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 GRANTING THE GENERIC DEFENDANTS' RULE 12 MOTION TO DISMISS ON THE GROUND OF PREEMPTION, GRANTING THE STORE-BRAND RETAILER DEFENDANTS' MOTION TO DISMISS OR STRIKE CONSOLIDATED MEDICAL MONITORING CLASS ACTION COMPLAINT AND CONSOLIDATED AMENDED CONSUMER ECONOMIC LOSS CLASS ACTION COMPLAINT, AND DENYING AS MOOT THE SPECIALLY-APPEARING NON-U.S. GENERIC MANUFACTURER DEFENDANTS' RENEWED MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION

This matter is before the Court on the Generic Defendants' ("Generic Manufacturer Defendants") Rule 12 Motion to Dismiss on the Ground of Preemption [DE 3105], the Store-Brand Retailer Defendants' ("Store-Brand Defendants") Motion to Dismiss or Strike Consolidated Medical Monitoring Class Action Complaint and Consolidated Amended Consumer Economic Loss Class Action Complaint [DE 3113], and the Specially-Appearing Non-U.S. Generic Manufacturer Defendants' ("Specially-Appearing Defendants") Renewed Motion to Dismiss for Lack of Personal Jurisdiction [DE 3108]. The Court held Hearings on the Generic Manufacturer and Store-Brand Defendants' Motions on June 4 and 7, 2021.[1] The Court has carefully considered the Motions, the Responses [DE 3326, 3329, 3409], the Replies [DE 3407, 3422, 3505], the Plaintiffs' Supplemental Filing [DE 3525], the arguments that the parties made during the Hearings, and the record and is otherwise fully advised in the premises. For the reasons set forth below, the Generic Manufacturer Defendants' Rule 12 Motion to Dismiss is **GRANTED**, the

[1] The Court also held a Hearing on other motions to dismiss pending in this litigation on June 3, 2021. The Court cites to arguments from all three Hearings in this Order.

Store-Brand Defendants' Motion to Dismiss or Strike is **GRANTED**, and the Specially-Appearing Defendants' Renewed Motion to Dismiss is **DENIED AS MOOT**. The Plaintiffs' claims against the Generic Manufacturer and Store-Brand Defendants are **DISMISSED WITHOUT LEAVE TO AMEND**.

I. Factual Background[2]

This case concerns the pharmaceutical product Zantac and its generic forms, which are widely sold as heartburn and gastric treatments. The molecule in question—ranitidine—is the active ingredient in both Zantac and its generic forms.

Zantac has been sold since the early 1980s, first by prescription and later as an over-the-counter ("OTC") medication. In 1983, the U.S. Food and Drug Administration ("FDA") approved the sale of prescription Zantac. AMPIC ¶ 240. GlaxoSmithKline ("GSK") first developed and patented Zantac. *Id.* ¶ 239. Zantac was a blockbuster—the first prescription drug in history to reach $1 billion in sales. *Id.* ¶ 240.

GSK entered into a joint venture with Warner-Lambert in 1993 to develop an OTC form of Zantac. *Id.* ¶ 233. Beginning in 1995, the FDA approved the sale of various forms of OTC Zantac. *Id.* ¶¶ 233, 237. The joint venture between GSK and Warner-Lambert ended in 1998, with Warner-Lambert retaining control over the sale of OTC Zantac in the United States and GSK retaining control over the sale of prescription Zantac in the United States. *Id.* ¶ 243. Pfizer acquired Warner-Lambert in 2000 and took control of the sale of OTC Zantac in the United States. *Id.* ¶ 245.

[2] A court must accept a plaintiff's factual allegations as true at the motion–to–dismiss stage. *West v. Warden*, 869 F.3d 1289, 1296 (11th Cir. 2017) ("When considering a motion to dismiss, we accept as true the facts as set forth in the complaint and draw all reasonable inferences in the plaintiff's favor.") (quotation marks omitted). Plaintiffs have set forth their factual allegations in three "master" complaints: the Amended Master Personal Injury Complaint ("AMPIC"); the Consolidated Amended Consumer Economic Loss Class Action Complaint ("ELC"); and the Consolidated Medical Monitoring Class Action Complaint ("MMC") (collectively, the "Master Complaints"). DE 2759, 2835, 2832-1. Unless otherwise noted, all citations will be made to the redacted versions of the Master Complaints.

The right to sell OTC Zantac in the United States later passed to Boehringer Ingelheim Pharmaceuticals and then to Sanofi. *Id.* ¶¶ 249-50, 253-55. When the patents on prescription and OTC Zantac expired, numerous generic drug manufacturers began to produce generic ranitidine products in prescription and OTC forms. *Id.* ¶¶ 260-62.

Scientific studies have demonstrated that ranitidine can transform into a cancer-causing molecule called N-nitrosodimethylamine ("NDMA"), which is part of a carcinogenic group of compounds called N-nitrosamines. *Id.* ¶¶ 348, 359, 365, 367. Studies have shown that these compounds increase the risk of cancer in humans and animals. *Id.* ¶¶ 398-404. The FDA, the Environmental Protection Agency, and the International Agency for Research on Cancer consider NDMA to be a probable human carcinogen. *Id.* ¶¶ 275, 279. The FDA has set the acceptable daily intake level for NDMA at 96 nanograms. *Id.* ¶ 302.

Valisure LLC and ValisureRX LLC, a pharmacy and testing laboratory, filed a Citizen Petition on September 9, 2019, calling for the recall of all ranitidine products due to high levels of NDMA in the products. *Id.* ¶ 322. The FDA issued a statement on September 13 warning that some ranitidine products may contain NDMA. *Id.* ¶ 323. On November 1, the FDA announced that testing had revealed the presence of NDMA in ranitidine products. *Id.* ¶ 333. The FDA recommended that drug manufacturers recall ranitidine products with NDMA levels above the acceptable daily intake level. *Id.* Five months later, on April 1, 2020, the FDA requested the voluntary withdrawal of all ranitidine products from the market. *Id.* ¶ 338.

II. Procedural Background

After the discovery that ranitidine products may contain NDMA, plaintiffs across the country began initiating lawsuits related to their purchase and/or use of the products. On February 6, 2020, the United States Judicial Panel on Multidistrict Litigation created this multi-district

litigation ("MDL") pursuant to 28 U.S.C. § 1407 for all pretrial purposes and ordered federal lawsuits for personal injury and economic damages from the purchase and/or use of ranitidine products to be transferred to the undersigned. DE 1. Since that time, approximately 1,400 plaintiffs have filed lawsuits in, or had their lawsuits transferred to, the United States District Court for the Southern District of Florida. In addition, this Court has created a Census Registry where tens of thousands of claimants who have not filed lawsuits have registered their claims. *See* DE 547.

The Plaintiffs filed their first Master Complaints on June 22, 2020. DE 887, 888, 889. In those Master Complaints, the Plaintiffs contended that the ranitidine molecule is unstable, breaks down into NDMA, and has caused thousands of consumers of ranitidine products to develop various forms of cancer. DE 887 ¶¶ 1, 6, 19. They alleged that "a single pill of ranitidine can contain quantities of NDMA that are hundreds of times higher" than the FDA's allowable limit. *Id.* ¶ 4. The Plaintiffs pursued federal claims and state claims under the laws of all 50 U.S. states, Puerto Rico, and the District of Columbia. *See generally* DE 889.

The Court has entered numerous Pretrial Orders to assist in the management of this MDL. In Pretrial Order # 36, the Court set a schedule for the filing and briefing of the first round of motions to dismiss under Rule 12 directed to the Master Complaints. DE 1346. The various Defendants filed motions to dismiss. The Court issued rulings on those motions on December 31, 2020, January 8, 2021, and February 23, 2021. *See* DE 2512, 2513, 2515, 2516, 2532, 2840.

Following an amendment to Pretrial Order # 36, the Plaintiffs filed the AMPIC on February 8, 2021. DE 2759. After the Court granted a two-week extension of time [DE 2720], the Plaintiffs filed the MMC [DE 2832-1] and the ELC [DE 2835] on February 22, 2021. In Pretrial Order # 61, the Court set a schedule for the filing and briefing of the second round of motions to dismiss under

Rule 12 directed to the Master Complaints. DE 2968. The Motions addressed herein were filed pursuant to that schedule.

III. The Master Complaints

A. The Amended Master Personal Injury Complaint

All individuals who filed a Short Form Complaint adopt the AMPIC. AMPIC at 2.[3] The Plaintiffs allege that they developed cancers from taking Defendants' ranitidine products. *Id.* at 1. The AMPIC "sets forth allegations of fact and law common to the personal-injury claims" within the MDL. *Id.* at 1-2. Each Plaintiff seeks compensatory damages, punitive damages, restitution, and all other available remedies. *Id.* at 1-2.

The Defendants "are entities that designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine." *Id.* ¶ 21. They are categorized into four groups: (1) Brand Manufacturer Defendants; (2) Generic Manufacturer Defendants; (3) Distributor Defendants; and (4) Retailer Defendants. Within each category, the AMPIC combines distinct corporate entities, including parents, subsidiaries, and affiliates, into single named Defendants.[4]

The AMPIC contains 17 counts and numerous state-specific sub-counts: Strict Products Liability—Failure to Warn Through Warnings and Precautions (Count I, 46 sub-counts); Negligence—Failure to Warn Through Warnings and Precautions (Count II, 48 sub-counts); Strict Products Liability—Failure to Warn Through Proper Expiration Dates (Count III, 46 sub-counts); Negligence—Failure to Warn Through Proper Expiration Dates (Count IV, 48 sub-counts); Failure to Warn Through the FDA (Count V, 15 sub-counts); Strict Products Liability—Design Defect Due to Warnings and Precautions (Count VI, 46 sub-counts); Strict Products Liability—Design

[3] Unless noted otherwise, all page number references herein are to the page numbers generated by CM/ECF in the header of each document.

[4] For example, Defendant "Sanofi" refers to five entities: Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., Sanofi SA, Patheon Manufacturing Services LLC, and Chattem, Inc. AMPIC ¶¶ 33-39.

Defect Due to Improper Expiration Dates (Count VII, 46 sub-counts); Negligent Failure to Test (Count VIII, 2 sub-counts); Negligent Product Containers (Count IX, 52 sub-counts); Negligent Storage and Transportation Outside the Labeled Range (Count X, 52 sub-counts); Negligent Storage and Transportation (Count XI, 52 sub-counts); Negligent Misrepresentation (Count XII); Reckless Misrepresentation (Count XIII); Unjust Enrichment (Count XIV, 52 sub-counts); Loss of Consortium (Count XV, 52 sub-counts); Survival Actions (Count XVI, 52 sub-counts); and Wrongful Death (Count XVII, 52 sub-counts). Counts I, II, VI, XII, and XIII are brought against every Brand Manufacturer Defendant. Counts III, IV, V, VII, VIII, and XI are brought against every Brand and Generic Manufacturer Defendant. Count IX is brought against every Brand and Generic Manufacturer Defendant that manufactured and sold ranitidine-containing pills. Count X is brought against every Retailer and Distributer Defendant. Counts XIV, XV, XVI, and XVII are brought against every Defendant.

B. The Consolidated Amended Consumer Economic Loss Class Action Complaint

One hundred and eighty named individuals bring the ELC on behalf of themselves and all others similarly situated. Each Plaintiff asserts that he or she purchased and/or used a ranitidine product during an approximate timeframe.

The Plaintiffs bring the action in their individual capacities and on behalf of numerous classes pursuant to Rule 23. The Plaintiffs bring state class actions under various state laws stemming from the Defendants' sale of prescription-strength ranitidine for approximately forty states.[5] Additionally, the Plaintiffs bring state class actions under approximately forty-three states' laws for the Defendants' sale of OTC ranitidine.

[5] The Plaintiffs have brought a varying number of state-law counts against each Defendant.

The Defendants named in the ELC are entities that "designed, manufactured, marketed, distributed, labeled, packaged, handled, stored and/or sold Zantac or generic Ranitidine-Containing Products." ELC ¶ 1. The Defendants are categorized into three groups: (1) Brand Manufacturer Defendants (Prescription and OTC); (2) Generic Prescription Manufacturer and/or Store-Brand Manufacturer Defendants (collectively, the "Generic Manufacturer Defendants"); and (3) Store-Brand Defendants. The ELC alleges 1,675 counts against the Defendants. The Plaintiffs bring claims for violation of various state consumer protection statutes, common-law unjust enrichment, common-law breach of quasi-contract, and breach of implied warranty.

C. The Consolidated Medical Monitoring Class Action Complaint

Fifty-two named individuals bring the MMC on behalf of themselves and the various classes established in the MMC. MMC ¶¶ 93-144. The Plaintiffs purchased and used ranitidine products in fourteen jurisdictions.[6] Each Plaintiff alleges that he or she purchased and used ranitidine products during an approximate timeframe.

There are five categories of classes: (1) Brand Manufacturer Prescription Medical Monitoring Classes; (2) Brand Manufacturer OTC Medical Monitoring Classes; (3) Generic Prescription Medical Monitoring Classes; (4) Store-Brand Medical Monitoring Classes; and (5) Store-Brand Manufacturer Medical Monitoring Classes. Within each category, there are state- and Defendant-specific classes. For example, within the third category (Generic Prescription Medical Monitoring Classes), several named Plaintiffs bring claims against Defendant Amneal on behalf of themselves and eleven state-specific "Amneal Prescription Medical Monitoring Classes." *Id.* ¶ 998. Within the fourth category (Store-Brand Medical Monitoring Classes), five named Plaintiffs bring claims against Defendant CVS on behalf of themselves and four state-specific

[6] Arizona, California, Colorado, District of Columbia, Florida, Indiana, Maryland, Missouri, Montana, Nevada, Ohio, Pennsylvania, Utah, and West Virginia.

"CVS Medical Monitoring Classes." *Id.* ¶ 1004. The various classes are comprised of individuals who purchased and used one of the Defendants' ranitidine products while residing in a particular state, and who have not been diagnosed with a Subject Cancer.[7]

The Defendants named in the MMC are "entities that designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold Zantac or generic Ranitidine-Containing Products." *Id.* ¶ 6. The Plaintiffs categorized the Defendants into three groups: (1) Brand Manufacturer Defendants (Prescription and OTC); (2) Generic Prescription Manufacturer Defendants and/or Store-Brand Manufacturer Defendants; and (3) Store-Brand Defendants. The MMC alleges 638 counts against the various Defendants.[8] Each count falls within one of five general causes of action: (1) Failure to Warn through Warnings and Precautions; (2) Failure to Warn through Proper Expiration Dates; (3) Failure to Warn Consumers through the FDA; (4) Negligent Product Containers; and (5) Negligent Storage and Transportation.

IV. Summary of the Parties' Arguments and the Court's Rulings

The Generic Manufacturer Defendants contend that all of the Plaintiffs' claims against them are pre-empted under two key Supreme Court cases that addressed the pre-emption of claims against generic drug manufacturers: *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) and *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013). The Generic Manufacturer Defendants argue that the claims against them for failure to warn consumers through the FDA are additionally pre-empted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Thus, the Generic Manufacturer Defendants maintain that all of the claims against them in all three Master Complaints must be dismissed. The Store-Brand Defendants assert that all of the claims against

[7] The Plaintiffs define "Subject Cancers" as "[t]hose cancers includ[ing] serious and potentially fatal bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancers." MMC at 3.
[8] While the MMC lists 640 total counts, there is no Count 222 or Count 223.

them likewise must be dismissed. The Specially-Appearing Defendants bring a challenge to personal jurisdiction. The Plaintiffs respond that none of their claims against the Generic Manufacturer and Store-Brand Defendants are pre-empted or subject to dismissal. The Plaintiffs maintain that the Specially-Appearing Defendants' personal-jurisdiction challenge is without merit.

The Court finds that *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017), compels the conclusion that *Buckman* pre-empts the claims against the Generic Manufacturer Defendants for failure to warn consumers through the FDA. The Plaintiffs' remaining claims against the Generic Manufacturer Defendants, as well as the claims against the Store-Brand Defendants, are pre-empted under *Mensing* and *Bartlett*. Therefore, the Court grants the Generic Manufacturer and Store-Brand Defendants' Motions to Dismiss. The Court's dismissal is without leave to amend. The Court denies as moot the Specially-Appearing Defendants' Renewed Motion to Dismiss.

V. Standard of Review

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 Rule 12(b)(6) motion to dismiss should be granted only when the pleading fails to contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The pleading must contain more than labels, conclusions, a formulaic recitation of the elements of a cause of action, and naked assertions devoid of further factual enhancement. *Id.* The "[f]actual allegations must be enough to raise a right to relief above the speculative level."

Twombly, 550 U.S. at 555; *see also Iqbal*, 556 U.S. at 678 (explaining that the plausibility standard "asks for more than a sheer possibility that a defendant has acted unlawfully").

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). But the court need not accept as true allegations upon information and belief that lack sufficient facts to make the allegations plausible. *Mann v. Palmer*, 713 F.3d 1306, 1315 (11th Cir. 2013) (citing *Twombly*, 550 U.S. at 551, 557); *see also In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 931 (6th Cir. 2014) ("The mere fact that someone believes something to be true does not create a plausible inference that it is true."). The court also need not accept legal conclusions couched as factual allegations. *Diverse Power, Inc. v. City of LaGrange, Ga.*, 934 F.3d 1270, 1273 (11th Cir. 2019). "Under Rule 12(b)(6), dismissal is proper when, on the basis of a dispositive issue of law, no construction of the factual allegations will support the cause of action." *Allen v. USAA Cas. Ins. Co.*, 790 F.3d 1274, 1278 (11th Cir. 2015) (quotation marks omitted).

VI. Analysis of the Motions to Dismiss

A review of the law applicable to drugs approved by the FDA is necessary to evaluate the arguments that the parties make in briefing the Generic Manufacturer and Store-Brand Defendants' Motions to Dismiss. Therefore, the Court first discusses (A) key statutes and regulations that govern the FDA's regulation of drugs, and (B) impossibility pre-emption and significant cases that have addressed impossibility pre-emption in the drug context. The Court then turns to (C) the Generic Manufacturer Defendants' Motion to Dismiss, (D) the Store-Brand Defendants' Motions to Dismiss or Strike, and (E) the Specially-Appearing Defendants' Renewed Motion to Dismiss.

A. Federal Regulation of Drug Products

The FDA regulates prescription and OTC drugs under the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. § 301 *et seq.* ("FDCA"). The FDCA provides a process for the FDA to approve a new drug through a new drug application ("NDA") and a process for the FDA to approve a drug that is the same as a previously approved drug through an abbreviated new drug application ("ANDA"). *See* 21 U.S.C. § 355. A drug must have an FDA-approved NDA or ANDA to be introduced into interstate commerce. *Id.* § 355(a).

1. NDAs

An NDA must contain scientific data and other information showing that the new drug is safe and effective and must include proposed labeling. *See id.* § 355(b)(1). The FDCA defines the term "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* § 321(m). The FDA may approve the NDA only if it finds, among other things, that the new drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling"; that there is "substantial evidence that the drug will have the effect it purports or is represented to have . . . in the proposed labeling"; that the methods and facilities for manufacturing, processing, and packaging the drug are adequate "to preserve its identity, strength, quality, and purity"; and that the labeling is not "false or misleading in any particular." *Id.* § 355(d). A drug approved under the NDA process, commonly referred to as a "brand-name drug," is "listed" by the FDA as having been "approved for safety and effectiveness." *See id.* § 355(j)(7). Following the approval of its NDA, a brand-name drug has a certain period of exclusivity in the marketplace. *See id.* § 355(j)(5)(F).

2. ANDAs

Subject to that period of exclusivity, a drug manufacturer may seek the approval of a drug that is identical in key respects to a listed drug by filing an ANDA. *See id.* § 355(j); *Bartlett*, 570 U.S. at 477 (explaining that a generic drug may be approved through the ANDA process "provided the generic drug is identical to the already-approved brand-name drug in several key respects"). A drug approved under the ANDA process is commonly referred to as a "generic drug." The ANDA must contain information showing that the generic drug has the same active ingredient(s), route of administration, dosage form, strength, therapeutic effect, and labeling as the listed drug and is "bioequivalent" to the listed drug. 21 U.S.C. § 355(j)(2)(A). With limited exceptions, the FDA may approve the ANDA only if it finds that the generic drug and its proposed labeling are the same as the listed drug and the listed drug's labeling. *See id.* § 355(j)(4); *see also* 21 C.F.R. § 314.94(a)(8)(iii), (iv) ("Labeling (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 . . . ."). One such exception is that the generic drug's proposed labeling "may include differences in expiration date" from the listed drug. 21 C.F.R. § 314.94(a)(8)(iv).

3. Changes to Drugs with Approved NDAs and ANDAs

The FDA also has requirements for when and how a drug manufacturer may change a drug (or drug labeling) that has an approved NDA or ANDA. *See id.* §§ 314.70, .97(a). These requirements differ depending on the category of change that the manufacturer seeks to make.

A "major change" is

> any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

Id. § 314.70(b)(1). Such changes include certain labeling changes; changes "in the qualitative or quantitative formulation of the drug product, including inactive ingredients"; changes "in the synthesis or manufacture of the drug substance that may affect the impurity profile and/or the physical, chemical, or biological properties of the drug substance"; and changes "in a drug product container closure system that controls the drug product delivered to a patient or changes in the type . . . or composition . . . of a packaging component that may affect the impurity profile of the drug." *Id.* § 314.70(b)(2)(i), (iv), (v), (vi). A major change requires a "supplement submission and [FDA] approval prior to distribution of the product made using the change." *Id.* § 314.70(b). This supplement is referred to as a "Prior Approval Supplement." *See In re Darvocet*, 756 F.3d at 923.

A "moderate change" is

> any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

21 C.F.R. § 314.70(c)(1). The process for making a moderate change is commonly called the "changes-being-effected" process or "CBE" process. *See Mensing*, 564 U.S. at 614. A moderate change generally requires a "supplement submission at least 30 days prior to distribution of the drug product made using the change." 21 C.F.R. § 314.70(c). The drug product with the change may be distributed prior to FDA-approval, but only after the passage of 30 days from the FDA's receipt of the supplement. *Id.* § 314.70(c)(4). This supplement is referred to as a "Changes Being Effected in 30 Days" supplement. *See id.* § 314.70(c)(3).

However, the FDA may designate certain moderate changes that may be made upon the FDA's receipt of the supplement and need not await the passage of 30 days. *Id.* § 314.70(c)(6). Such changes include certain changes "in the labeling to reflect newly acquired information" and

"changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess." *Id.* § 314.70(c)(6)(i), (iii). Where the passage of 30 days is not required, the supplement is referred to as a "Changes Being Effected" supplement. *Id.* § 314.70(c)(3).

Finally, a "minor change" is a change "in the drug substance, drug product, production process, quality controls, equipment, or facilities that ha[s] a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product." *Id.* § 314.70(d)(1). Such a change includes an "extension of an expiration dating period based upon full shelf life data on production batches obtained from" an approved protocol. *Id.* § 314.70(d)(2)(vi). A minor change must be "described in an annual report." *Id.* § 314.70(d).

B. Impossibility 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). Three key Supreme Court opinions have addressed impossibility pre-emption—a subset of conflict pre-emption—in the drug context.

1. *Wyeth v. Levine*

In *Wyeth v. Levine*, 555 U.S. 555, 559-60 (2009), a consumer of a brand-name drug brought common-law negligence and strict-liability claims under Vermont law against the brand-name drug's manufacturer for failure to provide an adequate warning on the drug's labeling. The Supreme Court held that the consumer's claims were not pre-empted because the brand-name drug manufacturer had not shown that it was impossible to comply with both federal law and the state-law duty to provide an adequate warning. *Id.* at 573. The CBE process permitted the brand-name drug manufacturer to "unilaterally strengthen" the warning on the drug's labeling without waiting for FDA approval. *Id.* at 568, 573 (citing 21 C.F.R. § 314.70(c)). The Court explained that it could not conclude that it was impossible for the brand-name drug manufacturer to comply with both federal and state law "absent clear evidence that the FDA would not have approved" a labeling change. *Id.* at 571. The brand-name drug manufacturer "offered no such evidence," and the fact that the FDA had previously approved the labeling did "not establish that it would have prohibited such a change." *Id.* at 572-73. Thus, impossibility pre-emption did not bar the consumer's claims against the brand-name drug manufacturer for an inadequate warning. *Id.* at 573.

2. *PLIVA, Inc. v. Mensing*

In *PLIVA, Inc. v. Mensing*, 564 U.S. at 610, consumers of generic drugs brought claims under Minnesota and Louisiana law against the generic drugs' manufacturers for failure to provide adequate warnings on the drugs' labeling. Upon the generic drug manufacturers' pre-emption challenge at the motion-to-dismiss stage, the Supreme Court described the analysis that a court must use when faced with an impossibility pre-emption question. "Pre-emption analysis requires us to compare federal and state law." *Id.* at 611. "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Id.* at 620. "[S]tate and federal law conflict where it is impossible for a private party to comply with both state and federal requirements." *Id.* at 618 (quotation marks omitted). The Court therefore began its analysis by identifying the state-law duties and the federal requirements for generic drug manufacturers with respect to labeling. *Id.* at 611.

As to the state-law duties, the law of Minnesota and Louisiana required "a drug manufacturer that is or should be aware of its product's danger to label that product in a way that renders it reasonably safe." *Id.*; *see id.* at 617 ("State tort law places a duty directly on all drug manufacturers to adequately and safely label their products."). The consumers had pled that the generic drug manufacturers knew or should have known that long-term use of their drugs posed a high health risk and knew or should have known that their labeling did not adequately warn of the risk. *Id.* at 611. The parties agreed that, if these allegations were true, state law required the generic drug manufacturers to use a different, safer label. *Id.* at 611-12. Turning to federal law, the Court described the generic drug manufacturers' federal duty as a "duty of 'sameness'": "A manufacturer seeking generic drug approval . . . is responsible for ensuring that its warning label is the same as the brand name's." *Id.* at 613 ("The FDA . . . tells us that it interprets its regulations to require that

the warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of 'sameness.'") (citing 21 U.S.C. § 355(j)(2)(A)(v)).

The Court then examined three proposed ways that the generic drug manufacturers could satisfy their state-law labeling duties while also complying with federal law. *See id.* at 614-21. First, the consumers argued that, as in *Wyeth*, the generic drug manufacturers could change their labeling through the CBE process. *Id.* at 614. The Court deferred to the FDA's position that generic drug manufacturers cannot use the CBE process to unilaterally strengthen their labeling. *Id.* at 614-15 ("The agency interprets the CBE regulation to allow changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label or follow the FDA's instructions."). The Court concluded that "the CBE process was not open to the [generic drug manufacturers] for the sort of change required by state law." *Id.* at 615. If the generic drug manufacturers "had independently changed their labels to satisfy their state-law duty, they would have violated federal law." *Id.* at 618.

Second, the consumers asserted that the generic drug manufacturers could satisfy their state-law duties by using "'Dear Doctor' letters to send additional warnings to prescribing physicians and other healthcare professionals." *Id.* at 615. But the FDA maintained that such letters qualified as labeling, needed to be consistent with a drug's approved labeling, and could not contain "substantial new warning information." *Id.* "[I]f generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly misleading." *Id.* (quotation marks omitted). The Court therefore concluded that federal law did not permit the generic drug manufacturers to send Dear Doctor letters. *Id.*

Third, the FDA contended that generic drug manufacturers could propose, and in fact were required under federal law to propose, "stronger warning labels to the agency if they believed such warnings were needed." *Id.* at 616 (explaining that the FDA's position was that "[g]eneric drug manufacturers that become aware of safety problems must ask the agency to work toward strengthening the label that applies to both the generic and brand-name equivalent drug"). For the purpose of its pre-emption analysis, the Court assumed that federal law required generic drug manufacturers "to ask for FDA assistance in convincing the brand-name manufacturer to adopt a stronger label, so that all corresponding generic drug manufacturers could do so as well." *Id.* at 617.

The Court, however, stated that asking the FDA for assistance "would not have satisfied the requirements of state law." *Id.* at 618. "State law demanded a safer label; it did not instruct the [generic drug manufacturers] to communicate with the FDA about the possibility of a safer label." *Id.* at 619. Asking the FDA for assistance "might eventually" lead to a safer label that would satisfy the state-law duty. *Id.* (stating that, had the generic drug manufacturers asked the FDA for assistance, they "would have started a Mouse Trap game" that, through actions of the FDA and the brand-name drug manufacturer, "eventually led to a better label"). But the Court rejected the proposition that pre-emption analysis should take into account the possible actions of third parties or the federal government. *Id.* at 620. Such an approach would "render conflict pre-emption largely meaningless." *Id.* at 620-21. "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 623-24. The Court ruled that impossibility pre-emption barred the consumers' claims because the generic drug manufacturers could not independently "comply with

both their state-law duty to change the label and their federal-law duty to keep the label the same." *Id.* at 618 ("We find impossibility here. It was not lawful under federal law for the [generic drug manufacturers] to do what state law required of them.").

3. *Mutual Pharmaceutical Co. v. Bartlett*

In *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. at 475, a consumer of a generic drug brought a design-defect claim under New Hampshire law against the generic drug's manufacturer. Upon the generic drug manufacturer's pre-emption challenge, the Supreme Court began its analysis, as it has in *Mensing*, with an identification of the relevant state and federal duties. *Id.* at 480. The Court explained that New Hampshire law required manufacturers "to ensure that the products they design, manufacture, and sell are not unreasonably dangerous." *Id.* at 482 (quotation marks omitted). A "drug's safety is evaluated by reference to both its chemical properties and the adequacy of its warnings." *Id.* at 475. Therefore, the state-law duty could "be satisfied either by changing a drug's design or by changing its label." *Id.* at 482.

The Court then stated that federal law prohibited the generic drug manufacturer from changing its drug's design and from changing its labeling. *See id.* at 482-86. Redesigning the drug was not possible under federal law because a generic drug is required "to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based." *Id.* at 483-84 (citing 21 U.S.C. § 355(j)(2)(A)(ii)-(v)). Redesigning also was not possible as a matter of "basic chemistry" because the drug at issue was "chemically incapable of being redesigned" due to its simple composition. *Id.* at 475, 484. As the Court held in *Mensing*, federal law prevented the generic drug manufacturer from independently changing the drug's labeling. *Id.* at 475, 486 (citing *Mensing*, 564 U.S. at 617). Thus, it was impossible under federal law for the generic drug manufacturer to satisfy its state-law duty. *Id.* at 486 (explaining that

federal law prohibited the generic drug manufacturer "from taking the remedial action required to avoid liability under New Hampshire law"); *see also id.* at 475 ("[S]tate law imposed a duty on [the generic drug manufacturer] *not* to comply with federal law." (emphasis in original)).

The Supreme Court rejected the First Circuit Court of Appeals' ruling below that the generic drug manufacturer could comply with both federal and state law by removing the drug from the market. *Id.* at 479. The Supreme Court stated that the option to stop selling a product was "no solution" to the existence of a conflict between state and federal law. *Id.* at 475. Adopting the "stop-selling rationale would render impossibility pre-emption a dead letter and work a revolution in this Court's pre-emption case law." *Id.*; *see id.* at 488 ("We reject this 'stop-selling' rationale as incompatible with out pre-emption jurisprudence. . . . In every instance in which the Court has found impossibility pre-emption, the 'direct conflict' between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting."). Pre-emption caselaw presumes "that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id.* at 488. The Court held that impossibility pre-emption barred the consumer's design-defect claim against the generic drug manufacturer. *Id.* at 486-87.

4. Application of *Mensing* and *Bartlett*

Courts routinely apply *Mensing* and *Bartlett* to find that claims against generic drug manufacturers are pre-empted, regardless of how plaintiffs style those claims. In *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1247 (11th Cir. 2013), for example, a plaintiff brought claims against a generic drug manufacturer for negligence, strict liability, breach of warranty, misrepresentation, and fraud. She argued that her claims were not pre-empted under *Mensing* because they were not based on inadequate labeling, but rather on a failure to communicate with medical providers about

a labeling change. *Id.* at 1248. The Eleventh Circuit Court of Appeals determined that the claims were pre-empted because their "gravamen" was that the generic drug manufacturer "failed to adequately warn medical providers of the risks associated with long-term use" of the generic drug. *Id.* at 1247, 1249 ("Because each of [the plaintiff's] claims . . . is premised upon an allegedly inadequate warning, they are all preempted by federal law."). The court rejected the plaintiff's "attempt to elude *Mensing* by clothing her allegations as 'failure-to-communicate' claims rather than failure-to-warn claims." *Id.* at 1249. The court explained that, "[n]o matter the garb" in which the plaintiff presented her claims, they were "at bottom" allegations that the generic drug manufacturer failed to warn of the dangers of long-term use of the generic drug. *Id.*

Similarly, in *Moretti v. Mutual Pharmaceutical Co.*, 852 F Supp. 2d 1114, 1114-15 (D. Minn. 2012), *aff'd*, 518 F. App'x 486 (8th Cir. 2013), a plaintiff brought claims against generic drug manufacturers for negligence, misrepresentation, fraud, infliction of emotional distress, and violation of state consumer protection statutes. She argued that her claims were not pre-empted because they were based on the generic drug manufacturers providing false information about a generic drug, concealing safety information, and failing to conduct and report the results of post-marketing surveillance. *Id.* at 1117-18. The district court held that the claims were pre-empted and stated that it was "not persuaded" by the plaintiff's attempt to differentiate her claims from *Mensing*. *Id.* at 1118-19. "Despite the different 'labels' given these claims, the essence of these claims is that important safety information as to [the generic drug] was not disseminated, or made clear, to the public or to the medical community." *Id.* at 1118.

Many other courts have likewise rejected attempts by plaintiffs to avoid pre-emption under *Mensing* and *Bartlett* through the characterization of their claims against generic drug manufacturers. *See, e.g.*, *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 391 (6th Cir. 2013)

(explaining that circuit courts "have interpreted *Mensing* to broadly preempt claims that are, at their core, claims that the generic manufacturer failed to provide additional warnings"); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 186 (5th Cir. 2012) ("Post-*Mensing*, . . . a seeming majority of federal district courts to consider other state-law tort claims have found them to be preempted based on the fact that the plaintiffs' claims are failure-to-warn claims under different names."); *Tsavaris v. Pfizer, Inc.*, 154 F. Supp. 3d 1327, 1338 (S.D. Fla. 2016) ("Plaintiff is pleading a failure to warn claim under the guise of a negligent misrepresentation claim."); *Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597, 607 (N.D. Miss. 2013) ("[N]o matter how Plaintiff styles her theories of recovery, her claims ultimately relate to the Generic Defendants' alleged failure to warn about the side effect of [the generic drug]. Therefore, all theories will be analyzed together under the umbrella of a failure to warn claim under Mississippi law.").

C. The Generic Manufacturer Defendants' Motion to Dismiss

The Generic Manufacturer Defendants contend that all of the claims against them in all three Master Complaints are pre-empted and must be dismissed. The Plaintiffs maintain that none of their claims are pre-empted. The Court now analyzes the Plaintiffs' claims against the Generic Manufacturer Defendants and the parties' arguments regarding those claims.

1. Claims for Failure to Warn Consumers Through the FDA

The Plaintiffs pled claims against the Generic Manufacturer Defendants for failure to warn consumers through the FDA in Count V of the AMPIC and in 51 counts in the MMC.[9] The Plaintiffs allege in these counts that the Generic Manufacturer Defendants breached state-law

[9] MMC Counts 199, 203, 210, 214, 218, 227, 240, 244, 251, 255, 259, 266, 279, 283, 290, 294, 298, 305, 318, 325, 332, 336, 340, 347, 360, 364, 371, 375, 379, 386, 399, 409, 413, 417, 424, 473, 480, 505, 509, 522, 535, 548, 552, 562, 569, 582, 595, 599, 609, 616, and 629.

duties to convey warnings to the FDA of the dangers of ranitidine products when those warnings could have reached consumers. *See, e.g.*, AMPIC ¶¶ 1407-08, 1412.

The Generic Manufacturer Defendants contend that these claims are pre-empted for two reasons. DE 3105 at 14, 37-38. Firstly, they argue that the claims are pre-empted under *Mensing* because the relevant state-law duty is the duty to warn consumers, and the Generic Manufacturer Defendants could not satisfy that duty independently while complying with federal law. *Id.* at 14-20; DE 3422 at 16-18. Secondly, the claims are pre-empted under 21 U.S.C. § 337(a) and binding legal precedent because they seek to enforce FDCA requirements on drug manufacturers to report to the FDA, and only the United States may enforce such requirements. DE 3105 at 20-22; DE 3422 at 20-22. The Plaintiffs respond that their claims are not pre-empted because they seek to enforce traditional state-law duties to warn that manufacturers owe to consumers and because the Generic Manufacturer Defendants could satisfy these duties independently while complying with federal law. DE 3326 at 27-38.

In the Court's Order Granting in Part and Denying in Part the Branded Defendants' Rule 12 Partial Motion to Dismiss Plaintiffs' Three Master Complaints as Preempted by Federal Law filed on June 30, 2021, at docket entry 3715, the Court concluded that the Plaintiffs' claims for failure to warn consumers through the FDA against the Brand Manufacturer Defendants are pre-empted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. at 348-53, for the reasons that the Eleventh Circuit Court of Appeals outlined in *Mink v. Smith & Nephew, Inc.*, 860 F.3d at 1330. For the same reasons given in that Order, the Plaintiffs' claims that the Generic Manufacturer Defendants failed to warn consumers through the FDA are pre-empted and therefore are dismissed. The Court need not reach the Generic Manufacturer Defendants' alternative argument that the claims are pre-empted under *Mensing*.

2. Claims for Failure to Warn and Negligence

Turning to the Plaintiffs' failure-to-warn and negligence claims against the Generic Manufacturer Defendants, the Court (a) describes the Plaintiffs' factual allegations with respect to ranitidine, (b) explains the specific legal claims, (c) outlines the parties' pre-emption arguments as to the claims, and then (d) evaluates the issues to reach a ruling.

a. Factual Allegations

The Plaintiffs allege that ranitidine is a highly unstable molecule that contains the ingredients needed to form NDMA, that is, nitroso (N) and dimethylamine (DMA). AMPIC ¶¶ 343, 364, 1989. As the ranitidine molecule degrades, parts of it break off and combine to produce NDMA. *Id.* ¶¶ 344, 347. Degradation occurs in two main ways. *Id.* ¶ 935.

Firstly, ranitidine degrades in the stomach and other organs of the human body. *Id.* ¶ 346. It degrades when exposed to fluids in the digestive system, particularly when accompanied by nitrites, which are chemicals commonly found in heartburn-inducing foods such as tacos and pizza. *Id.* ¶¶ 347, 373, 376-77. Ranitidine also degrades when it interacts with DDAH-1, an enzyme that is naturally present in organs such as the kidneys, liver, and bladder. *Id.* ¶¶ 378, 383-84.

Secondly, ranitidine degrades outside of the human body. *Id.* ¶¶ 6, 346. This degradation occurs over time when ranitidine is kept under "normal" conditions and stored "at room temperature." *Id.* ¶¶ 6, 339, 346, 389-90. But the rate of degradation increases if ranitidine is exposed to heat and/or humidity. *Id.* ¶¶ 6, 346, 389.

NDMA is "a well-known potent carcinogen" that is used to induce cancerous tumors in animals during laboratory experiments and that has no medicinal purpose. *Id.* ¶¶ 3, 274. There is no recommended daily dose of NDMA; the ideal level of exposure is zero. *Id.* ¶ 4. The FDA has set the acceptable daily intake level for NDMA at 96 nanograms, which would increase the risk of

developing cancer by 0.001% over the course of a lifetime. *Id.* ¶¶ 4, 302. A "single pill of ranitidine can contain quantities of NDMA that are hundreds, if not thousands, of times higher than the allowable limit." *Id.* ¶ 4.

The Generic Manufacturer Defendants either knew or should have known decades earlier that ingesting ranitidine exposes consumers to excessive and unsafe levels of NDMA. *Id.* ¶¶ 2, 951-52, 1956. They "knew that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA." *Id.* ¶¶ 1957, 1989. Also, federal law requires drug manufacturers to conduct stability testing on their products to assess drug stability and to determine appropriate storage conditions and expiration dates. *Id.* ¶¶ 413-16 (citing 21 C.F.R. §§ 211.137, .166). "Simple, widely available and cost-effective tests" would have reveled degradation and NDMA accumulation in ranitidine products. *Id.* ¶¶ 937-39, 1956. Additionally, research conducted before Zantac entered the market revealed elevated levels of NDMA in ranitidine when it was properly tested. *Id.* ¶ 405. The Generic Manufacturer Defendants knew or should have known about this research because it was published in medical literature. *Id.* ¶¶ 405, 407.

b. Legal Claims

Aside from the claims for failure to warn consumers through the FDA (addressed above), and the unjust-enrichment, derivative, and ELC claims (addressed below), the Plaintiffs' claims against the Generic Manufacturer Defendants are of two types: failure to warn consumers through accurate expiration dates and negligence.

i. Failure to Warn

The Plaintiffs, in the AMPIC, bring against the Generic Manufacturer Defendants Count III (Strict Products Liability—Failure to Warn Through Proper Expiration Dates) under the laws

of 46 jurisdictions; Count IV (Negligence—Failure to Warn Through Proper Expiration Dates) under the laws of 48 jurisdictions; and Count VII (Strict Products Liability—Design Defect Due to Improper Expiration Dates) under the laws of 46 jurisdictions. Although Count VII is brought under design-defect law, the Court refers to the count as raising a failure-to-warn claim because it, like Counts III and IV, is premised on the Generic Manufacturer Defendants' failure to warn consumers through accurate expiration dates. *See, e.g.*, *id.* ¶ 1749 ("Generic Manufacturer Defendants had a duty to provide proper warnings to ensure their ranitidine-containing products did not cause users and consumers to suffer from unreasonable and dangerous risks."); *id.* ¶ 1767 ("The warnings included on each ranitidine-containing product were inadequate because the expiration date improperly instructed Plaintiffs that ranitidine-containing products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time."); *cf. Bartlett*, 570 U.S. at 482 (giving New Hampshire as an example of a state where design-defect law "can be satisfied either by changing a drug's design or by changing its labeling"). The Plaintiffs also bring claims against the Generic Manufacturer Defendants for failure to warn through accurate expiration dates in the MMC.[10]

These failure-to-warn claims are based on the Plaintiffs' allegations that ranitidine degrades to form NDMA over time. AMPIC ¶¶ 936-38. The Plaintiffs allege that they would have ingested less NDMA had they consumed ranitidine shortly after it had been manufactured. *Id.* ¶¶ 935, 937. "[R]anitidine-containing products had expiration dating periods of one or two years, allowing accumulation of more and more unsafe levels of NDMA." *Id.* ¶ 938. "A much shorter

[10] MMC Counts 195, 198, 202, 206, 209, 213, 217, 221, 226, 230, 233, 236, 239, 243, 247, 250, 254, 258, 262, 265, 269, 272, 275, 278, 282, 286, 289, 293, 297, 301, 304, 308, 311, 314, 317, 321, 324, 328, 331, 335, 339, 343, 346, 350, 353, 356, 359, 363, 367, 370, 374, 378, 382, 385, 389, 392, 395, 398, 402, 405, 408, 412, 416, 420, 423, 427, 472, 476, 479, 483, 486, 489, 492, 495, 498, 501, 504, 508, 512, 515, 518, 521, 525, 528, 531, 534, 538, 541, 544, 547, 551, 555, 558, 561, 565, 568, 572, 575, 578, 581, 585, 588, 591, 594, 598, 602, 605, 608, 612, 615, 619, 622, 625, 628, 632, 635, and 638.

period of a matter of months would have ensured that ranitidine contained far lower levels of NDMA when consumed."[11] *Id.* Generic drug products need not use the same expiration dates as their brand-name equivalent drugs. *Id.* ¶¶ 436-37 (citing 21 C.F.R. § 314.94(a)(8)(iv)).

The Plaintiffs further allege that the Generic Manufacturer Defendants had a duty under state law "to provide proper warnings to ensure their ranitidine-containing products did not cause users and consumers to suffer from unreasonable and dangerous risks" or, stated more simply, a duty "to warn of the risks associated with the use of ranitidine." *Id.* ¶¶ 944, 946-47. The Plaintiffs concede that a shorter expiration date would not warn consumers that ranitidine may cause cancer. 6/4/21 Hearing Tr. at 170 ("I absolutely concede that an expiration date by itself would not warn the consumer of the risk of cancer, of course that is true."). The Plaintiffs, however, maintain that an expiration date is a warning of a risk; it is a warning not to consume a product after the expiration date and that the product is not safe to consume after that date, albeit without an explanation as to why. *Id.* at 164 (referring to an expiration date as a "warning when a consumer should not continue to take the product" and acknowledging that "it doesn't provide the explanation behind it"); 6/7/21 Hearing Tr. at 12-13 ("I do think [an expiration date] is a warning of danger. It is saying there is a risk if you consume it after this date. It is not telling you what the risk is, it is not being specific. . . . I think an expiration date would go a long way to alerting generic consumers of the dangers associated with Ranitidine . . . .").

The Plaintiffs allege that the Generic Manufacturer Defendants breached their duty to warn by failing to shorten their ranitidine products' expiration dates. AMPIC ¶ 965. Had ranitidine products contained shorter expiration dates, "Plaintiffs or their doctors would have heeded these

[11] During the June 3rd Hearing, the Plaintiffs explained their allegation that expiration dates should have been "a matter of months." The Plaintiffs took the position that an accurate expiration date would be "around" "one to two months" after a ranitidine product is manufactured, although the date should more precisely be identified at a later stage of this litigation. 6/3/21 Hearing Tr. at 28, 37-38.

warnings," "would not have consumed the volume of NDMA they ultimately did, and would not have been harmed by NDMA." *Id.* ¶ 966.

ii. Negligence

The Plaintiffs bring three categories of negligence claims against the Generic Manufacturer Defendants. First, the Plaintiffs bring AMPIC Count IX (Negligent Product Containers) under the laws of 52 jurisdictions against those Generic Manufacturer Defendants that made ranitidine in the form of pills. The Plaintiffs also bring claims against the Generic Manufacturer Defendants for negligent product containers in the MMC.[12]

These counts are based on the Plaintiffs' allegations that ranitidine degrades to form NDMA over time and degrades more rapidly when exposed to humidity. *Id.* ¶¶ 1988, 1990-91. The Plaintiffs allege that the ranitidine products they consumed "had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms)." *Id.* ¶ 1990. "Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods by consumers after the seal is broken. This exposes the remaining units to humidity over time, which produces NDMA." *Id.* ¶ 1991. The ranitidine pills that the Plaintiffs consumed would have had lower levels of NDMA (1) had there been fewer pills in each bottle, as the product would have been fully consumed more quickly and exposed to humidity for a shorter period of time; and (2) had the pills been packaged "in a blister pack or similar individually packaged container," which would have protected the pills from

[12] MMC Counts 196, 200, 204, 207, 211, 215, 219, 224, 228, 231, 234, 237, 241, 245, 248, 252, 256, 260, 263, 267, 270, 273, 276, 280, 284, 287, 291, 295, 299, 302, 306, 309, 312, 315, 319, 322, 326, 329, 333, 337, 341, 344, 348, 351, 354, 357, 361, 365, 368, 372, 376, 380, 383, 387, 390, 393, 396, 400, 403, 406, 410, 414, 418, 421, 425, 428, 474, 477, 481, 484, 487, 490, 493, 496, 499, 502, 506, 510, 513, 516, 519, 523, 526, 529, 532, 536, 539, 542, 545, 549, 553, 556, 559, 563, 566, 570, 573, 576, 579, 583, 586, 589, 592, 596, 600, 603, 606, 610, 613, 617, 620, 623, 626, 630, 633, 636, and 639.

exposure to humidity. *Id.* ¶ 1992. Generic drug products need not use the same packaging as their brand-name equivalent drugs. *Id.* ¶¶ 1993-94 (citing an FDA guidance manual).

The Plaintiffs also allege that the Generic Manufacturer Defendants had a duty under state law "to exercise reasonable care in choosing and making the containers for [their] products." *Id.* ¶ 2000. They breached this duty of care "by failing to utilize containers that would minimize the NDMA produced in [their] ranitidine-containing products." *Id.* ¶ 2001. As a result, "excessive levels of NDMA built up in the ranitidine-containing products," and "[t]hese high levels of NDMA caused Plaintiffs' injuries." *Id.* ¶ 2002.

Second, the Plaintiffs bring AMPIC Count XI (Negligent Storage and Transportation) under the laws of 52 jurisdictions. The Plaintiffs further bring claims against the Generic Manufacturer Defendants for negligent storage and transportation in the MMC.[13]

These counts are based on the Plaintiffs' allegations that ranitidine degrades to form NDMA more rapidly when exposed to heat and humidity. *Id.* ¶¶ 2436, 2439, 2442. The Plaintiffs allege that some Generic Manufacturer Defendants stored active pharmaceutical ingredients ("API") (ingredients for the finished ranitidine products) in their facilities. *Id.* ¶ 2445. They also stored finished ranitidine products in their facilities and transported the finished products to distributor warehouses. *Id.* ¶ 2444. The Generic Manufacturer Defendants failed to ensure that API and finished ranitidine products were stored and transported safely and were not exposed to excessive heat and humidity. *Id.* ¶¶ 2447-49, 2451, 2455. In addition, they shipped ranitidine products through the United States Postal Service or large common carriers such as FedEx and

[13] MMC Counts 197, 201, 205, 208, 212, 216, 220, 225, 229, 232, 235, 238, 242, 246, 249, 253, 257, 261, 264, 268, 271, 274, 277, 281, 285, 288, 292, 296, 300, 303, 307, 310, 313, 316, 320, 323, 327, 330, 334, 338, 342, 345, 349, 352, 355, 358, 362, 366, 369, 373, 377, 381, 384, 388, 391, 394, 397, 401, 404, 407, 411, 415, 419, 422, 426, 429, 475, 478, 482, 485, 488, 491, 494, 497, 500, 503, 507, 511, 514, 517, 520, 524, 527, 530, 533, 537, 540, 543, 546, 550, 554, 557, 560, 564, 567, 571, 574, 577, 580, 584, 587, 590, 593, 597, 601, 604, 607, 611, 614, 618, 621, 624, 627, 631, 634, 637, and 640.

UPS, which did not guarantee controlled temperature or humidity. *Id.* ¶ 2450. As a result, both API and finished ranitidine products were "systematically" subjected to excessive heat and/or humidity. *Id.* ¶¶ 2446, 2450, 2455.

The Plaintiffs further allege that the Generic Manufacturer Defendants had a duty under state law "to exercise reasonable care in transporting and storing" API and finished ranitidine products. *Id.* ¶¶ 2453, 2461. They breached this duty of care "by failing to implement or enforce policies to ensure ranitidine-containing products and ranitidine API remained free from excessive heat and humidity" during storage and transportation. *Id.* ¶¶ 2451, 2462. As such, "excessive levels of NDMA built up in the ranitidine-containing products," and "[t]hese high levels of NDMA caused Plaintiffs' injuries." *Id.* ¶ 2463.

Third, the Plaintiffs bring AMPIC Count VIII (Negligent Failure to Test) under Kansas and Texas law. These claims are not raised in the MMC. The Plaintiffs allege that "widely available, cost-effective, industry-standard" testing methods would have revealed that ranitidine degrades into NDMA. *Id.* ¶¶ 1952, 1954-55. The Generic Manufacturer Defendants had a duty under state law "to exercise reasonable care in testing of ranitidine-containing products to ensure the products were not unreasonably dangerous to consumers and users." *Id.* ¶¶ 1973, 1979. They breached this duty of care when they "did not use widely available tests to detect NDMA." *Id.* ¶¶ 1962, 1976, 1982. Plaintiffs were injured as a result of the Generic Manufacturer Defendants' "failure to undertake to provide an adequate warning of the risks of ranitidine-containing products." *Id.* ¶¶ 1977, 1983.

c. The Parties' Arguments

The Generic Manufacturer Defendants argue that the failure-to-warn and negligence claims brought against them are pre-empted under *Mensing* and *Bartlett*. DE 3105 at 14. The legal duties

for these state-law causes of action are the duty to adequately warn of risks and the duty to use reasonable care. *Id.* at 22-28, 33-37. The Generic Manufacturer Defendants could not independently satisfy those duties while complying with federal law. *Id.* at 12. State law would require them to redesign or re-label ranitidine products, which they could not do under their federal duty of sameness. *Id.* at 8, 12, 14. They were not required to stop selling the products in order to comply with both federal and state law. *Id.* at 14. Thus, the failure-to-warn and negligence claims are pre-empted.

The Plaintiffs assert that the claims are not pre-empted. *See* DE 3326. The Plaintiffs concede that the legal duties for failure-to-warn and negligence causes of action, stated at a "high level of generality," required the Generic Manufacturer Defendants to do things with respect to ranitidine that they could not independently do under federal law.[14] 6/4/21 Hearing Tr. at 148, 164, 170-71. But, the Plaintiffs maintain that the "general" duties for the causes of action have within them many narrower and more specific "sub-duties." *Id.* at 148 (arguing that, under a common-law duty phrased "[a]t a high level of generality," "there may well be 17 different duties imposed by the common law"); *id.* at 202 (asserting that "state common law typically announces the duty at a high level of generality and then basically creates different sub duties for the specific facts and circumstances"). A ranitidine manufacturer's duty to warn includes within it a duty to warn of the cancer risk that ranitidine poses and a duty to warn through an accurate expiration date. *Id.* at 148 (arguing that a ranitidine manufacturer has "a duty to warn that the drug causes cancer, and a duty to warn of the proper expiration date"); *id.* at 170-71 (asserting that, "because the common law is

[14] The Plaintiffs acknowledge, for example, that the duty to warn requires warnings that the Generic Drug Manufacturers could not give under federal law. 6/4/21 Hearing Tr. at 169 (explaining that "state law would also require the generics to do more, it would require them to add a cancer warning, but we cannot plead that against them because of preemption"); *id.* at 194 (stating that "we recognize that the common law is broader than all of the things that the generics could actually do"); 6/7/21 Hearing Tr. at 3-4 ("It is true that separately, under state law and behaving as a reasonably prudent manufacturer would, state law would impose a duty also to warn about cancer risk, but only the brands could satisfy that duty. We fully acknowledge that the generics could not.").

stated at a high level of generality," the duty to warn under Alabama law "actually imposes at least two duties on manufacturers"). Similarly, a ranitidine manufacturer's duty to use reasonable care includes within it duties to properly package ranitidine and to properly store and transport ranitidine. 6/7/21 Hearing Tr. at 4-5 (asserting that the duty to "behave as a reasonably prudent manufacturer would under the circumstances . . . is going to impose a lot of sub duties"); *id.* at 9-10 (arguing that state negligence law "imposes multiple different requirements on manufacturers of products, . . . a requirement to properly store and transport your drug, a requirement to put it in proper packaging").

The Plaintiffs argue that a legal claim may be premised on a breach of any one of these "sub-duties." 6/4/21 Hearing Tr. at 148 (arguing that "a failure to perform any one of [the sub-duties] is sufficient to support the element of breach for the cause of action"); 6/7/21 Hearing Tr. at 11 (asserting that "any one breach is enough to support a Plaintiff verdict"). The Plaintiffs have brought claims against the Generic Manufacturer Defendants only for failing to do those things that they could do independently while complying with federal law, that is, only for breaching those "sub-duties" that they could have satisfied under federal law. DE 3326 at 7-8, 13-20. According to the Plaintiffs, those claims are not pre-empted. 6/4/21 Hearing Tr. at 149 ("The entire cause of action for negligence does not fall to preemption just because one theory is foreclosed . . . ."); *id.* at 204 ("Plaintiff[s] get[] to choose the theories of recovery that they are going to pursue, and preemption doesn't change that.").

The Generic Manufacturer Defendants characterize the Plaintiffs' approach as asking the Court to "prune away," "blue pencil," or "alter[] requirements of state-law causes of action" to "invent" "customize[d] tort claims that escape federal preemption." DE 3422 at 5-6; *see also* 6/4/21 Hearing Tr. at 139-40. The Generic Manufacturer Defendants argue that *Mensing* and

Bartlett foreclose such an approach because the Supreme Court held in each case that an entire state cause of action was pre-empted when generic drug manufacturers could not satisfy the legal duty at issue. DE 3422 at 6-8; 6/4/21 Hearing Tr. at 128, 157.

d. Analysis and Conclusion

i. Duties Versus "Sub-duties"

Consistent with *Mensing* and *Bartlett*, the Court must compare the state-law duties for the failure-to-warn and negligence claims to the relevant federal duties and, through such a comparison, determine whether the claims are pre-empted. The Court undertakes such an analysis below in subsection (ii). Before undertaking that analysis, however, the Court first addresses the Plaintiffs' argument regarding "sub-duties."

The Plaintiffs contend that, although they have brought failure-to-warn claims, the relevant state-law duty for pre-emption purposes is not the duty to warn of known risks. They similarly contend that, although they have brought various negligence claims, the relevant state-law duty for pre-emption purposes is not the duty to use reasonable care. The Plaintiffs argue that the Court should not base its pre-emption analysis on these "high level," commonly known duties; rather, the "sub-duties" that fall within the broader duties should control the Court's analysis.

The Plaintiffs provide no authority for the proposition that their proffered "sub-duties" are, in fact, duties. In the Court's experience, there is no such *tort* as "Negligent Choosing and Making of Containers" or "Negligent Transporting and Storing of Products." Instead, a failure to reasonably package a product or a failure to reasonably transport a product are merely *fact patterns* that would permit a plaintiff to bring the tort of ordinary negligence. In other words, the failure to properly package a product or the failure to properly transport a product are theories of breach, not independent duties.

The Court provided the Plaintiffs with an opportunity to identify authority for the proposition that their proffered "sub-duties" are independent legal duties. At docket entry 3517 the Court required the Plaintiffs to file a supplement to their Response to the Generic Manufacturer Defendants' Motion to Dismiss. The Court identified representative state-law "sub-duties" pled in the AMPIC and asked the Plaintiffs to provide authority for the existence of those duties under state law. Their supplement confirmed the Court's preliminary conclusion—that the "sub-duties" the Plaintiffs allege actually are theories of breach—because they cited to examples of cases with fact patterns involving, for example, product containers. DE 3525. The Plaintiffs also cited to state pattern jury instructions, but the cited jury instructions were for routine failure-to-warn and ordinary negligence causes of action. *See, e.g.*, Ala. Pattern Jury Instr. Civ. 32.16 ("Negligence is the failure to use reasonable care to prevent harm to others. A (manufacturer/supplier/ distributor/seller) is negligent when it either does something that a reasonably prudent (manufacturer/supplier/distributor/seller) would not do in a similar situation, or it fails to do something that a reasonably prudent (manufacturer/supplier/distributor/seller) would have done in a similar situation."). The Plaintiffs' proffered jury instructions contained no discussion of "sub-duties."

Of course, courts and attorneys alike may commonly refer, in the colloquial sense, to a particular fact pattern underpinning a theory of breach as a "duty," such as the duty to clean up a puddle of liquid in a store aisle or the duty to keep a sidewalk in good repair. But the actual duty under state law is the duty to use reasonable care, not the duty to clean up dangerous puddles or to keep sidewalks in good repair. Normally, the distinction between an actual legal duty and a specific theory of breach may not matter, but under *Mensing* and *Bartlett* the *precise* duty *does*

matter. Even the Plaintiffs, during the Hearings, comingled the concept of "sub-duties" with fact patterns forming a theory of breach:

> Applying that high-level standard to the particular facts and circumstances of any individual case, there may well be 17 different duties imposed by the common law . . . . To name but a few common law duties that would apply to a reasonably prudent manufacturer of Ranitidine, it had a duty to warn that the drug causes cancer, and a duty to warn of the proper expiration date, and a duty to redesign the molecule to make it safer.
>
> It is true enough that the generics could not perform **two of those duties** consistent with Federal law, but the crucial point is that a failure to perform any one of them is sufficient to support **the element of breach** for the cause of action in negligence.

6/4/21 Hearing Tr. at 148 (emphasis added).

The Court rejects the Plaintiffs' theory that "sub-duties" are cognizable (and divisible) legal duties, let alone the duties to be used for comparison in federal pre-emption analysis. While "sub-duties" may have their place in a plaintiff's strategic approach to litigating a case, they do not fit within the required paradigm for pre-emption analysis. The Court, therefore, does not rely upon the Plaintiffs' proffered "sub-duties" to conduct its pre-emption analysis.

ii. Comparison of State and Federal Duties

Having rejected the notion that the Court should base its pre-emption analysis on "sub-duties," the Court conducts its analysis by identifying the proper state-law duties for the causes of action that the Plaintiffs pled, identifying the relevant federal duty, and then comparing the state and federal duties to determine whether a conflict exists. *See Mensing*, 564 U.S. at 611 ("Pre-emption analysis requires us to compare federal and state law."). Identifying a generic drug manufacturer's federal duty is straightforward because the Supreme Court described that duty in both *Mensing* and *Bartlett*. A generic drug manufacturer's duty under federal law is a duty of sameness, meaning that the manufacturer must ensure that its generic drug is the same as the

brand-name equivalent drug in key respects. *Bartlett*, 570 U.S. at 477; *Mensing*, 564 U.S. at 613. Thus, a generic drug's chemical composition and labeling must be the same as the brand-name equivalent drug. *Bartlett*, 570 U.S. at 483-86; *Mensing*, 564 U.S. at 613.

In identifying the appropriate state-law duties, the Fourth Circuit Court of Appeals' decision in *Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014), is instructive. In that case, a consumer of a generic drug brought claims against the drug's manufacturer under Maryland law for, among other things, negligent testing, inspection, and post-market surveillance. *Id.* at 473, 476. The consumer argued that these claims were not pre-empted under *Mensing* because they were "premised on independent Maryland duties unrelated to labeling." *Id.* at 476. The Fourth Circuit stated that it was "not clear that Maryland law recognizes specific causes of action for negligent testing, inspection, and surveillance" and construed the alleged negligent acts as "in actuality merely a particular act or omission in an overall negligent sale." *Id.* at 477. "Divorced from the context of an eventual sale to the consumer, [the generic drug manufacturer] could not owe any duty to that consumer to perform any testing or inspection on its product, and there could therefore be no cause of action for negligence." *Id.* The court identified the state-law duty at issue as the "general duty" for a negligence claim in the products-liability context—the duty to protect consumers from injury—and held that the consumer's negligence claims were pre-empted because it was "clear that a generic drug manufacturer whose product is unreasonably dangerous as sold could not satisfy that duty without changing its warnings, changing its formulation, exiting the market, or accepting tort liability." *Id.* at 476-77.

As in *Drager*, where there was no specific cause of action for negligent testing, there are no specific causes of action for failure to warn through proper expiration dates, negligent product containers, negligent storage and transportation, or negligent failure to test. In fact, the Plaintiffs

concede that their claims based on expiration dates are failure-to-warn claims and that there is no separate state-law cause of action specific to failing to warn through expiration dates. 6/4/21 Hearing Tr. at 181 ("We are not trying to redefine any of the causes of action, we are not trying to say that the common law says there is such a granular cause of action that it is titled failure to have an adequate expiration date. It is still going to be just the general common law failure to warn . . . ."). The Plaintiffs also concede that their negligence-based counts raise ordinary negligence claims. *Id.* at 178 (stating that "this is just a negligence claim"). Therefore, as in *Drager*, this Court must analyze the Plaintiffs' claims for pre-emption purposes using the legal duties for failure-to-warn and negligence causes of action.

With respect to the Plaintiffs' failure-to-warn claims, the Generic Manufacturer Defendants' legal duty is "to warn of the risks associated with the use of ranitidine." *See* AMPIC ¶¶ 994, 946, 1160, 1162, 1746, 1748. States refer to this duty in different ways. *See, e.g.*, *id.* ¶ 964 ("Under Alabama law, a manufacturer has the duty to provide an adequate warning to consumers of a product's danger when used in its intended manner."); *id.* ¶ 972 ("Under Arizona [law,] manufacturers have a duty to adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution."); *id.* ¶ 984 ("Under Colorado law, a manufacturer has the duty to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use."). But the Plaintiffs have not argued that the way in which any particular state refers to its duty to warn should impact the Court's pre-emption analysis. In other words, the Plaintiffs have not argued that this Court must undertake a state-by-state review of the law on failure to warn in order to conduct its analysis.

As to the negligence claims, the Plaintiffs pled that the Generic Manufacturer Defendants' state-law duties are "to exercise reasonable care in choosing and making the containers for [their] products," "to exercise reasonable care in transporting and storing [their] products," and "to exercise reasonable care in the testing of ranitidine-containing products to ensure the products were not unreasonably dangerous to consumers and users." *See id.* ¶¶ 1973, 2000, 2461. The Plaintiffs clarified during the Hearings that they have pled ordinary negligence claims and that the legal duty for these claims is the duty to use reasonable care. 6/4/21 Hearing Tr. at 178 (stating that "this is just a negligence claim"); 6/7/21 Hearing Tr. at 4-5 (stating that "the duty under most state's law stated at a very high level of generality—let's take negligence, for example—is behave as a reasonably prudent manufacturer would under the circumstances").

These legal duties—the duty to warn of the risks associated with the use of ranitidine and the duty to use reasonable care—are *the* state-law duties in failure-to-warn and negligence claims. This is reflected in state pattern jury instructions. In Florida, for example, the pattern jury instruction for a cause of action for strict liability failure to warn is: "A product is defective when the foreseeable risks of harm from the product could have been reduced or avoided by providing reasonable instructions or warnings, and the failure to provide those instructions or warnings makes the product unreasonably dangerous." Fla. Standard Jury Instr. Civ. 403.8. And the Florida pattern jury instruction for a negligence cause of action in a products-liability case is:

> Negligence is the failure to use reasonable care, which is the care that a reasonably careful [designer] [manufacturer] [seller] [importer] [distributor] [supplier] would use under like circumstances. Negligence is doing something that a reasonably careful [designer] [manufacturer] [seller] [importer] [distributor] [supplier] would not do under like circumstances or failing to do something that a reasonably careful [designer] [manufacturer] [seller] [importer] [distributor] [supplier] would do under like circumstances.

Fla. Standard Jury Instr. Civ. 403.9.

The Plaintiffs acknowledge that the Generic Manufacturer Defendants could not satisfy these legal duties—the duty to warn of the risks associated with the use of ranitidine and the duty to use reasonable care—under federal law. The Generic Manufacturer Defendants could not warn consumers of the alleged risks that ranitidine posed when the labeling on brand-name ranitidine products did not contain such warnings. Furthermore, accepting the Plaintiffs' allegations about ranitidine as true, no drug manufacturer could satisfy its duty to use reasonable care by releasing ranitidine products into the marketplace as they were designed and labeled. The plain language of *Mensing* and *Bartlett* could end the Court's analysis for pre-emption purposes here. *See Mensing*, 564 U.S. at 618 ("We find impossibility here. It was not lawful under federal law for the [generic drug manufacturers] to do what state law required of them."). That is, because the Generic Manufacturer Defendants could not satisfy what state law required, the Plaintiffs' failure-to-warn and negligence claims are pre-empted. But, the Court further expands upon its analysis.

iii. The Breadth of the Plaintiffs' Claims

The Plaintiffs recognize that many claims against generic drug manufacturers sounding in failure to warn and ordinary negligence are pre-empted. They recognize, for example, that a failure-to-warn claim premised on a theory that the Generic Manufacturer Defendants should have warned of a risk of cancer is pre-empted. *See* 6/4/21 Hearing Tr. at 169; 6/7/21 Hearing Tr. at 3-4. But the Plaintiffs maintain that their specific claims are not pre-empted. They argue that, to the extent the Court concludes that ranitidine-based failure-to-warn and negligence claims are pre-empted in the general sense, there is an outer limit to that pre-emption. For their authority, the Plaintiffs cite to the principle that state law is pre-empted only to the *extent* of a state-federal conflict. DE 3326 at 7 & n.1; 6/4/21 Hearing Tr. at 144-46; *see, e.g.*, *Crosby v. Nat'l Foreign Trade Couns.*, 530 U.S. 363, 372 (2000) (stating that "state law is naturally preempted to the extent

of any conflict with a federal statute"); *English*, 496 U.S. at 79 (explaining that "state law is pre-empted to the extent that it actually conflicts with federal law"). The Plaintiffs argue that their claims are outside of the "extent" of pre-emption; their claims—their theories of breach—rest solely upon actions that the Generic Manufacturer Defendants *could* have taken under federal law and, as a result, the claims are not pre-empted.

This argument is unpersuasive because the Plaintiffs have pled claims rooted in a broad theory of design defect. Contrary to the Plaintiffs' characterization of their pleadings, they have not brought narrow, independent claims against the Generic Manufacturer Defendants. Their claims are tantamount to design-defect claims, and design-defect claims against generic drug manufacturers are pre-empted. *See Bartlett*, 570 U.S. at 483-87.

The Plaintiffs brought design-defect claims in the original Master Complaints, alleging that the Generic Manufacturer Defendants should be held liable for every sale of ranitidine. *See, e.g.*, DE 887 at 109. The Plaintiffs' legal position was that the design-defect claims were not pre-empted because *Bartlett* did not apply to the claims. *See* DE 1978 at 32; DE 1976 at 16-29. The Court rejected that position and dismissed all of the claims that the Plaintiffs had brought against the Generic Manufacturer Defendants. *See* DE 2512.

Although the Plaintiffs repled their claims after the Court's dismissal, the core of their pleadings remains virtually identical to the pleadings that the Court dismissed. The Plaintiffs still allege that ranitidine is a defectively designed molecule; it is highly unstable and apt to form a potent carcinogen. *See, e.g.*, AMPIC ¶¶ 3, 343-44, 364. The Plaintiffs still allege that ranitidine is dangerous at all points in time from the moment it is manufactured; it is harmful when consumed as directed (particularly when accompanied by nitrites in the stomach) and when stored at room temperature in accordance with its labeling, etc. *See, e.g.*, *id.* ¶¶ 6, 339, 346-47.

Thus, even though the Plaintiffs' claims purport to be based on theories other than design defect, the Plaintiffs' design-defect theory remains at the center of this case and, by extension, at the center of all of the Plaintiffs' claims. By way of example, the Plaintiffs' expiration-date claims seek to impose liability on the Generic Manufacturer Defendants because the expiration dates on ranitidine products should have been shorter. *Id.* ¶ 938. But why should the expiration dates have been shorter? Not because of the loss of any of ranitidine's potency over time, nor because of any steady decay. Instead, the Plaintiffs' answer is that ranitidine is dangerous from the moment it is created—it is a volatile, unstable, ticking-time-bomb that *will*, through exposure to heat and humidity or through exposure to room temperature, degrade into a carcinogen. *Id.* ¶ 935. Indeed, the Plaintiffs maintain that ranitidine is so dangerous and so defective that it should only be ingested for a period of one or two months from the moment that it is created. *Id.* ¶ 938; 6/3/21 Hearing Tr. at 28, 37-38.[15]

In another example of design defect, the Plaintiffs' temperature-based claims seek to impose liability on the Generic Manufacturer Defendants because they did not affirmatively chill the ingredients used to make ranitidine in the manufacturing process. AMPIC ¶ 2448; 6/3/21 Hearing Tr. at 44. But why should the Generic Manufacturer Defendants have chilled ingredients? Not because the FDA-approved process for manufacturing ranitidine required chilling, but because ranitidine was a defective molecule that required chilling to counteract its defect. AMPIC ¶ 2439.

Behind each of these examples is the Generic Manufacturer Defendants' alleged knowledge of all of the defects inherent in the design of ranitidine itself. The Plaintiffs have not bifurcated the knowledge imputed to the Brand Manufacturer Defendants, responsible for

[15] Because the Plaintiffs have not alleged how long it takes for ranitidine products to pass from creation in a factory into consumers' hands, the Court is uncertain whether a one to two month window of opportunity to sell the products is equivalent to a mandate to stop selling them altogether.

designing ranitidine, from the knowledge imputed to the Generic Manufacturer Defendants required to follow the FDA-approved process for ranitidine production. *Id.* ¶¶ 2, 405-08; 6/7/21 Hearing Tr. at 9 ("[W]e do allege that the generic manufacturers had the same knowledge as the brand manufacturers, and if they didn't they should have had that knowledge. They are charged as being experts in the field."). Thus, the theme running through the entirety of the Master Complaints is that the Generic Manufacturer Defendants knew that ranitidine was a defective molecule, knew that ranitidine would cause cancer in consumers, and knew that they were powerless to correct the design flaw, but yet should have undertaken acts that still would not make ranitidine reasonably safe. Accepting the Plaintiffs' position and taking their allegations as true, ranitidine could not be made reasonably safe outside of a corrected design or labeling, but the Generic Manufacturer Defendants could correct neither the design nor the labeling under federal law. *See Bartlett*, 570 U.S. at 483-87.

The Plaintiffs' various theories concerning the breadth of ranitidine's inherent design defects have been incorporated into the counts brought against the Generic Manufacturer Defendants. *See, e.g.*, AMPIC ¶ 935 (alleging within the count for strict products liability failure to warn through proper expiration dates that "the NDMA levels in ranitidine increase as the drug breaks down in the human digestive system and interacts with various enzymes in the human body"); *id.* ¶ 1989 (alleging within the count for negligent product containers that ranitidine has "an inherent risk of degrading into NDMA because it has . . . all the ingredients needed to form NDMA").[16] Allegations of the defective design of ranitidine are pervasive throughout the Plaintiffs' pleadings.

[16] To the extent that the Plaintiffs attempt to remove through judicial admission any paragraphs in their counts, they are not permitted to amend the pleadings through a judicial admission. *See, e.g.*, *Sinclair Refin. Co. v. Tompkins*, 117 F.2d 596, 598 (5th Cir. 1941) ("Pleadings are for the purpose of accurately stating the pleader's version of the

The essence of the Plaintiffs' claims is that ranitidine is defectively designed. But for the alleged design defect, the Plaintiffs would have no claims. *Cf. Guarino*, 719 F.3d at 1249 (stating that a plaintiff's claims were, "at bottom," pre-empted allegations that a generic drug manufacturer failed to warn of a generic drug's dangers, "[n]o matter the garb" in which the claims were presented); *Strayhorn*, 737 F.3d at 391 (explaining that circuit courts have found claims pre-empted under *Mensing* that, "at their core," sought to hold generic drug manufacturers liable for failing to provide additional warnings). The Plaintiffs' attempt to bring narrow claims against the Generic Manufacturer Defendants that fall outside the scope of pre-emption is belied by the pleadings themselves. To hold the Generic Manufacturer Defendants liable under the claims pled against them would be akin to holding them liable for selling the defective ranitidine molecule. But they were not required to stop selling ranitidine in order to comply with federal law while avoiding liability under state law. *See Bartlett*, 570 U.S. at 488 ("Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability."). The Plaintiffs' claims against the Generic Manufacturer Defendants, rooted in design defect and the properties of the ranitidine molecule, are pre-empted under *Mensing* and *Bartlett*.

iv. Conclusion

In sum, the Plaintiffs concede that federal law prevented the Generic Manufacturer Defendants from giving *all* necessary warnings about the risks of ingesting ranitidine and from taking *all* reasonable steps to protect consumers from the dangers of ranitidine. The Plaintiffs maintain that the Generic Manufacturer Defendants could only make the warnings better (albeit

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case, and they bind unless withdrawn or altered by amendment."); *see* DE 3326 at 26. Even were the Plaintiffs to remove these incorporated allegations from the counts brought against the Generic Manufacturer Defendants, the Court's analysis would be unchanged.

ultimately inadequate) and make ranitidine less dangerous (albeit not safe). But unreasonably unsafe drug products may not be sold under any cause of action before the Court.

In this case, the Plaintiffs' failure-to-warn, design-defect, and negligence claims against the Generic Drug Manufacturers in the AMPIC and the MMC that are premised on expiration dates, product containers, storage and transportation, and testing are pre-empted. Together with the Court's ruling above that the claims for failure to warn consumers through the FDA are pre-empted, AMPIC Counts III, IV, V, VII, VIII, IX, and XI as pled against the Generic Manufacturer Defendants are dismissed and all of the counts against them in the MMC (Counts 195-429 and 472-640) are dismissed.

3. The Plaintiffs' Remaining Claims

The Court turns to the Plaintiffs' remaining claims against the Generic Manufacturer Defendants. Count XIV of the AMPIC is a claim for unjust enrichment, wherein the Plaintiffs allege that the Generic Manufacturer Defendants were "unjustly enriched as a result of their wrongful conduct." AMPIC ¶ 2725. The Plaintiffs concede that this count must be dismissed if the Court accepts the Generic Manufacturer Defendants' pre-emption argument. 6/7/21 Hearing Tr. at 35-36 ("I agree . . . that if you dismiss all of the other claims against [the Generic Manufacturer Defendants], the unjust enrichment claim can't stand on its own."). AMPIC Count XIV as against the Generic Manufacturer Defendants is therefore dismissed.

Counts XV, XVI, and XVII of the AMPIC are claims for loss of consortium, damages for the estates of deceased consumers, and wrongful death. As the Court stated in its rulings during the prior round of motions to dismiss, the parties agree that these "derivative claims" must be dismissed if all other claims against a defendant are dismissed. DE 2512 at 52; *see also In re Darvocet*, 756 F.3d at 936 (affirming a district court's dismissal of "derivative claims for wrongful

death, survivorship, unjust enrichment, loss of consortium, and punitive damages" when the district court had dismissed all "underlying claims" because the derivative claims "stand or fall with the underlying claims on which they rest"). AMPIC Counts XV, XVI, and XVII as against the Generic Manufacturer Defendants are dismissed.

All of the claims against the Generic Manufacturer Defendants in the ELC are premised on failure to shorten expiration dates on ranitidine products, failure to properly package the products, or both. ELC at 5-6. The Plaintiffs concede that these claims "are necessarily preempted if the claims against them in the AMPIC are preempted." 6/4/21 Hearing Tr. at 206. The counts against the Generic Manufacturer Defendants in the ELC (Counts 409-1062 and 1198-1675) are therefore dismissed. Thus, all claims against the Generic Manufacturer Defendants in all three Master Complaints are dismissed.

D. The Store-Brand Defendants' Motion to Dismiss or Strike

The Plaintiffs bring claims against the Store-Brand Defendants—CVS, Rite Aid, Walgreens, and Walmart—in the MMC and the ELC. The AMPIC does not name Store-Brand Defendants as a category of defendants. The MMC raises claims against the Store-Brand Defendants for failure to warn through accurate expiration dates, negligent product containers, and negligent storage and transportation. The ELC raises claims against them for violation of state consumer protection statutes, common-law unjust enrichment, common-law breach of quasi-contract, and breach of implied warranty. The claims in the ELC are premised on failure to shorten expiration dates on ranitidine products and failure to properly package the products. ELC at 5-6.

The Plaintiffs allege that the Store-Brand Defendants are "private-label distributors" that contracted with generic drug manufacturers to make ranitidine products that the Store-Brand

Defendants sold in their own stores under their own store brands. *See, e.g.*, MMC ¶¶ 79, 451-53. The FDA holds private-label distributors responsible for ensuring that their drug products comply with federal current good manufacturing practices ("cGMPs"), which are controls to ensure drug safety, quality, and purity. *Id.* ¶¶ 453, 461, 482 (citing 21 C.F.R. § 210.1(a)). Contracting with a manufacturer to make a product does not exonerate a private-label distributor from this responsibility. *Id.* ¶¶ 454, 480. A private-label distributor is required to conduct, or cause the manufacturer to conduct, stability testing on a drug product. *Id.* ¶ 493.

The Plaintiffs further alleged that compliance with both the cGMPs and with state law required the Store-Brand Defendants to ensure that their ranitidine products contained accurate expiration dates, that the products were properly packaged, and that the products and their ingredients were appropriately stored and transported. *Id.* ¶¶ 483, 491, 505, 7519-20, 7534-35, 7548-49. Like the Generic Manufacturer Defendants, the Store-Brand Defendants knew or should have known that ranitidine was dangerous because it had an inherent risk of degrading to form NDMA over time and with exposure to conditions in the human body, nitrites, heat, and humidity. *Id.* ¶¶ 489, 495, 506. Thus, according to the Plaintiffs, the Store-Brand Defendants can be held liable for failure to warn and for negligence.

The Plaintiffs have not alleged nor argued that the Store-Brand Defendants had any greater authority under federal law to change their store-brand ranitidine products' design or labeling than did the Generic Manufacturer Defendants with respect to generic ranitidine products. The Store-Brand Defendants incorporate by reference the Generic Manufacturer Defendants' pre-emption arguments. DE 3505 at 8-9. For the same reasons that apply to the Generic Manufacturer Defendants, the Store-Brand Defendants could not independently satisfy their state-law duty for a failure-to-warn or a negligence cause of action while complying with federal

law. The Plaintiffs' failure-to-warn and negligence claims against the Store-Brand Defendants in the MMC are therefore pre-empted. MMC Counts 430-71 are dismissed. The Plaintiffs' claims against the Store-Brand Defendants in the ELC, premised on failure to shorten expiration dates and on failure to properly package, are likewise pre-empted. ELC Counts 1063-1197 are dismissed. Thus, all claims against the Store-Brand Defendants in the MMC and the ELC are dismissed.[17]

E. The Specially-Appearing Defendants' Renewed Motion to Dismiss

The Specially-Appearing Defendants—Ajanta Pharma Ltd., Apotex Inc., Aurobindo Pharma Ltd., Cadila Healthcare Ltd., and Wockhardt Ltd.—are corporations that are citizens of foreign countries and that challenge personal jurisdiction. DE 3108; AMPIC ¶¶ 43, 55, 63, 143, 149. Each Specially-Appearing Defendant is named as a Generic Manufacturer Defendant. Because the Court has dismissed all of the Plaintiffs' claims against the Generic Manufacturer Defendants, the Specially-Appearing Non-U.S. Generic Manufacturer Defendants' Renewed Motion to Dismiss for Lack of Personal Jurisdiction [DE 3108] is denied as moot.

VII. Leave to Amend

The Court has dismissed all of the claims pled against the Generic Manufacturer and Store-Brand Defendants. The Court now addresses why its dismissal is without leave to amend. In general, a plaintiff must be given at least one opportunity to amend a complaint. *Bryant v. Dupree*, 252 F.3d 1161, 1163 (11th Cir. 2001). After a plaintiff's first opportunity to amend, leave for additional amendments may be denied because of "undue delay, bad faith or dilatory motive on the part of the movant, repeated failures to cure deficiencies by amendments previously

[17] The claims against CVS, Rite Aid, Walgreens, and Walmart in the AMPIC, in which these entities are named as retailers, were dismissed without leave to amend in the Court's Order Granting the Retailer and Pharmacy Defendants' Motion to Dismiss Amended Master Personal Injury Complaint and Granting the Distributor Defendants' Motion to Dismiss Amended Master Personal Injury Complaint filed on June 30, 2021, at docket entry 3716.

allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, or futility of amendment." *Andrx Pharms., Inc. v. Elan Corp., PLC*, 421 F.3d 1227, 1236 (11th Cir. 2005) (alteration omitted) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

This MDL contains approximately 1,400 cases and spans in excess of 3,700 docket entries. The Generic Manufacturer and Store-Brand Defendants, over the course of the past sixteen months, have no doubt incurred substantial costs in the form of motion practice and discovery, as well as costs associated with the Court's own administration of the MDL such as status conferences and special master fees. Juxtaposed to these significant costs, at no time have the Plaintiffs pled a claim against the Generic Manufacturer and Store-Brand Defendants that is not pre-empted and that states a claim upon which relief may be granted. The Court provided the Plaintiffs a fair and just opportunity to plead claims against the Generic Manufacturer and Store-Brand Defendants; this is not a case where the Plaintiffs lack in resources, such that they were unable to research and prepare a complaint over the past sixteen months. While *nominal* expenses incurred as a result of amendment do not amount to undue prejudice, the litigation costs imposed upon the Generic Manufacturer and Store-Brand Defendants by virtue of a third round of motion practice and on-going discovery would be anything but nominal. *See Loggerhead Turtle v. Cnty. Council*, 148 F.3d 1231, 1257 (11th Cir. 1998). The Court concludes that permitting the filing of additional master pleadings against the Generic Manufacturer and Store-Brand Defendants would result in undue prejudice to them.

The Court further concludes that permitting the Plaintiffs to file a third round of master pleadings against the Generic Manufacturer and Store-Brand Defendants would be futile. The Plaintiffs previously brought claims against the Generic Manufacturer Defendants that were premised on design defect and failure to provide consumers adequate warnings. But such claims

are pre-empted, and the Court dismissed all of the claims against the Generic Manufacturer Defendants for that reason. *See* DE 2512 at 27-30. The Court gave the Plaintiffs the opportunity to replead claims based on, among other things, expiration dates, storage and transportation conditions, and warning through the FDA. *Id.* at 53. The Plaintiffs pled such claims but, for all of the reasons given above, those claims are still pre-empted claims. Giving the Plaintiffs further opportunity to plead viable claims against the Generic Manufacturer and Store-Brand Defendants would be futile.

At some point the pleadings must begin to close, and that time has come. Thus, the Court's dismissal of the Plaintiffs' claims against the Generic Manufacturer and Store-Brand Defendants is without leave to amend.

VIII. Conclusion

For the foregoing reasons, it is **ORDERED AND ADJUDGED** that the Generic Defendants' Rule 12 Motion to Dismiss on the Ground of Preemption at docket entry 3105 is **GRANTED**. The Store-Brand Retailer Defendants' Motion to Dismiss or Strike Consolidated Medical Monitoring Class Action Complaint and Consolidated Amended Consumer Economic Loss Class Action Complaint at docket entry 3113 is **GRANTED**. All of the Plaintiffs' claims against the Generic Manufacturer and Store-Brand Defendants in the Master Complaints are **DISMISSED WITHOUT LEAVE TO AMEND**. The Specially-Appearing Non-U.S. Generic Manufacturer Defendants' Renewed Motion to Dismiss for Lack of Personal Jurisdiction at docket entry 3108 is **DENIED AS MOOT**.

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 8th day of July, 2021.

ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

Copies furnished to Counsel of Record