IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In re Testosterone Replacement	**)**	
Therapy Products Liability Litigation	**)**	**No. 14 C 1748**
Coordinated Pretrial Proceedings	**)**	**MDL No. 2545**

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

Plaintiffs in this multidistrict litigation proceeding (MDL) allege that they have suffered injuries caused by defendants' testosterone replacement therapy (TRT) drugs. Some of the defendants filed a motion to dismiss plaintiffs' state-law claims arising from the use of certain generic TRT drugs, arguing that federal law preempts such claims under *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013). In response, plaintiffs argued that their claims were not preempted as a matter of law or, alternatively, that additional discovery was necessary to make the preemption determination. The Court granted defendants' motion. *See In re Testosterone Replacement Therapy Prods. Liab. Litig.* ("*In re TRT*"), No. 14 C 1748, 2015 WL 6859286, at *6 (N.D. Ill. Nov. 9, 2015). In doing so, the Court dismissed all claims against defendants Pfizer, Inc. and Pharmacia & Upjohn Company, LLC (Pfizer or the Pfizer defendants) and Auxilium Pharmaceuticals, Inc. (Auxilium) arising from the use of Pfizer's generic TRT drug Depo-Testosterone and Auxilium's generic TRT drug Testopel and denied plaintiffs' request for additional discovery on the preemption issue. *Id.*

Plaintiffs have now filed a motion for reconsideration and for clarification of aspects of the Court's order. In particular, plaintiffs urge the Court to reconsider its

denial of plaintiffs' request for discovery and to clarify whether it intended its order to dismiss all of plaintiff's claims, including those which sound in fraud. In this particular instance, it is immaterial whether the motion is treated as a motion to clarify or a motion for reconsideration, so the Court treats it as a motion for reconsideration.

A. Previous order

In its previous order, the Court ruled that plaintiffs' state-law claims arising from the use of Depo-Testosterone and Testopel were preempted because defendants, as manufacturers of these generic TRT drugs, could not avoid liability under those claims without also violating federal law. The Supreme Court held in *Mensing* that federal law requires manufacturers of generic drugs to ensure that their drugs' warning labels are identical to the FDA-approved labels of their brand-name counterparts and prohibits such manufacturers from independently changing their drugs' labels. *Mensing*, 131 S. Ct. at 2577–78. This "ongoing federal duty of 'sameness'," *id.* at 2575, presents a conflict with state laws that would require manufacturers of generic drugs to alter (that is, to strengthen) their drugs' warning labels in order to avoid liability. *Id.* at 2581. Thus the Supreme Court has held that state-law failure-to-warn and design-defect claims based on the alleged inadequacy of a generic drug's warning label are preempted because it would be impossible for manufacturers of such drugs to comply with both state and federal law. *See id.* (failure-to-warn claims); *Bartlett*, 133 S. Ct. at 2473 (design-defect claims).

In their briefing on the motion to dismiss, the parties focused on whether the preemption analysis of *Mensing* and *Bartlett* applies to drugs like Depo-Testosterone and Testopel—drugs that are generic in the sense that the FDA approved them

pursuant to an abbreviated new drug application (ANDA) but resemble the brand-name drugs at issue in *Mensing* and *Bartlett* because they are "reference listed drugs" (RLDs) whose labels subsequent ANDA applicants must match.[1] The Court determined, in accordance with recent FDA statements and with every other federal court to consider the issue, that a generic drug's status as an RLD does not exempt the manufacturer from the preemption analysis outlined in *Mensing* and *Bartlett*. *In re TRT*, 2015 WL 6859286, at *6. The Court concluded that manufacturers of such drugs, like the manufacturers of the drugs at issue in *Mensing* and *Bartlett*, may not independently alter their drugs' warning labels and thus cannot comply simultaneously with state and federal law regarding the content of their labels. *Id.*

Though plaintiffs disagree with the Court's conclusion concerning the applicability of *Mensing* and *Bartlett* to RLD manufacturers, they concede that mere disagreement cannot form the basis for a motion to reconsider. Plaintiffs urge the Court to reconsider, however, two subsequent steps in its analysis: (1) the conclusion that all of plaintiffs' claims, including their fraud-based claims, are preempted, and (2) the decision to deny plaintiffs' request for additional discovery that they contend might prove that defendants' were, at some point, permitted to alter their labels independently.

B. Preemption of fraud-based claims

Having determined that defendants were prohibited from independently altering their drugs' labels, the Court concluded that all of plaintiffs' state-law claims were preempted. In reaching that conclusion, the Court understood plaintiffs to have

[1] The Court discusses the concepts of an ANDA drug and an RLD drug in greater depth in its prior opinion. *See In re TRT*, 2015 WL 6859286, at *1.

conceded that the viability of each of their claims depended upon defendants' ability under federal law to independently alter their warning labels. *See In re TRT*, 2015 WL 6859286, at *6 ("As plaintiffs concede, all of their claims against [defendants] . . . "flow, to some extent" from the [defendants'] alleged failure to alter their drugs' warning labels, and thus all of plaintiffs' claims against those defendants are preempted.") (internal citation omitted). Plaintiffs did, to be sure, focus their briefing on the question of whether manufacturers of generic RLDs could independently change their warning labels. But upon further review and reflection, the Court no longer believes that plaintiffs specifically conceded that their fraud-based claims would fall if the Court disagreed with them on the preemption issue. As a result, the Court now addresses directly whether plaintiffs' fraud-based claims can survive preemption based on the allegations of fraudulent off-label promotion.

Though neither the Seventh Circuit nor any other circuit court has addressed whether fraud claims against manufacturers of generic drugs based on off-label promotion are preempted under *Mensing*, other district courts have ruled that such fraud-based claims are viable, and the Court finds their reasoning persuasive. For example, in *Arters v. Sandoz Inc.*, 921 F. Supp. 2d 813 (S.D. Ohio 2013), the court ruled that state-law failure-to-warn claims against the manufacturer of a generic drug were preempted under *Mensing* because the defendant manufacturer could not comply with the state's failure-to-warn law without changing the drugs' label in violation of federal law. *Id.* at 819. But the court also ruled that state-law fraud claims based on defendants' allegedly fraudulent or unreasonably dangerous promotion were not preempted. *See id.* at 819–20 ("Nothing in the [Federal Food, Drug, and Cosmetic Act]

requires defendants to promote their drug for an off-label use, nor is the federal law otherwise at odds with . . . fraud claims brought by plaintiffs."); *see also Elmore v. Gorsky*, No. 2:12-CV-00347, 2012 WL 6569760, at *3 (S.D. Tex. Dec. 17, 2012) ("[T]he Court declines to find that any and all conduct that falls within the Plaintiffs' allegations of promoting Risperdal for ***off***-label uses in an illegal scheme necessarily fall within the concept of the regulation of labeling.") (emphasis in original). This Court agrees. Defendants' obligations under state fraud law to refrain from falsely promoting their drugs for unapproved uses do not conflict with their obligations under federal law to maintain their warning labels. Because the fraud-based claims based on off-label promotion do not make it impossible to comply with both state and federal law, those claims are not preempted under *Mensing* or *Bartlett*.

Although plaintiffs' citations to case law that supports this argument first appeared in their reply on the motion to reconsider, defendants have had the opportunity to respond via their surreply. Defendants argue that the FDA's broad understanding of the "labeling" with which generic defendants must maintain consistency would include the types of "off-label" promotions plaintiffs allege and that federal courts have dismissed comparable "off-label" claims as preempted under *Mensing* and *Bartlett*. *See* 21 C.F.R. § 202.1(l)(2) (including as labeling "[b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter"); *Rojas v. Teva Pharms., USA, Inc.*, 920 F. Supp. 2d 772, 780 (S.D. Tex. 2013); *Stephens v. Teva Pharm., U.S.A., Inc.*, 70 F. Supp. 3d 1246, 1250 (N.D. Ala. 2014).

But even if defendants' "off-label" advertising and promotion would be considered "labeling" under FDA regulations, this would not change the fact that defendants could refrain from engaging in their allegedly false promotion of their drugs for off-label uses without violating their federal duty to maintain the "sameness" of their labeling. That is, nothing in the approved warning labels for defendants' drugs requires them to promote those drugs for unapproved off-label uses.

In addition, the cases defendants cite do not directly address whether *Mensing* and *Bartlett* preempt fraud-based claims based on off-label promotion and are distinguishable nevertheless. Unlike in this case, the plaintiffs' assertion in *Stephens* that the defendants engaged in off-label promotion was "belied by the actual claims in the complaint," which did not contain allegations of affirmative off-label misrepresentations. *Stephens*, 70 F. Supp. 3d at 1250–51. Similarly, in *Rojas*, the court granted judgment on the pleadings for the plaintiffs' fraud claims not on preemption grounds, but because of the plaintiffs' failure to allege fraud with particularity, and it concluded that a claim for off-label promotion regarding the length of time the drug should be used was, in reality, indistinguishable from the plaintiffs' failure-to-warn claims. *See Rojas*, 920 F. Supp. 2d at 780. Plaintiffs in this case, on the other hand, have alleged fraud with adequate particularity, *see In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14 C 1748, 2014 WL 7365872, at *6–*7 (N.D. Ill. Dec. 23, 2014), based on allegations of affirmative off-label promotion. For the reasons discussed, those fraud-based claims survive preemption.

Plaintiffs' claims for fraud (Claim Seven), consumer protection (Claim Nine), and unjust enrichment (Claim Ten) are based in part on allegations of fraudulent off-label

promotion. Under the analysis described above, these claims would not require defendants to violate federal law to escape liability. Thus none of these claims are preempted to the extent they are based on allegations of fraudulent off-label promotion. In addition, the counts plaintiff has labeled "wrongful death" (Claim Eleven), "survival action" (Claim Twelve), "loss of consortium" (Claim Thirteen), and "punitive damages" (Claim Fourteen) survive to the extent they derive from plaintiffs' claims arising from fraudulent off-label promotion.

C. Request for additional discovery

Plaintiffs also argue that the Court misunderstood their argument in support of their request to conduct additional discovery prior to a ruling on the preemption issue. Plaintiffs had argued that additional discovery could turn up evidence showing that the FDA had previously approved defendants' independent labeling changes, demonstrating that such changes are permissible under federal law. In support of their request, plaintiffs submitted evidence of two changes made to the label for Depo-Testosterone in 1991 and 1996, respectively. The Court denied plaintiffs' request, concluding that the preemption question was primarily a legal one and that additional discovery would not alter the legal conclusion the Court had reached. *See In re TRT*, 2015 WL 6859286, at *6.

Plaintiffs point to the Court's statement that additional facts about whether defendants "*attempted* to make such unilateral changes would not alter [its] legal conclusion," *id.* (emphasis added), as an indication that the Court misunderstood their argument. The evidence they hoped to discover, they explain, is not evidence that defendants attempted to make changes, but rather evidence that the FDA approved

such changes and provided an explanation for why such changes were permissible under federal law. But even if the Court had more carefully articulated the nature of the evidence plaintiffs sought to uncover through their proposed discovery, plaintiffs' argument that additional discovery is warranted before ruling on the preemption issue would remain unpersuasive.

Plaintiffs contend that discovery on this issue is particularly appropriate because the Court relied heavily on the FDA's interpretation of its own regulations in determining that manufacturers of generic RLDs were unable to change their warning labels unilaterally. If additional discovery revealed that FDA took a contrary position, plaintiffs argue, this would provide an important counterweight to the interpretations on which the Court relied. Plaintiffs also note that FDA might have previously taken a different position on the issue from the one the Court understood the agency to be taking in the guidances it issued in 2013. In such a situation, plaintiffs argue, the position the agency took prior to the time each plaintiff first used the drugs at issue would be much more relevant than the position the agency later took in 2013.

The Court might find this argument more persuasive if there were a basis to believe that the FDA had actually taken a position contrary to the one it took in its 2013 statements. But the reasons plaintiffs offer for this proposition amount to little more than speculation. As defendants convincingly argue, the examples of their prior label changes appear to be changes made (1) in response to a newly enacted statute and FDA's implementing regulations or (2) in response to an FDA request to update the label. Thus the changes made were not of the independent sort needed to avoid preemption. *See Mensing*, 131 S. Ct. at 2579 ("The question for 'impossibility' is

whether the private party could independently do under federal law what state law requires of it."). As an attachment to their reply, plaintiffs submit an additional letter that Auxilium sent to the FDA in 2015 requesting a change to its label for Testopel.[2] Not only is that letter consistent with the Court's conclusion that defendants may not make independent changes to their labels, but FDA's response to that letter provides further support for the Court's conclusion. As defendants note, supported by their submission of the letter the FDA sent in response, the FDA responded to Auxilium's letter by confirming that such changes require the agency's advance approval and may not be made independently. In short, plaintiffs have failed to identify a non-speculative reason for suspecting that additional discovery will uncover the evidence they hope it will.

If courts were to grant discovery requests based on the speculative possibility that a defendant's correspondence with a federal agency might shed light on the agency's interpretation of its own regulations, the issue of federal preemption would have to be postponed to the summary judgment stage in numerous cases. But as defendants note, "every other federal court to consider whether state-law claims involving [generic] RLDs are preempted under *Mensing* has done so in the context of a motion to dismiss or a motion for judgment on the pleadings." Defs.' Opp. to Mot. for Reconsideration at 5–6 (listing cases). Plaintiffs fail to respond to this point in their reply, and they have cited no case in which a court declined to rule on a similar preemption issue in a motion to dismiss or for judgment on the pleadings to allow for additional discovery. Indeed, at least one other court has specifically denied such a request. *See Garza v. Wyeth LLC*, No. 2:12-CV-198, 2015 WL 364286, at *4 (S.D. Tex.

[2] Plaintiffs also submit another letter from 2014, which appears to be a draft of the letter submitted in 2015.

Jan. 27, 2015) (denying request for discovery and stating that the "preemption decision is not evidence-based but is rather a question of law"). The Court sees no reason to take a different path in this case.

Conclusion

The Court grants plaintiffs' ANDA-related motion for reconsideration and for clarification in part and denies it in part [dkt. no. 1099]. For the reasons discussed above and in the Court's previous order, plaintiffs' request for additional discovery is denied, and plaintiffs' various claims for design defect and failure to warn (Counts One, Two, Three, Four, Five, and Six, and Eight) arising from the use of defendants' TRT drugs Depo-Testosterone and Testopel are dismissed. Plaintiffs' remaining claims (Counts Seven, Nine, Ten, Eleven, Twelve, Thirteen, and Fourteen) survive to the extent they are based on allegations of fraudulent off-label marketing but are otherwise dismissed.

MATTHEW F. KENNELLY
United States District Judge

Date: March 7, 2016