps to adhere to one another and to the stomach lining, and the caustic nature of the ibuprofen as possible causes of Englehard's ulcer. He believes that the Defendants should warn consumers not to lie down immediately after taking Advil Liqui-Gel capsules, which is a gel cap ibuprofen formulation. He also believes that the Defendants should tell consumers to take the product with food, to take the product with water, and to rehydrate prior to taking the product if dehydrated.

Mr. Wingate concedes that he did not cite any published data sources in his expert report, refer to any data analysis he performed, refer to any methodologies he reviewed to reach his conclusions, or cite to published research, clinical trials, or scholarly articles in his expert reports. Instead, Mr. Wingate relied on his experience as a pharmacist. For example, Mr. Wingate refers to his practice at the Rehabilitation Institute of Chicago, where the standard practice is to keep patients upright following the administration of tablet formulations of ibuprofen. But this experience has nothing to do with ibuprofen gel cap formulations, as they are not on the formulary at the Rehabilitation Institute of Chicago.

And even with thirty-five years of experience as a pharmacist, Englehard's case is the only case Mr. Wingate is aware of where a patient suffered this type of adverse event after taking ibuprofen. Mr. Wingate contacted three associations that collect information concerning drug safety and did not learn of any particular risks associated with Advil Liqui-Gel capsules. Mr. Wingate does not cite any adverse reports, clinical trials, product advisories, or other industry materials that support his opinions. He even concedes that he did not have enough information to provide to his colleagues at the Rehabilitation Institute of Chicago concerning purported risks associated with ibuprofen gel caps.

“[T]o be admissible, a medical expert’s ultimate opinion must be grounded in the scientific process and may not be merely a subjective belief or unsupported conjecture.” *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009). Though not a medical doctor, Mr. Wingate is a licensed pharmacist who has been involved with patient care. *Cf. United States v. Chube II*, 538 F.3d 693, 697 (7th Cir. 2008) (recognizing pharmacologist with doctorate in clinical pharmacology as a medical expert). Accordingly, he is a medical expert who cannot “render opinions unless those opinions are based upon some recognized scientific method and are reliable and relevant under the test set forth by the Supreme Court in *Daubert*.” *Lewis*, 561 F.3d at 705.

Here, Mr. Wingate’s has offered nothing more than speculation and conjecture. He concedes that he based his opinions on inferences he drew from the circumstances of Englehard’s injury. (Dkt. No. 78 at 120:25-121:24.) He does not cite any scientific or medical literature that supports his opinions. (*Id.*) He is not aware of any similar cases to Englehard’s (*id.* at 95:5-9), he contacted several entities that compile information concerning drug safety and none reported any information that supports his opinion (*id.* at 51:23-61:11, 95:15-18), and has not identified any reports of specific problems with ibuprofen gel caps (*id.* at 57:14-59:22). In short, Mr. Wingate has not identified any facts or data that support his failure to warn opinion. He also has not identified any facts or data, other than Dr. Blitstein’s opinion, that support his causation opinion, which he appears to offer in connection with his failure to warn opinion.

Nor has he identified any reliable reasoning or methodology that supports his opinions. He admits that he does not have any experience with issues concerning the labeling of over the counter products, to include NSAIDs. (*Id.* at 126:12-23.). He also admits that he has not done the clinical studies necessary to determine whether a change to ibuprofen gel cap labels is necessary.

(*Id.* at 99:20-100:21.) Unable to point to personal experience or industry studies that support his opinion, Mr. Wingate has failed to provide any indicia of reliability as to his opinions. Therefore, this Court grants the Defendants' motion to exclude the testimony of Mr. Wingate.

C. Dr. Mark Blitstein

Dr. Mark Blitstein is a medical doctor. He graduated from Loyola University Chicago Stritch School of Medicine in 1976, completed his residency at Northwestern University Medical Center in 1979, and completed a fellowship in gastroenterology at the University of California San Francisco Medical Center in 1981. He is a licensed physician and currently practices as a gastroenterologist for the Northwestern Medical Faculty Foundation in Lake Forest, Illinois. He has been a practicing gastroenterologist for thirty-two years.

He treated Englehard in 2006 after Englehard presented with a gastrointestinal hemorrhage. Englehard reported taking Advil prior to coming to the hospital. An endoscopy revealed an ulcer in his stomach that was bleeding. Dr. Blitstein had previously treated hundreds of patients for similar ailments.

According to Dr. Blitstein, medical literature indicates that ibuprofen can adversely affect the stomach by causing inflammation, erosion, ulcers, and breakdowns of the lining of the stomach. In this case, Dr. Blitstein opines that ibuprofen caused Englehard's ulcer because it remained at the very top of his stomach, where it was in direct contact with the lining of his stomach. Dr. Blitstein reached this conclusion because Englehard reported that he had lain down after taking ibuprofen and Dr. Blitstein previously had observed patients who presented with ulcers in an unexpected area after lying down.

Here, the Defendants' challenge Dr. Blitstein's opinions as beyond his expertise, lacking reliable reasoning or methodology, and not helpful to the trier of fact. But the Defendants' challenges go to the probative weight of Dr. Blitstein's testimony, not its admissibility. Dr.

Blitstein is a board-certified gastroenterologist who treated Englehard's ulcer. He has experience treating other patients with similar ulcers. His education and experience qualify him to offer his opinion as to the cause of Englehard's ulcer.

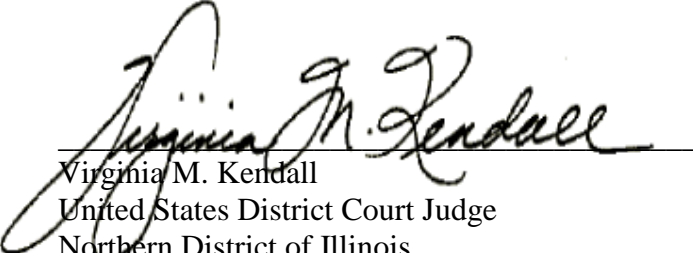
Even though the endoscopy Dr. Blitstein performed was diagnostic as opposed to etiological, Dr. Blitstein reached a conclusion as to the cause of Englehard's ulcer by based on his medical experience in similar cases. That experience distinguishes Dr. Blitstein's opinions from other cases where the medical expert had not seen similar cases. *See, e.g., Porter v. Whitehall Labs., Inc.*, 9 F.3d 607, 615 (7th Cir. 1993) (noting that expert admitted that, if his hypothesis was correct, it would be the first case where ibuprofen caused rapidly progressive glomerulonephritis). It also distinguishes Dr. Blitstein from Mr. Wingate in this regard. And it distinguishes Dr. Blitstein's opinions from cases where the medical expert simply relied on timing to conclude that medication caused an ailment. *See Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904-05 (holding that district court did not abuse its discretion by excluding expert opinion on causation premised on the temporal relationship between taking a medication and the onset of symptoms). Dr. Blitstein's reasoning is sound—several patients have experienced ulcers in rare places, and all of those patients experienced ulcers in rare places when they lay down immediately after taking medication, therefore lying down may have caused the ulcers. Edward Jenner used similar reasoning when he discovered the vaccine for smallpox based on his observation that milkmaids who contracted cowpox did not catch smallpox. So did Ignaz Semmelweis when he discovered that doctors should wash their hands before seeing patients based on his observation that the incidence of puerperal fever was lower when doctors followed this practice.

Whether he fully understands the mechanism implicated by his reasoning, whether medical literature contradicts his reasoning, and whether his education and experience lend credence to his reasoning are matters for cross-examination. “[W]hether the cause put forth by a qualified expert actually proximately caused the injury at issue is a question for the jury at trial; a district court should only evaluate whether an expert's conclusion on causation was reasoned and based on a reliable methodology.” *Gayton v. McCoy*, 593 F.3d 610, 619 (7th Cir. 2010). At this stage in the litigation, Dr. Blitstein’s education, experience, and reasoning are sufficient to render his opinions reliable under Rule 702.

Finally, Dr. Blitstein’s testimony will assist the trier of fact. His opinions concern the cause and treatment of Englehard’s ulcer and stomach bleed. The Defendants’ concede that whether Advil Liqui-Gel capsules caused Englehard’s stomach bleed lies at the center of this case. (Dkt. No. 58 at 1.) Dr. Blitstein’s opinions, if credited, will help the trier of fact make that determination. Therefore, this Court denies the Defendants’ motion to exclude the testimony of Dr. Blitstein.

CONCLUSION

For the reasons stated herein, this Court grants the Defendants’ motion to exclude the testimony of David Wingate (Dkt. No. 57) and denies the Defendants’ motion to exclude the testimony of Dr. Mark Blitstein (Dkt. No. 59).


Virginia M. Kendall
United States District Court Judge
Northern District of Illinois

Date: March 25, 2014