UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

MDL NO. 2924
20-MD-2924

JUDGE ROBIN L. ROSENBERG
MAGISTRATE JUDGE BRUCE E. REINHART

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ORDER DENYING THE BRAND OTC DEFENDANTS' RULE 12 PARTIAL MOTION TO DISMISS PLAINTIFFS' SECOND AMENDED ECONOMIC LOSS CLASS COMPLAINT AS PREEMPTED BY FEDERAL LAW

This matter is before the Court on the Brand OTC Defendant's Rule 12 Partial Motion to Dismiss Plaintiffs' Second Amended Economic Loss Class Complaint ("SAELC") as Preempted by Federal Law ("Motion to Dismiss").[1] DE 4107. The Court held a hearing on the Motion on October 4, 2021 ("the Hearing"). The Court has carefully considered the Motion, the Response [DE 4240], the Reply [DE 4319], the arguments that the parties made during the Hearing, and the record and is otherwise fully advised in the premises. For the reasons set forth below, the Motion to Dismiss is **DENIED**.

The Plaintiffs named in the SAELC are individuals who purchased brand-name prescription and over-the-counter ("OTC") ranitidine products over varying periods of time. They contend that they were deceived into purchasing ranitidine products that break down into the cancer-causing molecule N-nitrosodimethylamine ("NDMA"), information that the Brands, the manufacturers of brand-name ranitidine, failed to include on product labeling. *See, e.g.*, SAELC at 11-14. The Plaintiffs bring the SAELC on behalf of themselves and various proposed classes,

[1] The moving Defendants are Boehringer Ingelheim Pharmaceuticals, Inc., Chattem, Inc., Sanofi US Services Inc., Sanofi-Aventis U.S. LLC, Patheon Manufacturing Services, LLC, Pfizer Inc., and GlaxoSmithKline LLC (collectively, the "Brands"). The SAELC may be located at docket entry 3883. All page number references herein to documents on the Court's docket are to the page numbers generated by CM/ECF in the header of each document.

raising nearly 400 counts under the laws of U.S. states and Puerto Rico for violations of state consumer protection statutes, unjust enrichment, breach of quasi-contract, and breach of implied warranty. Among their requested relief, the Plaintiffs seek refunds for their purchase of brand-name prescription and OTC ranitidine products.

The Brands now move to dismiss the claims in the SAELC related to OTC ranitidine products. The Court (A) reviews legal authority relevant to the Motion to Dismiss, (B) explains relevant prior rulings of the Court, and (C) describes the parties' arguments, before (D) providing its analysis and conclusion.

A. Relevant Law

A court may grant a motion to dismiss a pleading if the pleading fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A court ruling on a motion to dismiss accepts the well-pled factual allegations as true and views the facts in the light most favorable to the plaintiff. *Jones v. Fransen*, 857 F.3d 843, 850 (11th Cir. 2017). A "complaint may be dismissed under Rule 12(b)(6) when its own allegations indicate the existence of an affirmative defense, so long as the defense clearly appears on the face of the complaint." *Quiller v. Barclays Am./Credit, Inc.*, 727 F.2d 1067, 1069 (11th Cir. 1984), *aff'd en banc*, 764 F.2d 1400 (11th Cir. 1985). The Motion to Dismiss seeks dismissal based on the affirmative defense of federal pre-emption.

The Supremacy Clause of the U.S. Constitution provides that the laws of the United States "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "It is basic to this constitutional command that all conflicting state provisions be without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981) (citing *McCulloch v. Maryland*, 17 U.S. 316, 427 (1819)). The pre-emption doctrine is

derived from the Supremacy Clause. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992).

Supreme Court caselaw has recognized that state law is pre-empted under the Supremacy Clause in three circumstances. *English v. Gen. Elec. Co.*, 496 U.S. 72, 78 (1990). First, "Congress can define explicitly the extent to which its enactments pre-empt state law." *Id.* Second, "state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." *Id.* at 79. Third, state law is pre-empted "to the extent that it actually conflicts with federal law . . . where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (citation and quotation marks omitted). The first and third types of pre-emption—respectively called express pre-emption and implied pre-emption—are relevant to the Motion to Dismiss.

1. Express Pre-emption

Congress has expressly pre-empted certain claims with respect to OTC drugs. With limited exceptions, "no State or political subdivision of a State may establish or continue in effect any requirement . . . that is different from or in addition to, or that is otherwise not identical with, a requirement" for OTC drugs in the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. § 301 *et seq.* ("FDCA"). 21 U.S.C. § 379r(a). The Supreme Court has interpreted statutes that pre-empt state "requirements" as pre-empting, among other things, common-law causes of action. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008) ("Absent other indication, reference to a State's 'requirements' includes its common-law duties.").

A statute that expressly pre-empts state requirements that are different from or in addition to federal requirements "does not prevent a State from providing a damages remedy for claims

premised on a violation of" a U.S. Food and Drug Administration ("FDA") regulation. *Id.* at 330 (applying 21 U.S.C. § 360k(a) of the Medical Device Amendments of 1976). "[T]he state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.*; *see Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) ("Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."); *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447 (2005) (holding that 7 U.S.C. § 136v(b) of the Federal Insecticide, Fungicide, and Rodenticide Act, which pre-empts state labeling requirements that are in addition to or different from federal requirements, does not pre-empt a state labeling requirement "if it is equivalent to, and fully consistent with," federal requirements). "In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted . . . the plaintiff must show that the requirements are genuinely equivalent." *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011) (quotation omitted). "State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law." *Id.* (quotation omitted).

The federal statutes concerning misbranded drugs are relevant here. A drug is misbranded if, among other defects, "its labeling is false or misleading in any particular" or "it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling." 21 U.S.C. § 352(a)(1), (j). Federal law prohibits the misbranding of any drug in interstate commerce and the introduction into interstate commerce of any misbranded drug. *Id.* § 331(a), (b). Only the United States Government may enforce the FDCA. *Id.* § 337(a) (providing that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States"); *Ellis v. C.R. Bard,*

Inc., 311 F.3d 1272, 1284 n.10 (11th Cir. 2002) (explaining that "no private right of action exists for a violation of the FDCA").

2. Implied Pre-emption

As already explained, federal law pre-empts state law "where it is impossible for a private party to comply with both state and federal requirements" or "where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *English*, 496 U.S. at 79 (quotation marks omitted). The Supreme Court addressed both impossibility and obstacle pre-emption in *Wyeth v. Levine*, 555 U.S. 555 (2009), a case where a consumer of a brand-name prescription drug brought state-law negligence and strict-liability claims against the drug's manufacturer for failure to provide an adequate warning on the drug's labeling. The consumer alleged that the labeling was deficient because it failed to instruct clinicians to administer the drug through an IV drip rather than through an injection. *Id.* at 559-60. The Supreme Court's ruling on obstacle pre-emption is relevant here.

The drug manufacturer argued that the consumer's claims were pre-empted because state-law claims imposing labeling requirements would obstruct the purposes and objectives of the federal regulation of drug labeling. *Id.* at 573. The drug manufacturer maintained that, "[o]nce the FDA has approved a drug's label, a state-law verdict may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered the stronger warning at issue." *Id.* at 573-74 (characterizing the drug manufacturer's position as arguing "that the FDCA establishes both a floor and a ceiling for drug regulation"). The Supreme Court disagreed. The Court stated that evidence showed that Congress enacted the FDCA to bolster consumer protection against harmful drugs, but that Congress did not provide a federal remedy for consumers harmed by drugs because it determined that one was unnecessary when common-law claims were available to

provide appropriate relief for injured consumers. *Id.* at 574 & n.7. The Court further stated that the fact that Congress had not enacted an express pre-emption statute for prescription drugs demonstrated that Congress did not believe that state-law claims posed an obstacle to the FDCA's objectives. *Id.* at 574-75. Congress's "silence on the issue [through the lack of an express pre-emption statute], coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. Thus, obstacle pre-emption did not bar the consumer's state-law claims against the drug manufacturer for an inadequate warning. *Id.* at 581.

The Supreme Court also addressed obstacle pre-emption in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, patients claiming injuries from the use of orthopedic bone screws in their spines brought state-law fraud claims against a consulting company for misrepresentations that the company had made to the FDA while assisting the screws' manufacturer to obtain FDA approval to market the screws. *Id.* at 343. The patients contended that the consulting company had represented to the FDA that the screws would be marketed for use in bones in the arms and legs, when the screws actually were intended for spinal use, and had gained the FDA's market approval as a result of this misrepresentation. *Id.* at 346-47. The Supreme Court held that these claims were pre-empted for a combination of reasons. *See id.* at 348-53.

First, the Court stated that various federal statutory and regulatory provisions empower the FDA to detect, deter, and punish fraud against the FDA, and Congress intended the United States exclusively to enforce these provisions. *Id.* at 348-49 & n.4 (citing 21 U.S.C. § 337(a)). Next, the Court explained that giving the FDA the discretion and flexibility to employ its enforcement options was "a critical component of the statutory and regulatory framework under which the FDA

pursues difficult (and often competing) objectives," and the FDA's "somewhat delicate balance" of its objectives could be "skewed" if state-law claims for fraud on the FDA could proceed. *Id.* at 348-50 (stating, as an example of this balancing, that the FDA must both ensure that medical devices are reasonably safe and effective and ensure that qualifying medical devices are on the market within a relatively short period of time).

The Court then stated as "a practical matter" that permitting state-law fraud-on-the-FDA claims would "dramatically increase the burdens" that applicants for FDA approval face and could deter potential applicants from seeking FDA approval out of fear of exposure to unpredictable civil liability under state law. *Id.* at 350-51. Applicants who were not deterred from applying for FDA approval might "submit a deluge of information that the Administration neither wants nor needs" out of fear that their disclosures may later be judged insufficient in state court, and this "deluge" could burden the FDA's evaluation of applications and delay its approval process. *Id.* at 351. Finally, the Court explained that the patients' fraud-on-the-FDA claims existed "solely by virtue of the FDCA disclosure requirements" and did not rely on "traditional state tort law which had predated" the FDCA. *Id.* at 352-53. For these reasons, the Court concluded that the patients' fraud claims were pre-empted. *Id.* at 353.

The Eleventh Circuit Court of Appeals applied *Buckman* in *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017), to hold that a negligence claim brought under Florida law was pre-empted. In *Mink*, a plaintiff who maintained that he had sustained injuries due to a hip replacement system sued the device's manufacturer for negligence, among other claims. *See Mink v. Smith & Nephew, Inc.*, 0:15-cv-61210-BB (S.D. Fla.), DE 29. The negligence claim was based in part on the manufacturer's alleged failure to report known or knowable safety information about the device to the FDA, including through the submission of annual reports, adverse event reports,

and device defect reports required under federal regulations. *Id.* at 12-28. The plaintiff asserted that these violations constituted common-law negligence under Florida law and that he was enforcing common-law duties that the manufacturer owed to him, "but only to the extent that [the duties were] parallel to and not different from or in addition to the requirements of federal law." *Id.* at 12-13.

The Eleventh Circuit explained that the plaintiff's negligence claim based on failure to report to the FDA was a claim for negligent failure to warn and ruled that the claim was pre-empted. *Mink*, 860 F.3d at 1329-30. The court reasoned that the plaintiff's "theory of liability [was] based on a duty to file a report with the FDA" and was "very much like the 'fraud-on-the-FDA' claim the Supreme Court held was impliedly preempted in *Buckman*." *Id.* at 1330. "In both cases, a plaintiff alleged a manufacturer failed to tell the FDA those things required by federal law." *Id.* The court concluded that federal law pre-empted the plaintiff's claim "insofar as [the manufacturer's] duty [was] owed to the FDA and [the plaintiff's] theory of liability [was] not one that state tort law has traditionally occupied." *Id.*

3. Interplay Between Express and Implied Pre-emption

The Eleventh Circuit explained in *Mink* how express and implied pre-emption work together. Express pre-emption bars state-law claims that impose requirements different from or additional to federal requirements. *Id.* at 1327 (citing *Riegel*, 552 U.S. at 321-22 and *Wolicki-Gables*, 634 F.3d at 1301-02). Implied pre-emption bars state-law claims that seek to privately enforce duties owed to the FDA. *Id.* (citing *Buckman*, 531 U.S. at 348). "These two types of preemption, operating in tandem, have created what some federal courts have described as a 'narrow gap' for pleadings." *Id.* "To make it through, a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct

violated that federal requirement (avoiding implied preemption)." *Id.* The plaintiff may proceed "so long as she claims the breach of a well-recognized duty owed to her under state law and so long as she can show that she was harmed by a violation of applicable federal law." *Id.* (quotation marks omitted).

B. The Court's Prior Rulings

The parties' respective arguments in briefing the Motion to Dismiss implicate several prior rulings of this Court. The SAELC marks the third Master Complaint in which the Plaintiffs have brought class claims under state law for refunds for the purchase of OTC ranitidine products. The Brands moved to dismiss these claims from the first such complaint, the Consolidated Consumer Class Action Complaint, arguing that the claims were expressly pre-empted under 21 U.S.C. § 379r(a). DE 889; DE 1580 at 16-22. Among their arguments, the Plaintiffs asserted that their claims did not impose requirements different from those under the FDCA because ranitidine products were misbranded as that term is defined in 21 U.S.C. § 352 and because their claims were based on a state-law duty not to sell a dangerous drug that paralleled the federal requirement in § 331 not to sell a misbranded drug. DE 1976 at 30-32.

The Court determined that the Plaintiffs' assertion that their OTC refund claims paralleled federal misbranding law could not "be squared with their pleadings" for six reasons: (1) the Plaintiffs had not pled any standalone counts for misbranding or identified any state with a cause of action imposing requirements identical to federal misbranding law; (2) very few of the counts that they had pled referenced misbranding at all; (3) federal misbranding law "arguably" applied only to labeling, but the Plaintiffs' claims encompassed more than labeling; (4) the Consolidated Consumer Class Action Complaint was a shotgun pleading that required amendment; (5) analysis of the parallelism argument would require "careful consideration" of whether state requirements

were greater than federal requirements, and the Court could not undertake careful analysis given the way that the Consolidated Consumer Class Action Complaint had been pled; and (6) the Plaintiffs' allegations of misbranding lacked clarity. DE 2532 at 27. The Court therefore rejected the Plaintiffs' parallelism argument but permitted them to amend to replead parallel claims. *Id.*

The Plaintiffs raised state-law claims for refunds for the purchase of OTC ranitidine products for the second time in the Consolidated Amended Consumer Economic Loss Class Action Complaint. DE 2835. The Brands again moved to dismiss the claims as expressly pre-empted under 21 U.S.C. § 379r(a). DE 3114 at 12-18. In opposition, the Plaintiffs reasserted that § 379r(a) did not pre-empt their claims because the claims paralleled federal misbranding law. DE 3325 at 12-19. The Plaintiffs contended that the "fundamental premise" of their claims was that "the label needed to warn about the risk of NDMA and cancer in order to avoid misleading consumers about the true nature of the product they were purchasing" and that the claims therefore paralleled federal law prohibiting the introduction of drugs that have "false or misleading" labeling and are therefore misbranded. *Id.* at 14-15 (citing 21 U.S.C. § 352(a)(1)). During a hearing before the Court, the Plaintiffs conceded that state-law claims that were not premised on a false or misleading label would not parallel federal misbranding law. DE 3683 at 206. The Plaintiffs also explained that they have not alleged precisely when ranitidine became misbranded. DE 3684 at 44-46.

In its second order addressing express pre-emption, the Court ruled that, "at least for now, the Plaintiffs' claims as alleged are sufficiently parallel" to federal misbranding law requiring an accurate, non-misleading label to survive the Brands' pre-emption challenge under § 379r(a). DE 3715 at 35-36. The Court could not definitely rule on whether any specific state-law claim paralleled federal misbranding law because such a ruling would require "detailed analysis that carefully compares the elements of a state cause of action with the elements of federal misbranding

law," and the parties had not briefed this detailed, state-specific analysis to the Court. *Id.* at 34-36. The Court explained that state-specific arguments could be raised at a future time.[2] *Id.* at 36. The Court therefore denied the Brands' motion to dismiss the OTC refund claims, with one exception. Because the Plaintiffs premised their parallelism arguments on a false or misleading label and "abandoned any defense of OTC claims that [were] not premised upon a false or misleading label," the Court dismissed with prejudice as pre-empted "any OTC claim not based upon a false or misleading label" and required the Plaintiffs to omit such claims from future pleadings. *Id.* at 36-37.

In making its ruling, the Court rejected an argument by the Brands that a drug product containing an FDA-approved label can never be misbranded, explaining that the Brands provided no binding authority to support this position. *Id.* at 31, 34. Authority did exist for the proposition that, at the time the FDA approves an OTC drug's label, the label is not false or misleading and the drug is not misbranded. *Id.* at 31 (citing as an example 21 C.F.R. § 330.10(a)(4)(v)). However, in a case previously before the Supreme Court, the FDA took the position in an amicus brief that a drug with an approved label could be misbranded "due to new, scientifically significant information that the FDA did not previously possess." *Id.* at 31-32 (citing *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 487 n.4 (2013) and the amicus brief at 2013 WL 314460).

The Court stated that it did not need to decide whether the definition of misbranding under federal law, as applied to an FDA-approved drug, was limited to that in 21 U.S.C. § 352 or whether, alternatively, misbranding required new and scientifically significant information that the FDA did not previously possess. *Id.* at 32. Even if this latter, higher standard applied, the Plaintiffs'

[2] The Court previously stated in a separate Order that the parties have the ability to seek to raise state-specific arguments at a later stage of this litigation. *See* DE 2968 at 4 ("To the extent that other state-specific issues become relevant at a later stage of the litigation, such as at the bellwether trial stage, the parties agree that they may seek leave of the Court to raise the issues at that time.").

allegations met the standard. *Id.* Specifically, the Plaintiffs alleged that the Brands "withheld information about ranitidine's propensity to form NDMA from the FDA," that the FDA had "recently learned" of this information, and that the FDA had issued a voluntary recall of ranitidine as a result. *Id.* ("Stated another way, it is the Plaintiffs' allegation that ranitidine products should never have been approved for OTC status, and were therefore misbranded, because the FDA-approved label was false and misleading and caused harm when taken as directed due to the [Brands'] deception."); *see also id.* at 31 (characterizing the Plaintiffs' allegations as being that, "when the FDA approved ranitidine, it did not have full and accurate information about ranitidine because, at that time, the [Brands] had withheld information about the dangers of ranitidine from the FDA"). Thus, the Plaintiffs had pled OTC refund claims that survived express pre-emption at the pleading stage.

Separate from claims for refunds for the purchase of OTC ranitidine products, the prior master pleadings filed by those Plaintiffs pursuing claims for personal injury or medical monitoring included counts against the Brands titled "Failure to Warn Consumers Through the FDA." *See, e.g.*, DE 2759 at 284; DE 2832-1 at 330. The Plaintiffs alleged in those counts that the laws of some states imposed a duty owed by product manufacturers to consumers to warn third parties, such as the FDA, about the dangers associated with products when the warnings could be expected to reach consumers. According to the Plaintiffs, the Brands failed to satisfy this duty when they did not report ranitidine's risk of NDMA formation and cancer to the FDA.

The Brands moved to dismiss all claims for failure to warn consumers through the FDA as impliedly pre-empted under *Buckman* and *Mink*. DE 3114 at 18-23. The Court ruled that *Mink* was directly on point and, as binding Circuit precedent, compelled a conclusion that the Plaintiffs'

claims were pre-empted. DE 3715 at 43-49. Thus, the Court dismissed with prejudice all claims for failure to warn consumers through the FDA. *Id.* at 49.

C. The Parties' Arguments

The Brands argue in the Motion to Dismiss that obstacle pre-emption bars all claims in the SAELC for refunds for the purchase of OTC ranitidine products. DE 4107. The Brands contend that the Court ruled in its second order addressing express pre-emption that the only OTC refund claims not expressly pre-empted are those premised on a theory that the labeling for OTC ranitidine products never should have been FDA-approved, and was misbranded, because the FDA did not have full and accurate information due to the Brands deceiving the FDA by withholding information about the dangers of ranitidine. *Id.* at 5, 7-8 (citing DE 3715 at 31-32). The Brands further contend that the Plaintiffs have conceded that their OTC refund claims are premised on the theory that the Brands deceived the FDA. *Id.* at 5, 7. Because the only OTC refund claims to survive express pre-emption are based on deception (that is, fraud) of the FDA, the claims are like those that the Supreme Court ruled were pre-empted in *Buckman*. *Id.* at 11-12, 17.

The Plaintiffs dispute: (1) that they have conceded that their OTC refund claims are based on the Brands' deception of the FDA; (2) that they have pled OTC refund claims that are based on FDA deception; and (3) that the Court ruled that only claims to survive express pre-emption are those based on FDA deception. DE 4240 at 5, 13-16. The Plaintiffs argue that their OTC refund claims are like the claims at issue in *Wyeth* and are not pre-empted because the claims are brought under traditional state law (not for violation of federal law) and are based on a defect in the warnings to consumers (not a defect in the Brands' communications with the FDA). *Id.* at 9-12.

D. Analysis and Conclusion

The Brands' arguments in the Motion to Dismiss are based on their understanding that the Court has ruled that the only OTC refund claims not expressly pre-empted are those premised on the Brands withholding safety information from, and therefore deceiving, the FDA. That understanding of the Court's Order is incorrect. The Court ruled, in the absence of state- and claim-specific briefing, that the OTC refund claims were not expressly pre-empted because they sought to enforce state law requiring an accurate, non-misleading label that paralleled federal misbranding law also requiring an accurate, non-misleading label. The Court did not determine whether the definition of misbranding under federal law requires new and scientifically significant information that the FDA did not previously possess. To the Court's knowledge, that is a position that the FDA has taken only in its amicus brief in *Bartlett*. *See* 2013 WL 314460. The FDA has not enacted a regulation defining misbranding in this way, even though it may promulgate regulations to enforce the FDCA. *See* 21 U.S.C. § 371(a).

The Court did not need to resolve the question of the correct definition of misbranding because, even if misbranding requires new and scientifically significant information that the FDA did not previously possess, the Plaintiffs' allegations met that definition. Moreover, the Court did not conclude that the Plaintiffs' OTC refund claims were limited to a theory that the Brands withheld information about ranitidine from the FDA. The Court did not conclude that the only OTC refund claims to survive express pre-emption were those premised on withholding information from the FDA. Furthermore, the Court did not rule that any of the Plaintiffs' claims survive express pre-emption, as the Court deferred that issue until such time as it considers state-specific arguments. Lastly, the Court did not conclude that withholding information from the FDA necessarily equates with deception or fraud on the FDA.

The Plaintiffs plead causes of action for violations of state consumer protection statutes, unjust enrichment, breach of quasi-contract, and breach of implied warranty. The Plaintiffs bring over 300 separate state-law counts for refunds for the purchase of OTC ranitidine products. The Court will describe two such counts as examples.

The Plaintiffs bring Count 111 against Pfizer for breach of implied warranty under Arkansas law. SAELC ¶¶ 1870-81 (citing Ark. Code Ann. § 4-2-314). The Plaintiffs allege that Pfizer warranted through its labeling that ranitidine was merchantable and fit for its ordinary and intended purpose when used according to the labeling, and that Pfizer breached this warranty because ranitidine was neither merchantable nor fit for its intended use when it caused cancer or created an unreasonable risk of cancer. *Id.* ¶¶ 1873-75. Count 111 incorporates several preceding paragraphs in the SAELC, including paragraphs alleging that Pfizer knew or should have known, through published scientific information, proper testing its own products, or otherwise, that ranitidine breaks down into cancer-causing NDMA. *See, e.g.*, *id.* ¶¶ 393, 1870.

As another example, the Plaintiffs bring Count 186 against Boehringer Ingelheim Pharmaceuticals, Inc. ("BI") for unjust enrichment under Alabama law. *Id.* ¶¶ 2868-75. The Plaintiffs allege that BI failed to disclose through its labeling that ranitidine was unsafe and unfit for human consumption, that consumers conferred a benefit on BI by paying for ranitidine products, and the BI was unjustly enriched because ranitidine was worthless. *Id.* ¶¶ 2870-73. Count 186 incorporates paragraphs alleging that BI also knew or should have known that ranitidine breaks down into cancer-causing NDMA. *See, e.g.*, *id.* ¶¶ 393, 2868.

Both breach of implied warranty and unjust enrichment are traditional state-law legal claims, as are the remaining legal claims in the SAELC. Accurately warning consumers about product dangers is a traditional area of state-law concern. The Brands have not argued otherwise.

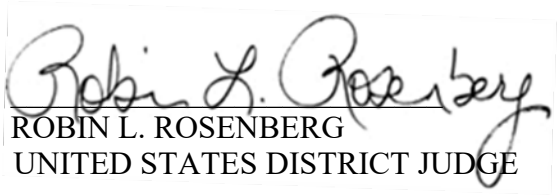
Upon the Court's review of Counts 111 and 186 and the incorporated paragraphs, no allegations address withholding information from or fraud on the FDA.[3] It does not appear on the face of the pleading, and the Brands have not argued, that the existence of the FDCA or the FDA, much less fraud on the FDA, is a necessary element of the implied-warranty claim, the unjust-enrichment claim, or any of the Plaintiffs' other legal claims under any state's law. The Court concludes that obstacle pre-emption does not bar the Plaintiffs' OTC refund claims in the SAELC as they are pled.

Finally, the Court addresses one additional matter that the Brands raised in their Reply in support of the Motion to Dismiss and during the Hearing. The Brands contend that the Plaintiffs' pleading in the SAELC fails to comply with the Court's Order dismissing with prejudice as pre-empted "any OTC claim not based upon a false or misleading label" and requiring the Plaintiffs to "omit claims not premised on a false or misleading label from future pleading." DE 3715 at 36-37 (declining to determine precisely which claims were not based on a false or misleading label because the parties had not adequately briefed the issue). The Brands assert that the SAELC contains "not only labeling claims, but also a range of already-dismissed allegations relating to manufacturing, expiration dates, storage, product containers, etc." DE 4319 at 9-10. The Court stated in its prior Order that, "[t]o the extent the Defendants believe that any future amended pleading improperly includes OTC counts that are not based upon a false or misleading label, that is a matter the Defendants may raise at such time as the Court hears arguments on state-specific matters." DE 3715 at 37. Thus, this is not an issue that the Court will take up at this stage of the litigation.

[3] The Plaintiffs do allege withholding of information from the FDA in paragraphs such as 305 to 312 of the SAELC. However, the Brands have identified no OTC refund claim in which these paragraphs have been incorporated.

For the foregoing reasons, it is **ORDERED AND ADJUDGED** that the Brand OTC Defendant's Rule 12 Partial Motion to Dismiss Plaintiffs' Second Amended Economic Loss Class Complaint as Preempted by Federal Law [DE 4107] is **DENIED**. The Defendants shall file their Answers to the Second Amended Economic Loss Class Complaint within 20 days of the date of this Order.

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 6th day of October, 2021.



ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

Copies furnished to Counsel of Record