IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

DOUGLAS M. RAY, JR.,

Plaintiff,

v. Civil Action No. 3:10cv136

ALLERGAN, INC., et al.,

Defendants.

MEMORANDUM OPINION

This matter is before the Court on DEFENDANT'S RENEWED RULE 50(b) MOTION FOR JUDGMENT AS A MATTER OF LAW (Docket No. 224). For the reasons set forth below, the motion will be denied in part on its merits and otherwise denied as moot.

BACKGROUND

The factual background and the procedural background are set forth in the MEMORANDUM OPINION addressing DEFENDANT'S RULE 59 MOTION FOR A NEW TRIAL (Docket No. 227), are adopted and incorporated herein, and will not be repeated.

LEGAL STANDARD

Pursuant to Fed. R. Civ. P. 50(b), a party who has moved for judgment as a matter of law at trial may, within twenty-eight days of the entry of judgment, renew the request for judgment as a matter of law, which may include an alternative request for a new trial. In ruling on a renewed motion for judgment as a

matter of law, a court has several options and may: (1) allow judgment on the verdict; (2) order a new trial; or (3) direct the entry of judgment as a matter of law on the claims. Fed. R. Civ. P. 50(b)(1)-(3). It is well-established that a "Rule 50(b) motion should be granted if a district court determines, without weighing the evidence or considering the credibility of the witnesses, that substantial evidence does not support the jury's findings." Konkel v. Bob Evans Farms, Inc., 165 F.3d 275, 279 (4th Cir. 1999) (citing White v. Cnty. of Newberry, 985 F.2d 168, 172 (4th Cir. 1993)). In other words, a district court may grant judgment as a matter of law "if there is no legally sufficient evidentiary basis for a reasonable jury to find for the [non-moving] party . . . ." Cline v. Wal-Mart Stores, Inc., 144 F.3d 294, 301 (4th Cir. 1998) (quoting Abasiekong v. City of Shelby, 744 F.2d 1055, 1059 (4th Cir. 1984)). And, a renewed motion for judgment as a matter of law is properly granted "if the nonmoving party failed to make a showing on an essential element of his case with respect to which he had the burden of proof." Wheatley v. Wicomico Cnty., Md., 390 F.3d 328, 332 (4th Cir. 2004) (citing Singer v. Dungan, 45 F.3d 823, 827 (4th Cir. 1995)).

DISCUSSION

All grounds for Allergan's motion for judgment as a matter of law are rendered moot by the decision to grant DEFENDANT'S RULE 59 MOTION FOR NEW TRIAL (Docket No. 227). Therefore, the

motion for judgment as a matter of law, to the extent that it relies on the grounds presented in that particular pleading, will be denied as moot.

However, in its briefing on DEFENDANT'S RULE 59 MOTION FOR NEW TRIAL (Docket No. 227), Allergan argued extensively that Ray's failure to warn claim is preempted by the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 et seq. and its implementing regulations. Of course, if Ray's claim is preempted, a new trial could not be granted. Rather, if Ray's claim is preempted, it would fail as a matter of law; and, therefore, it should have been presented as part of the motion for judgment as a matter of law under Rule 50.

Because Allergan extensively argued the matter of preemption as part of its motion for a new trial and because that is not the proper vehicle for presenting that issue, but, because Allergan has presented a motion for judgment as a matter of law under Rule 50 and that rule provides a vehicle for raising the question of preemption, the Court will consider Allergan's preemption arguments as a component of its Rule 50 motion, even though the textual presentation of that theory is in the new trial motion.

It is especially appropriate to take this course here because, at about the time the post-trial briefing was closed, the Supreme Court of the United States decided PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011). In its reply brief on the Rule

59 motion (filed one day after Mensing was issued), Allergan raised fully the preemption issues as it sees them in view of the decision of Mensing. For reasons neither readily apparent nor expressed, Allergan did not discuss the issue in its reply brief on the Rule 50 motion which was filed on the same date as the reply brief on the Rule 59 motion. Nonetheless, it would elevate form over substance to decline to address the important issue of preemption mainly because it was filed pursuant to the wrong rule. Accordingly, the question of preemption will be considered as if presented in the Rule 50 motion; and, for the following reasons, the motion will be denied.

Preemption

At trial, and on Ray's motion, all claims against Allergan, except the failure to warn claim, were dismissed. Allergan argues that Ray's failure to warn claim is preempted under the Supremacy Clause, citing PLIVA, Inc. v. Mensing, and other decisions.

The Supremacy Clause provides that "the Laws of the United States . . . shall be the supreme Law of the Land . . . ." U.S. Const. art. VI, cl. 2. Preemption is the application of the Supremacy Clause, resulting in the rule that "any state law that conflicts with federal law is without effect." Cippolone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (internal citations omitted). "Preemption is disfavored in areas of historic

importance to the states' police powers - areas such as public health and safety." Schedin, 808 F. Supp. 2d at 1130 (quoting In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig., No. 01-MDL-1396, 2004 WL 45503, at *5 (D. Minn. Jan. 5, 2004) (citing Kemp v. Medtronic, Inc., 231 F.3d 216, 222 (6th Cir. 2000))). See also Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 347 (2001) (contrasting "situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety.'") (cited in In re St. Jude, at *5 and quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)). Express preemption occurs when Congress preempts state law by so stating in express terms. Id. (internal citations omitted). That concept is not at issue here. Implied preemption occurs upon an inference that the state law is preempted. A court will find implied preemption "where it is impossible for a private party to comply with both state and federal law, and where under the circumstances of a particular case, the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objections of Congress." Crosby v. Nat. Foreign Trade Council, 530 U.S. 363, 372-73 (2000) (cited in Schedin, 808 F. Supp. 2d at 1131). It is Allergan's theory that it is so situated and is thus protected by the rule of implied preemption.

The question of the preemptive effect of the FDA's regulations for drugs is certainly not a new matter. For example, when the labeling rules were revised in 2006, the Federal Register recited the following discussion concerning the conflict that can exist between the FDA regulations and state law:

> State law actions can rely on and propagate interpretations of the act and FDA regulations that conflict with the agency's own interpretations and frustrate the agency's implementation of its statutory mandate. For example, courts have rejected preemption in State law failure-to-warn cases on the ground that a manufacturer has latitude under FDA regulations to revise labeling by adding or strengthening warning statements without first obtaining permission from FDA. [citations omitted]. In fact, the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's under the act. A manufacturer may, under FDA regulations, strengthen a labeling warning, but in practice manufacturers typically consult with FDA before doing so to avoid implementing labeling changes with which the agency ultimately might disagree (and that therefore might subject the manufacturer to enforcement action).

71 Fed. Reg. at 3934. The explanation of the 2006 revision to the FDA labeling rules goes on to address how state law requirements can undermine "safe and effective use" by "erod[ing] and disrupt[ing] the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use." Id. at 3935. "State law actions also

threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs." Id. [1]

Indeed, the explanation actually discusses preemption more directly by listing six types of claims that, according to the FDA, are preempted by FDA regulation, including "claims that a drug sponsor breached an obligation to warn by failing to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling," and "claims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or advertising, the substance of which had been proposed to FDA for including in labeling, if that statement was not required by FDA at the time plaintiff claims the sponsor had an obligation to warn . . . ." Id. at 3935-36. Notwithstanding these broad statements, the FDA ultimately acknowledged that "FDA recognizes that FDA's regulation of drug labeling will not preempt all State law actions." Id. at 3936.

The importance of the preemption issue and the fact that, as evinced by the above cited regulatory preamble, the FDA had changed its position on state tort law "persuaded us [the Supreme Court] to grant Wyeth's petition for certiorari." Wyeth v.

[1] That remarkably arrogant comment is at odds with the Supreme Court's view of the important role played by state law actions, see pp. 8-9 infra, and it reflects a most serious misapprehension of the limited role of the federal government. By citing the statement, the Court does not endorse it. Rather, it is cited merely to show that the preemption issue is not a novel one and to give it some context.

Levine, 555 U.S. 555, 563 (2009). In Wyeth, the FDA had approved Wyeth's drug labeling. The plaintiff had proceeded on a theory that Wyeth should have modified its warning label based on information known after the original warning had been approved and after one modification of the warning had been approved. Wyeth took the view that it could not have modified the warning under FDA regulations. Wyeth also argued that it was not possible for Wyeth to comply both the duties that were reflected in the state failure to warn claims and the federal labeling duties specified by the FDA. The Supreme Court, in Wyeth, rejected both arguments.

But, before doing so, the Supreme Court commented expressly on the language previously cited herein from the preamble to the 2006 regulations. In that regard, the Court explained that:

> Further, the preamble is at odds with what evidence we have of Congress' purposes, and it reverses the FDA's own longstanding position without providing a reasoned explanation, including any discussion of how state law has interfered with the FDA's regulation of drug labeling during the decades of coexistence. The FDA's 2006 position plainly does not reflect the agency's own view at all times relevant to this litigation. Not once prior to the Levine's injury did the FDA suggest that state tort law stood as an obstacle to its statutory mission. To the contrary, it cast federal labeling standards as a floor upon which States could build and repeatedly disclaimed any attempt to pre-empt failure-to-warn claims.

Wyeth v. Levine, 555 U.S. at 578.

The Court went on to explain that: "[i]n keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation." Id. Then, after explaining that the FDA had limited resources to monitor the thousands of drugs on the market and observing that the manufacturers had superior access to information about their products, the Court explained the important role that state court lawsuits play in uncovering unknown drug hazards and in providing incentives for drug manufacturers to disclose safety risks promptly. Id. at 578-79. It also then commented: "[f]ailure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." Id. at 579.

Against that background, the Court stated the question that was presented in the case as:

> Whether the FDA's drug labeling judgments 'preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use.'

Wyeth v. Levine, 555 U.S. at 563.

As does Allergan here, Wyeth argued that the state law failure to warn claims are preempted because it is not possible for Wyeth to have complied with both the state law duties that underlay Levine's claims and Wyeth's federal labeling duties.

Wyeth's principal theory on that score was that the FDA had approved the exact text of the proposed label and that a change in labeling could not have been made absent prior FDA approval. The Supreme Court rejected that view for reasons that are very pertinent here. Specifically, on that point, the Court held that:

> There is, however, an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval. Among other things, this 'changes being effected' (CBE) regulation provides that if a manufacturer is changing a label to 'add or strengthen a contra-indication, warning, precaution, or adverse reaction' or to 'add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product,' it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval.

Wyeth v. Levine, 555 U.S. at 568 (citing 21 C.F.R. § 314.70(c)(6)(iii)(A), (C)).

In like fashion, the Supreme Court rejected Wyeth's contention that, if it had unilaterally added such a warning (without approval of the FDA), it would have violated federal law respecting unauthorized distribution and misbranding. The Court held that strengthening the warning would not have made the drug at issue a new drug, and that strengthening the label would not have rendered that drug misbranded.

When discussing the issue, the Supreme Court explained that FDA regulations take account of "the fact that risk information accumulates over time and that the same data may take on different meaning in light of subsequent developments . . . ." Wyeth v. Levine, 555 U.S. at 569. Moreover, and especially pertinent in this case, the Supreme Court made the very logical observation that "the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation is difficult to accept." Wyeth v. Levine, 555 U.S. at 570 (explaining that neither Wyeth nor the FDA had identified any case in which the FDA had brought an enforcement action for strengthening a warning pursuant to the CBE regulation.) And, considering the very purpose of the FDA's regulations, it would be absurd to find that a manufacturer would be sanctioned for relying on the CBE regulation to bring truthful, accurate and informative information about a new risk.

Completing its decision on that point, the Supreme Court held that:

> The CBE regulation permitted Wyeth to unilaterally strengthen its warning, and the mere fact that the FDA approved [the drug's] label does not establish that it would have prohibited such a change.

Wyeth v. Levine, 555 U.S. at 573. That, of course, according to the Supreme Court, meant that Wyeth simply was unable to demonstrate its impossibility preemption defense.

Recognizing that Wyeth imposes a barrier to its preemption argument, Allergan focuses, instead, upon the recent decision of the Supreme Court in PLIVA, Inc. v. Mensing. According to Allergan, it is Mensing, not Wyeth, that controls the issue in this case. For the reasons that follow, the Court finds that Mensing simply does not apply here and that it does not change the fundamental principles announced two years earlier in Wyeth, a decision that the Supreme Court actually cited with approval in its decision in Mensing.

To begin, it is important to be mindful of the question actually decided in Mensing. On that point, the Supreme Court stated:

> The question presented is whether federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt, these state-law claims.

PLIVA, Inc. v. Mensing, 131 S. Ct. at 2572.

The decision then begins with an explanation of the drug at issue, making clear that it was a generic version of a brand-name drug, the warning labels for which had been first approved by the FDA in 1980 and "strengthened and clarified several times." Id. However, the plaintiffs in Mensing did not receive the brand-name drug. Rather, they were prescribed a generic version of the drug.

The plaintiffs alleged that the manufacturer of the generic drug had not changed the drug labels to adequately warn of the

danger despite mounting evidence that long-term use of the drug carried the risk of tardive dyskinesia that was far greater than that reflected on the label that the generic drug used. The generic label was the same as that used by the brand-name drug because federal regulations required generic drug manufacturers to use the labels that had been approved for and were being used for the brand-name drug.

In Mensing, the Supreme Court began its analysis by explaining that the federal law respecting labeling was far more complex than the common law requirements respecting the adequacy of labels. The Court explained that to secure FDA approval, the manufacturer had to prove that a drug was safe and effective and that the proposed label was accurate and adequate. The Court went on to explain that meeting those requirements "involves costly and lengthy clinical testing." PLIVA, Inc. v. Mensing, 131 S. Ct. at 2574. As the Court explained, the same pre-marketing requirements originally had applied to all drugs, generic and brand name. However, in 1984, Congress passed the Hatch-Waxman Amendment, pursuant to which generic drugs could be approved by the FDA "simply by showing equivalence to a reference listed drug that has already been approved by the FDA." Id.

As the Court explained, that permitted manufacturers to develop generic drugs inexpensively without having to duplicate the clinical trials. And, the Court explained that "[a] generic

drug application must also 'show that the [safety and efficacy] labeling proposed . . . is the same as the labeling approved for the [brand-name] drug.'" Id. At that point in the opinion, the Court made a most important observation when it explained that: "[a]s a result, brand-name and generic drug manufacturers have different federal drug labeling duties." Id.

Against that background, the Court then explained the critical issue that it had been called upon to decide as follows:

> What is in dispute is whether, and to what extent, generic manufacturers may change their labels *after* initial FDA approval.

Id. (emphasis in original).

The Court found that the FDA had interpreted its regulations to mean that the "changes being effected" (CBE) regulations would allow a generic drug manufacturer to change the label for generic drugs only "to match an updated brand-name label or to follow the FDA's instructions." Id. at 2575. And, the Supreme Court deferred to the FDA's interpretation of that regulation. Id.

The FDA also had determined that a Dear Doctor letter qualified as labeling and thus could not be sent by a generic manufacturer if it contained substantial new warning information because to do so would not be consistent with the drug's approved labeling that must match the labeling of the brand-name manufacturer. Again, the Supreme Court deferred to the FDA's interpretation. Id. at 2576. Under those circumstances (which,

of course, are not present here), the Supreme Court held that the manufacturer of a generic drug could not comply both with the federal regulations and state law respecting the duty to warn and, therefore, that the doctrine of impossibility preemption applied.

What was made quite clear by the Supreme Court in Mensing was that its decision did not disturb the decision in Wyeth. Indeed, the Supreme Court recognized that Wyeth had held that a brand-name manufacturer could make the changes under the CBE regulation and could unilaterally strengthen its warning without prior FDA approval. The Court went on to note that the manufacturers of generic drugs could not do the same thing. In so doing, the Court quite clearly reaffirmed the validity of Wyeth.

Indeed, the majority opinion recognized that its decision, distinguishing as it does between brand-name and generic manufacturers, would make little sense to most people. Further, the dissent described what it characterized as the "many absurd consequences" of the majority's decision. That may or may not be true, but the majority opinion's acknowledgement and the characterization in the dissent make quite clear that Mensing

applies only to generic drug manufacturers and does not alter the holding in Wyeth at all.[2]

Allergan urges the Court here to do what the Supreme Court did not do, extend the rationale of Mensing to brand-name drugs such as BOTOX®. The Court declines to take that course, instead finding that Wyeth controls the preemption issue in this case and, under Wyeth, Allergan could have used the CBE regulations to add to or strengthen its warning in the BOTOX® labeling without requiring prior approval by the FDA. Accordingly, the claim of failure-to-warn by requiring such a warning is not preempted.

As explained in the MEMORANDUM OPINION respecting the motion for new trial, the federal regulations do control what must be in a black box warning and so any theory based on a black box warning as a requirement of state law would be preempted. However, as also made clear in the MEMORANDUM OPINION respecting the motion for new trial, nothing in the regulations that govern Allergan's duties at the time at issue precluded using bold type or some other way of emphasizing and making prominent language respecting the information that was in its possession. Moreover,

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[2] As the dissent in Mensing makes clear, and as the majority opinion explicitly acknowledges, it makes little, if any, sense to treat brand-name drugs and generic drugs differently. But, that result is the consequence of deference to an agency's decision which, as the dissent explains, does not warrant deference. That issue, however, is not for resolution by a district court.

nothing in Mensing precludes Allergan, as distinct from a generic manufacturer, from sending a Dear Doctor letter.

For the foregoing reasons, Allergan's preemption argument lacks merit, and its motion under Rule 50 based on that theory is denied.

CONCLUSION

For the foregoing reasons, the DEFENDANT'S RENEWED RULE 50(b) MOTION FOR JUDGMENT AS A MATTER OF LAW (Docket No. 224) is denied as moot except as to the theory of preemption and as to that theory, the motion is denied on its merits.

It is so ORDERED.

/s/ REP

Robert E. Payne
Senior United States District Judge

Richmond, Virginia
Date: May 31, 2012