UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

MDL NO. 2924
20-MD-2924

JUDGE ROBIN L. ROSENBERG
MAGISTRATE JUDGE BRUCE E. REINHART

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ORDER DENYING THE DEFENDANTS' OMNIBUS MOTION TO DISMISS AND/OR STRIKE AMENDED MASTER PERSONAL INJURY COMPLAINT

This matter is before the Court on the Defendants' Omnibus Rule 12 Motion to Dismiss and/or Strike Amended Master Personal Injury Complaint (the "Motion to Dismiss"). DE 3111. The Court held a hearing on the Motion to Dismiss on June 3, 2021 (the "Hearing"). The Court has carefully considered the Motion to Dismiss, the Plaintiffs' Response thereto [DE 3424], the Defendants' Reply [DE 3507], the arguments that the parties made during the Hearing, and the record and is otherwise fully advised in the premises. For the reasons set forth below, the Defendants' Motion to Dismiss is **DENIED**.

I. Factual Background[1]

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. 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.

[1] 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.

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.

Plaintiffs filed their first Master Complaints on June 22, 2020. DE 887, 888, 889. In those Master Complaints, Plaintiff 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. On December 31, 2020, the Court found that the Plaintiffs' master complaints were shotgun pleadings and granted the Defendants' Motions to Dismiss. DE 2515. The Court granted the Plaintiffs leave to amend.

Following an amendment to Pretrial Order # 36, Plaintiffs filed the AMPIC on February 8, 2021. DE 2759. After the Court granted a two-week extension of time [DE 2720], 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 Defendants filed the Motion to Dismiss addressed herein pursuant to that schedule.

III. The Amended Master Personal Injury Complaint

All individuals who filed a Short Form Complaint adopt the AMPIC. AMPIC at 2.[2] The Plaintiffs allege that they developed cancers from taking the 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.[3]

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 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

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

[3] For example, Defendant "Sanofi" refers to five entities: Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., Patheon Manufacturing Services LLC, and Boehringer Ingelheim Promeco, S.A. de C.V. AMPIC ¶ 39.

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.

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

The Defendants seek to have the AMPIC dismissed and/or stricken. They contend that the AMPIC remains an impermissible shotgun pleading and that the Plaintiffs have not cured the deficiencies that the Court identified in its prior Order dismissing the Master Personal Injury Complaint ("MPIC"). *See* DE 887; DE 2515. In addition, the Defendants argue that the AMPIC fails to plausibly plead several of the claims raised.

In response, the Plaintiffs argue that the AMPIC is not a shotgun pleading and that they have fully complied with the Court's prior Order of dismissal. Additionally, the Plaintiffs provide specific citations to the allegations in the AMPIC that, according to them, satisfy federal pleading standards on plausibility.

The Court concludes that the AMPIC complies with federal pleading standards and complies with the Court's prior order of dismissal. The AMPIC contains enough factual content that, accepted as true, renders the Plaintiffs' claims plausible. Therefore, the Court denies the 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 Defendants' Motion to Dismiss

The Defendants argue that the AMPIC should be dismissed for several different reasons. For each issue, the Court reviews the parties' arguments, the relevant allegations, and the relevant law before providing its analysis and conclusion on the issue. Each issue is discussed in turn.

A. Shotgun Pleading

1. Arguments and Allegations

The Defendants argue that the AMPIC is a shotgun pleading that should be stricken or dismissed. DE 3111 at 23. In the prior round of motions to dismiss, the Court dismissed the MPIC as a shotgun pleading because it improperly lumped defendants together—sometimes across entire groups—without distinguishing their conduct, and despite each group conducting fundamentally different activities. *Id.* (citing DE 2515 at 19). The AMPIC repeats this sin, in violation of Rule 8 and Rule 9. *Id.* at 24-30.

The Plaintiffs respond that the AMPIC is not a shotgun pleading because it provides the Defendants adequate notice and no longer contains the shotgun infirmities that the Court identified in its prior Order on shotgun pleading at docket entry 2515 ("Shotgun Order"). DE 3424 at 16. Unlike the MPIC, the AMPIC pleads overall legal theories in primary counts, plus sub-counts on a jurisdiction-by-jurisdiction basis. *Id.* The AMPIC also incorporates only select factual allegations into each count, rather than every fact. *Id.* at 18. Moreover, the AMPIC distinguishes among groups of Defendants. *Id.* Even when multiple defendants are named in a complaint, the allegations can be read to be alleged against each defendant individually. *Id.* at 17, 19. Finally, the Plaintiffs' misrepresentation claims do not fail under Rule 9(b). *Id.* at 23.

2. Law on Shotgun Pleading

Rule 8(a) requires that any claim for relief contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A shotgun pleading fails "to one degree or another, and in one way or another, to give the defendants adequate notice of the claims against them and the grounds upon which each claims rests." *Weiland v. Palm Beach Cty. Sheriff's Office*, 792 F.3d 1313, 1323 (11th Cir. 2015). There are roughly four types of shotgun pleadings:

> The most common type—by a long shot—is a complaint containing multiple counts where each count adopts the allegations of all preceding counts, causing each successive count to carry all that came before and the last count to be a combination of the entire complaint. The next most common type . . . is a complaint that does not commit the mortal sin of re-alleging all preceding counts but is guilty of the venial sin of being replete with conclusory, vague, and immaterial facts not obviously connected to any particular cause of action. The third type of shotgun pleading is one that commits the sin of not separating into a different count each cause of action or claim for relief. Fourth, and finally, there is the relatively rare sin of asserting multiple claims against multiple defendants without specifying which of the defendants are responsible for which acts or omissions, or which of the defendants the claim is brought against.

Id. at 1321-23 (footnotes omitted).

Rule 9(b) states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). To satisfy Rule 9(b), a complaint must set forth:

> (1) precisely what statements were made in what documents or oral representations or what omissions were made, and (2) the time and place of each such statement and the person responsible for making (or, in the case of omissions, not making) same, and (3) the content of such statements and the manner in which they misled the plaintiff, and (4) what the defendants obtained as a consequence of the fraud.

Ziemba v. Cascade Int'l, Inc., 256 F.3d 1194, 1202 (11th Cir. 2001).

3. Analysis and Conclusion

In the Shotgun Order, the Court noted that the Plaintiffs' MPIC adopted or incorporated every factual allegation by reference. DE 2515 at 18. The Court also noted that the MPIC improperly lumped every defendant together across most of the 15 counts. *Id.* at 19. The Plaintiffs' lumping was particularly problematic because the Court understood that certain groups of defendants conduct fundamentally different activities than other groups. *Id.* The Court expected that with the benefit of discovery, the Plaintiffs could, on replead, "more precisely tailor their allegations to the proper categories" of Defendants. DE 2515 at 20.

In light of the Court's coterminous rulings, the Plaintiffs have adequately addressed both deficiencies in the AMPIC. Unlike the MPIC, the AMPIC incorporates only select factual allegations into each count. *Compare, e.g.*, DE 887 ¶ 453 (Count I, "Strict Products Liability—Failure to Warn," incorporating "each allegation set forth in the preceding paragraphs"), *with* AMPIC ¶¶ 476, 518 (Sub-Count I-1, "Alabama: Strict Products Liability—Failure to Warn Consumers through Warnings and Precautions," incorporating only select ranges of paragraphs). The Plaintiffs have also grouped the Defendants together more narrowly, for rather than alleging counts against all the Defendants, the Plaintiffs allege many counts against only one or both groups of Manufacturer Defendants (*i.e.*, Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants). Moreover, through 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 (June 30, 2021), claims against the Retailer and Distributor Defendants are dismissed from the AMPIC. As a result, and at least with respect to the remaining Defendants, the AMPIC does not cause the same confusion or present the same inconsistencies that the MPIC did.

Defendants' Rule 9(b) argument appears to be directed at Counts XII (Negligent Misrepresentation) and Count XIII (Reckless Misrepresentation). *See* DE 3111 at 29 (citing AMPIC paragraphs under each). The argument is premised on the Plaintiffs' allegations of false representations made "via the media, advertising, website, social media, packaging, and promotions, among other misrepresentations." *Id.* at 30. Defendants' Rule 9(b) argument seeks particularity as to this conduct. The Court denies the Defendants' Motion as to this argument without prejudice in light of the Court's Order Granting in Part and Denying in Part Brand-Name Manufacturer Defendants' Motion to Dismiss Plaintiffs' Innovator-Liability Claims (June 30, 2021).

Even if the Defendants view the AMPIC as imperfect, the Court is satisfied that the Plaintiffs have adequately addressed the shotgun pleading sins that were previously present. The AMPIC need not be perfect; it need only provide the Defendants with fair notice of the allegations. *Twombly*, 550 U.S. at 554-56. If the Court ordered the Plaintiffs to replead with the detail that the Defendants demand, the AMPIC would likely balloon to thousands of more pages and make an already massive pleading even larger. That would in turn jeopardize one major purpose of multidistrict litigation, namely to "promote the *just and efficient conduct*" of "actions involving one or more common questions of fact pending in different districts." 28 U.S.C. § 1407(a) (emphasis added).

Particularly in an MDL of this size, a district court retains wide discretion to ensure that the litigation progresses efficiently and without undue delay. This Court has exercised that discretion at various stages of the litigation in order to efficiently administer this MDL, including through the issuance of more than 60 Pretrial Orders. Its conclusion on this issue is consistent with fulfilling the Court's obligation to properly manage the MDL.

B. Failure to Plead the Claims Based on Expiration Dates and Product Containers

1. Arguments and Allegations

The Manufacturer Defendants contend that the Plaintiffs have failed to plausibly plead the claims based on improper expiration dates and product containers, and the Manufacturer Defendants therefore seek dismissal of Counts III, IV, VII, and IX. DE 3111 at 32. As to Counts III (Strict Products Liability—Failure to Warn Through Proper Expiration Dates), IV (Negligence—Failure to Warn Through Proper Expiration Dates), and IX (Negligent Product Containers), the Plaintiffs have not plausibly alleged that any Manufacturer Defendant knew or should have known that ranitidine degrades to form NDMA over time or due to exposure to moisture.[4] *Id.* at 33-35. As to Count VII (Strict Products Liability—Design Defect Due to Improper Expiration Dates), the Plaintiffs have not plausibly alleged a design-defect claim under any state's law, regardless of whether the state follows the Restatement of Torts' "risk-utility test" or its "consumer-expectations test" for design defect. *Id.* at 36-38.

The Plaintiffs respond that they have plausibly alleged that the Manufacturer Defendants knew or should have known that ranitidine degrades into NDMA due to time and exposure to moisture because (i) the ranitidine molecule contains all of the ingredients needed to form NDMA, (ii) federal law requires drug manufacturers to conduct stability testing on their products to assess drug stability, and (iii) research published in the 1980s revealed elevated levels of NDMA in ranitidine. DE 3424 at 29-33. The Plaintiffs have plausibly alleged a design-defect claim under both the "risk-utility test" and the "consumer-expectations test" in the Restatement of Torts. *Id.* at 27-28, 33-35.

[4] The Manufacturer Defendants do not make this argument for Count XI (Negligent Storage and Transportation).

The Plaintiffs allege that ranitidine internally degrades to form NDMA, that the level of NDMA in a ranitidine product increases over time, and that this higher level of NDMA increases the risk of cancer. AMPIC ¶¶ 935-36, 938. The cancer risk is lower if the product is consumed shortly after it is manufactured. *Id.* ¶¶ 937-38. Therefore, had ranitidine products had shorter expiration dates, the ranitidine that consumers ingested would have had lower levels of NDMA, and their cancer risks would have been lower. *Id.* ¶ 938. Pill bottles with a large number of pills are likely to be stored for long periods of time. *Id.* ¶ 1991. Selling ranitidine products with a smaller quantity of pills in each bottle would have ensured that the products were fully consumed closer to their dates of manufacture, when they contained lower levels of NDMA. *Id.* ¶ 1992. Ranitidine internally degrades to form NDMA more quickly at higher humidity levels. *Id.* ¶ 1988. Packaging ranitidine pills "in a blister pack or similar individually packaged container" would have protected them from exposure to humidity. *Id.* ¶ 1992.

The Plaintiffs also allege that the Manufacturer Defendants knew or should have known decades ago that ingesting ranitidine exposed consumers to excessive and unsafe levels of NDMA. *Id.* ¶ 2. 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.* ¶ 1989.[5] 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; *see* 21 C.F.R. § 211.166(a) ("There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates."). "Simple, widely available and cost-effective tests" would have revealed degradation and NDMA

[5] Plaintiffs make this allegation as part of Count IX (Negligent Product Containers). They do not make the allegation in the expiration-date counts: Count III, IV, and VII.

accumulation in ranitidine products. AMPIC ¶¶ 937-39. Furthermore, research conducted and published before Zantac entered the market revealed elevated levels of NDMA in ranitidine when it was properly tested. *Id.* ¶ 405. For example, a doctor published a note in a popular scientific journal in 1981 that discussed "the results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites—a substance commonly found in food and in the body." *Id.* ¶ 407.

2. The Restatement of Torts' Design-Defect Tests

Under the Third Restatement of Torts, a product "is defective in design when the foreseeable risk of harm posted by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe." Restatement (Third) of Torts: Products Liability § 2(b) (Am. L. Inst. 1998); *see Braswell v. Cincinnati Inc.*, 731 F.3d 1081, 1088 (10th Cir. 2013) (referring to this test for design defect as the "risk-utility test"). Under the risk-utility test, "a design is defective if the product could have been made safer by the adoption of a reasonable alternative design." Restatement (Third) of Torts: Products Liability § 2, cmt. d.

Under the Second Restatement of Torts,

> [o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property if . . . it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

Restatement (Second) of Torts § 402A(1) (Am. L Ins. 1965); *see Braswell*, 731 F.3d at 1087 (referring to this test for design defect as the "consumer[-]expectations test"). Under the consumer-expectations test, the "article sold must be dangerous to an extent beyond that which

would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." Restatement (Second) of Torts § 402A, cmt. i.

3. Analysis and Conclusion

The Court first addresses the adequacy of the Plaintiffs' pleading on the element of notice. The parties utilize a "known or should have known" standard in making their respective arguments about the sufficiency of the pleading. The parties have not briefed whether any state's law would use a different standard to meet the element of notice for any of the claims at issue. For purposes of analyzing the adequacy of the Plaintiffs' pleading, the Court utilizes a "known or should have known" standard. Should any party contend that the standard is different under a particular state's law, that party may raise the issue at the appropriate time in connection with state-specific arguments. *See* Pretrial Order # 61 ("To the extent that other state-specific issues become relevant at a later stage of the litigation, such as at the bellwether trial stage, the parties agree that they may seek leave of the Court to raise the issues at that time.").

The Plaintiffs have plausibly pled that the Manufacturer Defendants should have known, through stability testing of their ranitidine products, that ranitidine can degrade to form NDMA over time and due to exposure to moisture. The Plaintiffs allege that federal law requires all drug manufacturers to conduct stability testing on their products to assess drug stability and to determine appropriate storage conditions and expiration dates. AMPIC ¶¶ 413-16 (citing 21 C.F.R. § 211.166(a)). The Plaintiffs further allege that testing would have revealed degradation and NDMA accumulation in ranitidine products. *Id.* ¶¶ 937-39.

The Manufacturer Defendants argue that the Plaintiffs' allegations about stability testing are insufficient because they do not identify which tests the Manufacturer Defendants should have conducted that would have revealed ranitidine degradation or when such tests became available.

DE 3111 at 35. The Manufacturer Defendants assert that some of them manufactured ranitidine products decades in the past. *Id.*

But the Plaintiffs have identified one test that they maintain could have detected NDMA and that was available at all times that ranitidine products were manufactured. That is, the Plaintiffs have alleged that "mass spectrometry" was a "gold-standard" test that was available by at least 1982, around the same time that the FDA approved the first ranitidine product for sale. AMPIC ¶ 357 (faulting a 1982 GSK study for failure to use "gold-standard mass spectrometry")[6]; *see also id.* ¶ 240 (alleging that the FDA approved the sale of Zantac in 1983). And the Plaintiffs have alleged that "gas chromatography-mass spectrometry" testing in 2019 revealed high levels of NDMA in ranitidine pills. *Id.* ¶ 322. Through these allegations, in conjunction with the allegations about federal requirements for stability testing and the availability of testing that would have revealed degradation, Plaintiffs plausibly plead that the Manufacturer Defendants should have known that ranitidine can degrade to form NDMA with time and with exposure to moisture.[7] The Plaintiffs, therefore, have plausibly pled notice in Counts III, IV, and IX.

As to Count VII, and the Manufacturer Defendants' arguments regarding the Restatement of Torts' design-defect tests, the parties have not briefed which states use either the "risk-utility test" or the "consumer-expectations test." The Court's research has revealed that resolution of which states use which test is not so straightforward. *See, e.g.*, *Crawford v. ITW Food Equip. Grp., LLC*, 977 F.3d 1331, 1343 n.5 (11th Cir. 2020) (stating that "Florida courts have noted that the definition of a design defect is in a state of flux in Florida, and that in the byzantine world of

[6] The Plaintiffs have not incorporated paragraph 357 into their expiration-date or product-container counts. They have, however, incorporated paragraph 408 into those counts, and paragraph 408 similarly faults the same 1982 GSK study, albeit without explicitly mentioning mass spectrometry.

[7] Given this conclusion, the Court does not address the parties' arguments about notice based on ranitidine's molecular structure and research from the 1980's.

products liability it is unsettled whether the consumer-expectation test, risk-utility test or both should be applied in evaluating an alleged defect" (citation and quotation marks omitted)). Some states use alternative tests or hybrid tests. *See, e.g.*, *Potter v. Chi. Pneumatic Tool Co.*, 694 A.2d 1319, 1333-34 (Conn. 1997) (adopting "a modified formulation of the consumer expectation test" that incorporates risk-utility factors and then inquires whether a reasonable consumer would consider the product unreasonably dangers).

Based on the lack of briefing as to which states follow which design-defect tests, the Court is unable to rule on whether the 46 state sub-counts in Count VII are plausibly pled. The Court inquired about this issue during the Hearing. *See* Hearing Tr. at 43 ("How could the Court dismiss Count 7 entirely or dismiss certain state sub counts without first resolving that issue [of which states follow which tests]?"). The Manufacturer Defendants responded that the Plaintiffs' pleading of causation for Count VII was inadequate, regardless of which design-defect test a state might use. *Id.*

The Manufacturer Defendants, however, did not argue in their Motion to Dismiss that the Plaintiffs' pleading of causation is insufficient regardless of which test a state follows for design defect. *See* DE 3111 at 36-38. Due to the size and complexity of this MDL and the number of motions to dismiss the pleadings, the Court previously exercised its discretion to limit oral argument to only those issues that had been briefed. *See* DE 3548 at 2 ("Arguments from the parties must be limited to the arguments in the parties' briefing; the hearing is not an opportunity for the parties to raise new arguments for the first time."). The Court concludes that the adequacy of the Plaintiffs' pleading under any design-defect test is more appropriately resolved in the context of state-specific briefing, to the extent that such briefing becomes necessary. *See* Pretrial Order # 61. The Manufacturer Defendants' request to dismiss Counts III, IV, VII, and IX is denied.

C. Viability and Pleading of the Claims for Failure to Warn Consumers Through the FDA

In Count V, the Plaintiffs bring claims against the Manufacturer Defendants for failure to warn consumers through the FDA under the laws of 15 jurisdictions. Count V is raised under strict products liability laws in California, Hawaii, Louisiana, and Missouri and under negligence laws in Delaware, the District of Columbia, Indiana, Kentucky, Maryland, Massachusetts, Minnesota, Nevada, New York, Oregon, and Pennsylvania. The Plaintiffs allege in this count that the Manufacturer Defendants breached their duties, under the laws of these jurisdictions, 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 Manufacturer Defendants argue that Count V must be dismissed because it is not viable under the laws of the 15 jurisdictions and because it is not plausibly pled. DE 3111 at 19-20, 43-51. The Plaintiffs contend, in response, that the Count is plausibly pled and that the Manufacturer Defendants incorrectly interpret the laws of 13 jurisdictions in reaching their conclusion that the jurisdictions would not recognize the claim. DE 3424 at 35-44. The Plaintiffs concede that the District of Columbia and Indiana would not recognize the claim, and they seek leave to amend the AMPIC to raise the claims under the laws of Idaho and Wisconsin. *Id.* at 45.

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 (June 30, 2021), the Court concluded that Count V is pre-empted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), for the reasons that the Eleventh Circuit Court of Appeals outlined in *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017). The Court dismisses Count V with prejudice for that reason. In light of this ruling, the Court need not address

arguments directed to the viability of Count V under state law and pleading deficiencies or the Plaintiffs' request to add sub-counts under the laws of Idaho and Wisconsin.

D. Viability of the Claims for Negligent Failure to Test

1. Arguments and Allegations

Count VIII raises claims of negligent failure to test against the Manufacturer Defendants under the laws of Kansas and Texas. The Manufacturer Defendants assert that this Count must be dismissed because neither state recognizes such a cause of action as an "independent" tort. DE 3111 at 20, 51-54. In both states, the duty to test is recognized only as part of the broader duty to manufacture a reasonably safe product. *Id.* at 52-54.

The Plaintiffs respond that Kansas and Texas recognize claims for failure to test. DE 3424 at 48-50. They maintain that Connecticut also recognizes a claim for negligent failure to test, and they request permission to amend the AMPIC to raise the claim under Connecticut law.[8] *Id.* at 48.

The Plaintiffs allege in Count VIII that widely available testing methods have revealed that ranitidine degrades to form NDMA. AMPIC ¶ 1952. The Manufacturer Defendants could have, but did not, appropriately test their ranitidine products. *Id.* ¶¶ 1953, 1956, 1962-63. Had they done this testing, the Manufacturer Defendants could have determined earlier that ranitidine products pose a danger and warned of that danger, which would have led to an earlier product recall, additional testing, a reduction in product use, and/or additional warnings on product labeling. *Id.* ¶¶ 1954-55, 1959, 1964, 1967.

[8] The Plaintiffs did not move for leave to amend to add a Connecticut sub-count, and a party may not seek leave to amend a complaint in a response to a motion. *See Rosenberg v. Gould*, 554 F.3d 962, 967 (11th Cir. 2009) ("Where a request for leave to file an amended complaint simply is imbedded within an opposition memorandum, the issue has not been raised properly." (quotation marks omitted)). The Court will not entertain a motion to add a Connecticut sub-count at this stage of the litigation. Nothing in this ruling precludes an individual Plaintiff from seeking to raise a Connecticut claim for failure to test in an individual case.

2. Kansas and Texas Law on Testing Claims

"Kansas law recognizes only three ways in which a product may be defective: (1) a manufacturing defect; (2) a warning defect; and (3) a design defect." *Burton v. R.J. Reynolds Tobacco Co.*, 397 F.3d 906, 920 (10th Cir. 2005) (citing *Delaney v. Deere & Co.*, 999 P.2d 930, 936 (Kan. 2000)). The "core purpose of a duty to test is to avoid production of defective products." *Id.*; *see also Pfeiffer v. Eagle Mfg. Co.*, 771 F. Supp. 1133, 1139 (D. Kan. 1991) ("The duty to warn is a continuous one, requiring the manufacturer to keep abreast of the current state of knowledge of its products as acquired through research, adverse reaction reports, scientific literature, and other available methods."); *Lindquist v. Ayerst Lab'ys, Inc.*, 607 P.2d 1339, 1350 (Kan. 1980) (citing with approval an authority providing that the "rule is that a manufacturer has a duty to make such tests and inspections, during and after the process of manufacturer, as should be recognized as being reasonably necessary to secure the production of a safe product" (quotation marks omitted)). Thus, "a plaintiff alleging a breach of the duty to test must prove that one of these three types of product defects caused the claimant injury." *Burton*, 397 F.3d at 920 (referring to a jury finding of negligent failure to test as "co-extensive" with its finding of negligent failure to warn); *see also Miller v. Pfizer Inc.*, 196 F. Supp. 2d 1095, 1124 n.97 (D. Kan. 2002) (noting the parties' agreement that the "duty to warn and the duty to test are, for all practical purposes, coextensive" (quotation marks omitted)); *Lindquist*, 607 P.2d at 1350 ("[A] manufacturer who negligently fails to use reasonable care in making such tests and inspections, and thereby produces a defective article which causes damage while being put to an ordinary anticipated use, is liable for such damage." (quotation marks omitted)).

A "negligent testing claim is, as a matter of Texas law, a variation of an action for failure to warn." *Dow Agrosciences LLC v. Bates*, 332 F.3d 323, 333 (5th Cir. 2003) (citing *Am. Tobacco*

Co. v. Grinnell, 951 S.W.2d 420, 437 (Tex. 1997)), *vacated on other grounds*, 544 U.S. 431, 442 n.15 (2005) (expressing no view as to whether the claims pled were viable as a matter of Texas law); *see also Skotak v. Tenneco Resins, Inc.*, 953 F.2d 909, 912 & n.5 (5th Cir. 1992) (explaining that plaintiffs' negligence claim for failure to adequately test was "subsumed" within their claim for an inadequate warning). A negligent-testing claim is "inextricably intertwined" with a negligence claim for failure to warn where the testing claim is predicated on a "duty to test and ascertain the dangers inherent in [a manufacturer's] products about which it must warn consumers." *Grinnell*, 951 S.W.2d at 437.

3. Analysis and Conclusion

Under Kansas and Texas law, a claim for negligent failure to test does not succeed without proof of a product defect—the duty to test exists to discover product defects, and a showing of negligent testing requires a showing of a product defect. A claim for negligent failure to test, however, may be pled as a separate count from a product-defect count. The Defendants have provided no Kansas or Texas case to the contrary. Indeed, in *Burton*, the Tenth Circuit Court of Appeals affirmed a federal jury's verdict based on both negligent failure to test and a warning defect under Kansas law. 397 F.3d at 920-21; *see also Kinser v. Gehl Co.*, 184 F.3d 1259, 1272-73 (10th Cir. 1999) (affirming the use of a jury instruction on failure to test under Kansas law where the record justified the use of an instruction on duty to warn), *abrogated on other grounds by Weisgram v. Marley Co.*, 528 U.S. 440 (2000). And in *Grinnell*, the Texas Supreme Court evaluated whether summary judgment was appropriate for a negligent-testing claim along with a negligent-warning claim. 951 S.W.2d at 437. In the absence of any authority to support the dismissal of VIII as redundant, the Manufacturer Defendants' request to dismiss Count VIII is denied.

E. Punitive Damages

1. Arguments and Allegations

The Defendants argue that the Plaintiffs' request for punitive damages should be dismissed or stricken. DE 3111 at 63. The Plaintiffs do not plausibly allege specific facts to support their request for punitive damages, as required under federal pleading standards and Rule 8(a)(2) of the Federal Rules of Civil Procedure. *Id.* at 61–62. This is so because "[t]he allegations specific to Plaintiffs' punitive damages request are too conclusory and generalized to support punitive damages against any individual Defendants." DE 3507 at 23. Additionally, "the shotgun factual allegations underlying Plaintiffs' claims are also too conclusory and generalized to plead that any individual Defendant acted with the necessary state of mind to support punitive damages." *Id.*

The Plaintiffs assert that *Twombly* does not apply to a request for punitive damages because such a request is not a "claim" within the meaning of Rule 8(a)(2). DE 3424 at 53. The relevant portion of Rule 8 that relates to pleading punitive damages is Rule 8(a)(3), which requires only a demand for relief sought. *Id.* at 55. The Plaintiffs make such a demand in the AMPIC. Additionally, even if Rule 8(a)(2) and *Twombly* govern a request for punitive damages, the Plaintiffs have plausibly alleged specific facts in support of their demand for punitive damages. *Id.* at 56–57.

2. Federal Pleading Standards and Rule 8(a)(2)

Rule 8(a)(2) requires that any claim for relief contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Under *Iqbal*, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). A shotgun pleading fails "to one

degree or another, and in one way or another, to give the defendants adequate notice of the claims against them and the grounds upon which each claims rests." *Weiland*, 792 F.3d at 1323.

3. Analysis and Conclusion

In *Estate of Bass v. Regions Bank, Inc.*, 947 F.3d 1352, 1356 n.5 (11th Cir. 2020), the Eleventh Circuit applied the *Iqbal* pleading standard to the plaintiff's request for punitive damages, noting that the plaintiff's claim for punitive damages "exemplif[ied] the *Iqbal* problems created by shotgun pleadings." In that case, the plaintiff alleged that the defendant's conduct was "intentional, deliberate, reckless, and in conscious disregard for the consequences of its actions," thereby making the defendant "liable for punitive damages." *Id.* The court noted that such vague assertions "result[ed] in the obvious question—what 'conduct' is [the plaintiff] referring to? No one could know." *Id.* Thus, the court concluded that "[c]omplaints with such obvious deficiencies clearly run afoul of the specificity required by Rule 8(a)(2) and *Iqbal*" and are therefore "unacceptable in this Circuit." *Id.*

Other Circuits and several district courts within this Circuit have also applied Rule 8(a)(2) and *Iqbal* to requests for punitive damages. *See*, *e.g.*, *Pyskaty v. Wide World of Cars, LLC*, 856 F.3d 216, 227 (2d Cir. 2017); *Charvat v. EchoStar Satellite, LLC*, 630 F.3d 459, 463 (6th Cir. 2010); *Boring v. Google Inc.*, 362 F. App'x 273, 283 (3d Cir. 2010); *Doe v. Celebrity Cruises, Inc.*, 389 F. Supp. 3d 1109, 1116 (S.D. Fla. 2019); *Chicken Kitchen USA, LLC v. Maiden Specialty Ins. Co.*, No. 14-23282-CIV, 2015 WL 7294824, at *7 (S.D. Fla. Nov. 19, 2015); *Henderson v. Sun Pharms. Indus., Ltd.*, No. 4:11-CV-0060-HLM, 2011 WL 4024656, at *8 (N.D. Ga. June 9, 2011). The Court therefore analyzes Plaintiffs' request for punitive damages under Rule 8(a)(2) and *Iqbal*.

Although the Plaintiffs' "Exemplary/Punitive Damages Allegations" are directed at all Defendants [AMPIC ¶¶ 473-75], the Plaintiffs set forth "sufficient factual matter" throughout the AMPIC in support of their claim for punitive damages. *Iqbal*, 556 U.S. at 678.[9] The Plaintiffs allege that *every* Defendant knew the safety risks of ranitidine and recklessly disregarded that risk to human life. AMPIC ¶¶ 408, 429, 460, 473. Unlike in *Bass*, there is no question as to what conduct the Plaintiffs refer to in the AMPIC to support their request for punitive damages. *See Bass*, 947 F.3d at 1356 n.5. The Defendants' request to dismiss or strike the Plaintiffs' request for punitive damages as implausibly pled is denied. Whether the Plaintiffs are entitled to assert punitive damages under specific state laws may be addressed at a later juncture. *See* Pretrial Order # 61 at 4.

F. Failure to Plead the Negligent Storage and Transportation Claims

The Plaintiffs bring two negligence claims based upon the alleged propensity of ranitidine to form NDMA through exposure to heat, Count X and Count XI; both claims allege that the Defendants were negligent in the storage and transportation of ranitidine. The Defendants seek dismissal of both claims as implausibly pled. A claim is plausibly pled when the "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. Count X is brought against the Retailer and Distributor Defendants, while Count XI is brought against the Manufacturer Defendants. Because the Court has dismissed Count X, the Court need only determine whether Count XI should be dismissed in this Order, but the Court first briefly summarizes its dismissal of Count X.

[9] The Court dismissed the Retailer and Distributor Defendants from the AMPIC in its Order Granting the Retailer and Pharmacy Defendants' Motion to Dismiss AMPIC and the Distributor Defendants' Motion to Dismiss AMPIC (June 30, 2021). Accordingly, the Court addresses the sufficiency of the Plaintiffs' allegations as to the Manufacturer Defendants only.

The Court dismissed Count X for two primary reasons. First, Count X was premised on a single allegation of breach—that the Retailer and Distributor Defendants were negligent for choosing to ship some ranitidine through common carriers—but Count X included no allegations about the conditions (such as temperature) utilized by common carriers. Second, the Plaintiffs did not plead that the Retailers and Distributors had any knowledge about the alleged propensity of ranitidine to form NDMA when exposed to temperatures above room temperature. Thus, the Retailer and Distributor Defendants could not have known that ranitidine should be treated differently than any other room-temperature drug. For these reasons, Count X was implausibly pled, but neither ground for the dismissal of Count X applies to Count XI.

Unlike Count X, Count XI includes allegations about the Manufacturer Defendants' breach of the duty of ordinary care through actions other than their occasional use of common carriers. For example, the Plaintiffs allege that the Manufacturer Defendants did not properly store the chemical materials that were used to create ranitidine—the materials were kept too hot. AMPIC ¶ 2448. At the Hearing, the Plaintiffs confirmed that their theory for Count XI includes the theory that the Manufacturer Defendants should have affirmatively cooled the materials used to make ranitidine during the manufacturing process. Hearing Tr. at 44. This means that Count XI bears some similarity to the other counts that allege negligent manufacturing such as Count IX, Negligent Product Containers. Finally, and perhaps most importantly, the Plaintiffs have alleged that the Manufacturer Defendants had full knowledge of the allegedly dangerous propensity of ranitidine to form NDMA when exposed to any heat above room temperature. AMPIC ¶¶ 405-08, 2439. Thus, unlike a common carrier, a retailer, or a distributor, the Manufacturer Defendants would have known of the need to ensure that ranitidine never rose above room temperature, even

for a limited period of time. The Plaintiffs have "raised their right to relief above the speculative level." Count XI survives the Defendants' plausibility challenge.

G. Factual Inconsistencies

The Defendants argue that certain counts in the AMPIC are factually inconsistent because, within the allegations incorporated into the counts, the Plaintiffs advance multiple theories as to how ranitidine injured the Plaintiffs. *E.g.,* AMPIC ¶¶ 935-62. The Defendants contend that these different theories of injury are inconsistent. In response, the Plaintiffs argue that their theories are not inconsistent—they simply postulate *different* explanations for the Plaintiffs' injuries, not *inconsistent* explanations. The Court concludes that Plaintiffs' claims need not be dismissed or amended based on these alleged inconsistencies. To the extent the Plaintiffs' various theories for recovery implicate pre-emption concerns, that is a matter addressed in the Court's Order on the Generic Defendants' Rule 12 Motion to Dismiss on the Ground of Preemption.

H. Unjust Enrichment

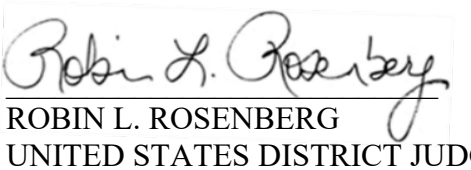
The Defendants argue that the Plaintiffs' claims for unjust enrichment (Count XIV) must be dismissed because the Plaintiffs failed to allege the following: (i) that they lack an adequate legal remedy for their purported harms; (ii) that they conferred an actionable and/or direct benefit on Defendants; and (iii) that the Defendants committed affirmative wrongdoing. DE 3111 at 54-61. In response, the Plaintiffs argue that: (i) the Court cannot determine whether Plaintiffs' lack an adequate legal remedy at this stage; (ii) Defendants' received the actionable benefit of the full price of ranitidine and the Plaintiffs need not plead that they conferred that benefit directly upon the Defendants; and (iii) the AMPIC alleges affirmative wrongdoing because it alleges Defendants' knowledge of ranitidine's risks. DE 3424 at 50–53.

Given that Plaintiffs bring unjust enrichment sub-counts under the laws of fifty-two jurisdictions, the Court would require more extensive state specific briefing to reach a conclusion. The Defendants' Motion is therefore denied without prejudice as to the unjust enrichment Count (Count XIV). Consistent with Pretrial Order # 61, the Defendants may seek leave of Court to raise this state-law issue at a later stage of the litigation.

VII. Conclusion

For the foregoing reasons, it is **ORDERED AND ADJUDGED** that the Defendants' Omnibus Motion to Dismiss and/or Strike Amended Master Personal Injury Complaint [DE 3111] is **DENIED**.

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 30th day of June, 2021.



ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

Copies furnished to Counsel of Record