UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

IN RE: LEVAQUIN PRODUCTS LIABILITY LITIGATION,	MDL No. 08-1943 (JRT)
This Document Relates to:	
JOHN SCHEDIN, Plaintiff,	Civil No. 08-5743 (JRT)
v. JOHNSON & JOHNSON; ORTHO-MCNEIL PHARMACEUTICAL, INC.; JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, LLC; and ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; Defendants.	**ORDER REGARDING DEFENDANTS' MOTIONS IN LIMINE**

Ronald S. Goldser, **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 Schedin.

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.

This multidistrict litigation is before the Court on defendants' motions in limine. Defendants' brought motions: to exclude petitions to the Food and Drug Administration

("FDA") from the Illinois Attorney General and the public watch group Public Citizen to strengthen Levaquin's label (Docket No. 61); to exclude evidence regarding post-2005 labeling (Docket No. 64); to exclude evidence or argument regarding defendants' duty to warn (Docket No. 67); to exclude references to, and evidence of, "ghostwriting" by defendants of academic articles (Docket No. 70); to exclude marketing materials used by defendants with people other than the plaintiff (Docket No. 72); to exclude "various issues" (Docket No. 75); to exclude evidence of, or reference to, Adverse Event Reports (Docket No. 76); and to exclude evidence concerning foreign regulatory action (Docket No. 83). The Court heard oral arguments and took these motions under advisement on November 3, 2010.

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.

ANALYSIS

I. FDA PETITIONS

Defendants move to exclude two petitions submitted to the FDA requesting stricter labeling of fluoroquinolones. In their motion, defendants point to a 2005 petition from the Illinois Attorney General ("AG Petition") and a 1996 petition from the public

watch group Public Citizen. At oral argument and in their response brief, plaintiffs withdrew the 1996 Public Citizen petition and indicated their intention to offer a Public Citizen petition from 2005.

A. The AG Petition

Defendants argue that the AG petition (Ex. B, Docket No. 61) is hearsay, irrelevant, and unduly prejudicial. Plaintiffs respond that the petition is relevant and admissible as an exception to the hearsay rule under Federal Rule of Evidence 803(8). At oral argument, defendants presented a supplemental brief arguing that the AG Petition does not fit the Rule 803(8) exception since the AG did not hold hearings or undergo its own fact finding regarding the subject of the petition.

Rule 803(8) allows for the admissibility of hearsay if the testimony amounts to a record, report, statement, or data compilation in any form of public offices or agencies that are a part of the activities of the office or involves a duty by law of that office. Fed. R. Evid. 803(8). Illinois courts have determined that the Attorney General has a duty to protect the health of its citizens. *People v. Pine*, 542 N.E.2d 711, 713 (Ill. 1989); *Pioneer Processing, Inc. v. E.P.A.*, 464 N.E.2d 238, 247 (Ill. 1984).

Defendants argue that the lack of hearings removes the petition from the public records exception. The Court notes that "courts construing the term 'factual findings' in Rule 803(8)(C) have given it broad scope." *Kehm v. Procter & Gamble Mfg. Co.*, 724 F.2d 613, 618 (8th Cir. 1983). The Eighth Circuit has previously upheld reports based on the fact finding of independent scientists under the public records exception. *Boerner v. Brown & Williamson Tobacco Co.*, 394 F.3d 594, 600–01 (8th Cir. 2005) ("The reports

also include factual findings, although these were made by independent scientists and not on the basis of independent research by the Surgeon General. We have held, however, that similar reports based on non-agency research were properly admitted under the public records exception.").

In fact, only

> if 'sufficient negative factors are present' to indicate the report is not trustworthy, . . . should [it be excluded]. The factors that may be used to determine admissibility include: (1) the timeliness of the investigation; (2) the special skill or experience of the official; and (3) possible motivation problems. But the burden is on the party opposing admission to demonstrate that the report is not reliable.

Ellis v. Int'l Playtex, Inc., 745 F.2d 292, 300-01 (4th Cir. 1984) (internal citations omitted). The only case cited by defendants to meet this burden concerned a public report that was excluded largely because it was based on unpublished material, available only to the task force that wrote the report, and the data was primarily gathered by the plaintiff's mother. *Wetherill v. Univ. of Chi.*, 518 F. Supp. 1387, 1391 n.4 (N.D. Ill. 1981). No such negative factors are present here.

Defendants further argue that the AG petition contains a second layer of hearsay in the individual citizen complaints and references to literature on the topic. The AG petition itself does not detail the individual citizen complaints: it only states that the office received them. As such, they are not being offered separately, and to the extent that they are being offered, it is for their effect on the listener (the Attorney General), thus the references are not hearsay. Fed. R. Evid. 801(c). The Court also finds no merit in defendants' arguments that the petition lacks relevance to the issues in the case or that it

should be excluded on Rule 403 grounds. The court denies the motion as it regards the AG petition.

B. The Public Citizen Petition

Defendants argue that the petition from Public Citizen suffer the same deficiencies as those in the AG petition and fail to meet the guidelines of the business records exception of Rule 803(6). The Eight Circuit has determined that:

> The language of Fed. R. Evid. 803(6) parallels the principles we articulated in *Kehm*, where we held that the public records exception assumes admissibility in the first instance and provides that the party opposing admission has the burden of proving inadmissibility. We therefore apply the same principles to admission of business records that we articulated for admission of public records in *Kehm*, and hold that once the offering party has met its burden of establishing the foundational requirements of the business records exception, the burden shifts to the party opposing admission to prove inadmissibility by establishing sufficient indicia of untrustworthiness.

Shelton v. Consumer Prods. Safety Comm'n, 277 F.3d 998, 1010 (8th Cir. 2002). Finding no indicia of untrustworthiness, and no merit to claims of irrelevance or undue prejudice, the Court denies the motion as to the Public Citizen petition.

II. POST-2005 LABELING

The Court defers its decision on the post-2005 labeling until all the *Daubert* orders addressing similar issues have been issued by the Court.

III. DUTY TO PLAINTIFF

Defendants move to exclude any argument that they owed a duty directly to the plaintiffs, arguing that the "learned intermediary doctrine" supplants any duty to an

individual. Plaintiffs respond that they have withdrawn all testimony that bears on this argument. The Court denies the motion as moot and notes that "motions *in limine* are not proper procedural devices for the wholesale disposition of theories or defenses." *SPX Corp. v. Bartec USA*, No. 06-14888, 2008 WL 3850770, at *3 (E.D. Mich. Aug. 12, 2008).

IV. GHOSTWRITING

Defendants move to exclude any reference to "ghostwritten articles" based on relevance and Rule 403 prejudice arguments. Plaintiffs note that courts have allowed references to "ghostwriting" when the articles were actually ghostwritten, and because published articles influence choices and referrals in the medical field in such a way that the actual prescribing doctor need not have read the article. *See, e.g., In re Seroquel Prod. Liab. Litig.*, No. 06-md-1769, 2009 WL 223140, *2–3 ((M.D. Fla. Jan. 30, 2009) (allowing the plaintiffs to make arguments and present evidence while avoiding the term "ghostwriting").

Defendants object to the term "ghostwriting" due to its potentially prejudicial character before the jury. Defendants make no plausible claim that they did not engage in ghostwriting, and plaintiffs point out that Dr. Beecher relied on others' recommendations to prescribe Levaquin – indicating that such articles are relevant to the field of knowledge about the product. Therefore, the Court denies the motion to the extent that defendants actually did engage in ghostwriting articles, but orders the parties to refrain from using, or allowing their witnesses to use, the term "ghostwriting."

V. MARKETING TO OTHERS

Defendants move to exclude any marketing material or statements that were not heard or relied upon by Dr. Beecher. They argue that without seeing the material, Beecher could not have relied upon it and it is therefore irrelevant. Plaintiffs respond that since Beecher used other doctor's recommendations as his primary source for identifying new drugs to prescribe, materials defendants used to market to others are relevant. Further, plaintiffs argue that any internal marketing materials, i.e. training materials, are relevant to how defendants trained their marketing and sales staff to minimize information about tendon rupture. The Court agrees that these materials are relevant and denies the motion.

VI. VARIOUS ISSUES

Defendants' motion in limine on various issues makes twenty-four separate points to exclude evidence, most of which fall into four general categories. The first – encompassing points 1, 2, 3, 5, 7, 10, 11, 17, 18, 19, 20, and 24 – are motions to order the plaintiffs to follow the Rules of Evidence. The second – encompassing points 4, 21, and 22 – are motions to order the plaintiffs to follow the Rules of Civil Procedure. Motions that lack specificity and are "essentially repetitive of well-established rules of evidence" are not generally granted. *Simpson v. Econ. Premier Assurance Co.*, No. 1:05-CV-35-M-D, 2006 WL 2590620, at *1 (N.D. Miss. Sept. 8, 2006). The court denies the motion as to these points.

The third category – encompassing points 12, 13, and 14 – refer to broad categories of evidence and the fourth category – encompassing points 15 and 16 – refer to

evidence the plaintiffs **may** raise, but have not yet. "Orders in limine which exclude broad categories of evidence should rarely be employed. A better practice is to deal with questions of admissibility of evidence as they arise." *Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). The Court denies the motion as to these points.

The remaining points deserve individual attention. Point 6 requests that references to the health and medical conditions of other persons be excluded on the basis of relevance. On its face, this argument has merit; however, without knowing what the proposed evidence might be, whether those injuries involved substantially-similar circumstances, or whether they were relevant to an expert's report, the Court finds this issue is not ripe for a ruling. The Court denies the motion as to this point but will respond to an appropriate objection during trial if potentially irrelevant information regarding third parties is raised.

Point 8 involves the mention of defendants' other products. The Court addressed this issue more substantively in its ruling on plaintiffs' motions in limine. The Court grants this portion of the motion to the extent that defendants' other products do not meet the "substantial-similarity standard" to be admissible. *Ahlberg v. Chrysler Corp.*, 481 F.3d 630, 637 (8th Cir. 2007).

Point 9 requests exclusion of marketing materials from other drug companies. Given that these materials would likely be irrelevant and might be confusing to the jury, the Court grants this portion of the motion.

VII. REFERENCE TO ADVERSE EVENT REPORTS

Defendants request the exclusion of evidence pertaining to databases of adverse event reporting ("AERs"). Defendants note that the FDA and other regulatory groups have found AERs insufficient to determine causation. Plaintiffs argue that AERs are admissible as they are sufficient to "signal" a safety issue.

Standing alone the AERs might not be permissible as evidence to make the causal link between the plaintiffs' injuries and Levaquin. However, they are commonly used by experts in the field to determine causation in correlation with **other evidence**. *See, e.g.*, *In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 950, 961–62 (D. Minn. 2009) (allowing evidence of AERs as a safety signal as discussed by Dr. Blume). Additionally, even if the AERs could not be admitted to prove causation, they arguably stand as notice to the manufacturer of a potential problem. To the extent that plaintiffs or plaintiffs' experts discuss AERs in this context, the Court finds no merit in the hearsay objection. The Court denies the motion.

VIII. FOREIGN REGULATORY ACTION

Defendants request exclusion of evidence of foreign regulatory action on the basis of relevance and hearsay. They highlight cases in which courts have excluded such information. Plaintiffs argue that the evidence is being offered as notice evidence. At oral argument, plaintiffs further discussed the manner in which the evidence is relevant to their narrative of defendants' motives related to labeling in the United States and protecting negative impacts on the U.S. market for Levaquin.

Examination of defendants' citations reveal that those cases turned on whether the foreign regulatory action differed from the FDA's response, *In re Seroquel Prod. Liab. Litig.*, 601 F. Supp. 2d 1313, 1315 (M.D. Fla. 2009), and whether other evidence of notice existed, *In Re Baycol Prod. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007). These are instances where the court ruled that the foreign regulatory evidence would be too confusing to an American jury. However, in this case, the plaintiffs are not presenting **final** regulatory action to which a jury might defer out of confusion. Rather they are presenting only preliminary actions in Europe, in conjunction with defendants' responses which were intended to limit the impact potential regulatory action in Europe might have on the U.S. market for the drug. As a result, the Court finds the evidence not only speaks to defendants' notice but to motive, is relevant, and is not hearsay.

Further, the Court finds it unlikely that a jury would be confused and simply defer to the foreign regulatory action, since the substance of the regulatory action is itself in dispute. As a result of these factors, the Court denies the motion only so far as to allow the evidence for the purposes of showing notice and motive. The Court does not want significant trial time devoted to this evidence.

ORDER

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

1. Defendants' Motion in Limine on FDA petitions [Docket No. 61] is **DENIED**.

2. Defendants' Motion in Limine on post-2005 labeling [Docket No. 64] is **DEFERED.**

3. Defendants' Motion in Limine duty to warn [Docket No. 67] is **DENIED as moot.**

4. Defendants' Motion in Limine on ghostwriting [Docket No. 70] is **DENIED**, with the exception that plaintiffs are ordered to not use, or solicit their experts to use, the term "ghostwriting."

5. Defendants' Motion in Limine on defendants' marketing to others [Docket No. 72] is **DENIED**.

6. Defendants' Motion in Limine on various issues [Docket No. 75] is **GRANTED in part, DEFERED in part, and DENIED in part**. The motion is granted as to points 8 and 9, deferred as to point 6, and denied as to all other points.

7. Defendants' Motion in Limine on Adverse Event Reporting [Docket No. 76] is **DENIED**.

8. Defendants' Motion in Limine on foreign regulatory actions [Docket No. 83] is **DENIED**.

DATED: November 9, 2010
at Minneapolis, Minnesota.

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