IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF ALABAMA SOUTHERN DIVISION

ASHLEY BARNHILL,	)	
Plaintiff	)	
v.	)	CIVIL ACTION NO. 06-0282-CB-M
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD.,	)	
Defendants.	)	

ORDER

This matter is before the Court on a motion for summary judgment filed by Defendant Teva Pharmaceuticals USA, Inc. (Doc. 173.) Upon careful consideration of Defendant's motion and supporting briefs, Plaintiffs' briefs in opposition and all evidence relevant to the issues raised, the Court finds that Defendant is entitled to summary judgment for the reasons set forth below. [1]

FINDINGS OF FACT

On January 27, 1998 Dr. Dina Jaalouk prescribed the antibiotic Keflex® to Plaintiff Ashley Barnhill for the treatment of streptococcal pharyngitis (strep throat). Plaintiff's mother filled the prescription[2] for a cephalexin product with National Drug Code (NDC) number 0093-3147-01. This NDC number is associated with the Abbreviated New Drug Application (ANDA) No. 62-702 held by Teva USA, and with Teva USA's 500 mg cephalexin capsules manufactured

[1] Plaintiff's motion to strike Defendant's designation of expert witnesses (doc. 160) and Defendant's motion for oral argument (doc. 190) are **denied**.

[2] Plaintiff was twelve years old at the time.

under this ANDA.[3] Simply put, Plaintiff's Keflex® prescription was filled with cephalexin, a generic substitute. For the last four decades cephalexin has been one of the most widely prescribed antibiotics worldwide and is extremely beneficial in the treatment of bacterial infections.

Plaintiff began taking cephalexin on January 27, 1998 and continued to take it for seven days. Plaintiff stopped taking cephalexin on February 2, 1998, but she ingested additional cephalexin (left over from the January 27th prescription) during the first week of March. Keflex® had been prescribed for Plaintiff on three occasions prior to January 1998, although there is no evidence that those prescriptions were filled or that Plaintiff actually took Keflex® or cephalexin any time prior to January 27, 1998. When Plaintiff's mother filled the prescription in January 1998, she did not receive any product literature, warnings or description of the drug's side effects or symptoms.

On March 10, 1998, Plaintiff returned to Dr. Jaalouk with complaints of red eyes and a rash. After Plaintiff's symptoms worsened over the next day, she went to her primary care physician who referred her to the Atmore Community Hospital. That evening Plaintiff was transferred to the University of South Alabama Children's and Women's Hospital (USA) where Plaintiff was diagnosed with SJS. The diagnosis was confirmed with a biopsy on March 12, 1998. Plaintiff remained at USA for treatment until April 7, 1998. During her hospitalization, Plaintiff experienced a stormy course of SJS.

[3] These are the facts proffered by the Defendant and agreed to by the Plaintiff. In simple language, Dr. Jaalouk prescribed Keflex® to treat Plaintiff's strep throat. The prescription was filled with the generic equivalent—cephalexin—which was manufactured by Teva. In this order, the Court will, at times, use cephalexin to refer to refer to both Keflex® and its generic equivalent.

SJS can have multiple potential causes, including drugs and infections. If no cause is established, it is considered to be idiopathic. SJS can result from a hypersensitivity reaction to various drugs, including cephalexin. There is no diagnostic test to determine a predisposition to SJS from cephalexin or from any other drug. In its most severe form, SJS is sometimes referred to as toxic epidermal necrolysis (TEN).

The manufacture and sale of branded and generic prescription drug products in the United States is a highly regulated industry, under the jurisdiction of the United States Food and Drug Administration (FDA). The FDA draws its statutory authority as to the approval of such manufacture and sale of drugs primarily from its enabling statute, the Food, Drug and Cosmetic Act, 21 U.S.. § 301 et seq., as amended by the Drug Price Competition and Patent Restoration Act of 1984 (the Hatch-Waxman Act) (collectively FDCA), and has promulgated regulations implementing such statutes, which may be found in pertinent part at 21 C.F.R. Part 314. The right to manufacture and market a branded drug in the United States is secured through the filing of a New Drug Application (NDA). 21 U.S.C. § 355. To obtain approval of a NDA, the applicant must demonstrate the safety and efficacy of the drug for its intended indications to the satisfaction of FDA, typically through the conduct of extensive clinical trials in humans. The right to manufacture and market a generic drug in the United States is secured through the filing of an abbreviated NDA (ANDA), which process is governed by the Hatch-Waxman Amendments (codified at 21 U.S.C. § 355(j)). Under these regulations, an ANDA applicant need only certify that the generic manufacturer will produce a bio-equivalent of the branded drug and that the labeling and warnings of the generic drug are identical to that of the approved innovator drug. 21 U.S.C. § 355(j)(2)(A). An ANDA applicant is not required or expected to conduct clinical trials to establish the safety and efficacy of its generic drug (which trials must be

conducted by the manufacturer of the branded drug). Rather, federal regulations limit the role and responsibility of an ANDA applicant to conducting so-called "bioequivalency" studies to establish that the dosage formulation of the generic product has the same pharmacological action in the human body as does the branded drug. 21 U.S.C. § 355(j).

Under the FDCA, the FDA also controls the labeling of prescription drugs. It is the FDA's role to review the proposed labeling submitted by the branded manufacturers and perform in-depth technical analysis and balancing of the benefits of the drug against he potential risks, to ultimately arrive at the final labeling. With respect to generic drugs, the labeling or "package insert" of the generic drug may not deviate in any material respect from that of its reference listed drug—all statements as to Warnings, Precautions, Contraindications, Adverse Reactions, etc. must adhere letter for letter to the language in the corresponding provisions of the labeling of the reference listed drug. 21 U.S.C. § 355(j). An ANDA holder does not have the right to enhance warnings on the label for its product through the mechanism of 21 C.F.R. § 314.70(c)(6(iii)(A), the so-called "Changes Being Effected Amendment (CBE) provision, which provision is, in the context of prescription pharmaceuticals available only to NDA holders.

In 1987, Teva USA's predecessor, Biocraft Laboratories, Inc., first received approval of its ANDA for its 250 mg and 500 mg cephalexin capsules. In 1996, Teva USA became owner of this ANDA. Teva USA'S 1996 and 1997 cephalexin package inserts, in effect at the time Plaintiff was prescribed cephalexin, state in pertinent part:

> **WARNINGS:** BEFORE CEPHALEXIN THERAPY IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE CONCERNING PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS AND PENICILLIN. CEPHALOSPORIN C DERIVATIVES SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS.
>
> SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE EPINEPHRINE AND OTHER EMERGENCY MEASURES.

> There is some clinical and laboratory evidence of partial cross-allergenicity of the penicillins and the cephalosporins. Patients have been reported to have had severe reactions (including anaphylaxis) to both drugs.
>
> Any patient who had demonstrated some form of allergy, particularly to drugs, should receive antibiotics cautiously. No exception should be made with regard to Cephalexin.
>
> . . .
>
> **PRECAUTIONS:** *General*—Patients should be followed carefully so that any side effects or unusual manifestations of drug idiosyncrasy may be detected. If an allergic reaction to Cephalexin occurs, the drug should be discontinued and the patient treated with the usual agents (e.g., epinephrine or other pressor amines, antihistamines, or corticosteroids).
>
> . . .
>
> **ADVERSE REACTIONS**
>
> . . .
>
> *Hypersensitivity*—Allergic reactions in the form of rash, urticari, angioedema, and rarely, erythema multiforme, Stevens-Johnson syndrome, or toxic epidermal necrolysis have been observed. These reactions usually subsided upon discontinuation of the drug. In some of these reactions, supportive therapy may be necessary.

The 1997 and 1998 volumes of the Physician Desk Reference (PDR) contain virtually identical language for the branded drug Keflex®, with the exception of permitted differences relating to the fact of a different manufacturer.

In her deposition testimony, Dr. Jaalouk could not pinpoint precisely when she became aware that Keflex® could cause SJS, although she believed it was during her medical residency. She also testified that is was possible, though less likely, that she became aware of that fact sometime after 1998. "If it's written in the books and I study from that book, I should have known." Jaalouk Dep. 116, ECF No 175-18. Dr. Jaalouk also testified that, as a physician, she expects a drug manufacturer to inform doctors of the side effects of a medication. If a potential

side effect is critical, she would want it both in the warnings and the adverse reaction section of the label.

PROCEDURAL BACKGROUND

Plaintiff initially filed this diversity action against Teva USA, Teva Pharmaceutical Industries, Ltd. and Eli Lilly & Company asserting, under Alabama law, various claims based on strict liability, misrepresentation negligence, breach of express warranty and breach of implied warranty of merchantability. Plaintiff's claims against Eli Lilly & Company, the manufacturer of Keflex®, were dismissed prior to commencement of discovery. (Doc. 61.) Plaintiff has agreed to the dismissal of her claims against Teva Pharmaceutical Industries, Ltd. Early in this litigation, Teva USA filed a motion to dismiss the complaint for failure to state a claim, which was partially successful. Plaintiff's claims based on strict liability and misrepresentation were dismissed. However, the Court rejected Defendant's argument that *all* state law claims were preempted by FDA regulations. Teva has nonetheless held steadfastly to its position, as similar preemption claims worked their way through the federal appellate system. During the pendency of this case, the United States Supreme Court decided two preemption cases, *Wyeth v. Levine*, 555 U.S. 555 (2009), and *Altria Group, Inc. v. Good*, 555 U.S. 70 (2008), and the parties provided additional briefs in light of those cases.

ISSUES PRESENTED

Of the many claims asserted in the complaint, only three remain: (1) negligent failure to warn; (2) negligent failure to conduct post-marketing surveillance; and (3) breach of the implied

warranty of merchantability.[4] As noted, Defendant continues to assert that all state law claims are preempted by FDA regulations promulgated pursuant to the FDCA. Defendant also argues that it is entitled to summary judgment because Plaintiff cannot meet her burden of proof on any of the three claims. Plaintiff argues that there is no FDA preemption of state law claims. With regard to the specific claims, Plaintiff contends that the evidence, viewed in the light most favorable to her, is sufficient to support a verdict in her favor.

LEGAL ANALYSIS

Summary Judgment Framework

Summary judgment should be granted only if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The party seeking summary judgment bears "the initial burden to show the district court, by reference to materials on file, that there are no genuine issues of material fact that should be decided at trial." *Clark v. Coats & Clark, Inc.*, 929 F.2d 604, 608 (11th Cir. 1991). Once the moving party has satisfied his responsibility, the burden shifts to the nonmoving party to show the existence of a genuine issue of material fact. Id. "If the nonmoving party fails to make 'a sufficient showing on an essential element of her case with respect to which she has the burden of proof,' the moving party is entitled to summary judgment." *United States v. Four Parcels of Real Property*, 941 F.2d 1428, 1437 (11th Cir. 1991) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986)) (footnote omitted). "In reviewing whether the nonmoving party has met its burden, the court must stop short of weighing the evidence and making credibility determinations of the truth of the matter. Instead, the evidence of the non-movant is to be believed, and all justifiable

[4] In her response brief, Plaintiff has conceded four claims: Failure to use reasonable care in formulating and manufacturing cephalexin, inadequate pre-clinical and clinical testing, breach of express warranty and the claim for punitive damages. Pl.'s Summ. J. Rsp. 23, ECF No. 184.

inferences are to be drawn in his favor." *Tipton v. Bergrohr GMBH-Siegen*, 965 F.2d 994, 999 (11th Cir. 1992) (internal citations and quotations omitted).

The factual disputes raised by the nonmoving party must be both material and genuine. "As to materiality, the substantive law will identify which facts are material. Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). "Genuine disputes are those in which the evidence is such that a reasonable jury could return a verdict for the non-movant. For factual issues to be considered genuine, they must have a real basis in the record." *Mize v. Jefferson City Bd. of Educ*., 93 F.3d 739, 742 (11th Cir. 1996) (quoting *Hairston v. Gainesville Sun Publishing Co.*, 9 F.3d 913, 918 (11th Cir. 1993)).

FDA Preemption

Defendant's preemption argument is a purely legal issue, and one that has already been decided in favor of the Plaintiff. Nevertheless, Defendant relies on *Levine*, an intervening United States Supreme Court decision, in its attempt to demonstrate that this Court erred in rejecting Defendant's preemption argument. In *Levine*, the Supreme Court held that state law failure-to-warn claims against the holder of a NDA (i.e., the brand name manufacturer) are not preempted. In so doing, the Court addressed (and rejected) many of the same preemption arguments Defendant has raised here. Nevertheless, this case is slightly different from *Levine* in that the Defendant is the holder of an ANDA (i.e., the generic manufacturer), which brings different FDA regulations into play. Nothing in *Levine* affects the Court's prior decision, which addressed the differences in regulations applicable to name brand and generic manufacturers. Recently, three courts of appeal have applied *Levine* in identical situations, and all three have

reached the same conclusion as this Court—FDA regulations do not preempt state law failure-to-warn claims against generic manufacturers. *Gaeta v. Perrigo Pharma. Co.*, 630 F.3d 1225 (9th Cir. 2011); *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir.), *cert. granted*, 131 S. Ct. 817 (2010); *Mensing v. Wyeth*, 588 F.3d 603 (2009), *cert. granted sub nom PLIVA, Inc. v. Mensing*, 131 S. Ct. 817 (2010).[5] Consequently, this Court declines to reverse its decision on the preemption issue.

Negligent Failure to Warn

Plaintiff contends that Defendant is liable for negligence due to its failure to provide an adequate warning of the risk of developing SJS associated with cephalexin. The elements of a cause of action are well-settled. Plaintiff must prove that Defendant had a duty to warn, that Defendant breached that duty, that she was injured and that Defendant's breach of duty was the proximate cause of her injury. *Prill v. Marrone*, 23 So. 3d 1, 7 (Ala. 2009). In this case, Defendant contests Plaintiff's ability to prove that it breached its duty or, if it did, that the breach was a proximate cause of her injury. Before considering issues of duty and proximate cause, the Court must determine the extent of a drug manufacturer's duty to warn under Alabama's learned intermediary doctrine.

Duty to Warn: Alabama's Learned Intermediary Doctrine

A properly prepared prescription drug is an "unavoidably unsafe" product which must be accompanied by an adequate warning. Alabama law does not require a direct warning to prescription drug users but adheres instead to the learned intermediary doctrine.

> [W]here *prescription* drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use. . . .Pharmaceutical companies then,

[5] The issue is currently under review by the Supreme Court in *Gaeta* and *Demahy*.

> who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

Stone v. Smith, Kline & French Lab., 447 So. 2d 1301, 1304 (Ala. 1994) (quoting *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir. 1974)). Hence, Defendant had a duty to warn Plaintiff's physician of the potential dangers associated with cephalexin, including the risk of developing SJS. The package insert and PDR entry in this case listed SJS as a potential adverse reaction, but Plaintiff challenges the adequacy of that that warning.

Adequacy of Warning

Defendant contends that its warning labels and inserts were sufficient to satisfy its duty to warn Plaintiff's physician. Plaintiff addresses the adequacy of the cephalexin warranty only in broad, vague terms. Unfortunately, Plaintiff dedicates little discussion to the adequacy of the warning as a separate element of proof and leaves it to the Court to decipher her theory of inadequacy. First, she argues, without citing any evidentiary support, that there are jury issues regarding the existence, reasonableness, placement and adequacy of any warning. The existence of the warning cannot be questioned, despite Plaintiff's argument to the contrary. Moreover, there is no evidence that warning information provided regarding the relationship between cephalexin and SJS was inaccurate. Plaintiff does cite evidentiary support for her theory that the warning was inadequate due to its placement--the testimony of her treating physician, Dr. Jaalouk. Dr. Jaalouk testified at deposition that, in general, she relies on the manufacturers to tell her the side effects of a drug. She also testified that, in general, information in the warnings section of a label or package insert carries more weight than information listed in the adverse reaction section. Further, Dr. Jaalouk testified that she would expect information about any relationship between SJS and the use of a drug to be in the warnings section. Based upon this

evidence, the Court will presume, only for purposes of this motion, that the warning was inadequate because the information about SJS was listed as an "Adverse Reaction" rather than under "Warnings".

Proximate Cause

Plaintiff must establish that the placement of the SJS information under "Adverse Reactions" rather than "Warnings" proximately caused Plaintiff's injuries. To prevail on a failure-to-warn claim under Alabama law, a plaintiff "must demonstrate a causal link between the allegedly inadequate warning and the injury. In cases such as these [involving prescription drugs and the learned intermediary doctrine], that means that the plaintiff[ ] must demonstrate that, had the defendant given an adequate warning, it would have been read and heeded by the prescribing physician[ ]." *Brasher v. Sandoz Pharma. Corp.*, 2001 U.S. Dist. Lexis 18364 (M.D. Ala. Sept. 21, 2001); *see also Bodie v. Purdue Pharma. Co.*, 236 Fed. Appx. 511, 516 (11th Cir. 2007) (applying Alabama law). Defendant argues that "Plaintiff cannot establish proximate causation because Plaintiff has put forth no evidence that Dr. Jaalouk would not have prescribed cephalexin for Plaintiff if the drug contained a different or stronger warning." Def.'s Summ. J. Brf. 21, ECF No. 174. Plaintiff counters that her proximate cause evidence is adequate to withstand summary judgment for two reasons. First, she contends that Dr. Jaalouk's testimony is sufficient because it demonstrates that the physician relied on prescription drug warning labels and inserts. Alternatively, Plaintiff argues that she has no burden to present evidence of proximate cause.

Theoretically, proof of proximate cause could take one of two forms: (1) evidence that Dr. Jaalouk would not have prescribed cephalexin at all if the warning had been stronger or (2) evidence that, though she still would have prescribed cephalexin, Dr. Jaalouk would have

changed her behavior or treatment in some way that would have resulted in a different outcome for the Plaintiff. As to the latter argument, the record is devoid of any evidence that the outcome would have been better or different come if the cephalexin had been prescribed or administered in a different manner.[6] Nor is there any evidence that Dr. Jaalouk would not have prescribed cephalexin if the warning had been different. In fact, at the time of her deposition--ten years after firsthand experience with Plaintiff's SJS--Dr. Jaalouk continued to prescribe cephalexin for the treatment of strep throat, the very same illness for which she treated Plaintiff.[7] The evidence cited by Plaintiff is much too vague and generalized to serve as proof of proximate cause. The critical issue is not the amount or type of attention Dr. Jaalouk would have given to the information on the label if the warning about SJS had been more prominently displayed. The issue is whether, and in what way, that information would have affected her decision to treat Plaintiff with cephalexin at that time.

Despite the lack of evidence, Plaintiff argues that "[c]learly a fact question remains as . . . to what degree a better warning would have altered Dr. Jaalouk's prescribing of Cephalexin." Pl.'s Summ. J. Rsp. 9, ECF No. 184. Relying on a Tenth Circuit case, *Thom v. Bristol Myers Squibb Co.*, 353 F.3d 848 (10th Cir. 2003), Plaintiff asserts that the mere existence of an inadequate warning creates a rebuttable presumption that the warning would have been heeded. Plaintiff's argument fails for two reasons. First, Alabama courts have not recognized such a

[6] For example, there is no reason to believe that Plaintiff's SJS would have been diagnosed earlier or treated differently if Dr. Jaalouk had taken different precautions when she prescribed the drug, such as warning Plaintiff or her mother of the potential for SJS.

[7] Because there is no way of determining whether a patient will develop a reaction to cephalexin, there is no way to minimize risk. A physician has only two choices—to prescribe cephalexin or not to prescribe it at all. Dr. Jaalouk's continued use of cephalexin to treat strep throat serves as evidence that she would have made the same decision to prescribe cephalexin to Plaintiff, no matter how the warning had been given.

presumption. In *Deere & Co. v. Grose*, 586 So. 2d 196 (Ala. 1991), the Alabama Supreme Court stated that "as concerns proximate cause, a negligent-failure-to-warn-adequately case should not be submitted to the jury unless there is substantial evidence that an adequate warning would have been read and heeded and would have prevented the accident." *Id.* at 198 (citing *Gurley v. American Honda Motor Co.*, 505 So. 2d 358, 361 (Ala. 1987)).

Even if a "read and heed" presumption existed, that presumption alone would not establish proximate cause. In *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806 (5th Cir. 1992), the Fifth Circuit rejected a plaintiff's contention that "causation is presumed, given an inadequate warning, in the context of an unavoidable risk." *Id.* at 814.[8] The court did, however, assume that that failure to provide an adequate warning entitles a plaintiff to a "rebuttable presumption that the learned intermediary would have read and heeded a proper warning." *Id.* That presumption falls far short of establishing proximate cause.

> But "heed" in this context means only that the learned intermediary would have incorporated the "additional" risk into his decisional calculus. The burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff.

Id. at 814. Any presumption that the prescribing physician would have "heeded" a proper warning holds even less sway in the instant case. Plaintiff has pointed to no substantive information that was omitted from the warning. At best, Plaintiff's evidence is that the *manner*

[8] As the court explained, such a presumption is logical only in the context of *avoidable* risk. *Id.* at 813-14. When the risk is avoidable, i.e., a choice between safe and unsafe use of a product, then it is reasonable to presume that a consumer would have minimized his risk by using the product safely. In other words, the consumer would have heeded a proper warning if one had been given. However, when the risk is *unavoidable*, as with a prescription drug, the same reasoning does not apply. *Id.* If the consumer acts in a way to minimize risk, then his decision to use an unavoidably unsafe product will be the same, irrespective of any warnings, *unless* the risk of using the product is greater than the risk of not using it.

of disclosing the risk of SJS was not commensurate with the gravity of the potential harm. Stated differently, the warning label was not wrong, it simply was not forceful enough. Because there is no evidence that a more forceful warning would have changed Dr. Jaalouk's decision to prescribe cephalexin, Plaintiff has failed to establish proximate cause.

Negligent Failure to Conduct Post-Marketing Surveillance

The Defendant can be held liable for negligent failure to conduct post-marketing surveillance only if it had a legal duty to do so. Plaintiff has failed to establish the existence of such a duty, at least one that was unfulfilled. It is axiomatic that a cause of action for negligence does not arise unless the defendant owed the plaintiff a duty of care. *Smitherman v. McCafferty*, 622 So. 2d 322, 324 (Ala. 1993). Whether a duty exists depends on "on a number of factors, including public policy, social considerations, and foreseeability [of harm]. The ultimate test of the existence of a duty to use due care is found in the foreseeability that harm may result if care is not exercised." *Armstrong Business Serv., Inc. v. AmSouth Bank*, 817 So. 2d 665, 679 (Ala. 2001) (internal citations and quotations omitted).

Identifying the duty has been slightly problematic in this case. In its summary judgment motion, Defendant presumed that Plaintiff's claim was based on a legal duty, created by FDA regulations, requiring a generic drug manufacturer to report adverse events related to its product. 21 C.F.R. § 314.80, 314.81(b)(2)(8). Defendant submitted evidence that it had complied with this requirement and thus satisfied its duty. In response, Plaintiff states that she "is not claiming that Teva failed to report events to the FDA[ ] but that Teva was negligent in monitoring other adverse events relating to Cephalexin." Pl.'s Summ. J. Brf. 38, ECF No. 174. The only evidence Plaintiff points to involves Defendant's acknowledgement that it did not track the adverse event experience of *other* cephalexin manufacturers. Absent a legal duty to track such

information—and Plaintiff has failed to identify the source of any purported duty--Defendant's failure to act does not amount to negligence.[9]

Breach of Implied Warranty of Merchantability

In general, Alabama law does not recognize a cause of action for breach of implied warranty of merchantability for inherently dangerous products. As the Eleventh Circuit has noted "courts applying Alabama law have seen fit to subsume U.C.C.-based breach of implied warranty claims into tort and product liability claims, where the product is fit for its intended use and there is no evidence of 'non-merchantability' other than a general allegation that the product contains inherent dangers." *Bodie*, 236 Fed. Appx. at 524. Plaintiff argues that her breach of warranty claim survives because there is evidence of "non-merchantability." Plaintiff relies on *Griggs v. Combe*, 456 So. 2d 790 (Ala. 1984), a case involving a question certified to the Alabama Supreme Court by the Eleventh Circuit. The plaintiff in *Griggs* had an allergic reaction to a topical analgesic and asserted, *inter alia*, a claim for breach of implied warranty of merchantability against the manufacturer. The question involved whether such a cause of action was available to the plaintiff against a drug manufacturer. The supreme court answered the question in the negative, explaining:

> For all that appears in the question before us, Griggs is the only person who has suffered this kind of injury in the long history of the use of the drug in question. We agree with the above authorities that a product must adversely affect at least some significant number of persons before a question of "merchantabilty" arises. Therefore, Griggs cannot recover under this theory, either.

[9] The Court cannot conceive of any foreseeable harm from the mere failure to track adverse events experienced by other companies.

Id. 793. Thus, *Griggs* left the door slightly ajar to the possibility of a breach-of-implied-warranty claim against a drug manufacturer, if the product adversely affected a "significant number of persons".

Plaintiff tries to slip through that narrow opening, arguing that cephalexin has adversely affected a significant number of people. To support her claim, Plaintiff relies on the report of Defendant's expert, Dr. Steven Lamm. Plaintiff points out that "Dr. Lamm [ ] cited an article by Jick and Derby published in 1995 which recorded the risk of SJS and or TEN following Cephalexin to be 1 case per 100,00 patients or 1 case for every 160,000 prescriptions." Pl.'s Summ. J. Brf. 28. Extrapolating from those figures (based on the number of Cephalexin prescriptions per year) Plaintiff arrives at the preposterous assertion that "75 people a year on average suffer from SJS or TEN after taking Cephalexin." Pl.'s Summ. J. Brf. 28. Dr. Lamm's report contains no such conclusion. Quite the opposite, Dr. Lamm found only 2 cases reported in the United States between 1992 and 2008. Dr. Lamm noted the *unreliability* of the Jick and Derby study, which was based on only 2 patients whose case histories are not described and therefore may have been exposed to other drugs associated with SJS and TEN. If the Jick and Derby figures were correct, Dr. Lamm points out, "then with annual cephalexin sales in the U.S. of over 12 million prescriptions per year one would predict an observed incidence of approximately 80 cases per year. *Not one such case has been reported in the published literature, and TEVA has informed me they are aware of only two alleged cases (including Ms. Barnhill) since they began selling cephalexin in the United States in 1992.*" Lamm Rpt.10, Pl.'s Ex. D, ECF No. 175-4. Dr. Lamm concluded that the risk of developing SJS or TEN from cephalexin exposure is "low, i.e., in the less than one per 10 million range." *Id.*

As an inherently dangerous product, cephalexin is presumed to be merchantable, i.e., fit for its intended use. Plaintiff relies on non-existent evidence to support her claim that it is not fit. Because Plaintiff's evidence fails, so does her claim for breach of implied warranty of merchantability.

CONCLUSION

This Court remains unpersuaded by Defendant's argument that FDA regulations preempt all state law claims against a prescription drug manufacturer. Nevertheless, Plaintiff's state law claims cannot survive summary judgment. Plaintiff has conceded that she is unable to prove many of the claims asserted in the complaint. As to the remaining claims—negligent failure to warn, negligent failure to conduct post-marketing surveillance and breach of implied warranty of merchantability—the evidence is insufficient to create a genuine dispute of material fact. Accordingly, the motion for summary judgment filed by Defendant Teva Pharmaceuticals USA, Inc. is hereby **GRANTED**.

DONE and **ORDERED** this the 9th day of May, 2011.

s/*Charles R. Butler, Jr.*
Senior United States District Judge