

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

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In re: LEVAQUIN PRODUCTS  
LIABILITY LITIGATION

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MDL No. 08-1943 (JRT)

**ORDER DENYING PLAINTIFFS'  
MOTIONS TO EXCLUDE EXPERT  
WITNESSES**

This Document Relates to All Actions

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This multidistrict litigation (“MDL”) is before the Court on plaintiffs’ motions to exclude the expert testimony of Drs. Seeger, Layde, Zhanel, Rodricks, and Holmes, under Federal Rule of Evidence 702. For the reasons set forth below, the Court denies the motions.

**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 alleged that it causes tendons to rupture.

## DISCUSSION

### I. 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 (8<sup>th</sup> 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.*

With regard to the third prong, Rule 702 prescribes that evidence is reliable if: (1) the testimony is based upon sufficient facts or data; (2) the testimony is the product of reliable principles and methods; and (3) the witness has applied the principles and methods reliably to the facts of the case. Fed. R. Evid. 702. The district court has a “gatekeeping” obligation to make certain all testimony admitted under Rule 702 satisfies these prerequisites. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597–98 (1993). The proponent of expert testimony has the burden to show by a preponderance of the evidence that expert testimony is admissible. *Lauzon*, 270 F.3d at 686; *see also Daubert*, 509 U.S. at 592. However, “[t]he rule clearly is one of admissibility rather than

exclusion.” *Lauzon*, 270 F.3d at 686 (internal quotation marks omitted). Rule 702 was not intended to “serve as a replacement for the adversary system.” *United States v. 14.38 Acres of Land Situated in Leflore Cnty., Miss.*, 80 F.3d 1074, 1078 (5<sup>th</sup> Cir. 1996). “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert*, 509 U.S. at 595. Therefore, expert testimony is admissible if it “rests on a reliable foundation and is relevant to the task at hand.” *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999).

## **II. PLAINTIFFS’ MOTIONS TO EXCLUDE EXPERT TESTIMONY**

### **A. Dr. John Seeger**

Dr. John Seeger (“Seeger”) is a practicing pharmacoepidemiologist with doctoral degrees in both pharmacy and epidemiology. He is an adjunct assistant professor in the Department of Epidemiology at the Harvard School of Public Health. He is the chief scientist in epidemiology at i3 Drug Safety where he conducted a study on Levaquin referred to by all parties as the “Ingenix study.” Plaintiffs move to exclude the testimony of Seeger based on alleged flaws with the administration and execution of the Ingenix study, including:

- Defendants commissioned the study and had a substantial financial stake in its outcome.
- Seeger was inexperienced as a researcher and study designer when he conducted the study.
- Seeger failed to preserve the study design parameters and underlying source data.

- Seeger was not blinded to exposure status during the study.
- Seeger made diagnosis-verification decisions he was unqualified to make for the purposes of the study.
- The study was not adequately designed to capture potential heightened risk for Achilles tendon rupture (“ATR”) in the elderly and those using corticosteroids.
- Seeger failed to account for flaws in the algorithm that disproportionately excluded elderly ATR patients in the study.

Plaintiffs do not challenge Seeger’s qualifications or the relevance of his testimony to explain or present the Ingenix study; rather, they paradoxically seek his exclusion based on the poor methodology used in the Ingenix study, while intending to introduce the study itself. Defendants argue that all of plaintiffs’ issues with Seeger’s conduct in the design and implementation of the Ingenix study go to the weight, not the admissibility of his testimony.

Plaintiffs have presented no persuasive Rule 702 issue for Seeger’s exclusion. Though the methods used to conduct the Ingenix study may have been flawed, only Seeger can answer certain questions related to the study – all the more so since parts of the underlying data and algorithms have been lost or destroyed. The issues plaintiffs raise can be appropriately addressed on cross-examination. *See Daubert*, 509 U.S. at 595. Additionally, since the Court anticipates both parties will question Seeger as a fact witness regarding the administration and execution of the study, the Court sees no utility in excluding him as an expert witness. *See Fed. R. Evid. 701*.

The Court therefore determines that since Seeger is qualified as an expert and is likely to testify as a fact witness, he is permitted to testify as an expert. Plaintiffs can

cross-examine him on any of the issues raised in their motion. The motion to exclude Seeger's expert testimony is denied.

**B. Dr. Peter Layde**

Dr. Peter Layde ("Layde") has an M.S. in epidemiology, and is a medical doctor. Layde is a professor in the Department of Population Health at the Medical College of Wisconsin and of Family and Community Medicine. He is also an adjunct professor in the Department of Population and Health Sciences in the Wisconsin School of Medicine and Public Health. Plaintiffs do not challenge Layde's qualifications; rather they argue that Layde's testimony should be excluded based on several alleged issues with the opinions expressed in his testimony.

Connection to his expert report: Plaintiffs argue that Layde's opinion – regarding the meaningfulness of a statistically significant association in particular studies from a clinical or public health perspective – is inadmissible because it is too general a statement for an epidemiologist to make and it is not tied specifically to his expert report. Defendants respond that relevance is the only issue and the proper means of evaluating association in a clinical context are relevant to the facts of this case.

The study of epidemiology necessarily involves statistical studies and a strong grasp of the principles of statistics. *Cf. In re Fosamax Prods. Liab. Litig.*, 645 F. Supp.2d 164, 187 (S.D.N.Y. 2009) ("E]pidemiology cannot objectively prove causation; rather causation is a judgment by epidemiologists and others interpreting epidemiological data."). Since the Rules embrace the notion that experts will "educate

the fact-finder on general principles” of their field, the Court does not find plaintiffs’ argument to exclude Layde’s testimony on this basis persuasive. Fed. R. Evid. 702 advisory comm. note, 2000 Amend.

Further, Rule 702 does not require strict adherence by an expert to their report, as is clear from provisions in the Federal Rules of Civil Procedure allowing supplements to expert reports. *See* Fed. R. Civ. P. 26(e). Logically, it makes little sense to allow experts to testify at all if they are limited to reciting their reports. Since experts can even use facts or data “made known to the expert at . . . the hearing” as the bases of their opinions, the Rules allow for some adjustments between an expert’s report and his or her other testimony. Fed. R. Evid. 703. As a result, relevancy is the primary issue and the Court sees no reason to exclude the proffered testimony on that basis.

Plaintiffs make the same assertions – of generality and remoteness from his written report – regarding Layde’s testimony that controlled studies are not useful for determining causation and that the Food and Drug Administration Adverse Event Reporting System is not useful for calculating incidence rates. For the same reasons as above, the Court finds these arguments unpersuasive.

Legal standard language: Plaintiffs seek to exclude Layde’s testimony due to his use of a “no convincing evidence” standard for causality, arguing that no such standard exists and that Layde has not fully defined the term. They argue this language is essentially a legal standard and therefore inadmissible. *S. Pine Helicopters, Inc. v. Phx. Aviation Managers, Inc.*, 320 F.3d 838, 841 (8<sup>th</sup> Cir. 2003) (holding that expert testimony on legal matters is not admissible). Defendants point to case-law in which similar

language has been used. *See, e.g., Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989 (8<sup>th</sup> Cir. 2001) (upholding the exclusion of an expert who was unable to produce “convincing evidence” of a causation between a drug and an adverse response). Defendants further assert that this is an issue for cross-examination and not a basis for exclusion.

The Court does not regard this testimony as legal testimony. Where courts have excluded such testimony, they have done so when experts have directly opined as to the law, not employed language that parallels legal language. *See, e.g., S. Pine Helicopters, Inc.*, 320 F.3d at 841; *United States v. Klaphake*, 64 F.3d 435, 438–39 (8<sup>th</sup> Cir. 1995). To the extent plaintiffs would like Layde to clarify his terminology, they are free to cross-examine him. If the defendants elicit testimony from Layde crossing the line into legal opinions, the Court can rule on an appropriate objection at that time and give a curative instruction to the jury if necessary.

Use of administrative databases: Plaintiffs move to exclude Layde’s testimony asserting that the studies he examined are limited because of their use of administrative databases. Plaintiffs assert that the underlying factual basis for this opinion is flawed since only one of the studies Layde examined used an administrative database, the others used medical records. Further, plaintiffs assert that Layde is not qualified to testify on the reliability of administrative databases. Defendants argue that these issues go to the weight and not the reliability of the evidence and are therefore not grounds for exclusion.

Disputes about the facts underlying an expert’s opinions are best addressed through the adversarial process and then by the jury as the ultimate fact-finder. *Daubert*,

509 U.S. at 595. Additionally, Rule 703 contemplates that experts may use a range of information in forming their opinions. Fed. R. Evid. 703. Layde's experience as an epidemiologist makes him qualified to testify about the usefulness of certain types of data regularly used in his work. See *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d at 187. Additionally, other courts have recognized that administrative databases do in fact present limitations in the field of epidemiology. E.g., *In re Seroquel Prods. Liab. Litig.*, 2009 WL 3806434, at \*14 (M.D. Fla. 2009) (noting that an expert "ably identified" confounding issues such as the limits of administrative databases.). Therefore, the Court sees no reason to exclude this evidence on the bases offered.

Opinions as an epidemiologist: Plaintiffs move to exclude Layde's opinion that **epidemiologic** data on ofloxacin can be applied to levofloxacin, on the basis that he is not a toxicologist, a pharmacologist, or a chemist. Defendants note that his opinion is based on epidemiology, a field in which Layde is an expert. The Court finds that Layde meets the requirements of expertise as understood by Rule 702 and is qualified to offer this opinion. If he strays out of his areas of proficiency during his testimony at trial, the Court will rule on an appropriate objection at that time.

Underlying studies: Plaintiffs allege that the eight studies Layde examined to form the bases of his opinions are factually flawed. Defendants respond that the weaknesses in studies relied on by experts go to the weight of the evidence and not the admissibility. *In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig.*, 493 F. Supp. 2d 1082, 1088 (D. Minn. 2007).

The Court finds no reason to exclude Layde's testimony based on the studies he examined. The studies present a wide enough range of results regarding the connection between ATR and fluoroquinolones that the expert cannot be said to have "selectively chose[n] his support from the scientific landscape." *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005); *see also id.* at 425 n.164 (noting courts that have excluded expert testimony for this type of selectivity).

Full exclusion: Based on the arguments above, plaintiffs argue that Layde should not be allowed to offer **any** opinion as to whether levofloxacin poses a greater risk of ATR than other fluoroquinolones. Defendants assert that since Layde has bases for his opinions and is qualified to offer them, he should not be excluded. The Court finds none of plaintiffs' arguments persuasive.

As expert testimony is admissible if it "rests on a reliable foundation and is relevant to the task at hand," *Kumho Tire Co., Ltd.*, 526 U.S. at 141, and Layde's testimony both rests on the reliable foundation of his experience and review of materials and is relevant, the Court finds no reason to exclude Layde as an expert and thus denies the motion in its entirety.

### **C. Dr. George Zhanel**

Dr. George Zhanel, Ph.D., ("Zhanel") is a professor of medical microbiology/infectious diseases at the University of Manitoba in Winnipeg, Canada. Zhanel has published widely in peer-reviewed medical and scientific journals on the efficacy and safety of anti-infective medications (particularly quinolones and

fluoroquinolones) in the treatment of infectious diseases. Zhanel's opinions about the safety and efficacy of levofloxacin in treating certain infectious diseases and the fundamental differences between levofloxacin and ofloxacin and other quinolones are based on years of research and experience with these medications in treating infectious diseases.

Plaintiffs offer no objections to Zhanel's qualifications to testify as an expert and they do not challenge the usefulness of his proposed testimony. *See* Fed. R. Evid. 702. Plaintiffs move only to narrow the scope of Zhanel's testimony based on his deposition testimony. Plaintiffs' motion centers on portions of his proposed testimony that supposedly contradict other evidence and thus make his conclusions unreliable and excludable under Federal Rule of Evidence 702.

Absence of opinion: First, plaintiffs argue that Zhanel should be excluded from testifying as to the relative tendon toxicity of various fluoroquinolones because during his deposition he refused to assess, **from an epidemiological point of view**, whether there were associational differences between the various fluoroquinolones and tendon toxicity. (*See* Zhanel Dep. 19:12–19, Jan. 20, 2010, Goldser Aff., Ex. A, Docket No. 1659 (“Q: Do you consider yourself an expert in epidemiology? A. I’m not a world-renowned epidemiologist, and don’t claim to be. I, again, have training in epidemiology, use epidemiology every single day, and have expertise in epidemiology. But I would not consider myself an intentionally-renowned epidemiologist, no.”).) Defendants object that the parsing of Zhanel's testimony misstates his opinions in this area.

Zhanel's deposition testimony makes clear that he did express an opinion on the relative toxicity of various fluoroquinolones. His perspective is informed by his training, background, and experience working with these drugs for twenty-five years from:

the genetic perspective, the test tube perspective, the animal perspective, the human perspective, and in addition someone who has gone to review the literature in vitro, in vivo, and human, to ask themselves the question is there an association with quinolones and tendinopathy, I have done that, and I think the answer is that there is an association.

(Zhanel Dep. 26:5–12, Goldser Aff., Ex. A, Docket No. 1659.) Zhanel's full deposition and expert report reflect his qualifications and ability to compare the drugs' tendotoxicity based on his own research and methodology, while relying on epidemiologists for an epidemiological perspective. The Court finds this testimony admissible. Zhanel's deference to epidemiologists on questions limited to epidemiology is appropriate given his perspective and experience with fluoroquinolones.

Unethical clinical trial: Plaintiffs argue that Zhanel should be excluded from testifying that a prospective, randomized, double-blind clinical trial is the only evidence that can demonstrate a comparative relationship among fluoroquinolones regarding tendon toxicity, because he stated in his deposition that such a test could not be ethically performed. Defendants argue that plaintiffs' characterization of Zhanel's testimony is inaccurate and that his testimony includes ethical ways to achieve similar testing results.

Zhanel testified in his deposition that the optimal test for determining a comparative relationship between different fluoroquinolones and tendon toxicity involves different sets of patients on different fluoroquinolones, a set who are not taking

fluoroquinolones, and a set on a placebo. (Zhanel Dep. 31:12–36:18, Goldser Aff., Ex. A, Docket No. 1659.) He explained that placing high-risk infectious patients – the elderly, those on concomitant corticosteroids, and patients with renal failure – on a placebo would be unethical, so the scientists performing the test could either run the random tests with a placebo control group on lower-risk populations, or run the tests without a placebo group. (*Id.*) It is not accurate to characterize Zhanel’s position as that the “only evidence” to demonstrate a comparative relationship between the different fluoroquinolones would be an unethical clinical trial. The Court finds this testimony admissible.

Discrepancies in testimony: Plaintiffs move to exclude Zhanel’s testimony that levofloxacin and ofloxacin have different toxicological and pharmacological profiles on the basis that this opinion varies from Zhanel’s deposition testimony, as well as from statements defendants have made to the Food and Drug Administration in their New Drug Applications. Additionally, plaintiffs move to exclude Zhanel’s testimony that levofloxacin is superior to moxifloxacin for upper respiratory illnesses and that levofloxacin is superior to ciprofloxacin for urinary tract infections on the basis that this testimony conflicts with other portions of his deposition testimony. Defendants respond with an analysis of how Zhanel’s deposition statements are neither internally inconsistent, particularly when viewed in their entirety, nor contrary to the New Drug Applications.

Rule 702 was not intended to “serve as a replacement for the adversary system,” *14.38 Acres of Land Situated in Leflore Cnty., Miss.*, 80 F.3d at 1078. Challenges based

on contradictory facts, as plaintiffs here allege, are best suited for cross-examination. *Daubert*, 509 U.S. at 595. The Court finds this testimony admissible.

In summation and based on the reasons stated above, the Court finds no basis to narrow Zhanel's testimony under Rule 702. As a result, the motion to exclude his testimony is denied.

**D. Dr. Joseph Rodricks**

Dr. Joseph Rodricks ("Rodricks") is a biochemist who holds a B.S. in chemistry, an M.S. in organic chemistry, and Ph.D. in biochemistry. He completed his post-doctoral scholarship at the University of California, Berkeley. He currently serves as a principal at ENVIRON International Corporation, where he works as a consultant in toxicology and human health risk assessment. He is also an adjunct faculty member at Johns Hopkins Bloomberg School of Public Health where he teaches courses in toxicology and risk analysis. Rodricks' testimony in this case regards the inability to use non-clinical animal studies to extrapolate opinions on tendon toxicity attributed to levofloxacin.

Plaintiffs make no objections to Rodricks' qualifications as an expert and do not challenge the relevancy of his testimony. As with their motion regarding Zhanel, plaintiffs move to exclude portions of Rodricks' testimony in which he allegedly expressed no opinion in his deposition and expert report.

As an initial matter, plaintiffs argue that Rodricks' opinions are based on the unsupportable theory that an absence of evidence is evidence. Courts have excluded such expert testimony as violative of a major tenet of science. *See Hall v. Baxter Healthcare*

*Corp.*, 947 F. Supp. 1387, 1470–71 (D. Or. 1996) (“Absence of evidence is not evidence for absence.”); *Evans v. Medtronic, Inc.*, 2005 WL 3547240, at \*10 (W.D. Va. 2005).

However, Rodricks’ reports and deposition comport with scientific norms regarding the absence of evidence. Rodricks does not want to render opinions on certain issues **because** there is an absence of evidence to support them; he is not arguing that the absence of evidence is, in and of itself, evidence. Yet, this seeming scientific caution on Rodricks’ part is the basis for much of plaintiffs’ motion to exclude his testimony. Plaintiffs’ arguments are unpersuasive.

Epidemiology testimony: Plaintiffs’ object to Rodricks offering opinions in the area of epidemiology. Defendants have conceded that Rodricks is not an expert in epidemiology, and they do not intend to introduce any testimony from Rodricks based solely on epidemiology. As the parties have reached an agreement on this issue, the Court considers this argument moot.

Absence of opinion: Plaintiffs argue that the Court should exclude Rodricks’ opinions regarding the comparative toxicity of ofloxacin and levofloxacin, whether fluoroquinolones can cause tendon disorder in humans, the comparative tissue penetration of ofloxacin and levofloxacin, and the comparative pharmacokinetics of ofloxacin and levofloxacin. The challenges are based on Rodricks’ responses to deposition questions that he had no opinions on these topics. Defendants argue that Rodricks’ statements that there was no reliable way to predict these assertions and comparisons are, in fact, opinions.

Rodricks' expert reports and deposition evidence opinions on these topics. For example, Rodricks testified that comparative toxicity cannot be predicted from the current data and studies on the issue. (*See, e.g.*, Rodricks Dep. 40:19–41:9, Feb. 17, 2010, Goldser Aff., Ex. C, Docket No. 1638 (“Q: Do you have a relative opinion about the relative tendinopathic toxicity of levofloxacin and ofloxacin in humans? A: Well, that would require– I don’t because that would require a study of the human data. And that goes together with my opinion that that relative tendency in humans is not reliably predictable from the experimental data.”).) The Court finds that Rodricks’ characterization of the reliability of the existing data is an opinion, is reliable as contemplated by Rule 702, and absent an independent basis for exclusion, is admissible.

Reliability of Animal Studies: Plaintiffs offer three grounds to support their argument that the Court should exclude Rodricks’ opinion that there is no reliable animal modeling to study the comparative tendon toxicity of fluoroquinolones. First, plaintiffs argue this opinion was first raised in Rodricks’ rebuttal opinion in violation of Rule 26(a)(2)(C)(ii) (requiring rebuttal testimony within 30 days after the other parties’ disclosure of an expert report). Second, plaintiffs argue that Rodricks’ opinion misuses animal modeling in a way that courts have found objectionable under *Daubert*. Third, plaintiffs argue that the Court should exclude Rodricks’ opinion on this matter because it is “just plain wrong.”

On the first issue, defendants point to the deposition transcript to demonstrate Rodricks’ consistent articulation of his opinion throughout the litigation. Rodricks’

deposition is replete with statements regarding the efficacy of animal studies. Contrary to plaintiffs' assertions, he did not first raise the issue in his rebuttal report.

Rodricks has opined that extrapolating animal testing to human outcomes is not reliable. (*See, e.g.*, Rodricks' Report ¶¶ 57–64, Goldser Aff., Ex. A, Docket No. 1638.) Courts have found that the issue of the admissibility of the **results** of animal testing may not be admissible as evidence of human reactions. *See, e.g., In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 743 (3d Cir. 1994). However, Rodricks' opinion is not related to the results of animal testing, but is rather that extrapolation from animals to humans is inappropriate. This opinion, in and of itself, does not raise any admissibility issues under Rule 702 since it “rests on a reliable foundation and is relevant to the task at hand,” *Kumho Tire Co., Ltd.* 526 U.S. at 141.

The third argument, that Rodricks is simply wrong in his conclusions, is best addressed through the adversarial system. *Daubert*, 509 U.S. at 595 (“Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”). The Court denies plaintiffs' motion.

Rebuttal Report: Plaintiffs move to exclude Rodricks' rebuttal report in its entirety as violative of Federal Rule of Civil Procedure 26(a)(2)(C)(ii). Plaintiffs argue that the opinions in the rebuttal report are new and do not specifically address plaintiffs' experts' reports. Plaintiffs therefore argue that the rebuttal report is not actually a “rebuttal” as understood by the Rule. Defendants argue that the opinions in the rebuttal appear

throughout Rodricks' deposition, and that Rodricks has addressed plaintiffs' witnesses in both his deposition and rebuttal report.

Review of the docket supports defendants' assertion that Rodricks has articulated his opinions consistently in both his deposition and rebuttal report. As a result, the rebuttal report does not contain "substantial additional opinions" prejudicing the plaintiffs as they claim. Moreover, Rule 26 imposes a duty on parties to supplement any disclosures that are incomplete or incorrect. Fed. R. Civ. P. 26(e)(1)(A). Rule 26 further allows experts to make "additions or changes" to their deposition or initial report, as long such additions or changes are timely. Fed. R. Civ. P. 26(e)(2). Since Rodricks' rebuttal report was timely, plaintiffs' objection is without merit. The Court denies the motion to exclude this testimony.

In summation, since Rodricks is qualified and his testimony is reliable and useful to the trier of fact, the Court denies in its entirety plaintiffs' motion to exclude Rodricks' testimony.

**E. Dr. George Holmes**

Dr. George Holmes ("Holmes") is an orthopedic surgeon and a professor of orthopedic surgery with a specialty in foot and ankle injuries. He is the author of a medical textbook and several journal articles on injuries to the foot and ankle, including ATR. To form his expert opinion for the Levaquin trials, Holmes reviewed the medical charts of Schedin and the other bellwether plaintiffs, relied upon his general knowledge

of the field after thirty years of practice in the area, and created case-specific reports of his opinions on the causation of each of the plaintiffs' injuries.

Plaintiffs do not challenge Holmes' qualifications but move to exclude his case-specific testimony as unreliable because 1) it was developed for the purposes of litigation without proper care, 2) he uses legal language, 3) he relies on an absence of evidence or inapplicable studies, 4) his opinions are contrary to fact, and 5) he opines on irrelevant issues.

Developed for litigation without appropriate care: Plaintiffs argue that Holmes' testimony should be excluded since a) it was developed solely for the purposes of litigation and b) Holmes did not exercise the proper degree of care expected of experts in the field. In particular, plaintiffs point to the amount of time Holmes spent reviewing the medical files (28.5 hours), his inability to recall the order in which he reviewed each file, his failure to study the relationship between fluoroquinolones and ATR before this litigation, and his inability to determine if he had formulated his opinions before or after reviewing the epidemiological studies. Defendants argue that review of medical records is an appropriate methodology for an expert of Holmes' training and experience to form an opinion, even if only offered for the sake of litigation.

Plaintiffs cite no case-law indicating the appropriate amount of time for a medical file review. The Rule 702 standard is whether the expert "is being as careful as he would in his regular professional work outside his paid litigation consulting." Fed. R. Evid. 702 advisory comm. note, 2000 Amend. (citing *Sheenan v. Daily Racing Form, Inc.*, 104 F.3d 940, 942 (7<sup>th</sup> Cir. 1997)). Given Holmes' qualifications and experience, the Court

declines to exclude his testimony on these grounds. Plaintiffs may use cross-examination to challenge Holmes, including in what order he reviewed documents and reports. Further, expert testimony is excludable if developed only for litigation **if** it is not supported in some way by the expert's research and expertise unrelated to the litigation. *Id.* Here, Holmes has extensive experience in ATR, thus the Court does not find his testimony unreliable simply because he only reviewed the medical records for the purposes of this litigation.

Legal standard language: Plaintiffs argue that Holmes' opinion that Levaquin was not "the substantial contributing cause" to their injuries should be excluded because the jury will be confused regarding the law of negligence. Defendants argue that Holmes uses the phrase in a medical, and not a legal manner. Additionally, defendants suggest that Holmes can adjust his opinions to conform to the Court's instructions.

It is a well-settled principle that "expert testimony on legal matters is not admissible." *S. Pine Helicopters, Inc.*, 320 F.3d at 841. However, the guiding principle for determining the applicability of Rule 702 is its usefulness to the trier of fact. Fed. R. Evid. 702. The Court does not find that Holmes' phrasing is grounds for exclusion because it is relevant and reliable as understood under Rule 702. *Kumho Tire Co., Ltd.*, 526 U.S. at 141. Defendants are ordered to advise Holmes to avoid saying "**the** substantial contributing factor" and instead employ the phrase "**a** substantial contributing factor" in his analysis to avoid any confusion.

Absence of Evidence: Plaintiffs argue that the Court should exclude Holmes' testimony that he would have seen more ATR in his practice corresponding with the

increase of fluoroquinolone prescriptions in the last fifteen years if such effects were caused by Levaquin. Holmes acknowledges that the use of fluoroquinolones medications as a class has been reported in the medical literature to have been associated with increased risk of ATR but dismisses the published research based on his own subjective observations. Defendants do not directly address this issue in their opposition brief.

As noted in the discussion regarding Rodricks, “absence of evidence is not evidence of absence.” *Hall*, 947 F. Supp. at 1470–71. “[T]he cases are legion that assert that expert testimony is inadmissible when it is based on speculative assumptions . . . .” *Grp. Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 753, 760 (8<sup>th</sup> Cir. 2003) (citing cases). “[C]ourts cast their assessment of how much speculation [on counterfactual estimations] is permissible in various verbal forms . . . : A certain amount of speculation is necessary, an even greater amount is permissible (and goes to the weight of the testimony), but too much is fatal to admission.” *Id.*

Given the inability to do a “perfect” clinical trial on Levaquin, the Court finds the amount of speculation in Holmes’ testimony does not cross the line into inadmissibility; rather this objection is ripe fodder for cross-examination. *Daubert*, 509 U.S. at 595. Therefore, the Court denies the motion to exclude Holmes’ testimony on these grounds.

Short-term use of oral corticosteroids: Plaintiffs argue that Holmes’ opinion that short-term use of oral corticosteroids causes ATR – and that Mr. Schedin’s ATR resulted from such use – is inadmissible as lacking factual support. Plaintiffs rely upon an article noting that if short-term use of oral corticosteroids caused ATR, there would have been more cases of ATR seen by the authors of the study. Defendants argue that there is

sufficient medical literature regarding the connection between short-term use of oral corticosteroids and ATR to warrant the admissibility of Holmes' opinions on the topic – even if the medical literature is not definitive on injected versus oral steroid use.

Disputes about the facts underlying an expert's opinions are best addressed through the adversarial process and then by the jury as the ultimate fact-finder. *Daubert*, 509 U.S. at 595. As noted above, there exist few, if any, “perfect studies,” so experts must extrapolate from existing information using their education and experience. The Court finds that Holmes is qualified to make these extrapolations and plaintiffs can cross-examine him about them. Therefore, the Court declines to exclude Holmes' testimony on these grounds.

Opinions contrary to fact: Plaintiffs argue that Holmes' opinion regarding Schedin's recovery from his ATR is inadmissible as contrary to fact. Holmes' report states that Schedin has recovered and should not be further limited by his ATR. (Holmes' Report on Schedin at 5, Goldser Aff., Ex. 3, Docket No. 2016.) Defendants argue that Holmes is an expert in orthopedic surgery and is therefore qualified to testify about the expected recovery of the plaintiffs.

The Eighth Circuit has found the inclusion of expert testimony that did not incorporate all relevant record facts reversible error. *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8<sup>th</sup> Cir. 2000) (“Because of the deficiencies in the foundation of the opinion, the expert's resulting conclusions were ‘mere speculation’ [and it was reversible error to not exclude them].” (citations omitted)). At the same time, expected medical outcomes are opinions, not facts. To the extent Holmes' testimony

strays from the reported facts, plaintiffs can rely on cross-examination to correct any inaccuracies. The Court may also strike or other disallow such testimony if necessary. At this point, the Court does not find Holmes' testimony excludable on these grounds.

Fluoroquinolones and hip fractures: Plaintiffs move to exclude Holmes' opinion regarding a relationship between ATR and hip fractures because it is beyond the scope of the litigation and therefore irrelevant. Defendants argue that Holmes' testimony is a response to the expert testimony of Dr. Zizic that Schedin is at a higher risk for hip fractures.

Zizic's report makes clear that the discussion of hip fractures relates to the likelihood that patients with ATR are at a higher risk of falling, and therefore suffering hip fractures, which in turn are correlated with increased mortality. (Zizic Report on Schedin at 11, Goldser Aff., Ex. 2, Docket No. 2016.) Holmes' report states that he is "not aware of any known association in the medical literature between [ATR] and the risk of hip fractures." (Holmes' Report on Schedin at 5, Goldser Aff., Ex. 3, Docket No. 2016.) Zizic's syllogism that ATR likely causes falls, falls carry an increased risk of hip fractures, therefore ATR is associated with a higher risk of hip fractures, need not be supported by medical literature to be admissible. While potentially off-topic, the Court finds that Holmes' response is not excludable. The defense can object during trial if it believes Holmes' testimony is irrelevant, or rely on cross-examination to identify any weakness in his logic.

**ORDER**

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

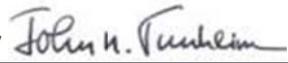
1. Plaintiffs' Motion to Exclude the Expert Testimony of Dr. John Seeger and Dr. Peter Layde [Docket No. 1641] is **DENIED**.

2. Plaintiffs' Motion to Exclude the Expert Testimony of Dr. George Zhanel [Docket No. 1656] is **DENIED**.

3. Plaintiffs' Motion to Exclude the Expert Testimony of Dr. Joseph Rodricks [Docket No. 1636] is **DENIED**.

4. Plaintiffs' Motion to Exclude the Expert Testimony of Dr. George Holmes [Docket No. 2014] is **DENIED**.

DATED: November 4, 2010  
at Minneapolis, Minnesota.

s/   
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JOHN R. TUNHEIM  
United States District Judge