

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

IN RE: LEVAQUIN PRODUCTS
LIABILITY LITIGATION,

MDL No. 08-1943 (JRT)

This Document Relates to:

CALVIN CHRISTENSEN,

Civil No. 07-3960 (JRT)

Plaintiff,

v.

ORDER

ORTHO MCNEIL PHARMACEUTICAL,
INC.; JOHNSON & JOHNSON
PHARMACEUTICAL RESEARCH AND
DEVELOPMENT, LLC; JOHNSON &
JOHNSON; and ORTHO-MCNEIL-
JANSSEN PHARMACEUTICALS, INC.,

Defendants.

Ronald S. Goldser and David M. Cialkowski, **ZIMMERMAN REED, PLLP**, 651 Nicollet Mall, Suite 501, Minneapolis, MN 55402-4123; and Lewis J. Saul, **LEWIS SAUL & ASSOCIATES**, 183 Middle Street, Suite 200, Portland, ME 04101, co-lead counsel for plaintiff Christensen.

John Dames and William V. Essig, **DRINKER BIDDLE & REATH LLP**, 191 North Wacker Drive, Suite 3700, Chicago, IL 60606-1698; Tracy J. Van Steenburgh, **NILAN JOHNSON LEWIS, PA**, 400 One Financial Plaza, 120 South Sixth Street, Minneapolis, MN 55402; James B. Irwin, V, **IRWIN, FRITCHIE, URQUHART & MOORE, LLC**, 400 Poydras Street, Suite 2700, New Orleans, LA 70130, liaison and lead counsel for defendants.

Before the Court are numerous motions in limine brought by plaintiff and defendants in preparation for trial. Because the Court finds the issues presented in some motions are the same or substantially similar to motions brought in the first bellwether trial of this multidistrict litigation (“MDL”), *Schedin v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 08-5743, and since the Court finds the management of the MDL, 08-1943, will benefit from adherence to the law of the case doctrine, the Court grants and denies the following motions in accordance with previous rulings based on the same or substantially similar facts and arguments. The Court additionally addressed below new motions in limine not governed by the law of the case.

BACKGROUND

This MDL, *In re: Levaquin Products Liability Litigation*, currently consists of 1197 cases involving the drug Levaquin. Levaquin is an antibiotic developed, manufactured, and marketed by defendants Ortho McNeil Pharmaceutical, Inc., Johnson & Johnson Pharmaceutical Research and Development, LLC, Johnson & Johnson, and Ortho-McNeil-Janssen Pharmaceuticals Inc. (collectively, “defendants”). Plaintiff Calvin Christensen was prescribed Levaquin in May 2006 while hospitalized for pneumonia. Shortly thereafter, he suffered a rupture of his right Achilles tendon, requiring surgical repair. He claims the rupture was the result of taking Levaquin. He has sued defendants for failure to sufficiently warn of the dangers he faced in taking the drug. Christensen’s case is the second bellwether trial in this MDL.

ANALYSIS

I. LAW OF THE CASE

“[T]he [law of the case] doctrine posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case. Law of the case directs a court’s discretion, it does not limit the tribunal’s power.” *Arizona v. California*, 460 U.S. 605, 618 (1983) (footnote and citation omitted). Indeed, “[a] court has the power to revisit prior decisions of its own or of a coordinate court in any circumstance, although as a rule courts should be loathe to do so in the absence of extraordinary circumstances such as where the initial decision was clearly erroneous and would work a manifest injustice.” *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988). Furthermore, utilizing the law of the case has no effect on the appeals process: “a district court’s adherence to law of the case cannot insulate an issue from appellate review” *Id.*

By adhering to the “law of the case,” a court gives continuing effect to a ruling made earlier in the same litigation. The phrase “expresses the practice of courts generally to refuse to reopen what has been decided, not a limit on their power.” This practice is tempered by a sound discretion, permitting reexamination in the light of changes in governing law, newly discovered evidence, or the manifest erroneousness of a prior ruling. **The doctrine of the law of the case has its application in multidistrict litigation** as well as in traditional litigation.

In re Multi-Piece Rim Prods. Liab. Litig., 653 F.2d 671, 678 (D.C. Cir. 1981) (emphasis added) (citations omitted). The Manual for Complex Litigation § 20.133 recommends the application of the law of the case doctrine to MDLs.

While the Eighth Circuit has not addressed the application of the law of the case doctrine to MDLs, it has noted that the doctrine “generally prevents relitigation of an issue previously resolved, and requires courts to adhere to decisions rendered in earlier proceedings. . . . [T]he doctrine is salutary and should be departed from only after careful consideration on situations arising in specific cases.” *Hulsey v. Astrue*, 622 F.3d 917, 924 (8th Cir. 2010) (internal citations and quotation marks omitted). As a result, the Court will apply the law of the case doctrine to motions before it that are the same or substantially similar to motions previously decided in this MDL.

A. Plaintiff’s Motions in Limine

Plaintiff filed motions challenging the admissibility of several of defendants’ experts under Federal Rule of Evidence 702 and the gatekeeping standards of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597–98 (1993). These motions regard the same experts as those at issue in the *Schedin* trial. Finding no newly discovered evidence, changes in the governing law, or manifest error in its previous rulings, the Court adheres to the law of the case regarding those experts. As a result, the Court denies the motions to exclude the testimony of John Seeger, Peter Layde, George Zhanel, and Joseph Rodricks.¹ (Docket No. 120.)

The Court also grants in part and denies in part the motion with respect to J. Paul Waymack. (Docket No. 120.) Waymack may testify as to general Food and Drug

¹ For the purposes of appeal, reference should be made to this Order, to the Court hearing transcript dated May 26, 2011, and to the Court’s Order denying the corollary motion in the MDL dated November 4, 2010. (Docket No. 2253, 08-1943.)

Administration (“FDA”) regulations about the approval process for drugs in the U.S. market and the manner in which a drug is initially labeled. Waymack may not offer an opinion on the regulatory history of Levaquin or the manner in which defendants could or should have acted in response to signals of increased tendon toxicity; nor may he offer an opinion regarding FDA regulations on label changes that contradicts *Wyeth v. Levine*, 555 U.S. 555 (2009), or the Court’s application of *Wyeth* in this case as reflected in previous orders. (*See, e.g.*, Order Denying J. as a Matter of Law, Docket No. 196, 08-5743.)²

B. Defendants’ Motions in Limine

Defendants filed several motions in limine to exclude evidence that are similar to motions filed in *Schedin*. Finding no newly discovered evidence, changes in the governing law, or manifest error in its previous rulings, the Court adheres to the law of the case and holds consonant with the previous orders. The motion to exclude evidence of ghostwriting is denied, with the limitation that the parties and their experts should refrain from using the term “ghostwriting.” (Docket No. 111.)

The motion to exclude various categories of evidence is denied in part and granted in part. The motion is granted regarding reference to other products of defendants that do not meet the “substantially similar” test for relevance, and granted regarding exclusion of marketing materials from other drug companies. The motion is denied in all other respects. (Docket No. 112.)

² For the purposes of appeal, reference should be made to this Order, to the Court hearing transcript dated May 26, 2011, and to the Court’s Order granting in part and denying in part the corollary motion in the MDL dated November 9, 2010. (Docket No. 2263, 08-1943.)

The motion to exclude Adverse Event Reporting is denied as plaintiff is offering such reporting to show notice of tendon events and therefore the reports are not hearsay. Fed. R. Evid. 801(c). (Docket No. 116.)

The motion to exclude the Public Citizen's petition and the Illinois Attorney General's petition to the FDA (Docket No. 118) is denied since the petitions are either business records or public reports and therefore are exceptions to the hearsay rules. *See* Fed. R. Evid. 803(6), (8).³

The motion to exclude evidence of label changes that occurred after Christensen's prescription is denied. Defendants argue that the FDA made the label changes based on scientific articles that were published after Christensen's prescription. (*See* Lenahan Aff., May 13, 2011, Ex. 5, Docket No. 132.) The Court has previously noted, however, that since the decision to change the label was based in part on articles that predated the plaintiff's prescription,⁴ the label changes are relevant and admissible. Therefore, the motion is again denied.⁵ (Docket No. 131.)

Defendants' motion to exclude statements related to the defendant's knowledge and intent (Docket No. 191) is granted in part and denied in part. Consistent with the Court's previous ruling, statements by plaintiff's experts that describe precepts of

³ For appeal purposes for the ghostwriting, various issues, Adverse Event Reports and FDA petition motions, refer to this Order and the Court's corollary Order in Schedin dated November 9, 2010. (Docket No. 117, 08-5743.)

⁴ The original Order addressed a prescription that was given in 2005. Christensen's prescription was given in 2006. This difference, however, does not materially affect the outcome of the analysis.

⁵ For appeal purposes refer to this Order and the Court's corollary Order in Schedin dated November 24, 2010. (Docket No. 165, 08-5743.)

academic research are admissible. However, statements that opine as to how defendants should have acted in the face of certain evidence cross the line to subjective opinions of personal belief and are inadmissible.⁶ The portion of the motion to bifurcate the proceedings is deferred. (Docket No. 191.)

II. NEW MOTIONS IN LIMINE

Plaintiff moves to exclude the testimony of Paul Cederberg (Docket No. 150), who performed an Independent Medical Examination (“IME”) pursuant to this Court’s Order on April 22, 2011. (Docket No. 106.) The Court determines that Cederberg’s testimony is relevant to a “condition in controversy” and his testimony is therefore admissible. However, the defendants’ motion for the IME was “limited to assessing Mr. Christensen’s Achilles tendons and his anticipated future treatment and rehabilitation.” (Mem. in Supp. at 3, Docket No. 101.) As a result, any questioning by or opinions of Cederberg related to causation are outside the scope of the IME as ordered by the Court and will not be admissible at trial. Admissible testimony from Cederberg is limited to “the plaintiff’s current physical condition . . . and his prognosis for future health.” (*Id.* at 2-3.)

Defendants’ motion in limine to exclude argument, evidence, and testimony that relates solely to plaintiff’s failure to communicate claim is under advisement and will be addressed by the Court prior to the start of trial on Tuesday May, 31, 2011. (Docket No. 175.) Since this motion incorporates the evidence at issue in the motion in limine to

⁶ For the purposes of appeal, refer to this Order and the Court’s corollary Order in the MDL dated November 10, 2010. (Docket No. 2267, 08-1943.)

exclude evidence of foreign regulatory actions (Docket No. 114), that motion is similarly deferred until the start of trial.

ORDER

Based on the foregoing, and the records, files, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Plaintiff John Christensen's Motion in Limine [Docket No. 120] is **DENIED in part and GRANTED in part**. The Motion is **GRANTED** insofar as Waymack's opinions diverge from the law and such that Waymack may not offer testimony about the regulatory history of Levaquin. The Motion is **DENIED** with regard to Joseph Rodricks, John Seeger, Peter Layde, and George Zhanel. All other issues raised in the Motion were **DENIED** at the Hearing on the Motion.
2. Defendants' Motion in Limine on Evidence of "Ghostwriting" [Docket No. 111] is **DENIED**.
3. Defendants' Motion in Limine on Various Issues [Docket No. 112] is **GRANTED in part and DENIED in part**. The motion is granted as to points 8 and 9, and denied in all other respects.
4. Defendants' Motion in Limine to Exclude Evidence of or Reference to Adverse Event Reports [Docket No. 116] is **DENIED**.
5. Defendants' Motion in Limine on Petitions to the FDA from Public Citizen and the Illinois Attorney General [Docket No. 118] is **DENIED**.
6. Defendants' Motion in Limine to Exclude Evidence Regarding Post-2006 Levaquin Labeling [Docket No. 131] is **DENIED**.

7. Defendants' Motion to Bifurcate the Proceedings [Docket No. 191] is **GRANTED in part, and DEFERRED in part**. The Motion is **GRANTED** in regards to excluding opinion evidence related to defendants' motive and intent and **DEFERRED** in all other respects.
8. Plaintiff's Motion in Limine Re: Paul Cederberg [Docket No. 150] is **GRANTED in part, and DENIED in part**. Cederberg's testimony is admissible but limited to plaintiff's current physical condition and prognosis for future health.
9. Defendants' Motion in Limine to Exclude Argument, Evidence, and Testimony that Relates Solely to Plaintiff's Failure to Communicate Claim [Docket No. 175] is **DEFERRED**.
10. Defendants' Motion to Exclude Evidence Concerning Regulatory Actions and Proposed Label Changes in Foreign Countries [Docket No. 114] is **DEFERRED**.

DATED: May 27, 2011
at Minneapolis, Minnesota.

John R. Tunheim
JOHN R. TUNHEIM
United States District Judge