UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

ELEANOR FULGENZI,	)	CASE NO. 5:09-cv-1767
PLAINTIFF,	)	JUDGE SARA LIOI
vs.	)	MEMORANDUM OPINION
PLIVA, Inc.,	)	
DEFENDANT.	)	

In this pharmaceutical products liability action, plaintiff Eleanor Fulgenzi ("plaintiff" or "Fulgenzi") alleges that she developed the severe neurological movement disorder tardive dyskinesia ("TD") after ingesting metoclopramide. The remaining defendant, PLIVA, Inc. ("defendant" or "PLIVA"), a manufacturer of a generic version of metoclopramide (which is known by the name brand of Reglan), moves for summary judgment on the sole surviving cause of action, a failure-to-warn claim brought under Ohio statutory law. (Doc. No. 102 ["MSJ"].) Plaintiff opposes the motion (Doc. No. 126 ["Opp'n"]), and PLIVA has filed a reply. (Doc. No. 129 ["Reply"].)

I. BACKGROUND

A. Prescription Drug Regulatory Background

While plaintiff's failure-to-warn claim is brought under Ohio law, it is necessary to first set forth the federal regulatory scheme governing the manufacture and distribution of prescription medication as it serves as the backdrop, and in some sense sets the boundaries, for plaintiff's claim. Pursuant to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et.*

seq., the FDA is charged with the responsibility of approving new drugs. *See* 21 U.S.C. § 355(a); *Riegel v. Medtronic, Inc*., 552 U.S. 312, 315, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008); *Merck KGaA v. Integra Lifesciences I, Ltd*., 545 U.S. 193, 196, 125 S. Ct. 2372, 162 L. Ed. 2d 160 (2005). A manufacturer seeking to market a new drug must file a New Drug Application ("NDA") with the FDA. 21 U.S.C. § 355(b). As part of its application, the manufacturer must demonstrate through pre-market trials and other relevant evidence that the drug is safe, and that the proposed labeling properly sets forth the correct dosage and possible risks. The NDA requires, among other things, that the manufacturer supply the agency with "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use[]" and "specimens of the labeling proposed to be used for such drug[.]" § 355(b)(1).

In contrast, drug manufacturers seeking to market a generic drug must file an Abbreviated New Drug Application ("ANDA"). The ANDA procedure, codified as amended in the Hatch-Waxman Act, 21 U.S.C. § 355(j)(2)(A), sets forth an expedited review process. To obtain approval, the manufacturer must demonstrate that the generic drug it seeks to market is approved as a listed drug, meaning that the new drug is the functional equivalent of a name-brand drug already approved by the FDA. 21 U.S.C. § 355(j)(2)(A)(iv). "One of the benefits to manufacturers who opt for the ANDA procedure is that they are required only to conduct 'bioequivalency' studies that establish that the generic and the reference-listed drug are pharmaceutically equivalent[.]" *Stacel v. Teva Pharm., USA*, 620 F. Supp. 2d 899, 905 (N.D. Ill. 2009). So long as the manufacturer can demonstrate that the generic drug is the pharmaceutical equivalent of its name-brand counterpart, the generic manufacturer need not duplicate the pre-

market trials conducted by the name-brand manufacturer. This advantage serves the purpose of the Hatch-Waxman Act to increase the availability of low cost generic drugs. *See id*. at 907.

Federal regulations further require that a generic drug's "[l]abeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug, except for changes required because of differences approved under a petition filed under § 314.93 or because the drug product and the reference listed drug are produced or distributed by different manufacturers." 21 C.F.R. § 314.94(a)(8)(iv). The FDA can reject an ANDA application if the information submitted by the generic manufacturer is "insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug[.]" 21 C.F.R. § 314.127(a)(7).

Thus, name-brand drug manufacturers and the manufacturers of the name-brand's generic counterpart face different sets of obligations with respect to their labels. Name-brand manufacturers must prove that the proposed label is "accurate and adequate." 21 U.S.C. § 355(b)(1), (d); *PLIVA, Inc. v. Mensing*, --U.S.--, 131 S. Ct. 2567, 2574, 180 L. Ed. 2d 580 (2011). The manufacturers of generic medications, on the other hand, are not independently required to demonstrate the accuracy or adequacy of their labels. Instead, generic drug manufacturers are obligated to ensure that their proposed warning label is identical to the label of the corresponding name-brand drug. This is sometimes referred to as the duty of "sameness." *See Morris v. PLIVA, Inc*., 713 F.3d 774, 776 (5th Cir. 2013).

B. Reglan and its Generic Counterpart

Reglan, the reference listed drug ("RLD") for metoclopramide, was first approved by the FDA in 1980, and has been traditionally prescribed to treat a variety of digestive illnesses, including "symptomatic gastroesophageal reflux and acute diabetic gastric stasis." (Doc. No. 60 (Second Amended Complaint ["SAC"]) ¶ 19.) In the years following Reglan's introduction, post-marketing studies revealed the risk of developing TD from the product's use. Patients with TD typically present with symptoms that include involuntary and uncontrollable movements of the head, neck, and face, as well as grotesque facial grimacing and tongue thrusting. In light of the acquired knowledge of the increased risk of developing TD from the use of Reglan, the brand-name's package insert was changed in 1985 to include a warning that TD may develop in patients treated with metoclopramide. Specifically, the insert warned that the development of symptoms associated with neurological diseases like TD was likely to occur in 1 in 500 patients treated with metoclopramide. (Doc. No. 102-4 (1985 Physicians' Desk Reference ["PDR"] for Reglan Label) at 3376[1].)

In 1987, the labeling for Reglan/metoclopramide was revised to include information that provided that use of metoclopramide was indicated for "short-term (4 to 12 weeks) therapy for adults with symptomatic, documented gastroesophageal reflux who fail to respond to conventional therapy." (Doc. No. 102-5 (1987 Label for Metoclopramide) at 3381.) Further, the Dosage and Administration section, advised, in relevant part, that: "[t]herapy for longer than 12 weeks has not been evaluated and cannot be recommended." (*Id*.)

Another significant labeling change, relating to the duration of treatment with the

[1] All page number references are to the page identification number generated by the Court's electronic docketing system.

drug, took place in 2004 when the FDA approved the name-brand manufacturer's request to add the following bolded statements directly under the heading in the Indications and Usage section of the package insert: "**The use of reglan® tablets is recommended for adults only. Therapy should not exceed 12 weeks in duration**." The approved revision also provided for a similar bolded sentence directly under the heading of the Dosage and Administration section: "**Therapy with reglan® tablets should not exceed 12 weeks in duration."** (Doc. No. 102-3 (2004 Reglan label) at 3366, 3372.) For purposes of the present summary judgment motion, it is undisputed that PLIVA failed to revise its generic label for metoclopramide to include the 2004 updated sentences, even though the duty of "sameness" imposed by federal regulation required PLIVA to do so.

In 2009, the FDA announced that it would approve further changes to the warning on the Reglan label, as well as the addition of a black-box warning—the strongest warning sanctioned by the FDA—that "[t]reatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. . . . Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases." *Mensing*, 131 S. Ct. at 2572.

C. Plaintiff's Treatment History with Metoclopramide

Plaintiff was prescribed Reglan by three different physicians, for varying lengths of time, between July 2004 and August 2007. (SAC ¶ 17; Doc. No. 103-15 (Expert Report of Richard M. Trosch, M.D.) at 3929; *see also* Doc. No. 103-1 (Memorandum in Support of Motion to Strike Dr. Trosh's Testimony ["Mot. to Strike"]) at 3677 and supporting exhibits.) While each physician wrote prescriptions for the brand name Reglan, it is undisputed that a pharmacist filled each prescription with the generic equivalent.

1. Dr. Shameem M. Ahmed

In July 2004, Dr. Ahmed, a board certified gastroenterologist, diagnosed plaintiff with gastroparesis after an EGD revealed "[l]arge amounts of undigested food" throughout her stomach.[2] (Doc. No. 102-15 (Office Visit Notes of Dr. Ahmed) at 3438-3440.) He wrote plaintiff four prescriptions for Reglan between July 22, 2004 and September 30, 2004, and two more prescriptions for Reglan on August 10, 2006 and September 21, 2006. (Mot. to Strike at 3677 and supporting exhibits; *see also* Doc. No. 102-20 (Excerpts from the Deposition of Dr. Ahmed ["Ahmed Dep. I"]) at 3525.) The first three prescriptions were filled with generic metoclopramide manufactured by Teva, Inc. (Mot. to Strike at 3677.) The two prescriptions issued in 2006 were filled with metoclopramide manufactured by Mutual.[3] (*Id*.) Only the prescription written on September 30, 2004 was filled with metoclopramide manufactured by PLIVA. (*Id*.) In February 2005, Dr. Ahmed discontinued this medication after he determined that plaintiff's symptoms were not improving. (Dr. Ahmed Depo. at 8289-90, 8325.) For reasons that are not entirely clear from the record, Dr. Ahmed restarted plaintiff on Reglan in 2006.

In his deposition, Dr. Ahmed testified that he had been familiar with the name-

[2] The record also demonstrates that plaintiff has suffered and/or continues to suffer from myriad other medical ailments and conditions, including: depression, anxiety, chronic diarrhea, breast cancer, shingles with post-herpetic neuropathy, migraines, hypertension, hiatal hernia, obesity, restless leg syndrome, insomnia, allergic rhinitis, chronic renal insufficiency/failure, and osteoarthritis. (Doc. No. 102-8 (Lake Hospital System Medical Notes); Doc. No. 102-9 (Dr. Lackey Medical Notes); Doc. No. 102-10 (Lake Health Preoperative Record); Doc. No. 102-11 (Urology Inc. Questionnaire); Doc. No. 102-12 (Crystal Clinic Medical Notes); Doc. No. 102-13 (Aetna Records); Doc. No. 102-14 (Lake Health Summary).)

[3] It is worth noting that Mutual's package insert contained the 2004 warning. (Doc. No. 102-6 (Affidavit of Robert Dettery) ¶¶ 4-5.)

brand drug Reglan since the mid-1970's when he was a medical student. (*Id*. at 8301.) He explained that, when a new medication is released, he tries to read the available literature on it, including the package inserts from the manufacturers. (*Id*. at 8302.) He further explained that, "once you get used to [the drug, however], there is a comfort level that you develop . . . ."[4] (*Id*.) Having such a comfort level with Reglan, he is unsure whether he reviewed the packaging information for it, and, in any event, he testified that he did not review the package insert or labeling for Reglan prior to prescribing it for plaintiff. (*Id.*) He also testified that he had never heard of PLIVA, or ever reviewed any written materials about metoclopramide from PLIVA, though he indicated that he knew that when a prescription is written for a brand name drug, the generic equivalent may be dispensed. (*Id*. at 8303-04.) Rather, he maintained that he relied on his clinical experience and his past knowledge of Reglan in prescribing it for plaintiff. (*Id*.)

Nonetheless, he also testified that he has "changed significantly" his use of Reglan since the time of plaintiff's treatment. (*Id*. at 8315.) He testified that he rarely prescribes it for elderly patients, and he documents informed consent with all patients who receive a prescription for it. (*Id*. at 8316.) Additionally, when asked if the 2004 warning that metoclopramide was not to be used beyond twelve weeks would have affected him if it had been brought to his attention, he replied: "It would have, but, again, you know, with everything that's going around us now, we are still using the medicine after proper informed consent." (*Id*. at 8319.) Likewise, when asked if his use of the drug would have changed if the 2004 warning had been brought to his attention earlier, he responded "Probably to some degree, yes." (*Id*. at 8320.)

[4] Dr. Ahmed testified candidly that what "commonly happens with newer, high—you know, medications that are coming out with what we call biologics and things like that, so—but on the other hand, doctors are really lazy, and not everything that comes across your desk you read it. I honestly tell you, there's so much material that comes in. Have I looked at everything? Probably not. So I—I can't answer you, what is my expectations in terms of a very old medicine like that." (Dr. Ahmed Depo. at 8333-34.)

2. Dr. Erica Sobolewski

Dr. Sobelowski, a family practice physician who served as plaintiff's primary care physician from May 2004 until January 2007, wrote five prescriptions for Reglan, one in September 2004 and four between September 2006 and June 2007. (Mot. to Strike at 3677.) Dr. Sobolewski was the physician who had referred plaintiff to Dr. Ahmed, and the first prescription for Reglan she wrote for plaintiff was, in essence, a renewal or continuation of Dr. Ahmed's prescriptions, which Dr. Sobolewski agreed to fill for plaintiff as a courtesy. (Doc. No. 126-26 (Excerpts from the Deposition of Dr. Sobolewski ["Sobolewski Dep."]) at 8238, 8241-43, 8246.) All of Dr. Sobolewski's prescriptions were filled with generic metoclopramide manufactured by PLIVA. (Mot. to Strike at 3677.)

In her deposition, Dr. Sobolewski testified that, at the time she first prescribed Reglan for plaintiff, she was generally familiar with the drug and knew that it had been around for a long time. (Sobolewski Dep. at 8249.) She stated that she did not recall ever reviewing a package insert for the brand name Reglan, or any generic metoclopramide product. (*Id*. at 8256-57.) In particular, when asked, "prior to writing that prescription for Mrs. Fulgenzi in September of 2004 for Regan, did you ever read any label or package insert for a generic metoclopramide product manufactured by PLIVA, Inc.," she responded "No, not that I recall." (*Id*. at 8257.)

Like Dr. Ahmed, Dr. Sobolewski testified that at some point after she treated plaintiff, she became more acutely aware of the link between metoclopramide and TD. (*Id*. at 8268.) While she was not sure that she had read the 2009 "black box" warning issued by the manufacturer of Reglan and/or the manufacturers of generic metoclopramide, she believes that around the general time of this warning, she changed her perception of the drug. (*Id*. at 8270.) According to Dr. Sobolewski, if she had been advised in 2004 that the warning for

metoclopramide had been revised to provide that therapy should not exceed twelve weeks, it would have affected her use of the drug in her practice. (*Id*. at 8272-74.)

3. Dr. Michael V. Baranauskas

Dr. Baranauskas has served as plaintiff's primary care physician since May 29, 2007, after plaintiff's treatment with Dr. Sobolewski ended. (Doc. No. 126-28 (Excerpts from the Deposition of Dr. Baranauskas ["Baranauskas Dep."]) at 8344, 8353.) He testified that when he first saw plaintiff, she reported that her major medical complaint related to her depression. Dr. Baranauskas responded by making adjustments to certain medications. (*Id*. at 8360.) At her second visit, on July 31, 2007, plaintiff reported that she believed she was having problems tolerating the medication Effexor, as she was experiencing oral and extrapyramidal-type movements, tongue, jaw, and grinding of her teeth. (*Id*. at 8363-64.) Believing these problems to be associated with plaintiff's treatment with Effexor, Dr. Baranauskas discontinued that medication. (*Id*. at 8365-67.)

A month later (August 2007), Dr. Baranauskas received a request from plaintiff's mail-in prescription company to refill plaintiff's prescription of Reglan. Dr. Baranauskas complied with the request, and approved a 90 day supply of Reglan, which the pharmacist filled with metoclopramide manufactured by PLIVA. (*Id*. at 8373-76, 8398-99; Mot. to Strike at 3677.) In connection with this prescription, Dr. Baranauskas testified that he had received some information from the pharmacist that called into question the dose of metoclopramide plaintiff

was receiving.[5] He further testified that the pharmacist provided some information about metoclopramide, which addressed age-related concerns and potential adverse outcomes including TD, and Dr. Baranauskas reviewed this information and his office discussed dosing levels with plaintiff before he signed off on the prescription.[6] (Baranauskas Dep. at 8382-8385.)

He did not, however, review any labeling or package inserts from any generic manufacturer of metoclopramide prior to prescribing Reglan for plaintiff, and he stated that he did not even know the names of any of the generic manufacturers. (*Id*. at 8399-8400.) He may have reviewed the package insert or the PDR for the brand name Reglan at some point in the past, but he did not review it before prescribing it for plaintiff. (*Id*. at 8399, 8404.) Nonetheless, he was certain that he has never reviewed any labeling or package inserts for a metoclopramide product sold by PLIVA. (*Id*. at 8399-8401.) And while he did not know at the time he prescribed Reglan for plaintiff that long-term use substantially increased the risk of developing movement disorders like TD, he subsequently came to appreciate this connection, which has caused him to effectively discontinue prescribing the medication in his practice. (*Id*. at 8410-13.) Had the 2004 label change been brought to his attention, he surmises that it would have "potentially" caused him to reevaluate his decision to prescribe it for plaintiff. (*Id*. at 8418.)

[5] In her opposition brief, plaintiff represents that the "pharmacy contacted Dr. Baranauskas questioning the dosage of metoclopramide prescribed to Ms. Fulgenzi, as it exceeded the maximum dosage recommended in PLIVA's label." (Opp'n at 7917 (citing Doc. No. 102-39)). The Court has carefully reviewed the exhibit from the pharmacy in question—Medco—and there is no indication that the pharmacy's information came from PLIVA or its package insert. The document includes the prescription, which was written for the name-brand Reglan, and provides some "prescribing information" about the drug. The only indication of where this information came from is in the section entitled "References" which identifies two medical journals. (*Id*. at 3662.)

[6] Dr. Baranauskas was not the only prescribing physician to receive inquiries from pharmacists regarding plaintiff's Reglan prescriptions. Dr. Sobolewski testified that plaintiff's pharmacy sent correspondence to her office, noting that plaintiff suffered from depression, underscoring the fact that depression is a known side effect of metoclopramide, and questioning the dosage that plaintiff had been prescribed. (Doc. No. 102-27 (Excerpts from Deposition of Dr. Sobolewski ["Sobolewski Dep. I"]) at 3579-3580.) It is undisputed that none of the pharmacy inquires touched upon the information contained in the 2004 warning relating to duration of treatment with Reglan/metoclopramide.

D. Plaintiff is Diagnosed with TD

Dr. Baranauskas referred plaintiff to a psychiatrist after discontinuing plaintiff's Effexor did not resolve her involuntary movement issues, and plaintiff was eventually seen by Dr. Bahman Sharif. (Baranauskas Dep. at 8366-67; Doc. No. 126-29 (Excerpts from the Deposition of Dr. Sharif ["Sharif Dep."]) at 8437-38.) Upon examination of plaintiff, Dr. Sharif determined that she should discontinue her use of metoclopramide, and he subsequently had discussions with Dr. Baranauskas about starting plaintiff on a plan to ween her off metoclopramide. (Sharif Dep. at 8443-45.) Dr. Sharif diagnosed plaintiff with TD caused by her long-term exposure to Reglan. (*Id*. at 8458, 8460.) Other physicians have reached similar conclusions about the origins of plaintiff's movement disorder. (Doc. No. 126-31 (Excerpts from the Deposition of Dr. Lewitt ["Lewitt Dep."]) at 8484; Baranauskas Dep. at 8416.)

E. Plaintiff's Lawsuit

On July 30, 2009, plaintiff brought suit in federal court against certain manufacturers of generic metoclopramide and brand name Reglan, raising a variety of state law tort claims, including defective design, breach of warranties, fraud, misrepresentation, and intentional infliction of emotional distress. (Doc. No. 1 (Complaint).) At the core of all of plaintiff's claims was the basic assertion that the drug manufacturers should have provided warnings alerting doctors and patients to the heightened risk of developing neurological complications from long-term use of metoclopramide. On January 25, 2010, plaintiff dismissed with prejudice all claims against the manufacturers of the brand name Reglan after it was determined that plaintiff had only ingested generic metoclopramide (Doc. No. 27 (Stipulation).)

At the request of the remaining parties, this Court stayed the action pending a ruling from the United States Supreme Court on the question of whether regulations promulgated

by the FDA relating to the labeling of generic medication preempt state laws that may require generic drug manufacturers to provide more stringent safety warnings on their products. (Doc. No. 57 (Order).) On June 23, 2011, the Supreme Court issued its decision in *Mensing*, wherein the Supreme Court found it impossible for PLIVA, as a manufacturer of generic metoclopramide, "to comply with both their state-law duty to change the label and their federal duty to keep the label the same." *Mensing,* 131 S. Ct. at 2578. The Supreme Court held federal law preempts "state tort-law claims based on certain drug manufacturers' alleged failure to provide adequate warning labels for generic metoclopramide." *Id*. at 2572.

Following the ruling in *Mensing*, this Court granted plaintiff leave to file an amended complaint. Included in her causes of action was a failure-to-warn claim under the Ohio Product Liability Act ("OPLA"), Ohio Rev. Code § 2307.76. (SAC at 1987-89.) On March 31, 2012, the Court granted PLIVA's motion to dismiss plaintiff's claims. In its decision, the Court found some claims abrogated by the OPLA, and others to be insufficiently pled under Rule 8 of the Federal Rules of Civil Procedure. Ultimately, the Court determined that "all of the claims, including those otherwise abrogated by the OPLA, hinge on the warnings the drug manufacturers gave, or from Plaintiff's perceptive, failed to give." (Doc. No. 67 (Opinion and Order) at 2429.) Accordingly, the Court determined that "regardless of how Plaintiff attempts to cast these claims, they are, at the core, failure-to-warn claims that are clearly preempted by *Mensing*." (*Id*. at 2428.)

On appeal (which was limited to this Court's ruling only as to plaintiff's product liability claims based on the 2004 failure to update), the Sixth Circuit rejected PLIVA's argument that plaintiff's claims were preempted on grounds of impossibility, to the extent that plaintiff's failure-to-warn allegations were limited to PLIVA's failure to communicate the

warning contained in the 2004 revision, as such a warning was allowed (and even required) under federal regulations. *See Fulgenzi v. PLIVA, Inc*., 711 F.3d 578, 584 (6th Cir. 2013). In so ruling, the court carefully defined the contours of plaintiff's surviving claim:

> We note at this point that Fulgenzi's claims survive only to the extent PLIVA's actions were permitted by federal law. She cannot claim that PLIVA should have included an aggressive black-box warning: any such allegations are preempted under *Mensing*. Instead, she is left to argue only that PLIVA's warning was inadequate *to the extent* that it did not include the language contained in the updated Reglan label from 2004. This leaves her with a weaker case than if she were suing a branded-drug manufacturer, but that is the statutory scheme provided to us by Congress. *See Mensing*, 131 S.Ct. at 2582.

Id. at 584 (emphasis in original).

Going forward, the Sixth Circuit cautioned that plaintiff's claim(s) "must pass through the 'narrow gap'" between emerging Supreme Court preemption law, "and will be constrained as a result. The arguments [plaintiff] makes, the proofs she offers, and the evidence she submits are all subject to limitation by preemption principles. Under *Mensing*, Fulgenzi's claims are viable only to the extent PLIVA's actions were permitted by federal law." *Id*. at 588 (internal citation omitted). Ultimately, the court concluded that plaintiff "must argue that PLIVA should have included the language contained in the updated Reglan label by soon after July 2004, and that the failure to include that language proximately caused her injuries."[7] *Id*.

[7]While the Sixth Circuit emphasized that plaintiff could not rely on the fact that PLIVA's failure to include the 2004 updated warning violated federal law to support her state law failure-to-warn claim, *see id*. at 587, it observed that "[f]ederal standards are . . . likely to arise in determining the adequacy of PLIVA's warning, since FDA approval and industry practices may be relevant to the state duty of care." *Id*. at 588-89.

II. SUMMARY JUDGMENT STANDARD

When a party files a motion for summary judgment, it must be granted "if the movant shows that 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). "A party asserting that a fact cannot be or is genuinely disputed must support the assertion by: (A) citing to particular parts of materials in the record . . . ; or (B) showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1).

In reviewing summary judgment motions, this Court must view the evidence in a light most favorable to the non-moving party to determine whether a genuine issue of material fact exists. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157, 90 S. Ct. 1598, 26 L. Ed. 2d 142 (1970); *White v. Turfway Park Racing Ass'n, Inc.*, 909 F.2d 941, 943-44 (6th Cir. 1990), *impliedly overruled on other grounds by Salve Regina Coll. v. Russell*, 499 U.S. 225, 111 S. Ct. 1217, 113 L. Ed. 2d 190 (1991). A fact is "material" only if its resolution will affect the outcome of the lawsuit. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986). Determination of whether a factual issue is "genuine" requires consideration of the applicable evidentiary standards. Thus, in most civil cases the Court must decide "whether reasonable jurors could find by a preponderance of the evidence that the [non-moving party] is entitled to a verdict[.]" *Id.* at 252.

Summary judgment is appropriate whenever the non-moving party fails to make a showing sufficient to establish the existence of an element essential to that party's case and on which that party will bear the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). Moreover, "[t]he trial court no longer has the duty

to search the entire record to establish that it is bereft of a genuine issue of material fact." *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479-80 (6th Cir. 1989) (citing *Frito-Lay, Inc. v. Willoughby*, 863 F.2d 1029, 1034 (D.C. Cir. 1988)). The non-moving party is under an affirmative duty to point out specific facts in the record as it has been established that create a genuine issue of material fact. *Fulson v. City of Columbus*, 801 F. Supp. 1, 4 (S.D. Ohio 1992). The non-movant must show more than a scintilla of evidence to overcome summary judgment; it is not enough for the non-moving party to show that there is some metaphysical doubt as to material facts. *Id.* (citation omitted).

III. ANALYSIS

A. Plaintiff States a Failure-to-Warn Claim under Ohio Law

In support of summary judgment, PLIVA argues, first, that plaintiff has fallen short of properly stating a "failure-to-warn" claim under Ohio statutory law. (MSJ at 3342.) Section 2307.76(A)(1) of the Ohio Revised Code provides that a product is defective due to inadequate warning under the OPLA when:

> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> [and]
>
> (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

To establish a failure-to-warn claim under the OPLA, a plaintiff must prove each of the following: "(1) a duty to warn against reasonably foreseeable risks; (2) breach of this duty; and (3) an injury that is proximately caused by the breach." *Monroe v. Novartis Pharm. Corp.*,

29 F. Supp. 3d 1115, 1125 (S.D. Ohio 2014) (quoting *Graham v. Am. Cyanamid Co*., 350 F.3d 496, 514 (6th Cir. 2003)). A warning is considered adequate "only if 'it reasonably discloses all inherent risks, and if the product is safe when used as directed.'" *McConnell v. Cosco, Inc*., 238 F. Supp. 2d 970, 976 (S.D. Ohio 2003) (quoting *Phan v. Presrite Corp*., 653 N.E.2d 708, 711 (Ohio Ct. App. 1994) and citing Restatement (Second) of Torts § 402A cmt. j).

While its argument is not entirely clear, PLIVA appears to posit that plaintiff's statutory failure-to-warn claim is fatally deficient because the alleged omitted warning—that treatment with metoclopramide should not exceed 12 weeks—fails to identify the risk associated with the product; namely, the risk of developing TD. (MSJ at 3343.) Yet, the Sixth Circuit rejected a similar argument of PLIVA's that an inadequate omitted warning could not serve as the basis for a failure-to-warn claim under the OPLA. Specifically, the court observed:

> PLIVA also tries to argue that there is no such thing as a "failure-to-*inadequately*-warn" claim under Ohio law. Appellee Br. at 30. To start, Fulgenzi's complaint does not have to be read as asserting such a claim. While her allegation that any warning short of the FDA's 2009 "black-box" warning was unreasonable is preempted, she is free to argue in the alternative that any label lacking Reglan's 2004 updated warning was inadequate. Further, there is nothing in the Ohio product-liability law inconsistent with a claim that a defendant failed to warn, even inadequately. In a failure-to-warn case, the plaintiff must show that "[t]he manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided." Ohio Rev. Code § 2307.76. Since Fulgenzi alleges that the non-updated warning used by PLIVA in 2004 does not meet the standard of reasonable care, this element is satisfied.

Fulgenzi, 711 F.3d at 587 (emphasis in original). In so ruling, the court observed that "[i]t may well be more difficult to prove proximate causation in a case where the warning that the defendant failed to provide was also legally inadequate. But there is no reason to believe that a severely inadequate warning would never cause an injury that a moderately inadequate warning would have prevented." *Id*.

Here, of course, PLIVA would have been precluded by its federal duty of "sameness" to add to the 2004 warning by explaining that the 12 week treatment limit was necessitated by a concern that long-term use of metoclopramide could lead to neurological disorders, such as TD. Still, even if federal regulations would have left the 2004 warning arguably inadequate under the OPLA, plaintiff remains free to attempt to show that use of this inadequate warning would have prevented her neurological injuries.

In any event, the question of whether plaintiff's second amended complaint stated a claim under the OPLA was foreclosed by the Sixth Circuit's ruling, which provided:

> Thus Fulgenzi does not fail to properly state a claim. Fulgenzi alleges that PLIVA's use of the old warning ("Therapy longer than 12 weeks has not been evaluated and cannot be recommended.") instead of adding the updated one **("Therapy should not exceed 12 weeks in duration.")** was unreasonable, and the proximate cause of her injuries. At the motion-to-dismiss stage, it is sufficiently plausible that the use of a neutral warning disavowing approval instead of a bold-faced warning affirmatively discouraging long-term use proximately caused Fulgenzi's injury. Whether in fact these allegations are true is a matter for further proceedings.

Id. at 588 (bolding in original). Plaintiff's claim survives PLIVA's initial argument in support of summary judgment.

B. **Plaintiff Cannot, as a Matter of Law, Establish Proximate Cause**

Of course, at the summary judgment stage, a plaintiff must do more than merely offer complaint allegations that state a cause of action. As the Sixth Circuit alluded to in its order of remand, the ultimate question in this case is whether PLIVA's failure to update its label in 2004 to include the bolded warning that "**[t]herapy should not exceed 12 weeks in duration[]**" was the proximate cause of plaintiff's injuries. According to PLIVA, plaintiff cannot meet this element of her failure-to-warn claim, and summary judgment, in its favor, is warranted. In support, PLIVA advances a number of (lack of) proximate cause arguments, two of which are as

follows:[8] First, according to PLIVA, the learned intermediary doctrine bars plaintiff's claim. Recognized under Ohio law, and codified at Ohio Rev. Code § 2307.76(C), the learned intermediary doctrine provides that a drug manufacturer satisfies its duty to warn of known risks by providing an adequate warning to the medical professional of the risks associated with the drug's use. *Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160, 164 (Ohio 2002) (quotation marks and citation omitted). But the Court need not determine whether this doctrine applies because PLIVA's second argument—that proximate cause is lacking because the record shows that plaintiff's prescribing physicians did not rely upon PLIVA's deficient 2004 warning label—is dispositive.

The undisputed facts in the record establish that plaintiff's physicians did not ever read, let alone rely on, PLIVA's inadequate 2004 warning. As set forth above, proximate cause is an essential element that plaintiff must establish in order to prevail on her Ohio failure-to-warn claim. *See Graham*, 350 F.3d at 514. "A plaintiff 'not only must convince the fact finder that the warning provided is unreasonable, hence inadequate, but he also must establish the existence of proximate cause between the [product] and the fact of the plaintiff[']s injury.'" *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 936 (S.D. Ohio 2010) (quoting *Hisrich v. Volvo Cars of N. Am., Inc.*, 226 F.3d 445, 450-51 (6th Cir. 2000)) (further citation omitted). "'In analyzing the proximate cause issue as it relates to failure-to-warn cases,' the Ohio Supreme Court 'divided proximate causation . . . into two sub-issues: (1) whether the lack of adequate warnings

[8] PLIVA also offers other arguments in support of summary judgment, including: that it did not nor should not have reasonably known of the risks associated with its product, that there is no evidence that it failed to act with reasonable care, and that plaintiff cannot establish that her injuries were the result of ingesting generic metoclopramide. The Court need not address these issues, which, in any event, appear to involve disputed issues of fact, because plaintiff's inability to establish genuine issues of material fact as to proximate causation necessitates summary dismissal of her failure-to-warn claim.

contributed to the plaintiff's [use of the product], and (2) whether [use of the product] constitute[d] a proximate cause of the plaintiff's injury.'" *Hisrich*, 226 F.3d at 451 (quoting *Seley v. G.D. Searle Co.*, 423 N.E.2d 831, 838 (Ohio 1981)).

Under Ohio law, there exists "a presumption that if an adequate warning is given it will be read and heeded, which benefits the manufacturer." *Monroe*, 29 F. Supp. 3d at 1125 (citing, among authorities, Restatement (Second) of Torts § 402A cmt. j.) In contrast, where an inadequate warning is given, the presumption favors the plaintiff. *Id*. ("That is, the failure to adequately warn was a proximate cause of the plaintiff's ingestion of the drug.") (quotation marks and citation omitted). "However, a defendant can rebut this presumption by showing that 'an adequate warning would have made no difference in the physician's decision as to whether to prescribe a drug or as to whether to monitor the patient thereafter.'" *Id*. (quoting *Seley*, 423 N.E.2d at 838).

PLIVA indirectly argues that any presumption in favor of proximate cause resulting from its inadequate warning is rebutted by the fact that plaintiff's prescribing physicians cannot say that they ever read a PLIVA package insert for metoclopramide—adequate or otherwise. "Indeed, the inadequacy of a warning cannot be the proximate cause of a plaintiff's injuries if the user of the product failed to read the warnings accompanying the product. Even if such a warning were adequate, it could not prevent the harm if the user did not read the warning." *McConnell*, 238 F. Supp. 2d at 978 (citing *Hisrich*, 226 F.3d at 451) (applying Ohio law); *see Web v. Smith*, No. 18859, 1998 WL 801944, at *5 (Ohio Ct. App. Nov. 18, 1998) ("Because nobody read or relied on the warning, any alleged inadequacy in the warning was not the proximate cause for Webb's injury.") Consequently, an inadequate warning in a prescription package insert cannot be the proximate cause of a resulting injury if the physician did not read

the insert prior to prescribing the medication. *See, e.g., Pustejovsky v. Pliva, Inc.*, 623 F.3d 271, 277 (5th Cir. 2010) (because physician did not recall ever reading the inadequate warning in the 2004 package insert for metoclopramide, the warning could not be the proximate cause of his patient's injuries); *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 996 (C.D. Cal. 2001) (because the physician did not read the package insert for Zoloft until after his patient committed suicide, "the inclusion of adequate warnings in that information would not have affected his decision" to prescribe the medication).

Dr. Ahmed testified that he has never reviewed any prescribing information from PLIVA for its metoclopramide product, and had never even heard of PLIVA. (Ahmed Dep. at 8302-03.) Dr. Baranauskas testified that, at the time he prescribed Reglan, he did not review a PLIVA metoclopramide package insert. (Baranauskas Dep. at 8400.) Dr. Sobolewski testified slightly less definitively when responding to the question of whether she had reviewed the PLIVA warning by adding to her "no" the qualifier "not that I recall." (Sobolewski Dep. at 8257.) Still, all three doctors stated that they did not read the PLIVA warning. This un-contradicted testimony demonstrates that an adequate warning would have made no difference and sufficiently rebuts the presumption that the inadequacy of the warning was the proximate cause of plaintiff's injuries.[9] Of course, plaintiff was not foreclosed from pointing to contrary

[9] Plaintiff appears to suggest that the causal connection between PLIVA's inadequate warning and her injuries can be made through the pharmacies that communicated with Drs. Baranauskas and Sobolewski regarding the dosage of Reglan these doctors prescribed. (*See* Opp'n at 7928 ("As Ms. Fulgenzi's physicians indicated their reliance upon pharmacists for relevant information, the evidence establishes that the instructions and warnings provided to these physicians by PLIVA was not only inadequate, it was nonexistent.") The record simply does not support plaintiff's representation that the information that prompted the pharmacies' inquires was taken from a PLIVA insert. As the Court has already observed, the correspondence from Medco gives no indication that the information in its flyer came from PLIVA, and, in fact, it cites other sources for its information on metoclopramide. (Doc. No. 102-39 at 3662.) Likewise, the correspondence from Rational Med to Dr. Sobolewski also fails to mention PLIVA and cites other sources for its information on the drug. (Doc. No. 102-26 at 3569.) Plaintiff cannot use guesswork and speculation to oppose a properly supported summary judgment motion.

evidence in the record that would suggest that these physicians did read and rely upon PLIVA's inadequate warning, but she has failed to do so.[10] Consequently, she has not demonstrated the existence of a genuine issue of material fact as to proximate cause, and PLIVA is entitled to summary judgment.[11] *See Seley*, 423 N.E.2d at 839 ("Where, as here, an adequate warning would have made no difference in the physician's decision as to whether to prescribe a drug or as to whether to monitor the patient thereafter, the presumption established by Comment j is rebutted, and the required element of proximate cause between the warning and ingestion of the drug is lacking.")

Of course, it is not surprising that none of plaintiff's prescribing physicians reviewed the PLIVA insert. The record establishes that the physicians had varying degrees of knowledge of the risks associated with Reglan at the time they prescribed the drug for plaintiff, and may (or may not) have reviewed the 2004 package insert provided by the manufacturers of Reglan. (Ahmed Dep. at 8302-03 [relied on clinical experience and past knowledge but did not rely on 2004 Reglan warning]; Sobolewski Dep. at 8257-58 [did not recall reading 2004 Reglan warning]; and Baranauskas Dep. at 8403-04, 8410 [may have previously read package insert or

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[10] To the extent that Dr. Sobolewski's guarded testimony could be construed as leaving open the possibility that she simply does not remember whether she read the warning, it is true that "[h]er lack of memory, of course, does not preclude the possibility that she had read these materials, neither can it sustain [plaintiff's] burden." *See Pustejovsky*, 623 F.3d at 277 (summary judgment appropriately granted to generic drug manufacturer where physician testified that she did not recall ever reading the package insert for the drug and the plaintiff came forward with no evidence that might have indicated that her doctor did rely on the insert in prescribing the drug). Plaintiff did not come forward with any evidence that would have created a factual dispute on this point.

[11] Plaintiff's failure-to-warn claim asserts that PLIVA "failed to adequately warn *consumers* and/or their health care providers" of the "significant risks of serious bodily harm, including but not limited [to] Tardiv Dysknesia . . . ." (Doc. No. 60 (Second Amended Complaint ["SAC"]) ¶ 119, emphasis added.) The SAC further alleges that "[p]laintiff and/or her prescribing health care providers relied upon the inadequate warning labels when prescribing and/or ingesting Reglan/Metoclopramide." (*Id.* ¶ 128.) However, the record before this Court on summary judgment demonstrates that plaintiff, like her physicians, did not read (and, therefore, was not affected by) PLIVA's inadequate warning. In her deposition, plaintiff testified that she had never even heard of PLIVA prior to taking metoclopramide, and further stated that, at no time, did she ever read any information about metoclopramide from PLIVA. (Doc. No. 106-1 (Deposition of Eleanor Fulgenzi) at 5413.)

PDR for Reglan but did not know of risk of long-term use].) The one thing they all have in common, however, is that they all prescribed Reglan, not the generic metoclopramide.[12] (Ahmed Dep. I at 3525; Sobolewski Dep. at 8246-47; Baranauskas Dep. at 8375, 8380, 8398-99.) Whether or not they read the Reglan insert, which coincidently had the adequate warning that is at issue in this litigation, the fact that they were prescribing the name-brand drug dictated that they would have had no reason to seek out an insert from one of several manufacturers of the

[12] Other courts have relied on this fact in applying the learned intermediary doctrine, as it exists in other state's laws, to dismiss similar cases brought against PLIVA and other manufacturers of metoclopramide. For example, in *Bell v. Pfizer, Inc*., the Eighth Circuit addressed PLIVA's failure to adopt the 2004 label change to its metoclopramide product. The court began with the fact that, like here, the plaintiff's "physician prescribed Reglan—not generic metoclopramide manufactured by PLIVA." 716 F.3d 1087, 1097 (8th Cir. 2013). It then added to it the fact that plaintiff "admit[ted] that in prescribing Reglan, her physician relied on information published in the brand defendants' package inserts and/or Physicians' Desk Reference . . . or otherwise disseminated by the brand defendants." *Id.* (quotation marks and citations omitted). The court found that these facts served to break the "causal link" between the plaintiff's injury and PLIVA's failure to incorporate the 2004 label change. *Id*. at 1097-98. (quotation marks and citation omitted); *see, e.g., Fullington v. Pfizer, Inc*., 720 F.3d 739, 747 (8th Cir. 2013) ("A manufacturer's inadequate warning is not a proximate cause of a plaintiff's harm so long as the prescribing physician had independent knowledge of the risk that the inadequate warning should have communicated.") (citing *Bell*, 716 F.3d at 1096-97).

In *Brinkley v. Pfizer, Inc*., the plaintiff attempted to distinguish *Bell* and *Fullington* by alleging that her prescribing physician, who like the physicians in *Bell* and *Fullington* had prescribed the brand name Reglan (and not the generic metoclopramide), was unaware of the 2004 warning contained in Reglan's label. *Brinkley*, 772 F.3d 1133, 1138 (8th Cir. 2014). Finding this to be a distinction without a difference, the court reasoned: "[t]hat [Brinkley] alleges her physician did not receive an adequate warning about Reglan does nothing to bridge the gap between her injury and Pliva's failure to update its label. Furthermore, whether from Pliva or the brand-name manufacturer, the adequacy of the instructions . . . made no difference in the outcome of [Brinkley's injury] because [Brinkley alleges her prescribing physician] did not read those materials." *Id*. at 1138-39 (quotation marks and citation omitted).

Again, the record is clear that plaintiff's physician's wrote prescriptions for Reglan, and not generic metoclopramide. (Ahmed Dep. I at 3525; Sobolewski Dep. at 8246-47; Baranauskas Dep. at 8375, 8380, 8398-99.) The logic employed by courts, such as the Eighth Circuit, would dictate that this fact severs the casual connection between PLIVA's inadequate warning and plaintiff's injuries as an adequate warning was available for the drug plaintiff's physicians prescribed, regardless of whether the physicians actually read it. However, the language of the Ohio statute that codified this doctrine suggests that the otherwise adequate warning must come from the manufacturer who supplied the drug in question. *See* Ohio Rev. Code § 2307.76(C). At a minimum, however, the fact that plaintiff's physicians prescribed the name brand drug further underscores the fact that PLIVA's warning could not be the proximate cause of plaintiff's injuries. *See, e.g., Pustejovsky*, 623 F.3d at 277 ("As [plaintiff] cannot demonstrate that PLIVA's inadequate warning was the producing cause of her injury, the learned-intermediary doctrine bars her recovery.").

generic counterpart.[13] While, at the end of the day, what matters is that the physicians did not read or rely on PLIVA's insert, the fact that the physicians prescribed the name-brand drug lends further support to the conclusion that they did not rely on the package insert from PLIVA.

Apparently recognizing the factual disconnect between PLIVA's inadequate 2004 warning label and her injuries, plaintiff suggests that "warnings and/or instructions can be defective and inadequate based, not only upon its content, but also due to *the manner in which they are communicated* . . . ." (Opp'n at 7928, emphasis added.) She further argues that PLIVA "did *nothing* to communicate the information added to the metoclopramide label in 2004" and "did not provide any warnings or instructions about its metoclopramide products to physicians at all." (*Id*. at 7928-29, emphasis and underlining in original). Plaintiff appears to be advancing the position that PLIVA should have found some other way to communicate the information in the 2004 updated warning to plaintiff's physicians. (*See id*. at 7928-29.) Such an argument is preempted by *Mensing*.

The Sixth Circuit has recently rejected a similar "failure-to-communicate" theory advanced against generic drug manufacturers. In *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig*., 756 F.3d 917 (6th Cir. 2014), the plaintiffs argued that generic drug manufacturers should have sent "Dear Doctor" letters directly to physicians to communicate risks associated with the use of their prescription medication. In affirming the district court's dismissal of the action, the court cited decisions from other circuits rejecting such an argument

[13] It is true that Dr. Ahmed testified in his deposition that he was aware that when he wrote the prescription for the name-brand Reglan it might be filled with the generic form metoclopramide. (Ahmed Dep. at 8304-05.) But this testimony alone cannot create a fact issue as to whether Dr. Ahmed read the PLIVA insert when there are numerous manufacturers of the generic form of Reglan, this physician testified unequivocally that he did not read PLIVA's insert, and, in fact, had never even heard of PLIVA.

on the grounds that a generic manufacturer's federal duty of "sameness" would prevent it from independently pursuing any means of communication not utilized by the name-brand drug manufacturer, as such unilateral action would inaccurately imply a therapeutic difference between the brand name and its generic equivalent. *Id*. at 932-33 (citing *Morris*, 713 F.3d at 777; *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013)); *see Strayhorn v. Wyeth Pharm., Inc*., 737 F.3d 378, 398 (6th Cir. 2013) (generic drug manufacturers were not permitted to send "Dear Doctor" letters directly to physicians); *see also Fulgenzi*, 711 F.3d at 581 n.1 (federal regulations provide that "labeling" includes not just the written label but also all communications with physicians, including "Dear Doctor" letters).

Because the manufacturer of the brand name Reglan did not communicate the content of the 2004 updated warning in any way other than by changing its label, the generic manufacturers were not free to pursue other forms of communication to disseminate this information. *See Strayhorn*, 737 F.3d at 398 ("Because no brand-name manufacturer sent a warning based on the 2004 label change, the generic manufacturers were not at liberty to do so.") (quoting *Morris*, 713 F.3d at 777.) Thus, while PLIVA was required to update its label in 2004 to match the change made by the manufacturer of Reglan, and plaintiff was permitted to pursue a failure-to-warn claim based on PLIVA's failure to make that change, any argument that PLIVA should have pursued other forms of communication is foreclosed by *Mensing*.

Likewise, plaintiff's argument that she can satisfy the proximate cause element of her failure-to-warn claim solely with physician testimony that, if the 2004 warning had been brought to their attention it would have impacted their decision to prescribe Reglan to plaintiff, suffers from the same deficiency. The generic drug manufacturers were under no duty to find alternative means of bringing the warning to the attention of plaintiff's physicians, and, in fact,

federal duty of "sameness" would actually have prevented it. The system put in place by Congress dictates the means and methods by which generic drug manufacturers may communicate warnings and label changes to physicians; a system that relies on physicians to read the warnings included in package inserts. That there may have been a more effective way to communicate this information to physicians is of no moment, and neither alters PLIVA's prescribed avenue for communicating with physicians, nor changes the fact that the prescribing physicians did not see (and therefore could not be impacted by) PLIVA's inadequate 2004 package insert in prescribing the medication for plaintiff.

Regardless of where the prescribing physicians obtained their information about Reglan/metoclopramide, or how they came to decide that it should be prescribed to plaintiff, the record is bereft of evidence that any of the physicians read PLIVA's inadequate warning. Consequently, an adequate warning from PLIVA would not have impacted any of the physician's decisions to prescribe Reglan to plaintiff. Ultimately, plaintiff's failure to demonstrate genuine issues of material fact as to the proximate cause of her injuries requires this Court to grant PLIVA summary judgment.

IV. CONCLUSION

For all of the foregoing reasons, defendant PLIVA's motion for summary judgment (Doc. No. 102) is granted. This case is dismissed.

IT IS SO ORDERED.

Dated: October 23, 2015

HONORABLE SARA LIOI
UNITED STATES DISTRICT JUDGE