

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: LEVAQUIN PRODUCTS
LIABILITY LITIGATION

MDL No. 08-1943 (JRT)

This Document Relates to All Actions

**ORDER ON DEFENDANTS' MOTION
TO EXCLUDE EXPERT TESTIMONY
ON DEFENDANTS' KNOWLEDGE,
MOTIVATIONS, AND INTENT**

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John Dames, **DRINKER BIDDLE & REATH LLP**, 191 North Wacker Drive, Suite 3700, Chicago, IL 60606-1698; William H. Robinson, Jr., **LECLAIR RYAN**, 1100 Connecticut Avenue N.W., Suite 600, Washington, DC 20036; and Tracy J. Van Steenburgh, **NILAN JOHNSON LEWIS, PA**, 400 One Financial Plaza, 120 South Sixth Street, Minneapolis, MN 55402, liaison and lead counsel for defendants.

Defendants claim that three of Plaintiffs' expert witnesses, Drs. Wells, Bisson and Zizic, intend to offer opinion testimony concerning defendants' knowledge, motivations and intent regarding the "Ingenix" Study and other studies on the impact of levofloxacin. Defendants have moved to exclude such testimony. Because it is clear under Rule 702 of the Federal Rules of Evidence that this type of expert opinion testimony is not based on specialized knowledge, merely reflects personal views and is thus irrelevant, and will not be useful to a jury, the Court grants Defendants' motion in part to the extent the challenged testimony concerns knowledge, motivation or intent of the defendants.

DISCUSSION

I. RULE 702 STANDARDS

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. Under Rule 702, proposed expert testimony is admissible if three prerequisites are met. *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). First, evidence based on scientific, technical, or specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. *Id.* Second, the proposed witness must be qualified. *Id.* Third the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that if the finder of fact accepts it as true, it provides the assistance the finder of fact requires. *Id.*

Courts have routinely excluded expert testimony regarding corporate knowledge, motivations, and intent, as irrelevant and inadmissible under Rule 702. *See In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1069 (D. Minn. 2007) (“[A]n expert may not testify as to ethical issues or to his personal views.”); *id.* (“The question of corporate intent is one for the jury, not for an expert.”); *In re Trasyolol Prods. Liab. Litig.*, 08-md-01928, 2010 WL 1489793, at *8 (S.D. Fla. Feb. 24, 2010) (“[I]nferences about the intent or motive of parties . . . lie outside the bounds of expert testimony, but are instead classic jury questions.” (internal quotation marks omitted)). The question raised by this motion concerns the extent to which plaintiffs' proposed testimony crosses this line.

II. OPINIONS OF PLAINTIFFS' EXPERTS WELLS, BISSON AND ZIZIC

Defendants' motion centers on isolated statements made by three of plaintiffs' proposed expert witnesses: Dr. Martin T. Wells, Dr. Gregory D. Bisson, and Dr. Thomas M. Zizic. Defendants claim that the doctors have, in their expert reports and/or depositions, asserted improper opinions on alleged knowledge, motivations, or intentions of defendants regarding the Ingenix study conducted at the request of defendants Ortho-McNeil-Janssen Pharmaceuticals and Johnson & Johnson Pharmaceuticals. The Ingenix study sought to assess whether and to what extent associations exist between Achilles tendon ruptures and the use of levofloxacin.

Defendants argue that the "proposed opinions stray beyond merely attempting to demonstrate purported 'flaws' in the Ingenix study . . . each proposed witness offers impermissible speculation regarding what Defendants . . . purportedly 'knew,' were 'motivated by,' and 'intended' regarding results of the Ingenix study" (Defs.' Mot. to Ex. KMI at 7.) Defendants argue that these opinions are irrelevant, and do not relate to any facts at issue. Further, defendants argue that even if the opinions were relevant, they would be inadmissible as matters to be determined by the jury, not experts. Defendants also argue that the opinions do not entail any specialized knowledge, are not the product of reliable methodology, and are merely each expert's subjective speculation.

A. Dr. Wells

Dr. Wells made two statements at issue in this motion:

- (1) "The Ingenix study was seriously flawed by bad epidemiological practice. The combination of bias and poor epidemiologic

practice is so rampant that one can easily conclude the study was intentionally designed to achieve a desired result regardless of the actual findings in the data."

(Expert Report of Martin T. Wells ¶ 4, Aff. of Tracy J. Van Steenburgh ("Steenburgh KMI Aff.") Ex. B, Docket No. 1677.)

- (2) "Johnson and Johnson's role in the series of Ingenix reports and the final publication is not clearly portrayed to the readers. The sponsor suggested selection of the raw data set. Pragmatically, it is by no means a preposterous assumption that this allows bias to be introduced into the dataset, as any withholding and misrepresentation of data possibly could. Finally, the study involved multiple conflicts of interest. "

(*Id.* ¶ 16.)

Plaintiffs argue that these opinions are not directed to defendants, but to the reliability and trustworthiness of the findings in the Ingenix study. Plaintiffs also argue that "to the extent that the opinions of Dr. Wells address 'intention,' they pertain to the intentions of the persons who designed and conducted the [] study . . . Whether [the study's designer] could have [] manipulated the Ingenix study, is directly relevant to the reliability and trustworthiness of the study's results." (Pls.' Opp'n at 5, Docket No. 2006.)

The Court disagrees. Dr. Wells' statements represent his subjective beliefs regarding an alleged bad motive or intent on the part of defendants or others who designed the study. The Court finds that his speculation about the **reason** for alleged methodological issues in the study are not the product of reliable methods, and will be excluded.

B. Dr. Bisson

Dr. Bisson made two statements at issue in this motion:

- (1) "[J]ohnson and Johnson was intimately involved with protocol development, choice of study outcome, selection of study population, review of interim results, and final publication . . . While this situation is not unusual, it nonetheless creates the possibility that the sponsor or those paid by the sponsor will consciously or unconsciously attempt to influence the study's methods so that the results are agreeable with the company's financial concerns."

(Expert Report of Gregory P. Bisson ¶ 39, Steenburgh KMI Aff. Ex. C, Docket No. 1677.)

- (2) "Given the inherent major financial conflict of interest and the involvement of Johnson and Johnson in the protocol development, it is not unrealistic to suggest that the study sponsor specifically directed scrutiny of fluoroquinolone exposure in this way [decreasing the number of fluoroquinolone-exposed cases but not cases exposed to other antimicrobials]."

(*Id.* ¶ 54.)

Plaintiffs argue that Dr. Bisson's opinions are directed to the reliability and trustworthiness of the study. (Pls.' Opp'n at 6.) Plaintiffs also argue "Dr. Bisson's report does not concern the motivation, knowledge, intention or ethics of the corporate Defendants, but rather what could reasonably be inferred from the objective facts and circumstances, that individuals employed or commissioned by Defendants may have done." (*Id.* at 7.)

The Court finds that the first statement by Dr. Bisson expresses a general methodological principle relating to scientific research. When critiquing a scientific process or report, it is unobjectionable for an expert to note potential sources of bias. *See, e.g., E.E.O.C. v. Bloomberg L.P.*, No. 07-CV-8383, 2010 WL 3466370, at *14 (S.D.N.Y.

Aug. 31, 2010) (excluding an expert witness because "[r]elying solely on the information fed to him by the [plaintiff] without independently verifying whether the information is representative [and unbiased] undermine[d] the reliability of his analysis.") The Defendants' motion is denied as to the first statement. However, Dr. Bisson's second statement crosses the line and expresses a subjective opinion that neither elaborates a general methodological principle, nor is the product of a valid inquiry with valid methods. Therefore, the Court finds the second statement inadmissible and the Motion is granted as to that statement.

C. Dr. Zizic

Dr. Zizic made one statement concerning the Ingenix study at issue.

"I think it's [] a general rule in the academic community that, number one, you have the ability to publish no matter who funds the study, the results, good, bad or ugly, and number two, that the sponsor of the study does not interfere with the conduct of the study, including the initial design of how [the Ingenix] study should be done."

(Dep. of Thomas M. Zizic 293:21-294:5, Dec. 15, 2009, Steenburgh KMI Aff. Ex. D, Docket No. 1677.)

Dr. Zizic's testimony unobjectionably describes a general precept of academic research. Defendants themselves note that "Dr. Zizic does not directly articulate any opinion regarding Defendants' purported motivations, knowledge, intent, or corresponding conduct in his report, but testified as such during his deposition." (Defs.' Mot. to Ex. KMI at 7.) The Court finds Dr. Zizic's testimony admissible and relevant, if offered as part of an expert opinion on the general standards by which academic research is conducted and Defendant's Motion is denied as to this statement.

Defendants also argue that Dr. Zizic offered a related opinion about what defendants recognized or should have done regarding other levofloxacin studies.

"The company should have recognized the need for Post-Marketing studies. Since there was considerable evidence that Magnesium supplementation and/or Vitamin E mitigated the damage in animals, studies of these therapies should have been conducted in humans."

(Zizic Rep. § C(9), Steenburgh KMI Aff. Ex. F, Docket No. 1677.) Defendants seek to exclude this opinion because they claim it is really an opinion on defendants' knowledge, motivations, intentions, and associated conduct regarding the Ingenix study. Plaintiffs contend it is not a comment on defendants' ethical behaviors like the opinion found excludable in *In re Trasyolol*.

Dr. Zizic's comment is very similar to the statements found inadmissible in *Trasyolol*. In particular, the expert witness in *Trasyolol* commented that it "was the responsibility of Bayer to examine [the] relationship in a detailed and direct manner much earlier" *In re Trasyolol*, 2010 WL 148793 at *7 n.18. Dr. Zizic says nearly the same thing, stating what he believes the company "should have recognized." The Court thus excludes Zizic's comment about what defendants "should have done" as inadmissible, as it is a subjective, personal belief, instead of reliable opinion testimony.

III. EXCLUSION UNDER RULE 403

Defendants argue in the alternative that if the Court finds the experts' testimony sufficiently reliable and relevant to be admissible under Rule 702, the testimony should be excluded under Rule 403 because its probative value would be substantially outweighed by the risk of undue prejudice, confusion of issues, or misleading the jury.

The Court disagrees. To the extent that any comments by Drs. Wells, Zizic, or Bisson are not excluded under Rule 702, the remaining admissible statements addressed in this Order do not create a substantial risk of undue prejudice, confusion of issues, or misleading the jury.

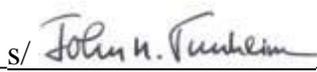
ORDER

Based on the foregoing, and the records, files, and proceedings herein, **IT IS HEREBY ORDERED** that defendants' motion to exclude plaintiffs' proposed experts testimony regarding defendants' purported knowledge, motivations, and intent [Docket No. 1675] is **GRANTED in part** and **DENIED in part**.

1. The motion is **GRANTED** as to both cited statements by Dr. Wells, the second cited statement by Dr. Bisson, and the second cited statement by Dr. Zizic.

2. The motion is **DENIED** as to the first cited statements by Drs. Bisson and Zizic.

DATED: November 10, 2010
at Minneapolis, Minnesota.



JOHN R. TUNHEIM
United States District Judge