

**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 REGARDING
PLAINTIFFS' MOTION TO
EXCLUDE EXPERT TESTIMONY
OF J. PAUL WAYMACK**

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This multidistrict litigation (“MDL”) is before the Court on plaintiffs’ motions to exclude the expert testimony of Dr. J. Paul Waymack (“Waymack”) (Docket No. 1851.) The Court heard oral arguments on October 22, 2010 and took the motion under advisement. The Court now grants in part, and denies in part, the motion for the reasons set forth below.

BACKGROUND

This multidistrict litigation consists of a significant number of cases involving the drug Levaquin. Levaquin is an antibiotic developed, manufactured, and marketed by defendants Johnson & Johnson, Ortho-McNeil Pharmaceutical, Inc., and Johnson & Johnson Pharmaceutical Research and Development, LLC. The plaintiffs were all prescribed Levaquin, and allege that it causes tendons to rupture.

ANALYSIS

I. *WYETH V. LEVINE*

As an initial matter, the parties disagree about the application to this litigation of *Wyeth v. Levine*, 129 S. Ct. 1187 (2009). Since this litigation involves a “black box” warning and class labeling, where *Wyeth* addressed the Changes Being Effected (“CBE”) labeling process of a single drug, the Court is aware that the decision to extend the principles of *Wyeth* to this case ventures into uncharted territory.

Wyeth concerned the drug Phenergan, and in particular the manner in which the drug, when injected into a patient’s vein, created a significant risk of catastrophic health consequences. After having her arm amputated as a result of such an injection, a trial court awarded plaintiff Diana Levine damages on state tort claims. *Wyeth*, the manufacturer of Phenergan, appealed, arguing that federal Food and Drug Administration (“FDA”) regulations pre-empted state law on the issue of labeling and the duty to warn. The FDA deemed the warnings on Phenergan’s label sufficient when it approved *Wyeth*’s New Drug Application (“NDA”) in 1955 and when it later approved changes in

the drug's labeling. The Supreme Court, in a 6-3 decision, determined that pre-emption did not apply. *Id.* at 1190–91.

In its decision, the Court detailed the history of the federal regulation of drugs and drug labeling. The discussion examined the intent of Congress in the enactment of the federal Food, Drug, and Cosmetic Act (“FDCA”) – which, most relevantly, provided for premarket approval of new drugs – and subsequent amendments that squarely placed the burden on the manufacturer to show its drug was safe for the public before approval would follow. *Id.* at 1195. In 2007, Congress granted the FDA the authority to require a drug manufacturer to change an already approved label, while it **did not** pass a provision in the Senate bill that would have required the FDA to pre-approve all such changes. *Id.* at 1196 (citing S. 1082, 110th Cong., 1st Sess., § 208, 107–14 (2007) (as passed) (proposing new § 506D)). Essentially, the *Wyeth* Court held, “federal labeling requirements create a floor, not a ceiling, for state regulation.” *Id.* at 1193.

The Court analyzed the pre-emption argument, reiterating the

two cornerstones of our pre-emption jurisprudence. First, the purpose of Congress is the ultimate touchstone in every pre-emption case. Second, in all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.

Id. at 1194–95 (internal quotations and citations omitted).

With these guiding principles, the Court held that Congress' intent in the federal drug regulatory scheme was 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.” *Id.* at 1197–98. Only “clear evidence” that the FDA would have rejected a label change relieves the manufacturer of this responsibility, *id.* at 1198, but the Court noted as absurd “the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning [No one] has identified a case in which the FDA has done so.” *Id.* at 1197. In contrast, the Court noted that state law tort claims “further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings.” *Id.* at 1200.

The Eighth Circuit, along with the Fifth Circuit and district courts in California, Florida, Georgia, Illinois, New Hampshire, North Carolina, Ohio, Oklahoma, Pennsylvania, Vermont, Washington, and West Virginia, have extended the principles of *Wyeth* to generic drug manufacturers – despite the fact that those manufacturers typically rely on the brand-name label warnings to sell their products. *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009); *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010); *Dorsett v. Sandoz, Inc.*, 699 F. Supp. 2d 1142 (C.D. Cal. 2010); *Munroe v. Barr Labs., Inc.*, 670 F. Supp. 2d 1299 (N.D. Fla. 2009); *Weilbrenner v. Teva Pharm. USA, Inc.*, 696 F. Supp. 2d 1329 (M.D. Ga. 2010); *Stacel v. Teva Pharm., USA*, 620 F. Supp. 2d 899 (N.D. Ill. 2009); *Bartlett v. Mutual Pharm. Co.*, 659 F. Supp. 2d 279 (D. N.H. 2009); *Couick v. Wyeth, Inc.*, No. 3:09-cv-210, 2009 WL 4644394 (W.D. N.C. Dec. 7, 2009); *Fulgenzi v. Wyeth, Inc.*, 686 F. Supp. 2d 715 (N.D. Ohio 2010); *Schrock v. Wyeth, Inc.*, 601 F. Supp. 2d 1262 (W.D. Okla. 2009); *In re Budeprion XL Mktg. & Sales Litig.*, No. 09-md-2107, 2010 WL 2135625 (E.D. Pa. May 26, 2010); *Kellogg v. Wyeth*, 612 F. Supp. 2d 437 (D.

Vt. 2009); *Laisure-Radke v. Par Pharm., Inc.*, 426 F. Supp. 2d 1163 (W.D. Wash. 2006); *Vitatoe v. Mylan Pharms., Inc.*, 696 F. Supp. 2d 599 (N.D. W. Va. 2010). A California court has also extended the principles to dietary supplements. *Jackson v. Balanced Health Prods., Inc.*, No.08-05584, 2009 WL 1625944 (N.D. Cal. June 10, 2009).

The Eighth Circuit's reasoning concerning the responsibilities of generic drug manufacturers is instructive in this case, as generic drug manufacturers are conceivably more limited in their abilities to change a drug's label contrary to the brand name label. The court reasoned that the manufacturer's duty to warn remained since they could "propos[e] a label change, [or] could have suggested that the FDA send out a warning letter to health care professionals." *Mensing*, 588 F.3d at 610.

Here, defendants were selling a drug subject to a class label in 2004 and a black box warning in 2008, both initiated by the FDA. Defendants maintain that since Levaquin was subject to class labeling, and since the FDA controls the contents of a black box warning, defendants could not have given stricter warnings, thus the holding in *Wyeth* does not control. The Court disagrees. In conjunction with the extension of *Wyeth* to generic drug labeling by the Eighth Circuit – where arguably different obstacles to label changes were present than those in *Wyeth* – the Court finds that the central holding of *Wyeth* controls here: "[T]he 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*, 129 S. Ct. at 1197–98. Given that defendants could have altered their label through the CBE process while not changing the remainder of the class label, or requested that the FDA

send letters to prescribers, or requested a black box warning earlier, the Court finds that defendants were not constrained by FDA regulations from adding additional warnings to their labels or otherwise warning their consumers. Indeed, it would be absurd to hold that the manufacturers of drugs which are subject to stricter warnings by the FDA due to higher risks of adverse effects have a **lesser** duty to maintain adequate warnings than the manufacturers of drugs with fewer adverse effects.

Therefore, the Court holds that the principles of *Wyeth* control in this case and orders the parties to ensure their witnesses, in particular witnesses testifying about FDA regulation, testify in accordance with this holding. With this reasoning in mind, the Court addresses plaintiffs' motion to exclude the testimony of Dr. J Paul Waymack.

II. DR. J. PAUL WAYMACK

Dr. J. Paul Waymack ("Waymack") is an independent drug development consultant who has four years of experience working for the FDA and regularly consults with drug companies on FDA compliance issues. Waymack received a Doctor of Science from the University of Cincinnati and a Doctor of Medicine from the Medical College of Virginia. Waymack prepared an expert report for this litigation, (Waymack Rep. Aug. 13, 2010 ("Waymack Rep."), Goldser Aff. Ex. 3, Docket No. 1853) and was then deposed. (Waymack Dep., July 23, 2010 ("Waymack Dep."), Goldser Aff. Ex. 1, Docket No. 1853.)

Plaintiffs move to exclude Waymack's testimony in its entirety as unreliable. Plaintiffs highlight a string of recent cases in which Waymack's testimony was excluded,

either in whole or in part, based on the same arguments asserted here. *See In re Traysol Prods. Liab. Litig.*, No 08-md-01928, 2010 WL 4259332 (S.D. Fla. Oct. 21, 2010); *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, Nos. 1:08 GD 50000, MDL 1909, 2010 WL 1796334 (N.D. Ohio May 4, 2010); *Robinson v. McNeil Consumer Healthcare*, No. 07-cv-05603 (N.D. Ill. Waymack exclusion order issued Aug. 12, 2009).

Plaintiffs argue that Waymack's testimony should be excluded because it is contrary to Supreme Court precedent and federal regulations, and his testimony regarding the relative risk of Levaquin compared to other fluoroquinolones does not incorporate all relevant epidemiological studies on the issue.

A. Standard of Review

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. Fed. R. Evid. 702. Under Rule 702, proposed expert testimony is admissible if it meets three prerequisites. *Lauzon v. Senco Prod., 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 understanding the evidence. *Id.* Second, the proposed witness must be qualified. *Id.* Third, the proposed evidence must be reliable 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.* Expert opinions that are contrary to law are excludable as unreliable. *In re Gadolinium*, 2010 WL 1796334, at *31.

B. Testimony Contrary to Law

Plaintiffs argue that Waymack's opinion that the FDA is the ultimate authority on the content of a warning label is contrary to the Supreme Court's decision in *Wyeth*. 129 S. Ct. at 1197–98. Further, plaintiffs allege that Waymack's testimony is contrary to FDA regulations. For example, Waymack's opinions vary from FDA regulations in a number of areas, including:

- The use of adverse event data to issue a more serious warning than the existing warning. *Compare* (Waymack Dep. at 43–49 (answering that a manufacturer could not use adverse event reports to request changes in a class label)), *with* 21 C.F.R. § 201.57(e) (prior to June 29, 2006) (“The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.”), *and* 21 C.F.R. §§ 314.70, 601.12 (discussing the manner for changing existing labels with no mention that adverse event reporting is disallowed as a basis for such changes).
- Class-label deviation. (*Compare* Waymack Rep. ¶ 90 (opining that defendants could not have differed the class label from that of others in the class), *with* Waymack Dep. at 18–19, 195–96, 185–87, 193–94, 190–92 (confronting Waymack with the FDA labels of several other drugs that have individual label differences from their class)).
- The standard of proof for making label changes under the FDA's CBE process which does not require prior FDA approval. *Compare* (Waymack Rep. ¶ 73

("[The] association between fluoroquinolone use and tendon pathology does not represent a proven cause and effect relationship" because it was not discovered through prospective randomized clinical trials)), *with* 21 C.F.R. § 201.57(e) (prior to June 29, 2006) ("The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship **need not have been proved.**" (emphasis added)).

- The authority of the FDA prior to statutory changes in 2007. (*Compare* Waymack Rep. ¶ 31 (discussing FDA approval as a requirement "necessary [for] changes to the labeling"), *with* Waymack Dep. at 132–37 (acknowledging that this statement is not accurate).)

Defendants argue that plaintiffs misconstrued the holding in *Wyeth*, that the factual and legal bases in *Wyeth* are sufficiently different as to be inapplicable to Waymack's testimony in this litigation, and that Waymack's testimony will conform to *Wyeth*. They argue that exclusion of Waymack's testimony precludes them from showing that the FDA would have disapproved of the label changes. Defendants assert that Waymack's exclusion in *Robinson* is irrelevant since it was based on different testimony and unrelated grounds. Defendants also assert that Waymack's exclusion was reversed in *In re Gadolinium* so plaintiffs' reliance on that case is improper.

C. Previous Exclusions of Waymack

A review of the courts' decisions in *Traysol*, *Robinson*, and *Gadolinium* support a cautious approach to allowing Waymack to testify. In *Robinson*, the court found Waymack unreliable because, in the face of *Wyeth*, Waymack failed to amend his testimony and this failure "demonstrate[d] a lack of diligence and a lack of reliability that cause[d the] court to question Dr. Waymack's opinions in all areas of his testimony." (Order of Judge Holderman in *Robinson*, Goldser Aff. Ex. 2, Docket No. 1853.) Defendants assert that Waymack has now amended his report to reflect the Supreme Court's holdings in *Wyeth*, yet Waymack admitted in his deposition that his opinions on the role and responsibility of the FDA in labeling relative to drug companies has not changed in years. (Waymack Dep. 184–85.) This admission indicates that Waymack continues to disregard the law on the issue and could confuse the jury if his testimony is admitted without clear limitations.

Further, the court in *Gadolinium*, contrary to defendants' characterization of the holding, excluded Waymack's case-specific testimony – testimony which Waymack has admitted **is the same** in this litigation. (Order of Judge Polster at 20, Van Steenburgh Aff. Ex. C, Docket No. 2049; Waymack Dep. 184–85.) The *Gadolinium* court allowed Waymack to testify only because plaintiffs "did not seek the wholesale exclusion of his testimony" and since he was the defendant's only regulatory expert. He was permitted to testify "on the rest of the regulatory process except for labeling obligations." (Order of Judge Polster at 20, Van Steenburgh Aff. Ex. C, Docket No. 2049.) Here, plaintiffs seek the wholesale exclusion of Waymack's testimony.

The court's decision in *Traysol* reveals further issues with Waymack's proposed testimony. The court reviewed Waymack's testimony in depth and determined that Waymack continued to offer opinions contrary to law. For example, the court found that Waymack's opinions regarding major changes to a label through the CBE process were in violation of *Wyeth. In re Traysol Prods. Liab. Litig.*, 2010 WL 4259332, at *4, *6. Waymack makes the exact same assertion in his expert report in this litigation. (Waymack Rep. ¶ 55.) The court found that Waymack's opinion that the FDA was the ultimate authority on the label of a drug was also contrary to *Wyeth. In re Traysol Prods. Liab. Litig.*, 2010 WL 4259332, at *3, *6. Waymack again makes the exact same assertion in this litigation. (Waymack Rep. ¶ 31.)

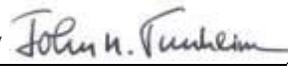
While disconcerting that Waymack refuses to alter his opinions in the face of Supreme Court decisions and the consistent exclusion he has faced, and will continue to face, the Court believes the *Traysol* and *Gadolinium* courts' approach of limiting, rather than entirely excluding, his testimony is the proper course of action, since Waymack can be of assistance to the jury in understanding the process of FDA approval of drug labels and the overall regulatory scheme. However, the Court will not allow Waymack to testify contrary to *Wyeth* or to this Court's determination on the application of the *Wyeth* to this case, and defendants are warned that any attempt to elicit such testimony would violate the Court's order. Accordingly, the Court will allow Waymack to testify to general FDA regulations about the approval of drugs for the U.S. market and the process by which a drug is labeled initially. Waymack may not offer an opinion on the regulatory history of Levaquin, the manner in which defendants' could or should have acted in

response to signals of increased tendon toxicity, or FDA regulations on label changes that contradict either *Wyeth* or this Court's understanding of *Wyeth* as articulated in this Order.

ORDER

Based on the foregoing, and the records, files, and proceedings herein, **IT IS HEREBY ORDERED** that Plaintiffs' Motion to exclude the testimony of J. Paul Waymack [Docket No. 1851] is **GRANTED in part**, insofar as Waymack's opinions diverge from the law as explained by the Court in Part I, and such that Waymack may not offer testimony about the regulatory history of Levaquin.

DATED: November 9, 2010
at Minneapolis, Minnesota.

s/ 

JOHN R. TUNHEIM
United States District Judge