

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

JO BELLE BALDONADO,	)	
	)	
Plaintiff.	)	
	)	
v.	)	
	)	Case No. 04 C 4312
WYETH <i>and its division</i> ,	)	
WYETH PHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	
	)	

**MEMORANDUM OPINION AND ORDER**

AMY J. ST. EVE, District Court Judge:

On July 30, 2012, Defendant Wyeth filed a “Renewed Motion in Limine No. 4 to Bar Evidence, Argument, and Expert Opinions Concerning the Number of Women Whose Breast Cancer was Purportedly Caused by Hormone Therapy.”<sup>1</sup> (R. 340, Def.’s Mot.) Despite the breadth of its caption, the motion is relatively narrow: Defendant seeks to exclude the expert opinions of Dr. Graham Colditz “regarding the number of women in which HT allegedly caused breast cancer.” (R. 344, Def.’s Mem. at 1.) The motion is denied as described below.

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<sup>1</sup>Defendant filed its original motion on June 15, 2012 (R. 249), but the Court denied that motion without prejudice because, among other reasons, Defendant challenged the anticipated testimony of a witness that Plaintiff had already withdrawn. (R. 334.)

## BACKGROUND<sup>2</sup>

### I. Dr. Graham Colditz

Defendant does not challenge Dr. Colditz's expert qualifications. For purposes of background, Dr. Colditz is an expert epidemiologist who "stud[ies] the causes and prevention of disease at the level of population." (Colditz Dep. at 16.) His "primary focus is on cancer." (*Id.*) Dr. Colditz holds a medical degree from the University of Queensland in Brisbane, Australia, which he earned in 1979. (*Id.* at 16-17.) Additionally, as Dr. Colditz explained at his deposition

I have a Master of Public Health from the Harvard School of Public Health. I have a Doctorate in Public Health from the Harvard School of Public Health. I have an M.D./Ph.D. equivalent from the University of Queensland on top of the medical degree, and I've been admitted to the Australian Faculty of Public Health Medicine, which in some circles, is also considered equivalent to a higher degree.

(*Id.* at 17-18.) Dr. Colditz's educational background has involved "broad training in statistics, epidemiology, health policy, [and] behavior," and has provided him with a "grounding in research skills" to work "in the public health sector." (*Id.* at 18.)

Dr. Colditz currently serves as the Associate Director for Prevention and Control at the Alvin J. Siteman Cancer Center, and the Niess-Gain Professor in the School of Medicine, Department of Surgery, at the Washington University School of Medicine in St. Louis. (*Id.* at 18-19.) He has previously held academic and medical appointments at Harvard University, the University of Michigan, and the University of Queensland. Dr. Colditz has authored and published more than 700 articles in peer-reviewed journals. (*Id.*) He has written or co-authored

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<sup>2</sup>The Court presumes familiarity with the factual and procedural background of this litigation. For a more detailed discussion of this case, see, for example, the Court's Memorandum Opinion and Order dated May 31, 2012 that denied Defendant's motion to exclude the expert testimony of Dr. Elizabeth Naftalis. (R. 228.)

six books, in addition to over 100 “reviews, editorials [or] commentaries.” (*Id.* at 21.) Dr. Colditz has served in a leadership capacity in numerous professional associations, including from 2000-2004 as the Director of the New England Division of the American Cancer Society and from 2003-2006 as the Director of the Harvard Center for Cancer Prevention. Dr. Colditz has received professional recognition for his work and, in addition to myriad other experiences, has served as the Editor-in-Chief of the journal *Cancer Causes and Control* and as a principal investigator on the Nurses Health Study, a decades-long study of chronic diseases in women, including the relationship between hormone therapy and cancer. (*Id.* at 25-30.)

## **II. Evidence at Issue**

In advance of trial, Plaintiff has designated certain portions of Dr. Colditz’s deposition testimony for trial. Defendant presently moves to exclude the following deposition testimony:<sup>3</sup>

COUNSEL: Have you done an estimate of the number of women per year who have gotten breast cancer that was caused by their use of E plus P, estrogen plus progestin?

COLDITZ: Yes, I have made that calculation, just as other epidemiologists have in their publications.

COUNSEL: Now, you mentioned that this calculation that you did to come up with this estimate was similar to calculations you’ve seen in the literature; is that right?

COLDITZ: I am using the same standard methods as we have in our discipline, epidemiology, to estimate the number of cases in the population. The same methods have been used to estimate the number of cases in Norway, the number of cases in the United Kingdom, and so I say I am using the standard methods consistent with the approach that others have used, yes.

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<sup>3</sup>The Court limits its consideration to the specific testimony that Defendant challenges and expresses no view on the admissibility of Dr. Colditz’s designated testimony that Defendant has not challenged.

COUNSEL: And what is your estimate of the number of women per year who have gotten breast cancer because of their use of estrogen plus progestin?

COLDITZ: I estimate that between 8 and 15,000 women per year in the United States develop breast cancer because of the use of estrogen plus progestin therapy.

....

COUNSEL: And the number of fewer cases, the 14,000 fewer cases seen per year since the WHI, how does that match up with your calculation of estimating that 8,000 to 15,000 breast cancers were being caused in women by the use of E plus P?

COLDITZ: Well, this falls exactly within the range that I had previously estimated for the number of cases caused each year by the use of E plus P.

....

COUNSEL: Your opinion that E plus P caused an estimated 8,000 to 15,000 breast cancers in women per year, is that an opinion you hold to a reasonable degree of medical probability?

COLDITZ: Yes.

....

(R. 375, Def.'s Reply at 2 (quoting and citing R. 365, Pl.'s Resp., Ex. 7, Colditz Dep. Desig. at 6, 24).)

For purposes of its motion, Defendant proffers the following background information:

To measure breast cancer incidence rates, Dr. Colditz relies upon information reported by the Surveillance, Epidemiology, and End Results ("SEER") cancer registry, a database that attempts to count the number of cancers in the United States (but draws from registries covering only approximately 26% of the United States population). He theorizes that because the SEER data shows fewer estrogen-receptor positive breast cancers in post-menopausal women during the period that HT usage was declining, he can attribute the decline in breast cancer rates primarily to the contemporaneous decline in HT usage.

(R. 344, Def.'s Mem. at 6.)

## ANALYSIS

Defendant seeks to exclude Dr. Colditz's foregoing testimony on the basis that it is "irrelevant" under Rules 401 and 402; "unreliable and speculative" under Rule 702 and *Daubert*; and "inflammatory and unfairly prejudicial" under Rule 403. (R. 344, Def.'s Mem. at 7, 10, 13.) Defendant additionally argues that "admitting Dr. Colditz's opinions would violate Wyeth's due process rights." (*Id.* at 14.)

### I. Relevance – Rules 401 and 402

The Court begins with the threshold issue of relevance. Rule 401 provides that "[e]vidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401; *see also Whitehead v. Bond*, 680 F.3d 919, 930 (7th Cir. 2012). Relevant evidence is generally admissible, but "irrelevant evidence is not admissible." Fed. R. Evid. 402. "The Federal Rules of Evidence do not limit [a party] to the 'most' probative evidence; all relevant evidence is admissible and the Rules define relevance broadly." *United States v. McKibbins*, 656 F.3d 707, 711 (7th Cir. 2011). The Seventh Circuit recently reminded district courts that "[a] party faces a significant obstacle in arguing that evidence should be barred because it is not relevant, given that the Supreme Court has stated that there is a 'low threshold' for establishing that evidence is relevant." *United States v. Boros*, 668 F.3d 901, 907 (7th Cir. 2012) (citing *Tennard v. Dretke*, 542 U.S. 274, 285, 124 S. Ct. 2562, 159 L. Ed. 2d 384 (2004)).

Here, in response to Defendant's relevance challenge, Plaintiff represents that she will seek to introduce the testimony for purposes of proving (1) general causation (i.e. that Prempro is capable of causing breast cancer) and (2) the nature of the actual risks of Prempro for purposes

of Plaintiff's failure to warn and failure to test claims, as well as showing the "reprehensibility of Wyeth's actions" as a factor justifying punitive damages. (R. 365, Pl.'s Resp. at 1.) The Court will consider reprehensibility in the context of Defendant's due process argument below.

With regard to the first two bases, Plaintiff reasons that she has the burden at trial to show that Prempro has the capacity to cause breast cancer, and also to show that Defendant failed to adequately warn or test Prempro "in the context of the actual risk of the drug." (R. 365, Pl.'s Resp. at 8.) For these reasons, she argues, the evidence is relevant under Rules 401 and 402. The Court agrees. *See Boros*, 668 F.3d at 903 ("the threshold for relevance under Rule 401 is quite low"); *accord Okuda v. Wyeth*, No. 04-CV-80 (D. Utah July 24, 2012) (holding that evidence of "the number of women whose breast cancers were purportedly caused by hormone therapy" is "relevant to the issue of general causation, as well as the need for further testing, the adequacy of the warnings given, and the risk/benefit analysis."); *Fraser v. Wyeth*, No. 04-CV-1373, Tr. of Pretrial Conf. (D. Conn. Mar. 14, 2012) (statement of the Court: "[Dr. Colditz's calculations are] some evidence that you can use that's tested to the rigors of public health and epidemiological principles that tells you by those standards there is some evidence of general causation with efforts to weed out what else might be causing it."); *Schutter v. Wyeth, Inc.*, No. 05 C 955 (N.D. Ill. Feb. 24, 2012) ("the studies appear to be relevant to reprehensibility and the risks and benefits of the drugs").

The testimony at issue – that a certain number of women "develop breast cancer because of the use of [E+P] therapy" – tends to show that Prempro, a leading E+P therapy, can cause breast cancer generally, and tends to inform the nature of the actual risk of the drug. *See Kuhn v. Wyeth*, 686 F.3d 618, 633 (8th Cir. 2012) (stating with approval that expert relied on

“epidemiological evidence to support his opinion that short-term use of Prempro increases the risk of breast cancer”); *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1337 (11th Cir. 2010) (stating that the absence of epidemiological studies makes it “more difficult” to prove general causation); *Needham v. White Labs., Inc.*, 847 F.3d 355, 359 (7th Cir. 1988) (observing in a pharmaceutical liability case arising under Illinois law that, “[i]nvestigation of the dangers of a product is a form of (or step toward) precaution against those dangers; so the greater the potential dangers, the greater the duty of inquiry”); *In re Yasmin and YAZ (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 09-MD-2100, 2011 WL 6302287, at \*12 (S.D. Ill. Dec. 16, 2011) (holding that expert epidemiologist’s testimony “supports the general causation question grounded in epidemiology”); *accord Nat’l Enviorn. Dev. Ass’n’s Clean Air Proj. v. E.P.A.*, 686 F.3d 803, 812 (D.C. Cir. 2012) (stating with approval that a government agency considered epidemiologic studies “to inform its view of the population-level risk”). Defendant’s arguments to the contrary (for example, that Dr. Colditz’s calculations are over-inclusive) go the weight of the evidence, not its admissibility under Rules 401 and 402. *See Okuda v. Wyeth*, 04-CV-80 (D. Utah July 24, 2012) (holding that alleged “[w]eaknesses in the studies giving rise to” excess breast cancer calculations go to the weight of the evidence, not its relevance). *Cf. United States v. Hawkins*, 499 F.3d 703, 711 (7th Cir. 2007) (holding that issues of weight did not destroy the relevance of the evidence at issue).

## **II. Reliability – Rule 702 and Daubert**

Next, Defendant argues that the “Court should exclude Dr. Colditz’s estimates” pursuant to Rule 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993), because the estimates “rest on unsupported, speculative assumptions and

fundamentally unsound methodology.” (R. 344, Def.’s Mem. at 10.)

Under Rule 702, “[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: (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; (b) the testimony is based on sufficient facts or data; (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 district court functions as a gatekeeper with respect to testimony proffered under Rule 702 to ensure that the testimony is sufficiently reliable to qualify for admission.” *Mihailovich v. Laatsch*, 359 F.3d 892, 918 (7th Cir. 2004) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999)). Whether to admit expert testimony rests within the discretion of the district court. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997). “The goal of *Daubert* is to assure that experts employ the same ‘intellectual rigor’ in their courtroom testimony as would be employed by an expert in the relevant field.” *Jenkins v. Bartlett*, 487 F.3d 482, 489 (7th Cir. 2007) (quoting *Kumho Tire Co.*, 526 U.S. at 152).

In support of its motion, Defendant argues that Dr. Colditz “bases his conclusion that HT caused breast cancer in thousands of other women on a simplistic comparison of two trends: breast cancer incidence and HT use.” (R. 344, Def.’s Mem. at 11.) Defendant contends that “the two trends do not reliability support” his opinions because Dr. Colditz (1) assumes causation, but does not prove it; (2) ignores individual risk factors; (3) does not isolate women who took Prempro rather than another drug; (4) does not account for different durations of use or



“compliance with the prescribed regimen”; (5) fails to account for alternative explanations for the decline in breast cancer during 2002 and 2003, such as a decline in mammography; and (6) does not point to any “reliable scientific studies that support his estimates.” (*Id.* at 11-13.)

Defendant advances these six broad-based arguments – in the span of just over two double-spaced pages – but largely fails to develop the arguments or support them with relevant citations to the record.<sup>4</sup> Additionally, Defendant does not meaningfully discuss the specific methodology that Dr. Colditz employed or even general principles of epidemiology.

In any event, based on the Court’s review of the parties’ briefs and its independent review of the record, it is clear that Dr. Colditz’s opinions are reliable for purposes of Rule 702 and *Daubert*. Dr. Colditz, as an epidemiologist, “focuses on populations and not on individual causation.” (Colditz Dep. at 172-73 (quoting counsel’s question to which the witness ascribed).) As he testified, “[w]e will measure exposures in individuals, but we’re focusing on the diseases that are important at the population level, that are coming from both aggregate population data and individual data[.]” (*Id.* (“Other disciplines focus on describing the individual and the singular level of activity.”).) In approaching the calculations at issue, Dr. Colditz testified that he applied generally accepted and standard principles and methods of epidemiology. In his

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<sup>4</sup>For example, Defendant’s first argument relies solely on Dr. Colditz’s testimony from an unrelated 2007 state court case. (*See* R. 344, Def.’s Mem. at 11, Ex. 2.) Defendant’s second, third, fourth, and fifth arguments are largely devoid of record citation (argument three contains no citations whatsoever). (*Id.* at 11-13.) Defendant’s fifth and sixth arguments cite exclusively to the expert declaration of one of Defendant’s own experts. (*Id.*) *Cf. Morisch v. United States*, 653 F.3d 522, 529 (7th Cir. 2011) (“In a case of dueling experts . . . ‘it is left to the trier of fact, not the reviewing court, to decide how to weigh the competing expert testimony.’”) (quoting *Wipf v. Kowalski*, 519 F.3d 380, 385 (7th Cir. 2008)). Defendant’s sixth argument – that Dr. Colditz “points to no reliable published scientific studies that support his estimates” – is conclusory and completely fails to address Dr. Colditz’s deposition testimony or otherwise. (*Id.* at 13.)

words:

I am using the same standard methods as we have in our discipline, epidemiology, to estimate the number of cases in the population. The same methods have been used to estimate the number of cases in Norway, the number of cases in the United Kingdom, and so I say I am using the standard methods consistent with the approach that others have used, yes.

....

We used a standard epidemiological approach to estimate th[e] number [of breast cancers]. The factors that feed into the arithmetic that we do is the relative risk, the increase in risk with the combination therapy, the proportion of women in the age group who are using combination therapy, and the total number of cancers diagnosed in the United States in women in the age range who are either taking or choosing not to take combination therapy.

(*Id.* at 38, 82.) Dr. Colditz further testified that he employed the same methodology that is described in most every textbook of epidemiology.” (*Id.* at 82; *see also id.* at 633 (“It is the body of evidence that we put together to conclude causation, just as the International Agency For Research on Cancer has done.”).)

Additionally, Dr. Colditz has published his calculations in a peer-reviewed journal, *Breast Cancer Research*. (R. 287, Ex. 5, Colditz, “Decline in Breast Cancer Incidents Due to Removal of Promoter: Combination Estrogen Plus Progestin,” 9 *Breast Cancer Research* (Vol. 9, No. 108, 2007).) Others have offered similar calculations. (*See* R. 287, Ex. 2 (media report on a New England Journal of Medicine article regarding 200,000 excess breast cancers from E+P); *id.*, Ex. 15 (article in leading medical journal, *The Lancet*, stating: “Use of HRT by UK women aged 50-64 years in the past decade is estimated to have resulted in an extra 20,000 incident breast cancers, combined oestrogen- HRT accounting for 15,000 of these additional cancers.”); *accord* Colditz Dep. at 38-39.)

For all of these reasons, the Court rejects Defendant's challenge to the reliability of the expert opinions at issue for purposes of admission under Rule 702 and *Daubert*. *Accord Schutter v. Wyeth, Inc.*, No. 05 C 0998 (N.D. Ill. Feb. 24, 2012) (holding that there is no "real argument" that the studies on excess breast cancers "were not conducted with accepted epidemiological methodologies"); *Deutsch v. Wyeth*, No. MID-L-0998-06-MT (N.J. Super. Ct. June 19, 2007) ("The Court finds that Dr. Colditz is qualified to offer his opinions and that the methodology that he used to determine excess breast cancers is generally accepted. . . . Dr. Colditz opinion about excess breast cancers relating to combination hormone therapy is reliable and based on a standard method used by epidemiologists."). *Cf. Hines v. Wyeth*, No. 04-CV-0690, 2011 WL 2680718, at \*4 (S.D. Va. July 8, 2011) (rejecting *Daubert* challenge to expert's opinion on general causation, and observing that the expert relies on "various peer-reviewed articles and epidemiological studies" including research by Dr. Colditz).

### **III. Rule 403**

Defendant alternatively seeks to exclude the evidence on the basis that it is "inflammatory and unfairly prejudicial." (R. 344, Def.'s Mem. at 13.) Rule 403 provides that the trial court, in its discretion, "may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403; *see also United States v. Khan*, 508 F.3d 413, 417 (7th Cir. 2007) ("Rule 403 codifies the district court's broad discretion to control the admission of evidence."). According to Defendant, "[t]he obvious purpose" of the evidence "is to incite jury passion and prejudice by suggesting that Wyeth grievously injured thousands of women each

year.” (R. 344, Def.’s Mem. at 13.) Defendant continues that the underlying data “is far too general to support causation, and therefore, such numbers are likely to confuse and mislead the jury unfairly to Wyeth’s prejudice.” (*Id.* at 13-14 (further stating that “[t]o mitigate the prejudice, Wyeth would need to present complicated testimony about the origins, statistical validity, and significance of the calculations and data in question, thereby lengthening the trial unnecessarily”).)

Defendant’s argument, however, relies on a misapplication of the legal standard under Rule 403. As the Seventh Circuit has stated, “the probative value of the evidence must not merely be outweighed, it must be substantially outweighed, by its negative consequences, to be excludable.” *Mattenson v. Baxter Healthcare Corp.*, 438 F.3d 763, 771 (7th Cir. 2006); *see also United States v. Dennis*, 497 F.3d 765, 769 (7th Cir. 2007) (“Rule 403 was never intended to exclude relevant evidence simply because it is detrimental to one party’s case; rather, the relevant inquiry is whether any unfair prejudice from the evidence substantially outweighs its probative value.”) (internal citation and quotation marks omitted). In its opening brief, Defendant makes no argument that the probative value of the evidence is “substantially” outweighed by the Rule 403 considerations.<sup>5</sup> The motion is therefore denied.

#### **IV. Due Process**

Finally, Defendant argues that the evidence is inadmissible under the Due Process Clause “as support for Plaintiff’s claim for punitive damages.” (R. 344, Def.’s Mem. at 14.) *See Philip*

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<sup>5</sup>After Plaintiff pointed out this defect, Defendant advanced a new argument in reply: that the probative value of the evidence is “substantially outweighed by the danger of unfair prejudice.” (R. 375, Def.’s Reply at 8.) The Court will not consider, for purposes of this motion, arguments raised for the first time in reply.

*Morris USA v. Williams*, 549 U.S. 346, 356-57, 127 S. Ct. 1057, 166 L. Ed. 2d 940 (2007) (“Evidence of actual harm to nonparties can help to show that the conduct that harmed the plaintiff also posed a substantial risk of harm to the general public, and so was particularly reprehensible[, but ] . . . jury may not go further than this and use a punitive damages verdict to punish a defendant directly on account of harms it is alleged to have visited on nonparties”);

*State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408, 416, 123 S. Ct. 408, 155 L. Ed. 2d 585 (2003) (identifying certain constitutional “guideposts” – including reprehensibility – that limit the authority of courts to impose punitive damages). Plaintiff responds that the evidence is “relevant to the issue of reprehensibility” under *Phillip Morris*. (R. 365, Pl.’s Resp. at 8-9.) Defendant disagrees in its reply. (R. 375, Def.’s Reply at 10 (“Dr. Colditz’s calculations are not relevant to the issue of reprehensibility.”).)

Neither party, however, addresses whether the evidence at issue has “any tendency to make . . . more or less probable” any fact that is “of consequence” to the question of punitive damages. Fed. R. Evid. 401. The constitutional limits stemming from the due process clause cannot answer that question in the first instance; only the substantive law of Illinois can. *See Huddleston v. United States*, 485 U.S. 681, 108 S. Ct. 1496, 99 L. Ed. 2d 771 (1988) (“Relevancy is not an inherent characteristic of any item of evidence but exists only as a relation between an item of evidence and a matter properly provable in the case.”) (internal citation and quotation marks omitted). “In a diversity action such as this one, state law governs the factors a jury may consider in determining the amount of punitive damages, while federal law governs the district court’s review of the jury award and appellate review of the district court’s decision.” *Kempner Mobile Elecs., Inc. v. Southwestern Bell Mobile Sys.*, 428 F.3d 706, 714 (7th Cir.

2005).

Under Illinois law, a jury may award punitive damages if “the defendant has acted willfully, or with such gross negligence as to indicate a wanton disregard of the rights of others.” *Blount v. Stroud*, 395 Ill. App. 3d 8, 20, 333 Ill. Dec. 845, 915 N.E.2d 925 (2009) (citing *Kelsay v. Motorola, Inc.*, 74 Ill.2d 172, 186, 23 Ill. Dec. 559, 384 N.E.2d 353 (1978)). Following *State Farm*, the Illinois Supreme Court embraced reprehensibility as a relevant factor and further held, relying on *State Farm*, that:

Courts are instructed to consider the following factors when determining reprehensibility: (1) whether the harm caused was physical as opposed to economic; (2) whether the tortious conduct evinced an indifference to or a reckless disregard for the health and safety of others; (3) whether the target of the conduct was financially vulnerable; (4) whether the conduct involved repeated actions or was an isolated incident; and (5) whether the harm was the result of intentional malice, trickery, or deceit, or mere accident.

*Int’l. Union of Oper. Eng’rs, Local 150 v. Lowe Excavating Co.*, 225 Ill.2d 456, 470, 312 Ill. Dec. 238, 870 N.E.2d 303 (2006).

The parties have not attempted to explain how the evidence at issue “has any tendency to make” any of these factors “more or less probable.” Fed. R. Evid. 401. Nor is it immediately clear that the evidence has any such tendency, or that there is a sufficient evidentiary basis for the jury to so find. *See* Fed. R. Evid. 104(b). Relevance may well depend on the existence of other facts, including the extent of Defendant’s knowledge about the actual risk of Prempro during the relevant time period. *See id.* (“When the relevance of evidence depends on whether a fact exists, proof must be introduced sufficient to support a finding that the fact does exist.”). For all of these reasons, the Court denies the motion without prejudice. The Court need not reach the due process question unless the evidence is relevant under Rule 401 in

the first instance. If Plaintiff can show that it is, then Defendant may renew its argument at trial based on the purpose for which Plaintiff seeks to offer the evidence. *Cf. Williams v. Pugh*, No. 10-2700, 2012 WL 2899403, at \*3 (7th Cir. July 17, 2012) (observing that whether admission of certain evidence violates the constitution depends on the purpose for which it was offered); *Stephens v. Miller*, 13 F.3d 998, 1009 (7th Cir. 1994) (“The analysis therefore depends entirely on the purpose for which the testimony was offered.”) (Rover, J., concurring).

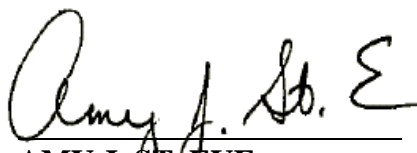
That said, as discussed above (*see supra* § II.A), the evidence at minimum is relevant to issues other than punitive damages. The Court will appropriately instruct the jury on the legal standard governing an award of punitive damages, including the permissible purposes for which the jury may consider evidence. *See Schutter v. Wyeth*, No. 05-CV-998 (N.D. Ill. Feb. 24, 2012) (stating in response to a due process challenge that “careful jury instructions would seem to mitigate any risk to Wyeth”) (citing *Philip Morris*, 549 U.S. at 354-56 (“[I]t is constitutionally important for a court to provide assurance that the jury will ask the right question, not the wrong one.”)). The parties should meet and confer and include appropriate jury instructions on the issue of punitive damages in their joint proposed jury instructions.

### CONCLUSION

The Court denies Defendant’s motion as described herein.

Dated: August 31, 2012

ENTERED

  
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AMY J. ST. EVE  
United States District Judge