UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

ETHEL KELLOGG, Plaintiff, v. WYETH, Individually and as Successor-in-Interest to A.H. ROBINS COMPANY, INC. and AMERICAN HOME PRODUCTS CORPORATION; SCHWARZ PHARMA, INC.; ACTAVIS, INC.; ACTAVIS-ELIZABETH, L.L.C.; ALPHARMA, INC.; PUREPAC PHARMACEUTICAL COMPANY, INC.; TEVA PHARMACEUTICALS, USA, INC.; BAR PHARMACEUTICALS, INC.; PLIVA, INC.; and DRUG COMPANY DOES 1 THROUGH 10, inclusive, Defendants.	:	Case No. 2:07-cv-82

Memorandum Opinion and Order

Ethel Kellogg has brought suit against the manufacturers of metoclopramide for injuries arising from her ingestion of the drug. Defendant Wyeth has moved to exclude the testimony of Plaintiff's experts Daniel Tarsy, M.D., Ronald Stewart, Ralph Bernstein, M.D. and Robert Nelson, Ph.D., pursuant to *Daubert v. Merrell Dow Pharmaceuticals., Inc.*, 509 U.S. 579 (1993). For the reasons that follow, the motions, ECF Nos. 317, 318, 319, and 320, are **granted in part and denied in part.**

The party proffering expert testimony has the burden of establishing its admissibility "by a preponderance of proof." *Id.* at 592 n. 10. Rule 702 of the Federal Rules of Evidence provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The rule requires a district court to ensure that scientific or technical evidence is both relevant and reliable. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999); *Daubert*, 509 U.S. at 589.

In assessing reliability, in addition to the factors set forth in Rule 702, a district court may consider

> (1) whether a theory or technique has been or can be tested; (2) "whether the theory or technique has been subjected to peer review and publication;" (3) the technique's "known or potential rate of error" and "the existence and maintenance of standards controlling the technique's operation;" and (4) whether a particular technique or theory has gained general acceptance in the relevant scientific community.

United States v. Williams, 506 F.3d 151, 160 (2d Cir. 2007) (quoting *Daubert*, 509 U.S. at 593-94). *Daubert*'s factors do not apply to all experts or in every case, however; the reliability inquiry is a flexible one. *Id*. (quoting *Kumho Tire*, 526 U.S. at 141; *Daubert*, 509 U.S. at 594).

The inquiry focuses "solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at

595. In keeping with the "liberal thrust" of the Federal Rules of Evidence, *id*. at 588, "[v]igorous 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." *Id.* at 596; *see also Olin Corp. v. Certain Underwriters at Lloyd's London*, 468 F.3d 120, 134 (2d Cir. 2006) (approving the techniques of cross-examination and presentation of opposing expert testimony to expose weaknesses in an expert's testimony).

Nevertheless, "proffered 'expert testimony should be excluded if it is speculative or conjectural.'" *Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 311 (2d Cir. 2008) (quoting *Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 21 (2d Cir. 1996)). "An expert's conclusory opinions are similarly inappropriate." *Id.*

Motion to Exclude Certain Testimony of Daniel Tarsy, M.D.

Wyeth moves to exclude certain expert opinions of Dr. Tarsy pursuant to Rules 401, 403 and 702 of the Federal Rules of Evidence. Specifically, Wyeth seeks to exclude "his opinions regarding metoclopramide that are based upon antipsychotic studies," testimony "[a]bout other doctors' prescribing practices and understanding of the metoclopramide labeling," and testimony "[t]hat side effects reported in studies conducted in the 1970s were misidentified as 'restlessness' or 'agitation' and instead

are likely akathisia." Wyeth's Mot. to Exclude Expert Ops. of Daniel Tarsy, M.D. 19, ECF No. 319.

Dr. Daniel Tarsy, a board-certified neurologist who specializes in movement disorders and a professor of neurology at Harvard Medical School, is an authority on the neurological effects of drugs such as metoclopramide. He will offer the opinion that the risk of developing tardive dyskinesia from long-term metoclopramide use, based on the then-available data, was far greater than was reflected in Reglan® labeling at the time Kellogg was taking the drug.

Wyeth finds fault with Dr. Tarsy's conclusion that metoclopramide is a neuroleptic drug, meaning, as he defines it, that it is capable of causing extrapyramidal symptoms ("EPS") and tardive dyskinesia. This position is hardly controversial, given that the Food and Drug Administration ("FDA") requires metoclopramide labeling to carry a warning about the risk of such side effects. *See* Reglan® Tablets Prescribing Information Nov. 2010, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/017854s055lbl.pdf; *see also PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 ("Evidence has accumulated that long-term metoclopramide use can cause tardive dyskinesia . . ."). Because of the dearth of direct studies of metoclopramide's potential to cause tardive dyskinesia, Dr. Tarsy reviewed the data for neuroleptic drugs as a whole, where the

overall prevalence of tardive dyskinesia is about fifteen percent.

Wyeth does not dispute this figure. It argues that Dr. Tarsy is not qualified to opine on the similarity of the pharmacological properties of metoclopramide and other neuroleptic drugs; that study data about neuroleptic drugs in general cannot be used to extrapolate the risk associated with metoclopramide, because the methodology is speculative; it is scientifically unsound to apply the properties of one drug to a different drug; and his opinion is not based on sufficient facts or data.

Dr. Tarsy, a neurologist, concededly is not an expert in neuropharmacology. He need not be a specialist in neuropharmacology if he has "knowledge, skill, experience, training, or education" that would assist the trier of fact, however. Fed. R. Evid. 702; *see e.g.*, *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006) (holding that neurologist with knowledge of causes of shoulder pain was qualified to testify concerning cause of shoulder injury, although not an orthopedist); *Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 437 (E.D.N.Y. 2011) (holding that oncologist and hematologist was qualified to opine on effects of pretreatment dental screening, although not a dentist or oral surgeon); *Blanchard v. Eli Lilly & Co.*, 207 F. Supp. 2d 308, 317

(D. Vt. 2002) (holding that psychiatrist was qualified to testify about the cause of a suicide, despite lack of expertise in pharmacology, epidemiology or toxicology). Dr. Tarsy is qualified to testify about the relative risk of tardive dyskinesia from use of metoclopramide.

Wyeth's other objections to this opinion attack its reliability. In the "conclusions" section of his report, Dr. Tarsy offers the "supposition" that based on collected and published data "the incidence of tardive dyskinesia with metoclopramide exposure is roughly equivalent to the incidence of tardive dyskinesia after exposure to the neuroleptic antipsychotic drugs in general." Tarsy Report 8, ECF No. 319-1. Dr. Tarsy explained that he used "supposition" as opposed to "conclusion" because the studies are a "positive indicator" that the incidence of tardive dyskinesia with metoclopramide and with neuroleptic antipsychotic drugs is roughly equivalent. Tarsy Dep. 193:7-14, Aug. 18, 2010, ECF No. 319-2.

"To be scientifically valid, the subject of expert testimony need not be 'known to a certainty' because, 'arguably, there are no certainties in science.'" *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 173 (S.D.N.Y. 2009) (quoting *Daubert*, 509 U.S. at 590). "[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate

validation—*i.e.*, 'good grounds,' based on what is known." *Daubert*, 509 U.S. at 590. Wyeth's contention that Dr. Tarsy's opinion is "purely speculative" blurs the distinction between scientifically grounded theories or ideas on the one hand and subjective belief or unsupported speculation on the other, a distinction that the *Daubert* Court took pains to draw. *See id.*

Dr. Tarsy acknowledges that his and others' opinion that the incidence of tardive dyskinesia with metoclopramide exposure is roughly equivalent to the incidence of tardive dyskinesia with exposure to the neuroleptic antipsychotic drugs is based on the lack of evidence that one neuroleptic drug is "safer" than another, and further acknowledges that retrospective studies of newer antipsychotic drugs suggest that they are associated with a lower incidence of EPS and possibly also tardive dyskinesia. These acknowledgments of the limitations of the data do not render his opinion inadmissible. *See Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002). The validity and strength of Dr. Tarsy's opinion is a matter for the jury to assess. *See Daubert*, 509 U.S. at 596; *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 154-55 (1997) (Stevens, J., concurring in part and dissenting in part).

Wyeth also seeks to preclude Dr. Tarsy from testifying regarding how doctors would interpret the metoclopramide labeling. Dr. Tarsy may testify about the risks of tardive

dyskinesia from metoclopramide use, and he may compare what is or was known at the time with what was disclosed in the labeling. He may opine on the label's accuracy and completeness. With the appropriate foundation, he may testify as to what the language and form of the label suggests to the average doctor. These observations do not attempt to predict doctors' prescribing practices or understandings, nor do they attempt to suggest what Kellogg's doctors understood about metoclopramide at the time. Such testimony would by contrast be excludable as speculative. *See, e.g.*, *Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 442 (E.D.N.Y. 2011); *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 461 F. Supp. 2d 271, 276 (D.N.J. 2006); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 556 (S.D.N.Y. 2004); *see also Daubert*, 509 U.S. at 589-90 ("[T]he word 'knowledge' connotes more than subjective belief or unsupported speculation."). Dr. Tarsy's assessment of the metoclopramide label's communication of information is admissible, if the testimony focuses on specialized observation resting on knowledge and experience "confessedly foreign in kind to the jury's own." *Kumho Tire*, 526 U.S. at 149 (quotation marks and citation omitted).

Wyeth also seeks to preclude Dr. Tarsy from testifying that reports from clinical trials in the 1970s that identified restlessness or agitation as a side effect of metoclopramide use

should have been reported as akathisia.[1] Kellogg does not intend to offer this opinion, but expects that Dr. Tarsy may comment that the existence of these side effects was likely akathisia and should have prompted further investigation. Testimony purporting to characterize side effects recorded more than three decades ago as more likely than not representing akathisia is not based on sufficient facts or data, and does not satisfy *Daubert*'s reliability requirement. *Daubert*, 509 U.S. at 590 ("[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method."). Dr. Tarsy may testify, consistent with his deposition testimony, that the existence of these side effects was a signal that should have prompted further investigation into the presence of akathisia. Tarsy Dep. 171:14-24, Aug. 18, 2010. He may not testify that the side effects identified in the Reglan® studies were more likely than not akathisia.

Accordingly, Wyeth's Motion to Exclude Expert Opinions of Daniel Tarsy, M.D., ECF No. 319, is **granted in part and denied in part.**

Motion to Exclude the Testimony of Ronald B. Stewart

Kellogg designated Ronald Stewart, a pharmacist and Professor Emeritus in the College of Pharmacy at the University

[1] "Akathisia" may be defined as a disorder characterized by motor restlessness.

of Florida with a Masters Degree in hospital pharmacy administration, as an expert witness in this case. In his report he states that he will testify that "metoclopramide is commonly used inappropriately for periods greatly exceeding the FDA approved indications and this leads to adverse reactions." Stewart Report 5, ECF No. 320-1. He will also testify about the "Taylor Paper," an article promoting the safety of long-term use of metoclopramide, published in the journal *Clinical Therapeutics* in 1984. Wyeth seeks the exclusion of both areas of testimony.

Kellogg agrees that her witness, who is not a medical doctor, may not testify about whether prolonged metoclopramide therapy is inappropriate. With that proviso, she argues that Stewart may testify that metoclopramide was frequently prescribed for periods of longer than twelve weeks, and that side effects were frequently experienced. Wyeth argues that this testimony is irrelevant to any issue in this case, and that the bases for Mr. Stewart's opinion are not reliable.

Evidence is relevant if "it has any tendency to make a fact more or less probable than it would be without the evidence; and []the fact is of consequence in determining the action." Fed. R. Evid. 401. The parties agree that at trial Kellogg will seek to demonstrate that Wyeth was responsible for disseminating information about metoclopramide that was false or misleading. To that end, testimony about the way metoclopramide has been used

is relevant to the issue of whether Wyeth's metoclopramide labeling was inaccurate or misleading. To be sure, this witness does not supply evidence that Kellogg's doctors were misled—evidence essential to the success of Kellogg's claims—but the testimony is not irrelevant to her case.

As to the reliability of Stewart's opinion that long-term metoclopramide use and adverse side effects was common or frequent, Kellogg states that it is "based on his review of published literature and discovery documents." Pl.'s Resp. 26, ECF No. 329-3; *see also* Stewart Report 5 ("My testimony will be based on my own study, my review of published literature and AHR internal documents that support the conclusions of my own study."). Although an expert may offer an opinion based on a review of the literature and material provided in discovery, *see* Fed. R. Evid. 703 ("An expert may base an opinion on facts or data in the case that the expert has been made aware of . . ."), this cursory reference to the sources of his opinion do not enable the Court to determine that Mr. Stewart's opinion is based on sufficient facts or data. Moreover, the vagueness of the characterization does not assist the jury to understand the evidence or to determine a fact in issue. Fed. R. Evid. 702(a). Although Mr. Stewart may extrapolate from existing data to opine on the commonness or frequency of long-term metoclopramide use or adverse side effects, in this case his opinion appears to be

connected to existing data only by his "ipse dixit." *Joiner*, 522 U.S. at 146. Consequently, although Mr. Stewart may testify that metoclopramide is prescribed for periods that greatly exceed the FDA-approved indications, and that patients have suffered adverse reactions, he may not characterize this as common or frequent, without specifically disclosing the facts or data upon which he makes this determination.

With regard to the Taylor Paper, Wyeth contends that Mr. Stewart's analysis is irrelevant and unduly prejudicial, and that he is unqualified to give his opinion about it. The Taylor Paper purported to evaluate the safety of metoclopramide for long-term use in patients with gastroesophageal reflux disease, finding that "[n]o serious side effects were encountered." Taylor Paper 1, ECF No. 320-7. The article was allegedly ghostwritten by A.H. Robins ("AHR") employees while AHR owned the rights to manufacture Reglan®.[2] Kellogg seeks to use Stewart's critique of the article as evidence that Wyeth's dissemination of information, in its labeling for Reglan® and otherwise, was false or misleading.

In order for a critique of the Taylor Paper to have any relevance in this case, Kellogg must be able to demonstrate that Wyeth bore some responsibility for its creation. Even assuming

[2] Wyeth, formerly known as American Home Products, acquired AHR in 1989.

that Wyeth can be held responsible for AHR's conduct, Kellogg has provided only speculation that AHR employees created the article or influenced its conclusions. Although there is evidence that the purported author, David Taylor, did not write the paper, Kellogg has provided no basis for the conclusion that it was ghostwritten by AHR employees. Mr. Stewart states that "AHR internal documents suggest that [sic] was written by A.H. Robins company employees. I believe that would make the paper fraudulent and very misleading. It is my belief that A.H. Robins Company selected a gastroenterologist with no research experience as the principal investigator on a very complex multicenter study." Stewart Report 5. Mr. Stewart's expertise, which may well qualify him to provide a critique of the paper, does not extend to the determination of its authorship or sponsorship. His opinion on that point is "[no] more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. Without admissible evidence of Wyeth's connection to the paper, the paper's deficiencies have no relevance to any issue in this case. Mr. Stewart's opinions on the Taylor Paper are therefore excluded as irrelevant.

Wyeth's Motion to Exclude the Testimony of Ronald B. Stewart, ECF No. 320, is therefore **granted in part and denied in part.**

Motion to Exclude the Testimony of Ralph Bernstein, M.D.

Wyeth moves to exclude the testimony of Dr. Bernstein for failure to timely disclose him as an expert witness, and because his testimony is irrelevant, lacks reliability and consists of speculation.

Kellogg disclosed three experts on March 24, 2010. Two months later, after the deadline for disclosure under Rule 26(a)(2) had passed, she disclosed Dr. Bernstein, a board-certified practicing gastroenterologist, as an expert witness. Twenty-two months following the late disclosure, Wyeth now claims prejudice because it has had no opportunity to depose him or otherwise prepare for his testimony.[3] Under the circumstances, the Court finds the late disclosure of Dr. Bernstein to be harmless. Fed. R. Civ. P. 37(c).

Rule 26(a)(2)(B), however, requires that an expert disclosure include a written report that among other things contains the witness's opinions and the facts or data considered by the witness. To date, Kellogg has not supplied Wyeth with a report from Dr. Bernstein.[4] She responds that Dr. Bernstein has

[3] It is apparent from Dr. Bernstein's disclosure that Wyeth has had an opportunity to depose him in four previous metoclopramide cases involving Wyeth. *See* Bernstein letter dated May 25, 2010, ECF No. 317-1.

[4] Dr. Bernstein attached a "Declaration" to his letter agreeing to testify, which he states reflects the testimony he expects to give in this case. *See* Bernstein Decl., ECF No. 317-2.

been deposed multiple times in other metoclopramide cases, and that Dr. Bernstein has submitted declarations in this and other metoclopramide cases in which he has outlined the expected areas of his testimony. Essentially she argues that Wyeth has long known the subject matter of Dr. Bernstein's expected testimony.

Although ordinarily the Court would regard the failure to provide an expert report as good grounds for exclusion of the witness's testimony, in this case, given Wyeth's obvious familiarity with Dr. Bernstein's opinions, *see* Wyeth's Mot. to Exclude Expert Ops. of Ralph Bernstein, M.D. 6-8, ECF No. 317, the Court will not exclude Dr. Bernstein's testimony in its entirety. However, Dr. Bernstein's testimony must be limited to those topics described in the Declaration dated April 7, 2010, that he has submitted in this case.

Dr. Bernstein's Declaration sets forth the fact that a prescription for a brand-name product such as Reglan® will be filled at the pharmacy with any one of several generic bioequivalent products unless the doctor specifies otherwise, as well as the sources of doctors' information about prescription drugs. Decl. ¶¶ 4-7. Wyeth argues that his opinions are irrelevant, that his opinions are statements of subjective belief, and that he has applied no discernible methodology to arrive at his conclusions.

The expected testimony is relevant. Kellogg will attempt to

show that Wyeth breached a duty to use reasonable care to avoid causing injury to consumers of generic bioequivalents to Reglan®. The jury will probably hear that Kellogg did not take Reglan®, but generic bioequivalents, and it is entitled to know why in order to place that information in context. It will also assist the jury to know the sources of doctors' prescription drug information in general, as well as what Kellogg's doctors relied upon. To be sure, testimony about what doctors do in general will not supply the necessary element of proximate cause in this case, but that does not render the testimony irrelevant.

The basis for Dr. Bernstein's expected testimony is his personal experience. "[G]eneral truths derived from specialized experience," *Kumho Tire*, 526 U.S. at 148 (internal quotation marks and citation omitted), are an acceptable basis for expert testimony. Dr. Bernstein does not intend to draw conclusions about the nature, adequacy or accuracy of the information doctors may derive about metoclopramide from these sources, nor does he offer to testify as to what other doctors think. He may however draw from his lengthy experience as a practicing gastroenterologist to tell the jury what sources doctors consult when making prescription decisions.

Wyeth's Motion to Exclude Expert Opinions of Ralph Bernstein, M.D., ECF No. 317, is therefore **granted in part and denied in part.**

Motion to Exclude the Testimony of Robert Nelson, Ph.D.

Robert Nelson is a clinical pharmacist with a Ph.D. in epidemiology. He worked for the FDA for more than twenty years in positions of increasing responsibility and scope in new drug review, epidemiology and post-marketing surveillance. He currently consults on drug safety, post-marketing surveillance, pharmacoepidemiology, therapeutic risk management and drug regulatory issues.

Wyeth seeks to preclude any testimony about Wyeth's state of mind, ethics and marketing. Kellogg agrees that she will not elicit testimony from Dr. Nelson that draws conclusions about Wyeth's intent, motive or state of mind. She argues, however, that Dr. Nelson may testify about standards of ethical conduct for drug companies.

Dr. Nelson does not claim to be an expert on standards of ethical conduct for drug companies, nor does he offer an opinion that Wyeth behaved unethically.[5] Deviation from industry standards of ethics is not an issue in this case, and testimony on that topic, if offered, is excluded as irrelevant. *See, e.g.*, *In re Rezulin*, 309 F. Supp. 2d at 544.

[5] He does opine that Wyeth failed to perform a comprehensive risk analysis of EPS, including tardive dyskinesia, and that labeling reporting a one in five hundred rate of occurrence of EPS was inaccurate and misleading. Nelson Report 4-5. These opinions do not express a view on corporate ethics or morality.

Wyeth also objects to any discussion of AHR marketing documents from the 1970s and 1980s, and notes that it will move to exclude the documents before trial. The Court denies without prejudice the motion to exclude testimony about the documents pending a determination of their relevance and admissibility.

In addition, Wyeth seeks to exclude Dr. Nelson's opinions regarding Wyeth's regulatory compliance for failure to articulate a standard for that compliance and because the opinions are irrelevant. If Kellogg is to prevail on a theory that Wyeth breached a duty of care, her regulatory expert's opinions that Wyeth failed to perform a comprehensive risk analysis or allowed inaccurate or misleading information to be included in its labeling are certainly relevant.

Kellogg will have to produce expert testimony concerning the appropriate standard of care, that is, what a reasonable pharmaceutical company would have done under similar circumstances. *See, e.g.*, *Bartlett v. Mut. Pharm. Co.*, 742 F. Supp. 2d 182, 195 (D.N.H. 2010), *aff'd* 678 F.3d 30 (1st Cir. 2012); *White v. Harris*, 2011 VT 115, ¶¶ 12-13, 36 A.3d 203, 207-08; *Provost v. Fletcher Allen Health Care, Inc.*, 2005 VT 115, ¶¶ 7-9, 890 A.2d 97, 99-100 (entry order). Dr. Nelson is expected to testify that while Wyeth held the held the rights to manufacture the brand name Reglan®, it was responsible for the accuracy of its product labels, for assuring that its product was

being used safely for intended uses, for monitoring adverse consequences associated with its product, for notifying the FDA of signals of risk, and to mitigate identified risks. Nelson Report 7-8. Wyeth complains that these opinions lack a regulatory or other objective standard, but these objections more properly attack the weight rather than the admissibility of the evidence. *See Bartlett*, 742 F. Supp. 2d at 195 (holding that pharmacologist with significant experience at the FDA as well as in pharmaceutical industry had an adequate foundation for his testimony about standards of care); *In re Fosamax*, 645 F. Supp. 2d at 191-92 (holding that a medical doctor with experience at the FDA would be permitted to testify about the reasonableness of a drug company's conduct). Wyeth may offer evidence that Wyeth in fact complied with FDA regulations; it will be the jury's function, if the evidence permits, to determine if an applicable standard of care was breached.

Concerning the epidemiological evidence, Wyeth concedes that Dr. Nelson may testify about general causation, but attacks his conclusion that the risk of developing EPS is much higher than the "one in five hundred" statement that appears on metoclopramide labeling. Dr. Nelson acknowledges that no incidence studies exist that would indicate the specific rate of tardive dyskinesia with long-term use. Nelson Dep. 125:16-126:16, ECF No. 318-2. He also points out that at least one

published study has reported a prevalence of twenty percent among patients treated with metoclopramide for at least twelve weeks, indicating indirectly that tardive dyskinesia is not a rare occurrence given long-term exposure. *Id.* 116:23-117:9.

Attacks on the soundness of Dr. Nelson's opinion that metoclopramide-induced tardive dyskinesia is not rare go to the weight, not the admissibility of this testimony. *See e.g.*, *Deutsch*, 768 F. Supp.2d at 433-34 (quoting *Quiet Tech. v. Hubel-Dubois UK Ltd.*, 326 F.3d 1333, 1340-41 (11 Cir. 2003)). Experts disagree about the accuracy of the "one in five hundred" statement in the metoclopramide label. The jury may hear evidence attacking or supporting its accuracy and/or tendency to mislead. The jury may also hear that the FDA did not require the deletion of the statement when the label was substantially revised in 2009. Absent admissible evidence about the FDA's reasoning, however, neither side is permitted to speculate why the statement remains a part of the label.

Wyeth's Motion to Exclude Certain Testimony of Robert Nelson, Ph.D., ECF No. 318, is therefore **granted in part, granted in part as unopposed, and denied in part**. Dr. Nelson may provide background information on the prescription drug industry and federal drug regulation. He may opine on the standard of care for a pharmaceutical manufacturer. He may testify about general causation, and to the opinions disclosed in his report, with the

exception of those discussed above. The admissibility of testimony about AHR's marketing documents and practices will be addressed when the admissibility of the underlying documents is addressed.

Dated at Burlington, in the District of Vermont, this 20th day of July, 2012.

/s/William K. Sessions III
William K. Sessions III
U.S. District Court Judge