UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

MARY KAREN MORETTI,

Plaintiff,

v.

WYETH, INC., et al.,

Defendants.

2:08-CV-396 JCM (GWF)

ORDER

Presently before the court is plaintiff Mary Karen Moretti's motion to alter and/or amend judgment. (Doc. #260). Defendants filed an opposition (doc. #261), and plaintiff filed a reply (doc. #262).

This case stems from the alleged injuries suffered by plaintiff as a result of ingesting the defendants' generic drug, metoclopramide. In her complaint, plaintiff asserts several claims against the defendants, including strict products liability, breach of warranty, negligence and fraud. Plaintiff's claims relate to the alleged false or misleading nature of the labeling on the drug. It is undisputed that the labeling and packaging used by the defendants for their generic drug was at all times approved by the Federal Food and Drug Administration.

Procedural History

After holding a hearing on the parties' respective motions for summary judgment and defendants' motion to dismiss, the court granted the defendants' motion for summary judgment (doc. #206), denied defendants' motion to dismiss based on federal preemption (doc. #198), and denied

James C. Mahan
U.S. District Judge

the plaintiff's motion for summary judgment (doc. #196). (Doc. #252). Following the court's ruling, defendants filed a motion to amend/correct the judgment (doc. #254), asserting that (1) the proposed and signed order did not accurately reflect the court's findings of fact and conclusions of law in support of the granting of their motion, and (2) it does not accurately reflect the court's statements at the oral hearing regarding the resolution of their motion to dismiss.

Subsequently, the court issued an order (doc. #259) addressing these concerns, which accurately reflected what the court stated during the hearing. Specifically, the order held that (1) "[r]ather than ruling that the claims were not preempted by federal law, the court actually held that it was "reluctant to handle the case on that basis," and instead ruled on the merits of the motion for summary judgment with regards to the issue of adequate warning, and (2) that the court stated during oral argument that "it wouldn't have made any difference here [if the statistics on the label were correct], because she didn't read the label." Further, the court vacated the proposed signed order (doc. #252), and entered the revised proposed order (doc. #255-1) as the final order in the case. (Doc. #259).

In the final judgment (doc. #255-1), the court held that "there is no genuine issue of material fact that (1) the labeling (also known as the package insert) for Pilva's metoclopramide met the applicable statutory and regulatory requirements of being the same as the labeling for the [r]eference [l]isted [d]rug, Reglan; (2) the labeling was approved by the FDA; and (3) the labeling warned that tardive dyskinesia was a risk of metoclopramide use." Further, the court concluded that "as a result, the label and warnings that accompanied the metoclopramide ingested by plaintiff were adequate as a matter of law." Additionally, the court held that the plaintiff "cannot prove that any alleged deficiency in Pliva's labeling was the proximate cause of any injury to [p]laintiff," because no genuine issue exists as to the fact that she did not read the labeling or other information provided for Pliva's drug.

Motion to Alter and/or Amend Judgment

In the plaintiff's motion (doc. #260), she asserts that this court's final order of judgment contains errors of law and fact, and that a reconsideration is appropriate. Further, she contends that

the case should be reinstated in light of the Ninth Circuit's recent ruling in *Gaeta v. Perrigo Pharmaceuticals Company.* 630 F.3d 1225, 2011 WL 198420 (C.A. 9 (Cal.)), 11 Cal. Daily Op. Serv. 987, 2011 Daily Journal D.A.R. 1269. Since plaintiff is presenting the court with a change in controlling law that is relevant to the court's ruling, it is treating the motion as one for reconsideration.

"Reconsideration is appropriate if the district court (1) is presented with newly discovered evidence, (2) committed clear error or the initial decision was manifestly unjust, or (3) if there is an intervening change in controlling law." *School Dist. No. 1J v. ACandS, Inc.*, 5 F.3d 1255, 1263 (9th Cir. 1993); *see* Fed. R. Civ. P. 59(e); *see also* Fed. R. Civ. P. 60(b).

A. Adequate As A Matter Of Law

As previously stated, the court held that the warning was adequate as a matter of law because it was approved by the FDA and complied with the requirement to be the same as the brand name drug. In the motion to amend (doc. #260), plaintiff relies on the court's ruling in *Gaeta* in asserting that this finding was in error. She contends that the facts are essentially the same in both cases–that the generic drug manufacturer failed to adequately warn by changing its labeling once it became aware of newly discovered risks.

In *Gaeta v. Perrigo Pharmaceuticals Company,* the court held that despite the approval by the FDA and the compliance with the "same as" requirement, it is "clear that generic manufacturers, just like their name counterparts, *must* take specific steps when they learn of new risks associated with their products," and "*shall* revise their drug labeling to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug." *Gaeta,* 630 F.3d 1231–1232; 21 C.F.R. § 201.57(e) (2004) (emphasis added)(internal quotations omitted). Further, the court held that there are several ways in which a generic manufacturer may amend its labeling or packaging to strengthen the warnings; "(1) the CBE process approved by the Supreme Court...; (2) the "prior approval" process; and (3) by asking the FDA to send "Dear Doctor" warning letters to health care professionals." *Id.*

Here, plaintiff alleges facts to support her assertion that the defendants were aware of new

risks associated with the drug, yet failed to take "specific steps" to revise the labeling. Specifically, in the plaintiff's second amended complaint (doc. #161), she contends, among other things, that the defendants (1) failed to investigate the accuracy of the drug label once they became aware of signals indicating a safety issue, (2) failed to review the medical literature, (3) relied upon the name brand to review the aforementioned literature, (4) failed to communicate the true and accurate risks and/or prevalence of severe neurological side effects resulting from the drug, (5) failed to modify the package insert "even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations," and (6) failed to monitor, review, and report any information relating to the long term use of the drug and ultimately "concealed" material facts from physicians and patients.

Since plaintiff's complaint is premised upon the assertion that defendants knew of recently discovered risks and failed to make any effort to change their labeling, this court finds that the case fits squarely within the case before the Ninth Circuit in *Geata.* As in that case, summary judgment is not appropriate here, because defendants, if they had knowledge of the new risks, should have taken steps available to them to adequately warn of the risks associated with the drug. In light of *Geata,* the label's mere compliance with the "same as" requirement and approval by the FDA do not bar recovery and do not necessarily deem the warnings "adequate as a matter of law." Therefore, the court's order (doc. #255-1) granting the motion for summary judgment based on this theory is vacated.

B. Proximate Causation

In the court's final judgment, it held that the plaintiff admittedly did not read any of the packaging, labels, or inserts associated with the drug, and that, "as a matter of law," any alleged deficiency could not be the proximate cause of the injury. (Doc. #255-1). In the plaintiff's motion to alter or amend (doc. #260), she contends that the court erred, because the testimony clearly indicated that although she did not read a "package insert," she did in fact read the actual bottle and did ask her physician about possible side effects.

There is a duty not only to create an adequate warning, but also to communicate that warning

to its intended recipients. *See United Stated v. State of Washington,* 251 F.2d 913, 916 (9th Cir. 1965), *citing Indian Towing Co. v. United States,* 350 U.S. 61 (1955). The FDA has clearly stated that for certain drugs "the safe and effective use of the drug requires additional labeling in nontechnical language to be distributed directly to patients by their healthcare provider or pharmacist." *See* Guidance: Drug Safety Information – FDA's Communication to the Public (2007), p. 7.[1] Therefore, plaintiff contends, if defendants had taken the steps necessary to adequately warn, using the plethora of means available to communicate to the patients and physicians, she would have seen the labeling on the bottle or been warned by her physician, and would "have stopped taking [the drug] immediately."

This, she asserts, creates a genuine issue as to whether an adequate warning, sufficiently communicated to the physicians and patients, would have reached her. In light of the "intervening change in controlling law" in *Gaeta* that there are means by which generic manufacturers can amend their warnings once they learn of risks, i.e. adding an additional warning on the bottle itself, the court is inclined to vacate its ruling on the issue.

Accordingly,

IT IS HEREBY ORDERED ADJUDGED AND DECREED that plaintiff Mary Karen Moretti's motion to alter and/or amend judgment (doc. #260) be, and the same hereby is, GRANTED.

IT IS THEREFORE ORDERED that the court's order (doc. #255-1) be, and the same hereby is, VACATED.

IT IS FURTHER ORDERED that defendants' motion for summary judgment (doc. #206) be, and the same hereby is, DENIED.

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[1] Found at: http://www.fda.gov/downloads/ICECI/ComplianceManuals/ComplianceProgramManual/UCM125411.pdf

IT IS FURTHER ORDERED that the above captioned case be reinstated.

DATED June 28, 2011.

UNITED STATES DISTRICT JUDGE