

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

HAROLD H. SCHARFF,)	
administrator of the estate of)	
Kathleen Scharff,)	
)	
Plaintiff,)	
v.)	CASE NO. 2:10-CV-220-WKW [WO]
)	
WYETH, <i>et al.</i> ,)	
)	
Defendants.)	

MEMORANDUM OPINION AND ORDER

On September 19, 2011, the court entered a Memorandum Opinion and Order (Doc. # 238 (the “Order”)) granting Defendants’ (collectively “Wyeth”) motion for summary judgment on Scharff’s remaining wantonness claim.¹ The Order disposed of the only remaining claim, and three independent reasons for granting summary judgment were provided. First, Plaintiff failed to meet the elements for his wantonness claim because there was no disputed material fact that would show it was likely or probable that a patient taking Prempro would develop breast cancer. Second, even assuming that Plaintiff could establish that it is likely or probable that

¹ On August 2, 2011, the court entered an order (Doc. # 223) partially granting Wyeth’s motion for summary judgment. In that order, the court granted summary judgment for Wyeth on negligence, AEMLD, breach of express warranty, fraud, and civil conspiracy claims. (Doc. # 223 at 18, 48.) The ruling was based upon grounds other than a lack of causation, and ruling was reserved on Wyeth’s causation arguments. (Doc. # 223 at 48.)

taking Prempro would cause breast cancer, Plaintiff did not produce sufficient evidence to establish that a reasonable jury could find that Wyeth had knowledge of that probability. Finally, the court determined that Wyeth could not be liable under a theory of wanton failure to warn when the label on the product Mrs. Scharff took specifically warned of the increased risk of breast cancer.

Within the time frame permitted by law, Mr. Scharff filed a motion for reconsideration pursuant to Rule 59(e) of the Federal Rules of Civil Procedure. (Doc. # 240.) Wyeth responded (Doc. # 245), and Mr. Scharff replied (Doc. # 246). The motion was further supplemented with a recent Alabama Supreme Court decision (Doc. # 249) to which Wyeth responded (Doc. # 255). This motion has been fully briefed and is ready for adjudication. Both sides have done a commendable job of briefing a complex question of law. For the following reasons, the Rule 59(e) motion for reconsideration is due to be denied.

I. STANDARD OF REVIEW²

A party moving the court to alter or amend its judgment pursuant to Rule 59(e) faces an extremely heavy burden. “[R]econsideration of a previous order is an extraordinary remedy to be employed sparingly.” *Sussman v. Salem, Saxon &*

² Discussion of jurisdiction, venue and the facts are omitted, as they have been sufficiently explicated in the prior orders of the court. (See Doc. # 223 at 2-5; Doc. # 238 at 2-38).

Nielsen, P.A., 153 F.R.D. 689, 694 (M.D. Fla. 1994). Rule 59(e) was not constructed “to give the moving party another bite at the apple” *Mincey v. Head*, 206 F.3d 1106, 1137 n.69 (11th Cir. 2000) (internal quotation marks omitted). A party “cannot use a Rule 59(e) motion to relitigate old matters, raise argument or present evidence that could have been raised prior to the entry of judgment.” *Michael Linet, Inc. v. Village of Wellington, Fla.*, 408 F.3d 757, 763 (11th Cir. 2005). Instead, the movant must demonstrate that one of three grounds for the motion exists: “(1) an intervening change in controlling law; (2) the availability of new evidence; and (3) the need to correct clear error or manifest injustice.” *Saenzpardo v. United Framing Constr. Co.*, No. 10-cv-00049, 2011 WL 5155094, at *1 (S.D. Ala. Oct. 31, 2011) (citing *Sussman*, 153 F.R.D. at 694).

II. DISCUSSION

Mr. Scharff does not point to an intervening change in the controlling law, the availability of new evidence, or manifest injustice as grounds for the Rule 59(e) motion. Instead, he argues that it was clear error to grant summary judgment on wantonness under each of the three alternative theories relied upon in the Order. Mr. Scharff’s Rule 59(e) motion must show that there was clear error in all three of the findings. *See Saenzpardo*, 2011 WL 5155094, at *1 (citing *Sussman*, 153 F.R.D. at 694).

The discussion proceeds in three parts, to mirror the three arguments put forth by Mr. Scharff. Part A discusses the “likely or probable” requirement for the wanton failure to warn claim in order to determine if it was clear error to find that the evidence presented by Mr. Scharff was insufficient to create a genuine issue of material fact on the wantonness claim. In Part B, the court addresses whether there was clear error in the evaluation of evidence on the element of Wyeth’s knowledge. In Part C, the discussion considers whether it was clear error to determine that Wyeth could not be liable under a theory of wanton failure to warn because the labeling on the product Mrs. Scharff took specifically warned of the increased risk of breast cancer. As explained below, Mr. Scharff’s arguments fall short of meeting the clear error standard on all three of these points, and the motion for reconsideration is due to be denied.

A. The Meaning of “Likely or Probable” for Alabama Wantonness Claims

Mark Twain crystalized the key issue in this action by writing, over a hundred years ago, that “[f]igures often beguile me, particularly when I have the arranging of them myself; in which case the remark attributed to Disraeli would often apply with justice and force: ‘[t]here are three kinds of lies: lies, damned lies, and statistics.’”³

³ Mark Twain, Chapters from My Autobiography, published in the North American Review (1906-09-07) available at <http://www.gutenberg.org/files/19987/19987.txt>.

Indeed, the issues surrounding the interpretation of the numerous scientific studies and extensive statistical evidence presented in this case threaten to drown one with information at the expense of real knowledge. Because of the volume of evidence submitted, a superficial view of this action may suggest that it should be allowed to go forward to a jury, because where there is this much smoke, there should be a fire. The evidence, however, can only go to a jury if it creates a genuine issue of material fact. The elements of an Alabama wantonness claim provide the context to make sense of the daunting mountain of evidence generated by the parties. Those standards determine how the fact-finder must sift the evidence. Only those facts that would meet the requirements of a wantonness claim, and not some other variety of claim, like negligence or products liability, can proceed to the jury.⁴

The summary judgment standard requires the court to determine if the evidence, as a matter of law and in the light most favorable to the non-moving party, is sufficient to go to a jury. Mr. Scharff repeatedly argues that the court usurped the role of the fact-finder. However, at the summary judgment stage, the court must serve as a gatekeeper. In order to understand which characterization is correct, the full

⁴ This is a key point to consider: the narrowness of the issue. While the voluminous evidence might have been able to support a theory of negligence, or some products liability claim, the only claim that survived the first summary judgment motion (Doc. # 223) was a wantonness claim. Square pegs cannot fit a round hole, and evidence that may have supported one of Mr. Scharff's other claims cannot simply be substituted into a separate claim with its own distinct rules and parameters.

context of a wantonness claim must be examined. The evaluation of this evidence mainly depends on the definition of “likely or probable” under Alabama law. That definition has implications for whether Mr. Scharff’s studies create a material issue of fact for the incidences of harm, and to Wyeth’s knowledge of that harm. For the following reasons, there was no clear error of law in finding that the evidence did not create a material issue of fact.

1. *The legal standards of wantonness*

Wantonness is “the conscious doing of some act or the omission of some duty while knowing of the existing conditions and being conscious that, from doing or omitting to do an act, injury will likely or probably result.” *Ex parte Essary*, 992 So. 2d 5, 9 (Ala. 2007) (citing *Bozeman v. Central Bank of the South*, 646 So. 2d 601 (Ala. 1994)). The standard of likely or probable injury is essential in evaluating wantonness claims. Each distinct act or omission must be likely or probable to result in injury.

Mr. Scharff’s argument fails to give proper credit to the requirement that injury be likely or probable. Throughout Mr. Scharff’s briefing, the argument is made that *any* chance of injury is sufficient for wantonness under Alabama law. In the words of Mr. Scharff: “Under Alabama law, a defendant is guilty of wantonness where the defendant acts or fails to act with knowledge that any person could be injured as a

result of the defendants' conduct.” (Doc. # 246 at 10.) Mr. Scharff goes on to argue that “under Alabama law, wantonness is engaging in conduct that the defendant knew or should have known could cause injury and injury was in fact caused, regardless of whether the odds of injury were 1 in 10 or 1 in 10,000.” (Doc. # 246 at 10.) Fundamentally, Mr. Scharff’s position is that any known chance of injury is sufficient for wanton conduct. This is simply not the law, as it would conflate wanton conduct with mere negligence. Alabama law draws a sharp contrast between these concepts.

Wantonness is a tort concept distinct from negligence, “not merely a higher degree of culpability than negligence.” *Ex parte Capstone*, No. 1090966, 2012 WL 887497, at *6 (Ala. Mar. 16, 2012) (internal quotation marks and citation omitted). “[N]egligence and wantonness are qualitatively different tort concepts.” *Id.*; *Ferguson v. Baptist Health Sys., Inc.*, 910 So. 2d 85, 92 (Ala. 2005). Wantonness involves an “act done or omitted with knowledge of the *probable consequence* and with reckless disregard of such consequence.” *Ex parte Capstone*, 2012 WL 887497 at *6 (emphasis altered).

For a negligence claim, the duty element is satisfied when someone “intentionally do[es] an act with knowledge that it contains a risk of harm to others.” Restatement (Second) of Torts § 500 (comment g) (cited in *Ex parte Capstone*, 2012 WL 887497 at *7 n.4). For a tortfeasor “to be reckless, [he] must recognize that his

conduct involves a risk substantially greater in amount than that which is necessary to make his conduct negligent.” *Id.* “The difference between reckless misconduct and conduct involving only such a quantum of risk as is necessary to make it negligent is a difference in the degree of the risk, but this difference of degree is so marked as to amount substantially to a difference in kind.” *Id.*⁵

The Alabama Supreme Court has found that “the two concepts [of negligence and wantonness] are as ‘unmixable as oil and water.’” *Lynn Strickland Sales & Serv., Inc. v. Aero-Lane Fabricators, Inc.*, 510 So. 2d 142, 146 (Ala. 1987) (overruled on other grounds in *Alfa Mut. Ins. Co. v. Roush*, 723 So. 2d 1250, 1256 (Ala. 1998)). “[Wanton misconduct] differ[s] in quality rather than in degree from ordinary lack of care.” *Prosser & Keeton on the Law of Torts* 212 (5th ed. 1984) (cited in *Lynn Strickland*, 510 So. 2d at 146). Wanton conduct is equivalent in law to intentional

⁵ The difference in the degree of risk necessary for wantonness was also emphasized by the concurring justices in *Ex parte Capstone*. 2011 WL 2164027, at *14 (“It is enough [for wantonness] that [the defendant] realizes or, from the facts which he knows, should realize that there is a *strong probability* that harm may result, even though he hopes or even expects that his conduct will prove harmless.”) (Murdock, J., concurring specially) (quoting Restatement (Second) of Torts § 500 (1965) (comment f)); *id.* (“[R]eckless misconduct results when a person, with no intent to cause harm, intentionally performs an act so unreasonable and dangerous that he or she knows or should know it is *highly probable* that harm will result.”) (Murdock, J., concurring specially) (quoting 57A Am. Jur. 2d Negligence § 276 (2004)) (emphasis added); *id.* at *15 (“[T]he defendant who acts in the belief or consciousness that the act is causing *appreciable risk of harm* to another may be negligent, and *if the risk is great* the conduct may be characterized as reckless or wanton”) (Murdock, J., concurring specially) (quoting W. Page Keeton *et al.*, *Prosser & Keeton on the Law of Torts* § 8, p. 36 (4th ed. 1984)) (emphasis changed); *see also id.* at *16 (Main, J., concurring specially).

conduct. *McKenzie v. Killian*, 887 So. 2d 861, 887 (Ala. 2004) (overruled on other grounds in *Ex parte Capstone*, 2012 WL 887497). Yet, wanton conduct also is distinct from intentional conduct. *See Ex parte Capstone*, 2012 WL 887497, at *5.

“To constitute willful or intentional injury there must be a knowledge of the danger accompanied with a design or purpose to inflict injury, whether the act be one of commission or omission, while in wantonness this design or purpose may be absent, and the act done or omitted with knowledge of the probable consequence, and with reckless disregard of such consequence.” *Central of Ga. Ry. v. Corbitt*, 218 Ala. 410, 411(1928) (internal quotations omitted); *see also Ex parte Capstone*, 2012 WL 887497, at *6. These statements of law demonstrate that Mr. Scharff’s interpretation of wantonness lacks the stringent elements that distinguish wanton conduct from negligent conduct.

2. Toole’s standard for likely or probable

Mr. Scharff challenges the conclusion that the court is bound by the decision in *Toole v. McClintock*, 999 F.2d 1430 (11th Cir. 1993), that an incidence rate of one percent or less is not likely or probable for purposes of wantonness. In *Toole*, the plaintiff’s breast augmentation surgery led to her developing scar tissue around the implant. 999 F.2d at 1432. In a subsequent procedure, she underwent a “closed capsulotomy,” where the surgeon manually compressed the affected breast to rupture

the scar tissue. This procedure ruptured her breast implants, causing serious injuries. The jury awarded plaintiff punitive damages on her wantonness claim. *Id.* at 1431. The Eleventh Circuit reversed, holding that the award could not stand because the evidence showed that the actual incidence of implant ruptures was slightly less than one percent. *Id.* While implant rupture was a serious injury, the court recognized it was not a “likely” event as required to find wantonness under Alabama law. In reversing an award of punitive damages by finding that evidence establishing a one percent chance of individual injury was not likely or probable, the *Toole* court provided guidance on wantonness claims. Anything less than one percent is not likely or probable by the reasoning of *Toole*. That court did not have to reach, and thus, did not decide, at what point beyond a one percent chance of injury that injury would qualify as likely or probable. Thus, one percent becomes the marker, or threshold, between a settled question that a risk of injury is not likely or probable as a matter of law, and a debatable question of whether the risk of injury is likely or probable.

The Eleventh Circuit also noted that the pertinent statistic for the wantonness risk analysis is the *likelihood of the actual injury suffered by the plaintiff*, not the overall rate of complications associated with the defendant’s product. *See id.* at 1435

n.13. In other words, the injury risk would be focused on the likelihood of actual injury to a particular plaintiff.

The Alabama Supreme Court has never explicitly quantified the threshold for finding a rate of injury to be likely or probable. Instead, in every case cited to this court, the supreme court has either held the evidence, as a whole and without reference to a specific threshold number, to be sufficient or insufficient. *See, e.g., McMahon v. Yamaha Motor Corp.*, No. 1100679, 2012 WL 677548, at *4 (Ala. Mar. 2, 2012).⁶ If the parties had found a controlling Alabama case that establishes a different threshold than *Toole*, it was not cited to the court, and the court has not found it.⁷

⁶ Mr. Scharff argues for the inference that the result in *McMahon*, along with an incidence rate cited by Yamaha in its brief to the state court (claiming a risk of injury that was only 0.08% for leg injuries), is a rejection of the standard in *Toole*. (Doc. # 252.) The *McMahon* court did not address this argument in its opinion. *See McMahon*, 2012 WL 677548, at *4. Instead, the *McMahon* court focused on defendants' own internal email, that stated that accidents "would likely be of the rollover variety" and would involve "the specific risk of arm/wrist and leg/ankle injuries," of the same kind suffered by the plaintiff in *McMahon*. Nothing in that opinion supports that the incidence rate argument was considered in the same way that it has been argued here, and there is nothing in the opinion itself that would demonstrate a rejection, explicit or implicit, of the *Toole* decision.

⁷ Mr. Scharff cites a number of cases involving traffic accidents in which wantonness claims were allowed to proceed to the jury. (*See* Doc. # 246 at 7 (citing *Monroe v. Brown*, 307 F. Supp. 2d 1268 (M.D. Ala. 2004); *Hornady Truck Line, Inc. v. Meadows*, 847 So. 2d 908 (Ala. 2002); *Henderson v. City of Mobile*, 611 So. 2d 249 (Ala. 1992); *Valley Building & Supply, Inc. v. Lombus*, 590 So. 2d 142 (Ala. 1991)). These cases involved driving behavior that was highly dangerous for the conditions, or illegal, such as failing to signal other cars at night while turning onto a busy highway, attempting to run a yellow light, or vastly exceeding the speed limit. These cases are distinguishable because the accidents that followed the dangerous behavior were the

Mr. Scharff argues that the court should defer to the Alabama Supreme Court's silence on the definition of likely or probable, rather than the Eleventh Circuit's explicit quantification of that standard. The suggestion that the Alabama Supreme Court's silence is meaningful is a stretch too far to ignore the governing precedent directly before the court. *Toole* is even more analogous to the present case, since that court's evaluation of the wantonness standards occurs in the context of liability for complications with the use of medical products. Mr. Scharff's citations to state cases where the courts apply wantonness in vastly different factual situations are not persuasive, especially since those cases often involve mere characterizations of the full record on appeal without distinguishing between the controlling evidence.

Nothing has been offered to the court in argument or analysis that casts doubt on the Eleventh Circuit's threshold established in *Toole*. "[D]istrict courts are bound by their governing appellate court's construction of state law unless later state court decisions indicate that the Court of Appeals' earlier prediction of state law was in error." *Estate of Miller ex rel. Miller v. Thrifty Rent-A-Car Sys., Inc.*, 609 F. Supp. 2d

kinds that the rules of the road are designed to prevent. These rules also serve as warnings about the risks of driving in that manner, thereby imparting knowledge to the driver of the risks involved in the conduct. Thus, the defendants were acting wantonly by breaking the rules of the road, since the violations could support a conclusion that the defendants knowingly engaged in an act that was likely or probable to cause injury. Even in the light most favorable to Mr. Scharff, the studies he cites do not rise to the level of well known rules for safe conduct on the roads. The analogy Mr. Scharff attempts to draw is distinguishable.

1235, 1249-50 (M.D. Fla. 2009) (internal quotation marks omitted). The Eleventh Circuit is obviously free to overrule this court, and the Alabama Supreme Court is likewise free to change or clarify state law governing the decisions of this court, but a district court cannot overrule either body when it comes to questions of Alabama law. Therefore, it was not clear error to follow the quantitative precedent of the circuit.

3. *Mr. Scharff's interpretation of "likely or probable" does not square with Alabama law*

Mr. Scharff characterizes as wantonness “a jury question where there is evidence that the defendant was aware that its conduct could result in an injury to another.” (Doc. # 241 at 10.) Considering that this definition leaves out the essential language that wantonness requires the injury to be likely or probable, this cannot be the standard for wantonness under Alabama law. “Wantonness is the doing of some act or omission with reckless indifference to the knowledge that such act or omission will likely or probably result in injury.” *Bozeman v. Central Bank of the South*, 646 So. 2d 601, 603 (Ala. 1994) (citing *Bishop v. Poore*, 475 So. 2d 486, 487 (Ala. 1985)); see also *Anderson v. Moore Coal Co.*, 567 So. 2d 1314, 1317 (Ala. 1990).

In Mr. Scharff's reply brief, he clarifies his position by arguing that "Alabama law does not and has never imposed any sort of qualifying threshold of actual injury in order to sustain a claim for wantonness." (Doc. # 246 at 4.) While there is no requirement for an actual number of injuries, Alabama law does require that the risk, or rate of that injury, be likely or probable. That itself is a qualification.

Perhaps Mr. Scharff's most compelling argument is that by the court's own analysis, the Colditz study, viewed in the light most favorable to Mr. Scharff, would have put Wyeth on notice that 4,320 women per year would develop breast cancer due to the use of E+P. (Doc. # 246 at 15.) Mr. Scharff argues that the net takeaway of all the studies from 1976 to 1995 means that "Wyeth knew or should have known that as many as 86,400 women had developed breast cancer due to the use of E+P." (Doc. # 246 at 16.) This statistic is seemingly reached by considering the full range of the millions of women who use or used E+P treatments, and then applying the relative risk statistic to this pool to argue that those cases can be linked to E+P usage. The conclusion Mr. Scharff wants the court to reach is that if there are going to be injuries, especially this many, there must be wantonness. This is a troubling notion, and possibly a correct one. If there is any association or risk of using E+P with developing invasive breast cancer, then there must come a point, when in a

sufficiently large group of users, some individual, no matter how marginal her risk, would suffer the unfortunate event of cancer.⁸ In a very large group, this might be a large number of people. While this may be a tragic reality, whether this reality is an actionable claim of wantonness is a different matter. It is not enough that a multitude of acts could cause injury, but rather a question of whether a specific act is likely or probable to cause injury.

Mr. Scharff's argument regarding the studies is insufficient to demonstrate wantonness because it fails to individualize this risk. When the individual risk for each woman is calculated, it is not a likely or probable event. For each of these women in the Colditz study, the court found that the relative risk⁹ of breast cancer of

⁸ This may, at bottom, simply be an exercise in drawing a line somewhere in the sand on the liability beachhead. But Mr. Scharff's insistence that it does not matter if the risk is 1 in 10, or 1 in 10,000, misses the point, as discussed earlier.

⁹ Relative risk is a different type of statistic than an incidence rate. It serves as a measure of a relationship and provides an indication of how likely it is that a phenomenon is causing a result. In this context an incidence rate expresses the risk that a member of the population will develop the disease within a specified period of time. Relative risk is a comparison between the incidence rate of an exposed population with a control population. It is a ratio, *and not a percentage likelihood*. A relative risk of 1 suggests that there is no relation between the phenomenon and result. Higher numbers indicate a stronger causal relationship. Thus, the relative risk cited by Mr. Scharff's studies fails to independently illuminate what the individual likelihood of risk is, because it is only a measure of the incidences of breast cancer the study can attribute to the use of E+P. Distinguishing between the different kinds of statistics explains some of the confusion over whether the *Toole* threshold is satisfied. Even if there is a strong relative risk, that just means that more cases of cancer can be associated with E+P usage, but it does not say how likely cancer is overall from using E+P.

1.35 for E+P consumption for five years or longer is insufficient, given the background risk of 1.26 and actual incidence of breast cancer in the general post-menopausal population, to create a factual dispute on likely or probable injury or Wyeth's knowledge of such. (*See* Doc. # 238 at 52.) This is because the additional relative risk, as a method for indicating causation, could not account for enough attributable actual risk to the population from taking E+P to pass the likely or probable threshold.

The Colditz study cited by Mr. Scharff identified 1,935 cases of invasive breast cancer among 69,586 post-menopausal women. 963 cases involved women who were taking or had taken some form of hormone therapy.¹⁰ If every case of breast cancer among that group could be attributed to E+P usage, it would constitute a 1.38% chance of developing breast cancer. But the relative risk means that even in the light most favorable to Mr. Scharff, not every case of breast cancer examined by the study among E+P users could be attributed to the use of E+P. In fact, fewer than half could

¹⁰ Conclusions about the subject's likelihood of contracting breast cancer based on length of time over which the subject received hormone therapy were presented in the study, and considered in the court's previous opinion. (*See* Doc. # 238 at 52.) In short, the less time spent on E+P, the fewer cases of breast cancer that could be attributed to the drug. The calculations used in this part to illustrate the flaws in the Colditz study are even more generous to Mr. Scharff, because they do not factor in the different lengths of time the subjects potentially used the drug. This is all to say that even the rough calculations do not favor Mr. Scharff's position.

be attributed to E+P usage.¹¹ Therefore, each individual woman's risk (her incidence rate) attributed in that study fell below the one percent threshold established in *Toole*. Mr. Scharff fails to meet the threshold on individual risk. While some studies did show an increase in relative risk, an increase or change in the relative risk alone is not enough to demonstrate that a risk is likely or probable. The bottom line is still the actual risk attributable to the agent; relative risk is only part of that calculation. Mr. Scharff was required to raise a genuine issue of material fact that the individual risk of breast cancer attributable to taking E+P was likely or probable to result in cancer. The studies do not support that burden.

Instead, Mr. Scharff argues that the evidence showed that some individuals taking Prempro would certainly be harmed, so harm, in general, was a likely or probable result of Wyeth's actions, even if no particular person was particularly likely to be harmed. Beyond the insufficiency of this argument in distinguishing between general occurrence and particularized risk, the adoption of Mr. Scharff's argument would lead to the following fallacy: It would turn wantonness into a form of negligence *per se*.

¹¹ A relative risk of 2.0 implies a 50% likelihood that an exposed individual's disease was caused by the agent. The lower relative risk in this study reveals that some number less than half of the additional cases could be attributed to E+P. As attributing even half of those cases would still fall below an actual risk of 1%, the study is insufficient, even in the light most favorable to Mr. Scharff, to support wantonness.

When acts are considered in the aggregate, even a low amount of risk for each particular action will result in harm to someone. If there is any risk whatsoever, over enough time and repetitions, an act will result in harm. But, the existence of some risk of harm to the general population is insufficient to demonstrate *for a specific plaintiff* that the defendant's specific act was likely or probable to result in injury. The only practical way to approach the act in a wantonness case is not to consider all acts in aggregate, but the specific act taken toward the specific plaintiff. Wyeth is alleged to have acted wantonly, not in bringing the drug to market, but in providing Prempro to Mrs. Scharff. It is her particular risk that matters in the analysis, and not whether strangers to this action were harmed. Fidelity to the standards that define wantonness requires that individual, particularized injury be likely or probable in order to constitute a claim of wantonness.

Mr. Scharff's argument would turn wantonness into the ultimate form of products liability. Any sufficiently large dissemination of any product that has some known inherent risk of harm *no matter how small* would qualify as wantonness under Mr. Scharff's argument. It is a tautology that once the marketplace gets large enough, any risk, no matter how small, becomes an actuarial certainty. If a fast food restaurant sold hamburgers, each with a one in a million chance of giving a customer

food poisoning, Mr. Scharff's argument would brand it wanton conduct to sell the millionth burger, much less any amount beyond that. The statistics would charge the seller with knowledge that someone, somewhere, was eventually going to be hurt. The same would logically apply for injuries from hammers, nails, cars, medicine, televisions, or any other product that could cause some kind of conceivable harm. With sufficient market exposure, even the safest product, or the safest uses of some item, would approach a certainty of some injury occurring, even if no injury is likely or probable with a distinct use or sale.

Personal conduct would fall afoul of this proposed interpretation as well. Any behavior that has any risk, as almost all behavior does, would become wanton if repeated often enough until the harm occurs. Since all drivers have some risk of getting into an accident, all would be wanton under this view if they plan to drive more than a few times in their life. This is all a problem for Mr. Scharff because wantonness is not a strict liability tort. It is nothing of the sort. If wantonness is not negligence, if it is something beyond that, it is certainly not a more intense version of negligence *per se*. Mr. Scharff's arguments cannot square with the robust standards of a wantonness claim, and are not persuasive.

In light of the elements of a wantonness claim, the nature of a wantonness cause of action, and the controlling law, Mr. Scharff has not met his burden of establishing that the court's decision on the likely or probable requirement in the motion for summary judgment was clearly erroneous, and his Rule 59(e) motion is due to be denied on this ground.

B. Sufficiency of the evidence on the element of Wyeth's knowledge

Mr. Scharff next argues that the court impermissibly weighed the evidence when it evaluated each study and the extensive record offered by Plaintiff to see if there was some evidence that would be sufficient to create a jury issue on Wyeth's knowledge of the dangers of E+P. On summary judgment, the court is required to evaluate the evidence, not to see if it actually proves the claim, but to see if a reasonable jury could find that the evidence proves the claim asserted. If this inquiry were satisfied merely by forceful rhetoric and repetition of arguments in briefs, then this case would be moving forward to trial.

Mr. Scharff does not cite any new controlling case law or newly discovered evidence that would serve as a Rule 59(e) challenge to the Court's judgment. Instead, Mr. Scharff argues it was clear error to find that Wyeth did not, as a matter of law, have knowledge of the risk of E+P, by evaluating the studies to determine if they

could provide a sufficient basis to impute knowledge to Wyeth of a likely or probable harm from Prempro.

“The ‘knowledge’ of the defendant is ‘the sine qua non of wantonness.’” *McMahon*, 2012 WL 677548, at *4; *Norris v. City of Montgomery*, 821 So. 2d 149, 156 n.9 (Ala. 2001). This inquiry is linked to the first question, of whether it was established that Prempro was likely or probable to cause breast cancer. The knowledge element is akin to the intent requirement for an intentional tort. In this action, it is inseparable from the evidence related to the causation of the likely or probable standard. For a wantonness claim, it is necessary not only to show that the harm was likely or probable, but that the defendant had knowledge of this risk as well at the time of its act or omission.

In his attempt to demonstrate knowledge, Mr. Scharff points to each of the studies in the medical literature that was supposed to have made Wyeth aware that Prempro and E+P treatments cause breast cancer. However, none of these studies passed the critical threshold of demonstrating, with reliable certainty or strength, a likely or probable breast cancer risk with E+P. (*See Doc. # 238 at 47–53.*) The difference between a real, or “appreciable,” risk of injury and a likely or probable risk

of injury is one of the key differences between a negligence claim and a wantonness claim. (*See* Doc. # 238 Part II.A.; *supra*, Part II.A.)

Mr. Scharff's argument that the court made impermissible inferences or credibility determinations about the evidence falls short of the mark. In fact, the court took all of Plaintiff's evidence at face value, assuming that the cited studies were accurate, subject to the *self-reported* caveats about their statistical significance. In other words, when a study expressed doubt about its own findings, the court must consider that doubt and its impact on what knowledge could be taken from it. Even in the light most favorable to Plaintiff, none of the cited studies demonstrated a sufficiently strong connection between invasive breast cancer and E+P treatment to reach a threshold of a 1% chance of individualized occurrence.

Mr. Scharff has not convincingly argued that any of the contested studies actually demonstrate that breast cancer was a likely or probable result of undergoing E+P treatment. Even the most favorable study demonstrates only a 0.42% increased incidence rate of breast cancer. The studies certainly raise questions of some additional risk. However, as previously explained, wantonness is not a mere additional risk, but indifference to a likely or probable risk. The evidence provided demonstrates concerns of a real risk (*i.e.*, not imaginary or uncertain risk), but

because the individual studies fail to demonstrate a risk that breaks the 1% threshold, it is not a risk that can rise to the level of making Wyeth aware that Prempro was likely or probable to cause breast cancer.

It is conceivable that the studies underreported the actual risk or occurrence of breast cancer with E+P usage. Hypothetically, even though Mr. Scharff did not prove with any study that breast cancer was a likely or probable event, other evidence (such as later studies of E+P) might have proven that cancer is a likely or probable result of using Prempro. But even if the studies were wrong or underplayed the risk, this evidence would still be insufficient to demonstrate wantonness, because the studies cited fail to carry enough force to create a jury issue that E+P usage causes cancer. Thus, the studies provide no basis for Wyeth to believe that cancer was a likely or probable result of E+P usage, even if the studies raised concerns. Concerns, risks, and potential correlations between Prempro and breast cancer do not equate with cancer being a likely or probable result of using E+P. Wyeth can only be charged with the knowledge that could be taken from the studies available to it at the times related to this suit. Mr. Scharff has not met his burden in establishing that the court's decision on the likely or probable requirement in the motion for summary judgment was clearly erroneous, and his Rule 59(e) motion is due to be denied on this ground.

C. Sufficiency of the Prempro warning on the risk of invasive breast cancer

Mr. Scharff does not argue that the actual warning provided by Wyeth¹² was insufficient. Instead, Mr. Scharff attacks Wyeth's conduct in opposing and responding to the studies, and in providing information to doctors that downplayed the risk. Under Alabama law, a *wanton* failure to warn claim focuses on whether the defendant "consciously and intentionally failed to give reasonable and adequate warnings with knowledge of, or reckless indifference to, the fact that the lack of warnings made [the plaintiff's] injury likely or probable." *Richards v. Michelin Tire Corp.*, 21 F.3d 1048, 1058 (11th Cir. 1994). "[T]he issue of punitive damages [on a wanton failure to warn theory] should not go to the jury when a manufacturer took

¹² Wyeth enclosed the following warning on its product that warned of the risk of the type of harm that eventually befell Mrs. Scharff:

Based on experience with estrogens and/or progestins:

1. Induction of malignant neoplasms

Breast cancer. Some studies have reported a moderately increased risk of breast cancer (relative risk of 1.3 to 2.0) in those women on estrogen replacement therapy taking higher doses, or in those taking lower doses for prolonged periods of time, especially in excess of 10 years. The majority of studies, however, have not shown an association in women who have ever used estrogen replacement therapy. The effect of added progestins on the risk of breast cancer is unknown, although a moderately increased risk in those taking combination estrogen & progestin therapy has been reported. Other studies have not shown this relationship.

While the effects of added progestins on the risk of breast cancer are also unknown, available epidemiologic evidence suggests that progestins do not reduce, and may enhance, the moderately increased breast cancer risk that has been reported with prolonged estrogen replacement therapy.

steps to warn plaintiff of the potential danger that injured him; those facts bar a finding that defendant was consciously indifferent.” *Toole*, 999 F.2d at 1436; *Richards*, 21 F.3d at 1059.

Toole prevents Mr. Scharff’s wanton failure to warn claim from surviving summary judgment. Even accepting Mr. Scharff’s argument and evidence that Wyeth engaged in an extreme disinformation campaign, which challenged the studies, muddied the waters with less reliable industry-funded studies, underplayed the risks with dear doctor letters, and engaged in suspicious attacks on the outside studies, these acts are not sufficient to overcome the warning requirement for wanton conduct. It is *undisputed* that Wyeth provided the following warning: “The effect of added progestins [to estrogen replacement therapy] on the risk of breast cancer is unknown, although a moderately increased risk [of breast cancer] in those taking combination estrogen/progestin therapy has been reported.” (Doc. # 245 at 13.) Further, Wyeth’s Prempro label referenced the relative risk associated with estrogens alone, of 1.3 to 2.0. Wyeth warned Dr. Reiland of the rate of risks that some studies had reported. The Prempro warning included a warning for breast cancer. It further warned Dr. Reiland that there was a potential for a relative risk of breast cancer greater than 1.3 to 2.0 with E+P therapy.

Under *Toole*, all that is required is a warning that does not evidence indifference toward safety. Mr. Scharff presents substantial evidence that the warnings could have been broader, stronger, or not tempered by contradictory information or caveats, and it is likely true that “[m]ore could have been done or said” by Wyeth. On these facts, however, “[Wyeth] did not exhibit indifference toward safety.” *Toole*, 999 F.2d at 1436. Accordingly, Wyeth did not act wantonly as a matter of law. Mr. Scharff’s Rule 59(e) motion has not demonstrated clear error on this ground.

III. CONCLUSION

For the forgoing reasons, it is ORDERED that Plaintiff’s Motion for Reconsideration (Doc. # 240) is DENIED.

DONE this 1st day of August, 2012.

/s/ W. Keith Watkins
CHIEF UNITED STATES DISTRICT JUDGE