No. _____

In the Supreme Court of the United States

MARILYN WILLIAMS, PETITIONER

v.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., ET AL., RESPONDENTS

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Petitioner Marilyn Williams is the latest victim ensnared by the "finality trap," which has confounded the lower courts for decades. The typical fact pattern is on display here. Ms. Williams brought five claims against the respondents. The district court dismissed all claims, four without prejudice, and one with prejudice and without leave to re-plead after finding it preempted by federal law. But to Ms. Williams, the game of litigation was not worth the candle without that claim restored. So she responded by filing an amended pleading that dropped all of her other claims, asserting only the claim that the district court found preempted. Then Ms. Williams dismissed her action under Rule 41(a) and appealed the district court's preemption ruling.

The Eleventh Circuit dismissed for want of jurisdiction, holding that Ms. Williams had not appealed a "final decision" within the meaning of 28 U.S.C. § 1291. The ruling deepens a longstanding circuit split over the construction of those jurisdiction-conferring statutory words. And the sharp disagreement among the lower courts is not academic. There is no doubt that, had Ms. Williams been before different courts of appeals, they would have wielded judicial power. The question presented is:

> Does an interlocutory ruling that dismisses some (but not all) of a plaintiff's claims with prejudice become an appealable "final decision" if the plaintiff voluntarily dismisses her action under Rule 41(a)?

PARTIES TO THE PROCEEDING

Petitioner Marilyn Williams was the plaintiff-appellant in the court of appeals.

Respondents Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim USA Corporation, and Walgreens Boots Alliance, Inc. were defendants-appellees in the court of appeals.

A corporate disclosure statement is not required because Ms. Williams is not a corporation. *See* Sup. Ct. R. 29.6.

STATEMENT OF RELATED CASES

Counsel is aware of no directly related proceedings arising from the same trial-court case as this case other than those proceedings appealed here.

TABLE OF CONTENTS

APPENDIX

TABLE OF AUTHORITIES

Cases

Statutes

Rules

Other Authorities

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PETITION FOR WRIT OF CERTIORARI

The courts of appeals have long disagreed on whether and when a plaintiff can appeal a partial-dismissal ruling by voluntarily dismissing her action under Rule 41(a). Some courts, such as the Fourth and Eighth Circuits, treat a voluntary dismissal as a "final decision" under 28 U.S.C. § 1291 and always allow litigants to appeal after such a dismissal.[1] Other courts, including the Second, Third, Sixth, and Seventh Circuits, say that a "final decision" exists after a voluntary dismissal only if the plaintiff disavows further pursuit of the unresolved claims or is legally incapable of resurrecting them.[2] The Ninth Circuit

1. *See infra* at 13–14.
2. *See infra* at 14–18.

and the Federal Circuit, by contrast, construe the words "final decision" to encompass appeals where there is no evidence that the voluntary dismissal was obtained to "manufacture" finality or "manipulate" the rule against interlocutory appeals.[3] And the Fifth Circuit finds a "final decision" following a Rule 41(a) dismissal only when the voluntary dismissal was "with prejudice."[4]

The Eleventh Circuit has added yet another reading of section 1291, holding that a court-approved voluntary dismissal under Rule 41(a)(2) will *always* confer finality, while a Rule 41(a)(1) voluntary dismissal, at least in Marilyn Williams's case, is not a "final decision." The Eleventh Circuit did not justify or explain why the finality of a voluntary dismissal should turn on whether it was obtained under Rule 41(a)(1) or Rule 41(a)(2). And it did not make clear whether or when a Rule 41(a)(1) voluntary dismissal could be appealable. Ms. Williams's petition presents an ideal vehicle for this Court to resolve a jurisdictional issue that has divided the courts of appeals for decades.

OPINIONS BELOW

The opinion of the court of appeals is available at 2022 WL 16729151, and it is reproduced at App. 1–18. The district court's opinions and orders are available at 512 F. Supp. 3d 1278 (S.D. Fla. 2021) and 510 F. Supp. 3d 1234 (S.D. Fla. 2020), and they are reproduced at App. App. 75–124 and App. 125–189.

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3. *See infra* at 18–20.
4. *See infra* at 22–23.

JURISDICTION

The court of appeals issued its opinion on November 7, 2022, and denied rehearing en banc on May 18, 2023. App. 190–191. On July 27, 2023, Justice Thomas extended the time to file a petition for certiorari until September 15, 2023. Ms. Williams timely filed this petition on September 15, 2023.

This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

28 U.S.C. § 1291 provides, in relevant part:

> The courts of appeals (other than the United States Court of Appeals for the Federal Circuit) shall have jurisdiction of appeals from all final decisions of the district courts of the United States . . . .

28 U.S.C. § 1291.

Rule 41(a) of the Federal Rules of Civil Procedure provides, in relevant part:

> (a) VOLUNTARY DISMISSAL.
>
> (1) *By the Plaintiff.*
>
> (A) *Without a Court Order.* Subject to Rules 23(e), 23.1(c), 23.2, and 66 and any applicable federal statute, the plaintiff may dismiss an action without a court order by filing:
>
> (i) a notice of dismissal before the opposing party serves either an answer or a motion for summary judgment; or

> (ii) a stipulation of dismissal signed by all parties who have appeared.
>
> (B) *Effect.* Unless the notice or stipulation states otherwise, the dismissal is without prejudice. But if the plaintiff previously dismissed any federal- or state-court action based on or including the same claim, a notice of dismissal operates as an adjudication on the merits.
>
> (2) *By Court Order; Effect.* Except as provided in Rule 41(a)(1), an action may be dismissed at the plaintiff's request only by court order, on terms that the court considers proper. If a defendant has pleaded a counterclaim before being served with the plaintiff's motion to dismiss, the action may be dismissed over the defendant's objection only if the counterclaim can remain pending for independent adjudication. Unless the order states otherwise, a dismissal under this paragraph (2) is without prejudice.

Fed. R. Civ. P. 41(a).

STATEMENT

Petitioner Marilyn Williams is suing manufacturers and retailers of Zantac, alleging that the drug is defectively designed because it degrades into a carcinogen that

caused her cancer.[5] The judicial panel on multidistrict litigation transferred her case (and all other Zantac cases) to the Southern District of Florida for coordinated or consolidated pretrial proceedings. *See In re Zantac (Ranitidine) Products Liability Litigation*, 437 F. Supp. 3d 1368 (J.P.M.L. 2020); 28 U.S.C. § 1407.

After receiving these Zantac cases, the district court appointed Plaintiffs' Leadership and directed them to prepare a "master complaint," which alleges facts, defendants, and claims but omits any mention of the plaintiffs or plaintiff-specific facts. Plaintiffs' Leadership, not any plaintiff or her individually retained lawyers, prepared and filed this document.

The district court also directed the individual plaintiffs to file their own "short-form complaints," which incorporate specified allegations of the master complaint while adding case-specific information, such as a plaintiff's name and injuries, and the particular claims asserted by that plaintiff. Ms. Williams's short-form complaint asserted five claims against each of the three respondents:

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5. Ms. Williams sued the respondents under diversity jurisdiction. *See* 28 U.S.C. § 1332. Ms. Williams is a citizen of Alabama. Respondents Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim USA Corporation are Delaware corporations with their principal places of business in Connecticut. Respondent Walgreens Boots Alliance, Inc. is a Delaware corporation with its principal place of business in Illinois. Ms. Williams is seeking damages from the defendants in excess of $75,000, exclusive of interest and costs. *See* Complaint, ECF No. 1, *Williams v. Boehringer Ingelheim Pharmaceuticals, Inc.*, No. 2:20-cv-00160-ALB-SMD (M.D. Ala.); Master Personal Injury Complaint, ECF No. 887, *In re: Zantac (Ranitidine) Products Liability Litigation*, No. 9:20-md-02924-RLR (S.D. Fla.).

(1) Strict products liability (failure to warn); (2) Strict products liability (design defect); (3) Negligence (failure to warn); (4) Breach of implied warranties; and (5) Breach of express warranties. Ms. Williams asserted these claims against Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim USA Corporation (the "brand-manufacturer defendants") and Walgreens Boots Alliance, Inc. (the "retailer defendant").

After the defendants moved to dismiss, the district court held that all design-defect (or misbranding) claims were preempted by federal law and dismissed with prejudice and without leave to re-plead. In a separate order, the district court dismissed the entire master complaint without prejudice as insufficiently pled under Rule 8 and instructed Plaintiffs' Leadership to file an amended master complaint.

In response to these orders, Ms. Williams filed an amended short-form complaint that asserts only the design-defect claim that the district court had previously dismissed with prejudice, dropping all of the remaining claims that were asserted in Ms. Williams's original short-form complaint.[6] Then Ms. Williams voluntarily dismissed

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6. For good measure, Ms. Williams's amended short-form complaint expressly renounces the earlier claims (other than the design-defect claim) that she had asserted in the original short-form complaint:

> Plaintiff's sole theory of liability is that the ranitidine she consumed was defectively designed under state law, and that these same design defects made ranitidine dangerous to health when used as instructed on the label such that it was misbranded under federal law. The ranitidine Plaintiff consumed was illegal to sell under federal law,

(continued…)

her action without prejudice under Rule 41(a)(1)(A)(i) and filed a notice of appeal.[7] The notice of appeal stated that Ms. Williams was appealing the distinct orders of the district court that had granted the defendants' motions to dismiss on preemption grounds. App. 202. Then it said:

> These Orders were made final with respect to Plaintiff Marilyn Williams on the 27th day of January, 2021, when Plaintiff amended her Short Form Complaint to eliminate all claims for which repleading was permitted by the Court's Orders.

App. 202–203. Ms. Williams took all of these actions before Plaintiffs' Leadership filed an amended master complaint.

Shortly after Ms. Williams appealed, the respondents moved to dismiss for lack of a "final decision" under 28 U.S.C. § 1291.[8] The court of appeals, after briefing and argument, agreed with the respondents' jurisdictional objections and held that "Ms. Williams' voluntary dismissal

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> and requires compensation under state design defect tort law.

App. 196 (¶ 13).

7. On November 15, 2021, nearly ten months after Ms. Williams appealed, the district court entered a judgment under Rule 54(b) dismissing nearly all of the claims asserted against Walgreens and the other "retailer defendants," including each of the five claims that Ms. Williams had asserted against Walgreens in her original short-form complaint. App. 19–21. The Rule 54(b) judgment did not address claims asserted against the Boehringer respondents or the other "brand-manufacturer defendants."

8. *See* Appellees' Motion to Dismiss Appeal for Lack Of Jurisdiction, ECF No. 36, No. 21-10306 (11th Cir.).

of her own amended [short-form complaint] did not have the effect of creating a final judgment." App. 13.

The court of appeals acknowledged that a district-court order granting a plaintiff's request for voluntary dismissal under Rule 41(a)(2) *would* qualify as a "final decision" that can be appealed under 28 U.S.C. § 1291. App. 13–14 (citing *Corley v. Long-Lewis, Inc.*, 965 F.3d 1222, 1231 (11th Cir. 2020)). But it insisted that Ms. Williams's *unilateral* dismissal under Rule 41(a)(1) could not confer appellate jurisdiction because "there is no final order from the district court on Ms. Williams' design defect claim," and therefore no "final decision" that Ms. Williams could appeal under 28 U.S.C. § 1291. App. 14.

The court of appeals offered several reasons in support of this conclusion. First, the court of appeals faulted Ms. Williams for "seeking to appeal matters related to the very claim she voluntarily dismissed through Rule 41(a)(1)." App. 14.

Second, the court of appeals noted that Plaintiffs' Leadership has since submitted an amended *master* complaint that includes two design-defect claims, and that this amended master complaint remains pending in the district court. App. 14.

Third, the court of appeals indicated that Ms. Williams should have waited for the district court to dismiss the design-defect claim that she listed in her amended short-form complaint, even though the district court had already dismissed that claim with prejudice. App. 14–15 ("Ms. Williams' subjective belief that the district court would dismiss her amended SFC . . . does not make a final judgment.").

Fourth, the court of appeals claimed that Ms. Williams could continue litigating in the district court, despite her decision to appeal, by filing a "second amended" short-form complaint. App. 15 ("Ms. Williams — who voluntarily dismissed her amended SFC without prejudice — could file a second amended [short-form complaint] today, checking the boxes for a different line-up of claims.").

Ms. Williams petitioned for panel rehearing and rehearing en banc, but the Eleventh Circuit denied the petition. She now respectfully seeks a writ of certiorari from this Court.

REASONS FOR GRANTING THE PETITION

The Eleventh Circuit's ruling deepens a longstanding division of authority on whether and in what circumstances a plaintiff may convert an interlocutory order that dismisses some (but not all) claims with prejudice into an appealable "final decision" by voluntarily dismissing her action under Rule 41(a).

Eleven of the thirteen federal courts of appeals have weighed in on the question, and the rules of decision splinter into at least four different camps. Ms. Williams's appeal would have been heard in at least six courts of appeals, would have been similarly dismissed in the Fifth Circuit, and would have met an uncertain fate everywhere else. The Court should grant certiorari to restore a clear and uniform meaning to the statutory words "final decision" that all litigants can follow. Jurisdictional rules should not be a costly trap for the unwary.

I. THE COURTS OF APPEALS ARE DIVIDED ON WHEN A RULE 41(A) DISMISSAL SHOULD ALLOW A PLAINTIFF TO APPEAL AN EARLIER PARTIAL-DISMISSAL RULING

When a district court dismisses some (but not all) of a plaintiff's claims with prejudice, it is common for litigants to respond as Ms. Williams did, dismissing their action under Rule 41(a) and then filing a notice of appeal. The courts of appeals have long been divided on whether (and in what circumstances) this tactic should be allowed,[9] and several courts of appeals have changed or refined their approach to the dismissal-and-appeal maneuver over time.[10]

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9. *See Robinson-Reeder v. American Council on Education*, 571 F.3d 1333, 1338–39 (D.C. Cir. 2009) ("[T]he circuits, and even cases within individual circuits, are divided over whether voluntary dismissal without prejudice of unresolved claims can suffice to make a district court's judgment final — and, if so, under what circumstances."); *Chappelle v. Beacon Communications Corp.*, 84 F.3d 652, 654 (2d Cir. 1996) ("The other courts of appeals are in disagreement over this question, with several of them displaying intra-circuit conflicts."); *James v. Price Stern Sloan, Inc.*, 283 F.3d 1064, 1066 (9th Cir. 2002) (acknowledging that "there is no unanimity on this issue" and noting the split in authority among the courts of appeals); *Arrow Gear Co. v. Downers Grove Sanitary District*, 629 F.3d 633, 636 (7th Cir. 2010) (Posner, J.) (acknowledging that the Seventh Circuit's rule on this issue departs from the approaches taken by the Eighth and Ninth Circuits); *Doe v. United States*, 513 F.3d 1348, 1352–54 (Fed. Cir. 2008) (acknowledging the circuit split and opting to follow the approach taken by the Ninth Circuit in *James,* 283 F.3d at 1069–70).

10. *See Page Plus of Atlanta, Inc. v. Owl Wireless, LLC*, 733 F.3d 658, 662 (6th Cir. 2013) (refusing to follow the rationale of *Hicks v. NLO, Inc.*, 825 F.2d 118, 120 (6th Cir. 1987), which allowed

(continued…)

The courts of appeals have struggled with this issue because Rule 41(a) dismissals are typically entered "without prejudice" to the plaintiff's ability to re-file.[11] This creates the concern that the dismissal is not truly "final," but instead a temporary dismissal designed to obtain an interlocutory appeal that would otherwise be foreclosed by 28 U.S.C. § 1291.

Consider a case in which a plaintiff brings two claims against a defendant, and the district court dismisses Claim A with prejudice but allows Claim B to go to trial. If the plaintiff responds by using Rule 41(a) to voluntarily dismiss the entire action "without prejudice," he could appeal the now-final ruling dismissing Claim A, but with the intent of resurrecting Claim B in the district court as soon as the appeal concludes. This would enable litigants to appeal a district court's otherwise interlocutory rulings by creating temporary "finality" through the voluntary-dismissal tactic, even if the litigant has every intention of undoing the finality and reinstating his unresolved claims after he secures his appellate-court ruling. There are (of

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plaintiffs to appeal voluntary dismissals only when the district court had signed off on it); *Hope v. Klabal*, 457 F.3d 784, 789–90 (8th Cir. 2006) (acknowledging inconsistencies and changes in the Eighth Circuit's treatment of this issue); *Corley v. Long-Lewis, Inc.*, 965 F.3d 1222, 1228 (11th Cir. 2020) (discussing and attempting to reconcile the Eleventh Circuit's "divergent decisions").

11. Fed. R. Civ. P. 41(a)(1)(B) ("Unless the notice or stipulation states otherwise, the dismissal is without prejudice."); Fed. R. Civ. P. 41(a)(2) ("Unless the order states otherwise, a dismissal under this paragraph (2) is without prejudice."); *see also Arrow Gear Co. v. Downers Grove Sanitary District*, 629 F.3d 633, 637 (7th Cir. 2010) (Posner, J.) ("When a claim is dismissed without prejudice, the plaintiff can refile it").

course) risks to using this strategy, as the statute of limitations for Claim B might expire during the appeal, or a district court might order the plaintiff to pay the costs of the previous action under Rule 41(d) if he tries to re-assert Claim B.[12] But the prospect of obtaining an otherwise-forbidden interlocutory appeal might be attractive enough to convince a plaintiff to take these risks—and to use Rule 41(a) to create a pseudo-finality that he plans to unwind once the appeal concludes.

Whether the understandable *policy* objections to this potential maneuver should have any bearing on the textual meaning of the words "final decision" is better left for merits briefing. Suffice it to say that the concern has spurred intractable divisions in the courts of appeals on the tests used to distinguish the permissible appeals from the impermissible ones.

A. The Fourth And Eighth Circuits: A Plaintiff Can Always Appeal A Partial-Dismissal Order By Voluntarily Dismissing The Action

The Fourth and the Eighth Circuits have hewed to the text of section 1291, adopting the most appellant-friendly standard among the federal courts of appeals. Both courts hold that a voluntary dismissal under Rule 41(a) creates "final," and thus appealable, "decisions" without regard to the appellant's state of mind or the possibility (or

12. *See* Fed. R. Civ. P. 41(d) ("If a plaintiff who previously dismissed an action in any court files an action based on or including the same claim against the same defendant, the court: (1) may order the plaintiff to pay all or part of the costs of that previous action; and (2) may stay the proceedings until the plaintiff has complied.").

impossibility) that abandoned claims could be reasserted in the future.

In *GO Computer, Inc. v. Microsoft Corp.*, 508 F.3d 170 (4th Cir. 2007), the Fourth Circuit wrote:

> Dismissals without prejudice naturally leave open the possibility of further litigation in some form. *What makes them final or nonfinal is not the speculative possibility of a new lawsuit*, but that they "end the litigation on the merits and leave nothing for the court to do but execute the judgment." When the district court dismissed some of GO's claims without prejudice, it was utterly finished with GO's case.

Id. at 176 (emphasis added) (citations omitted). The Eighth Circuit also holds that *all* voluntary dismissals under Rule 41(a) make the previously interlocutory partial-dismissal order an appealable "final decision":

> Following the granting of the motion for partial summary judgment, the court, on the parties' joint motion to dismiss and stipulation of dismissal filed pursuant to Fed. R. Civ. P. 41, dismissed without prejudice the remainder of the case. The effect of that action was to make the judgment granting partial summary judgment a final judgment for purposes of appeal, even though the district court had not so certified under Fed. R. Civ. P. 54(b).

Chrysler Motors Corp. v. Thomas Auto Co., 939 F.2d 538, 540 (8th Cir. 1991) (citation omitted). Subsequent decisions of the Eighth Circuit have followed the approach of

Chrysler and asserted jurisdiction over all appeals that follow a voluntary dismissal under Rule 41(a), without regard to whether the appellant is trying "manufacture" an appeal or "manipulate" the final-decision rule. *See Great Rivers Cooperative of Southeastern Iowa v. Farmland Industries, Inc.*, 198 F.3d 685, 689 (8th Cir. 1999) ("[W]hile we have no more desire to permit 'manufactured interlocutory appeals' than our sister circuits, we find no authority in § 1291 to decide that some 'final decisions' are appealable but others are not. Thus, in our view, the question whether parties will be permitted to 'manufacture' appeals in this fashion is not jurisdictional, as we observed without discussing the issue in *Chrysler*."); *Hope v. Klabal*, 457 F.3d 784, 789–90 (8th Cir. 2006) ("[M]any of our cases continue to follow the rule established in *Chrysler* and state that jurisdiction exists under the circumstances that we face here, without opining on whether the dismissed claims should be deemed dismissed with prejudice.").

Ms. Williams's appeal would have unquestionably been permitted in the Fourth and the Eighth Circuits, as her notice of voluntary dismissal under Rule 41(a) would be all that is needed to create the required finality.

B. The Second, Third, Sixth, And Seventh Circuits: A Plaintiff May Appeal Following A Voluntary Dismissal Only When The Appellant Cannot Resurrect The Unresolved Claims

The Second, Third, Sixth, and Seventh Circuits take a different approach. Rather than categorically conferring finality on a voluntary dismissal, these circuits instead focus on whether the appealing litigant remains *capable* of

reinstating the abandoned claims in the district court after the appeal concludes. In these circuits, a voluntary dismissal will allow a plaintiff to appeal a district court's earlier partial-dismissal order, but only when the plaintiff cannot revive the abandoned claims. This test for appellate jurisdiction will be satisfied if: (1) The statute of limitations on the abandoned claims has expired; (2) The appealing litigant makes a legally binding renunciation of any intent to further pursue the abandoned claims; or (3) Some other factor makes further litigation on the abandoned claims impossible.

The Second Circuit explained its approach in *Chappelle v. Beacon Communications Corp.*, 84 F.3d 652 (2d Cir. 1996):

> It is appropriate to take a practical view of the dismissal. In *Fassett* [*v. Delta Kappa Epsilon (New York)*, 807 F.2d 1150 (3d Cir. 1986)], for example, the district court dismissed the plaintiffs' claims against all but one defendant. The plaintiffs then stipulated to the dismissal of their claim against that defendant without prejudice. An appeal of the prior dismissal was nonetheless allowed, because the statute of limitations had run against the claim dismissed without prejudice. Thus, although nominally dismissed "without prejudice," that claim had been "voluntarily and finally abandoned." 807 F.2d at 1155.

Id. at 654 n.3; *see also Fassett v. Delta Kappa Epsilon (New York)*, 807 F.2d 1150, 1155 (3d Cir. 1986). So a voluntary dismissal in the Second Circuit can confer appellate

jurisdiction to review a district court's partial-dismissal order, but only when there is no genuine opportunity to reinstate the unresolved claims in the district court. *See Alix v. McKinsey & Co.*, 23 F.4th 196, 202–03 (2d Cir. 2022) (allowing plaintiff to appeal an earlier partial-dismissal ruling after a Rule 41(a) voluntary dismissal, but only because he explicitly disclaimed an intent to revive the unresolved claims in an addendum to his appellate briefing); *Rabbi Jacob Joseph School v. Province of Mendoza*, 425 F.3d 207, 211 (2d Cir. 2005) (dismissing appeal when the plaintiff refused to permanently abandon the unresolved claims after being provided the opportunity at oral argument).

The Third Circuit takes the same approach, asking whether the appealing litigant's "ability to refile" the abandoned claims has been "foreclosed." *S.B. v. KinderCare Learning Centers, LLC*, 815 F.3d 150, 152–53 (3d Cir. 2016) ("[A] dismissal without prejudice may be appealed under circumstances where the plaintiff's ability to refile is foreclosed."); *id.* at 152 (claiming that this test for appellate jurisdiction will be satisfied if the district court "imposes unreasonably onerous conditions on the plaintiff's right to refile the dismissed action"); *cf. Ahmed v. Dragovich*, 297 F.3d 201, 207 (3d Cir. 2002) (allowing plaintiff to appeal an order dismissing a case without prejudice where the statute of limitations had expired and any attempt at refiling would have been unsuccessful).

Likewise in the Sixth Circuit, where the test for appellate jurisdiction turns entirely on whether the appealing litigant retains the ability to resurrect the abandoned claims after the appeal. *See Page Plus of Atlanta, Inc. v.*

Owl Wireless, LLC, 733 F.3d 658, 659 (6th Cir. 2013) ("Does a party's conditional dismissal of unresolved claims, in which the party reserves the right to reinstate those claims if the case returns to the district court after an appeal of the resolved claims, create a final order under 28 U.S.C. § 1291? No."); *id.* at 660 ("The point of the finality requirement is not to let the parties pause the litigation, appeal, then resume the litigation on a half-abandoned claim if the case returns.").

And the Seventh Circuit takes the same tack, allowing litigants to appeal partial-dismissal orders after a voluntary dismissal of the action, but only when they unequivocally abandon the unresolved claims. *See India Breweries, Inc. v. Miller Brewing Co.*, 612 F.3d 651, 657 (7th Cir. 2010) ("[T]he potential resurrection of these claims . . . destroyed finality."); *id.* (litigants must "fully extinguish[] all lingering claims before they attempt to invoke the jurisdiction of this court"); *Arrow Gear Co. v. Downers Grove Sanitary District*, 629 F.3d 633, 636 (7th Cir. 2010) (Posner, J.) ("A dismissal without prejudice doesn't *always* enable a suit to be refiled, even in a different court, and when that is so—the litigation is over, its resolution in the district court final—there is no objection to an immediate appeal.").[13] The Seventh Circuit will also allow litigants to clarify on appeal that they have no intention of further pursuing the unresolved claims, and litigants who do so

13. *See also First Health Group Corp. v. BCE Emergis Corp.*, 269 F.3d 800, 801 (7th Cir. 2001) ("[T]he dismissal of one claim or theory without prejudice, with a right to reactivate that claim after an appeal on the remaining theories, makes the judgment nonfinal.").

can appeal after a voluntary dismissal. *See id.* at 637; *India Breweries*, 612 F.3d at 657–58 ("Miller managed to wedge through one of its narrowest holes by unequivocally dismissing its counterclaims with prejudice after we pressed the matter at oral argument. We consequently have jurisdiction over this appeal and accordingly proceed to the merits." (citation omitted)).

Ms. Williams's appeal would have been allowed to proceed in each of these four circuits because: (1) The statute of limitations has expired on the four unresolved claims that she dropped from her amended short-form complaint; and (2) Ms. Williams has repeatedly and unequivocally stated that she has no intention of pursuing those claims any further.[14] The Eleventh Circuit's refusal to allow appeal despite Ms. Williams's inability to further litigate the four abandoned claims is incompatible with the law of the Second, Third, Sixth, and Seventh Circuits, and the divergent approaches are outcome-determinative.

C. The Ninth Circuit And The Federal Circuit: A Plaintiff May Appeal Following A Voluntary Dismissal Only When There Is An Absence Of "Intent To Manipulate" The Appellate Court's Jurisdiction

The Ninth Circuit takes a more contextualized approach that focuses on the intent of the appealing party,

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14. *See* Appellant's Response in Opposition to Appellees Motion to Dismiss, ECF No. 45, No. 21-10306 (11th Cir.), at 8 ("Ms. Williams had no interest in pursuing the narrow theories available."); *id.* at 9 ("If Ms. Williams lost this appeal, she could not re-file different claims that would be adjudicated again and appealed again — her sole claim would have been adjudicated, and she has relinquished her right to replead other claims.").

asking whether the voluntary dismissal was obtained to "manufacture" finality or "manipulate" the jurisdictional rule against piecemeal appeals:

> We start by observing that there is no evidence James attempted to manipulate our appellate jurisdiction by artificially "manufacturing" finality. We have always regarded evidence of such manipulation as the necessary condition for disallowing an appeal where a party dismissed its claims without prejudice.

James v. Price Stern Sloan, Inc., 283 F.3d 1064, 1066 (9th Cir. 2002). The Ninth Circuit also places weight on whether a litigant obtains a court-approved voluntary dismissal under Rule 41(a)(2), as opposed to a dismissal by unilateral notice or stipulation of the parties under Rule 41(a)(1). *See id.* ("James's dismissal was pursuant to court order under Rule 41(a)(2). The district court's participation in the process is an additional factor alleviating concerns about a possible manipulation of the appellate process."). In this respect, the Ninth Circuit's approach shares a similarity with the Eleventh Circuit's opinion, which also distinguished court-approved voluntary dismissals under Rule 41(a)(2) from notices or stipulations of dismissal under Rule 41(a)(1). App. 13–14.

The Ninth Circuit allows plaintiffs to appeal partial-dismissal orders after a voluntary dismissal of their action if: (1) The district court approves the dismissal; and (2) There is no evidence in the record of an "intent to manipulate" the rules of appellate jurisdiction:

> [W]hen a party that has suffered an adverse partial judgment subsequently dismisses remaining claims without prejudice with the approval of the district court, and the record reveals no evidence of intent to manipulate our appellate jurisdiction, the judgment entered after the district court grants the motion to dismiss is final and appealable under 28 U.S.C. § 1291.

James, 283 F.3d at 1070. It is unclear whether Ms. Williams's appeal would have survived dismissal in the Ninth Circuit. On the one hand, there is no possibility of an "intent" to "manipulate" the final-decision rule of 28 U.S.C. § 1291, as Ms. Williams has unequivocally relinquished the four unresolved claims and the statute of limitations has expired on each of them. But Ms. Williams filed a notice of voluntary dismissal under Rule 41(a)(1)(A)(i) rather than obtain a court-approved dismissal order under Rule 41(a)(2), and the Ninth Circuit (like the Eleventh Circuit) believes that counts for something in the jurisdictional calculation. But regardless of whether Ms. Williams would have prevailed under the Ninth Circuit's case law, it is clear that the Ninth Circuit's approach differs from the impossible-to-revive-the-unresolved-claims test of the Second, Third, Sixth, and Seventh Circuits—which further reinforces the division of authority among the lower courts.

The Federal Circuit has also endorsed the Ninth Circuit's approach in *James* after acknowledging and discussing the circuit split on the issue. *See Doe v. United States*, 513 F.3d 1348, 1352–54 (Fed. Cir. 2008).

D. The D.C. Circuit: A Plaintiff Cannot Appeal Following A Voluntary Notice Of Dismissal Under Rule 41(a)(1), At Least When The Statute Of Limitations Does Not Prevent Re-filing Of The Unresolved Claims

The D.C. Circuit has ruled narrowly on this issue, holding that a stipulation of voluntary dismissal under Rule 41(a)(1) will not normally create finality and cannot be used as a substitute for obtaining a judgment under Rule 54(b). *See Robinson-Reeder v. American Council on Education*, 571 F.3d 1333, 1339 (D.C. Cir. 2009) ("All we have is the parties' stipulation [of voluntary dismissal], which cannot substitute for a court order under [Rule 54(b)].").

The D.C. Circuit did not reach or resolve whether or in what circumstances a court-approved voluntary dismissal under Rule 41(a)(2) will create finality or allow an appeal from an earlier partial-dismissal order. *See id.* ("In this case, there was no court order dismissing the remaining claim; rather, dismissal was accomplished by stipulation of the parties alone pursuant to Federal Rule of Civil Procedure 41(a)(1)." (footnote omitted)). And in a footnote, the D.C. Circuit left open the possibility that it *might* align with the Second, Third, Sixth, and Seventh Circuits, treating a voluntary dismissal under Rule 41(a)(1) as final *if* the abandoned claims are impossible to reassert. *See id.* at 1339 n.7 ("Nor has Robinson-Reeder suggested that the voluntary dismissal of her defamation claim was effectively 'final because [she] could not refile it due to a lapsed statute of limitations' or any other analogous constraint.").

It is unclear whether Ms. Williams's appeal would have been allowed in the D.C. Circuit. Her case is distinguishable from *Robinson-Reeder* because the statute of limitations has expired on her abandoned claims and she has expressly renounced any intent to reinstate them. The outcome would depend on whether the D.C. Circuit would adopt the impossibility test or instead align itself with the Fifth or Eleventh Circuits.

E. The Fifth Circuit: A Plaintiff May Appeal Following A Voluntary Dismissal Only When The Dismissal Was "With Prejudice"

The Fifth Circuit has established the strictest test for appeals from voluntary dismissals, allowing them only when the unresolved claims were dismissed with prejudice. *See Marshall v. Kansas City Southern Railway Co.*, 378 F.3d 495, 499–500 (5th Cir. 2004) ("[T]he 'settled rule in the Fifth Circuit [is] that appellate jurisdiction over a non-final order cannot be created by dismissing the remaining claims *without prejudice.*'" (quoting *Swope v. Columbian Chemicals Co.*, 281 F.3d 185, 192 (5th Cir. 2002))). A voluntary dismissal without prejudice will never convert an earlier ruling of the district court into an appealable "final decision" in the Fifth Circuit. *See Williams v. Seidenbach*, 958 F.3d 341, 343 (5th Cir. 2020) (en banc) ("Under our precedents, there is no final decision if a plaintiff voluntarily dismisses a defendant without prejudice"); *id.* at 344 (only a "*with* prejudice" voluntary dismissal under Rule 41(a) can confer appellate jurisdiction in the Fifth Circuit).

The Fifth Circuit's test is straightforward, but somewhat atextual and arbitrary. The test presumes that the

plaintiff could specify certain *claims* as dismissed voluntarily "with prejudice," but Rule 41 speaks of actions, not claims. Besides, court-ordered dismissals without prejudice (and with permission to replead) generally are appealable, because courts construe the notice of appeal as standing on the complaint as-written. For these or other reasons, the Fifth Circuit is the only circuit in which the permissibility of appeal following a Rule 41(a) dismissal stands or falls entirely on whether the voluntary dismissal was taken "with prejudice" or "without prejudice." Ms. Williams's appeal would have been dismissed for lack of jurisdiction in the Fifth Circuit—the same fate that it met in the Eleventh Circuit—because her unilateral notice of dismissal is presumptively without prejudice. *See* Fed. R. Civ. P. 41(a)(1)(B) ("Unless the notice or stipulation states otherwise, the dismissal is without prejudice.").

F. The Eleventh Circuit: Court-Approved Voluntary Dismissals Under Rule 41(a)(2) Are Final *Per Se*, But The Status Of Unilateral Or Stipulated Voluntary Dismissals Under Rule 41(a)(1) Is Unclear

The Eleventh Circuit's jurisprudence on this issue is the most eclectic of the bunch. The Eleventh Circuit holds that a court-approved voluntary dismissal under Rule 41(a)(2) will *always* confer finality and permit appeal of an earlier partial-dismissal order. *See Corley v. Long-Lewis, Inc.*, 965 F.3d 1222, 1229 (11th Cir. 2020) ("[A]n order granting a motion to voluntarily dismiss the remainder of a complaint under Rule 41(a)(2) qualifies as a final judgment for purposes of appeal. And because the Corleys appealed from such an order, we have jurisdiction under section 1291." (citations and internal quotation marks

omitted)); *McGregor v. Board of Commissioners*, 956 F.2d 1017, 1020 (11th Cir. 1992) ("An order granting a plaintiff's motion for voluntary dismissal pursuant to Rule 41(a)(2) qualifies as a final judgment for purposes of appeal." (internal quotation marks omitted)). The decision below reaffirmed *Corley*'s holding that Rule 41(a)(2) dismissals will satisfy the finality requirement in the Eleventh Circuit, but it distinguished Ms. Williams's appeal on the ground that she had unilaterally dismissed her action under Rule 41(a)(1) without court approval:

> In *Corley*, we held that "an order granting a motion to voluntarily dismiss the remainder of a complaint under Rule 41(a)(2) 'qualifies as a final judgment for purposes of appeal.'" In this case, however, Ms. Williams is seeking to appeal matters related to the very claim she voluntarily dismissed through Rule 41(a)(1).

App. 13–14 (citations omitted).

But whether and when the Eleventh Circuit will permit a litigant to appeal after filing a notice or stipulation of dismissal under Rule 41(a)(1)—as opposed to obtaining a court-approved order of voluntary dismissal under Rule 41(a)(2)—is far from clear, and the Eleventh Circuit has not explained why appeals following Rule 41(a)(1) and (a)(2) dismissals should be subject to different rules. The opinion below, for example, criticizes Ms. Williams for "seeking to appeal matters related to the very claim she voluntarily dismissed through Rule 41(a)(1)." App. 14. But that is *always* the case when a plaintiff appeals after a voluntary dismissal under Rule 41(a)(1) *or* (a)(2), because the *entire action* is dismissed when a plaintiff obtains a

voluntary dismissal under either prong. *See Perry v. Schumacher Group of Louisiana*, 891 F.3d 954, 958 (11th Cir. 2018) ("It is clear from the text that only an '*action*' may be dismissed. There is no mention in the Rule of the option to [dismiss] a portion of a plaintiff's lawsuit—*e.g.*, a particular *claim*—while leaving a different part of the lawsuit pending before the trial court."); *State Treasurer of Michigan v. Barry*, 168 F.3d 8, 15 (11th Cir. 1999) ("[T]he rule speaks of voluntary dismissal of 'an action,' not a claim"). If the idea is that Ms. Williams cannot appeal the district court's order dismissing her design-defect claim with prejudice because she voluntarily dismissed that "claim" under Rule 41(a), then no plaintiff would ever be allowed to appeal after a voluntary dismissal because the "action"—which includes both the appealed claims and the abandoned claims—has been dismissed, and that remains the case when a plaintiff obtains a court-approved voluntary dismissal under Rule 41(a)(2).

The opinion below also says that "there is no final order from the district court on Ms. Williams' design defect claim." App. 14. But the district court dismissed the design-defect claim *with prejudice*. The only thing that can keep that from being a "final order" is the fact the Ms. Williams had brought additional claims that were dismissed without prejudice and with leave to replead. Ms. Williams has unequivocally relinquished those additional claims, and her sole remaining design-defect claim was dismissed with prejudice before she voluntarily dismissed her entire action and appealed. If that does not make the district court's ruling into a "final order" on the design-defect claim, then no litigants could ever appeal a partial-

dismissal order after voluntarily dismissing their action under Rule 41(a)(1) or (a)(2).

The court of appeals also denied finality because it claimed that Ms. Williams could "file a second amended [short-form complaint] today" that reasserts her design-defect claim. App. 15. But that statement is patently untrue. Ms. Williams has *appealed* the district court's dismissal of her design-defect claim,[15] and the notice of appeal divests the district court of jurisdiction to consider that claim from Ms. Williams until after the appeal concludes. *See Griggs v. Provident Consumer Discount Co.*, 459 U.S. 56, 58 (1982) ("The filing of a notice of appeal . . . divests the district court of its control over those aspects of the case involved in the appeal."); *Coinbase, Inc. v. Bielski*, 143 S. Ct. 1915, 1919 (2023) (same). If the court of appeals' holding hinges on the mistaken belief that Ms. Williams could continue litigating her design-defect claim in the district court while appealing it, then it is not clear how future panels of the Eleventh Circuit will handle this issue when they realize that *Griggs* and *Coinbase* prohibit appellants from simultaneously litigating claims in the trial and appellate courts. Finally, the court of appeals observed that the amended *master* complaint includes two design-defect claims that were then pending in the district court,[16] but Ms. Williams is not pleading those claims (which, despite a superficial similarity, are based on liability theories Ms. Williams is not pursuing) and is not a party to those proceedings because she has voluntarily dismissed her entire action.

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15. App. 202–203.

16. App. 14.

So it is hard to determine why, exactly, the panel opinion chose to deny the existence of a "final decision" with respect to Ms. Williams's design-defect claim, which was dismissed with prejudice by the district court, or how future panels of the Eleventh Circuit will deal with litigants who appeal after dismissing their action under Rule 41(a)(1). It is, however, safe to say that a court-approved order of voluntary dismissal under Rule 41(a)(2) will create a "final decision" in the Eleventh Circuit, however murky the law of that court may be with respect to unilateral notices of voluntary dismissals or stipulated dismissals under Rule 41(a)(1).

II. THE QUESTION PRESENTED IS RECURRING AND IMPORTANT

The jurisdictional question that Ms. Williams poses—and that has perplexed almost every court of appeals—arises so frequently that courts and commentators have given it an ignominious name: the finality trap. *See CBX Resources LLC v. ACE American Insurance Co.*, 959 F.3d 175, 175–77 (5th Cir. 2020); *Perry v. Schumacher Group of Louisiana*, 891 F.3d 954, 959 n.3 (11th Cir. 2018); *Alix v. McKinsey & Co.*, 470 F. Supp. 3d 310, 318 (S.D.N.Y. 2020); Bryan Lammon, *Disarming the Finality Trap*, 97 NYU L. Rev. 173 (2022); Bryan Lammon, *Manufactured Finality*, 69 Vill. L. Rev. ____ (forthcoming 2024), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4572017; Terry W. Schackmann & Barry L. Pickens, *The Finality Trap: Accidentally Losing Your Right to Appeal (Part II),* 58 J. Mo. B. 138 (2002). This trap befalls a litigant who dismisses her action under Rule 41(a) and abandons certain claims so she can appeal others dismissed

with prejudice by the district court. If she has the misfortune of being in the wrong court of appeals that proceeds to dismiss for want of a "final decision," the trap is sprung. One might think a dismissal for want of a final decision is merely justice delayed; that the appellate court will eventually be able to give the litigant audience on the merits.

But the finality trap works a far more pernicious result, as Ms. Williams's case reveals. The claims she dropped and promised never to pursue in the future are gone forever. That is the very feature necessary to obtain a "final decision" in the Second, Third, Sixth, and Seventh Circuits. But what of the one claim she actually wants to pursue that the district court previously dismissed with prejudice? If the decision below stands, that claim too is impossible to resurrect. By dismissing her entire *action* under Rule 41(a)(1), her design defect claim is no longer in the district court. And by holding that it did not have jurisdiction over her one-count complaint, the design-defect claim was never properly in the Eleventh Circuit either. Quite apart from preemption, the statute of limitation continued to run, and has now expired. To reassert her design-defect claim, Ms. Williams must file a *new* action in the district court, only for her claim to be unceremoniously dismissed with prejudice as time barred, as res judicata, or both. The Eleventh Circuit will never have occasion to review the preemption order, which, as to Ms. Williams, will never become a "final decision[]" subject to appellate review. *See* Lammon, *Finality Trap*, *supra* at 174 (2022); Lammon, *Manufactured Finality*, *supra* at 39 n.189.

Ms. Williams is not the first to experience this unmerciful result. And absent this Court's intervention, she will not be the last. To be sure, federal courts cannot enlarge their jurisdiction merely to avoid unpleasant outcomes. But the rules governing when jurisdiction exists should be clear. *See Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 535 U.S. 826, 832 (2002) (praising the well-pleaded complaint rule for its "clarity and ease of administration," which "serves as a 'quick rule of thumb' for resolving jurisdictional conflicts." (citation omitted)); *Sebelius v. Auburn Regional Medical Center*, 568 U.S. 145, 153–54 (2013) ("[W]e have adopted a 'readily administrable bright line' for determining whether to classify a statutory limitation as jurisdictional."). Murky or debatable jurisdictional doctrines require litigants and the judiciary to divert resources toward preliminary skirmishes before a court can even consider the merits of a case. This drives up the already-high decision costs of litigation by piling on what might be called "predecision costs"—the costs associated with squabbles over jurisdiction, venue, and the relevant standard of review that precede the ultimate fight over the merits.[17] Unclear jurisdictional rules are especially pernicious because they can cause entire trials or

17. *See* Adrian Vermeule, *Introduction: Mead in the Trenches*, 71 Geo. Wash. L. Rev. 347, 356 (2003) ("In various areas, law incurs not only first-order decision costs but what might be called predecision costs (i.e., costs of allocating decisions between or among different jurisdictions, different decision-makers, or different standards of review by a given decision-maker); Jacob E. Gersen, *Unbundled Powers*, 96 Va. L. Rev. 301, 357 (2010) ("[J]urisdictional determinations can involve high decision costs . . . particularly when cases involve fuzzy boundaries").

appeals to be wasted if an appellate panel or an en banc court sees the jurisdictional issue differently from the previous tribunals handling the case. *See, e.g.*, *Grupo Dataflux v. Atlas Global Group, L.P.*, 541 U.S. 567, 582 (2004) (vacating a trial verdict for lack of complete diversity, and noting litigation had gone on "for more than 6 ½ years, including 3 ½ years over a conceded jurisdictional defect").

The myriad interpretations of section 1291 that constitute the finality trap are the polar opposite of clear. *See, e.g.*, *Hope*, 457 F.3d at 789 ("[T]his circuit has been less than clear in establishing the rules for finality when parties dismiss some of their claims without prejudice in order to appeal a partial summary judgment order or an interlocutory order of dismissal."); *Corley*, 965 F.3d at 1228 ("Our precedent splinters in multiple directions on whether voluntary dismissals without prejudice are final."); *id.* at 1236 (Pryor, C.J., concurring) (describing Eleventh Circuit precedents as "an egregious mess" that "are difficult to harmonize"); *Robinson-Reeder*, 571 F.3d at 1338–39 ("[C]ases within individual circuits, are divided over whether voluntary dismissal without prejudice of unresolved claims can suffice to make a district court's judgment final—and, if so, under what circumstances."). That opacity is never a virtue. But it is thrown into particularly sharp relief now that it threatens to deprive a cancer victim of her one and only opportunity to litigate her case.

The Court should resolve this issue so that litigants can *know* when, if ever, they can appeal after a voluntary dismissal. The words Congress chose to vest appellate

courts with jurisdiction should no longer be a trap for the unwary.

III. THERE IS NO REASON TO AWAIT FURTHER PERCOLATION, AS NEARLY EVERY COURT OF APPEALS HAS RULED AND THE ISSUE HAS BEEN EXTENSIVELY DISCUSSED IN JUDICIAL OPINIONS AND SCHOLARSHIP

The Court should grant certiorari on this issue now, as there is nothing to be gained by waiting for additional courts to weigh in. Eleven circuits have already ruled on whether and to what extent litigants can appeal partial-dismissal rulings after voluntarily dismissing their action under Rule 41(a). *See supra* at 10–27.[18] There has been rich and thorough discussion of this issue in lower-court opinions, including opinions written by some of the nation's most thoughtful and respected jurists.[19] And there have been scholarship and bar-journal articles written on the topic,[20] which will further assist this Court's consideration if it takes up the petition.

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18. We have not yet found cases from the First Circuit or the Tenth Circuit that purport to resolve when a plaintiff can appeal a district court's partial-dismissal order after voluntarily dismissing the action under Rule 41(a). The First Circuit noted the issue in *Donahue v. Federal National Mortgage Ass'n*, 980 F.3d 204 (1st Cir. 2020), but declined to rule on it. *See id.* at 207.

19. *See, e.g.*, *Robinson-Reeder*, 571 F.3d 1333 (Garland, J.); *GO Computer*, 508 F.3d 170 (Wilkinson, J.); *Arrow Gear*, 629 F.3d 633 (Posner, J.).

20. *See* Bryan Lammon, *Disarming the Finality Trap*, 97 NYU L. Rev. 173 (2022); Terry W. Schackmann & Barry L. Pickens, *The Finality Trap: Accidentally Losing Your Right to Appeal (Part II),* 58 J. Mo. B. 138 (2002).

Ms. Williams's petition presents the issue cleanly, and the Court's resolution of the circuit conflict will be outcome-determinative of whether Ms. Williams can appeal. And it is especially appropriate to grant certiorari in response to an appellate-court ruling that departs from the approach taken in every other circuit to have considered and ruled upon this issue.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted.

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APPENDIX

[DO NOT PUBLISH]

In the United States Court of Appeals
For the Eleventh Circuit

No. 21-10305

IN RE: ZANTAC (RANITIDINE)
PRODUCTS LIABILITY LITIGATION

9:20-cv-80555
ARTHUR CARTEE,

Plaintiff-Appellant,

versus

BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC.,
PFIZER, INC.,
GLAXOSMITHKLINE LLC,

Defendants-Appellees.

No. 21-10306

IN RE: ZANTAC (RANITIDINE)
PRODUCTS LIABILITY LITIGATION

9:20-cv-80512-RLR
MARILYN WILLIAMS,

Plaintiff-Appellant,

versus

BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC.,
BOEHRINGER INGELHEIM USA CORPORATION,
WALGREENS BOOT ALLIANCE, INC.,

Defendants-Appellees.

Appeals from the United States District Court
for the Southern District of Florida
D.C. Docket No. 9:20-md-02924-RLR

(Filed Nov. 7, 2022)

Before JORDAN and LAGOA, Circuit Judges.*

PER CURIAM:

The appellants, Arthur Cartee and Marilyn Williams, are two of the thousands of plaintiffs alleging personal injury claims in *In re Zantac (Ranitidine)*, MDL No. 2924. Because there is no final district court decision with respect to the amended complaints of Mr. Cartee and Ms. Williams, we dismiss their appeals for lack of appellate jurisdiction.

I

Mr. Cartee and Ms. Williams both alleged that they took ranitidine products to treat mild heartburn.

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* After oral argument, Judge Luck recused himself from this case. This opinion is therefore issued by a quorum. *See* 28 U.S.C. § 46(d); 11th Cir. R. 34-2.

Starting in 2006, Mr. Cartee began taking both prescription and over-the-counter generic ranitidine. He developed prostate cancer in 2012. Ms. Williams started taking Zantac, an over-the-counter brand-name drug, in 2011. She was diagnosed with abdominal and ovarian cancer in 2016.

A

On February 6, 2020, the U.S. Judicial Panel on Multidistrict Litigation created an MDL in the Southern District of Florida—MDL No. 2924—for purposes of centralizing pretrial proceedings in actions alleging that ranitidine, the active ingredient in Zantac, breaks down to form an alleged carcinogen known as N-Nitrosodimethylamine (NDMA).

After the MDL was created, Mr. Cartee and Ms. Williams each filed separate federal lawsuits—Mr. Cartee in Illinois and Ms. Williams in Alabama—alleging that ranitidine caused their cancers. Their actions were transferred to the MDL.

A few months after the transfers, the parties filed a proposed order coordinating the filings of master complaints. This order, known as Pretrial Order # 31, was adopted and entered by the district court.

The Order required the personal injury plaintiffs to "file a Master Personal Injury Complaint [or MPIC] on behalf of all Plaintiffs asserting personal injury claims in MDL No. 2924." MDL D.E. 876 at 2. The Order stated that "[a]ll claims pleaded in the [MPIC] will

supersede and replace all claims pleaded in any complaint previously filed in or transferred to MDL No. 2924. . . ." *Id.*

In addition, the Order directed the personal injury plaintiffs to attach a Master Short Form Complaint (or SFC) to serve as a template "for each individual case." *Id.* The individual plaintiffs were to provide certain information, such as their names, injuries, places of residence, and the defendants being sued. *See id.* The SFCs took the form of a worksheet that allowed each plaintiff to fill in the blanks as to who was being sued and to check boxes for which claims were being asserted. *See id.* The SFC also contained a clause indicating that it incorporated all allegations from the MPIC. *See id.* The Order stated that, "[f]or each action directly filed in or transferred to MDL No. 2924 subject to this Order, the [MPIC] together with the Short Form Complaint shall be deemed the operative Complaint." *Id.* at 3.[1]

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[1] MDL No. 2924 therefore "employe[d] the device of a master complaint, supplemented by individual short-form complaints that adopt the master complaint in whole or in part." *In re Zofran (Ondansetron) Products Liability Litig.*, MDL No. 1:15-md-2657-FDS, 2017 WL 1458193, at *6 (D. Mass. Apr. 24, 2017). The master complaint contained allegations common to all plaintiffs asserting the same types of claims, while the short-form complaints contained allegations specific to each individual plaintiff. *See In re Taxotere (Docetexel) Prod. Liab. Litig.*, 995 F.3d 384, 387 (5th Cir. 2021). *See also* Manual for Complex Litigation (Fourth) § 40.52 (Fed. Jud. Ctr. 2004) (providing sample case management order governing mass tort claims using master and short-form complaints).

Shortly thereafter, the personal injury plaintiffs filed the MPIC. The MPIC named no individual plaintiffs. Instead, it incorporated them by reference. The MPIC states it "is not intended to consolidate for any purpose the separate claims of the individual Plaintiffs in this MDL," and that it "does not constitute waiver or dismissal of any actions or claims asserted in those individual actions." MDL D.E. 887 at 2. The MPIC refers to the plaintiffs' cases as individual "actions" throughout. *See id.* at ¶¶ 216, 434–35.

As directed, Mr. Cartee and Ms. Williams both filed short form complaints to go with the MPIC.

In his SFC, Mr. Cartee sued four brand-name manufacturers (Boehringer, GlaxoSmithKline, Sanofi, and Sanofi-Aventis) and two retailers (Walgreens and Walmart). He checked the boxes for Counts I–XIII of the MPIC, leaving out only Count XIV (a survival action) and Count XV (a wrongful death claim). As discussed below, he filed an amended SFC shortly thereafter, dropping the Sanofi entities from the list of brand-name defendants from which he sought to recover.

In her SFC, Ms. Williams sued two brand name manufacturers (Boehringer Ingelheim Pharmaceuticals and Boehringer Ingelheim USA) and one retailer (Walgreens), and she indicated that any distributors and repackagers she might sue were then unknown. She checked the boxes for five different counts in the MPIC, including those asserting claims for strict products liability, failure to warn, and breaches of

warranties. Like Mr. Cartee, and as discussed below, Ms. Williams later amended her SFC.

B

The district court dismissed the entire MPIC without prejudice as a shotgun pleading. *See* MDL D.E. 2515 at 13. In a separate order, the court also held that any claims "based on an allegation that a brand-name drug's FDA-approved formulation renders the drug misbranded" were preempted by the Food, Drug, and Cosmetics Act, 21 U.S.C. § 301 *et. seq.*, "because the drug's manufacturer cannot independently and lawfully change a drug formulation that the FDA has approved." MDL D.E. 2532 at 24. The court ordered the personal injury plaintiffs to omit misbranding allegations if they amended the MPIC. *Id.* at 25.

In another order, the district court ruled that any state without a supreme court decision supporting the plaintiffs' "innovator liability" theory of negligent misrepresentation (i.e., any state other than Massachusetts and California) would not recognize a duty by brand-name manufacturers to consumers of generic ranitidine. *See* MDL D.E. 2516 at 14. The district court granted plaintiffs who brought such claims against defendants in courts outside of California and Massachusetts leave to amend "to plead a prima facie case of personal jurisdiction in California or Massachusetts." *Id.* at 8, 24. The district court did not dismiss any individual SFCs.

After the MPIC was dismissed and before any amended MPIC was filed, Mr. Cartee filed a second amended SFC. This SFC only checked the box for Count VIII, asserting negligent misrepresentation, against three of the brand name manufacturers (Boehringer, GlaxoSmithKline, and Pfizer). The second amended SFC eliminated all other claims and deleted the retailer defendants. It also added the following paragraph:

> Plaintiff is suing for injuries related only to generic consumption. Plaintiff's sole theory of liability is that Boehringer Ingelheim Pharmaceuticals, Inc., GlaxoSmithKline LLC, and Pfizer, Inc. negligently misrepresented the safety of ranitidine through their labeling of branded Zantac, that it was foreseeable that generic manufacturers of ranitidine would copy those misrepresentations, and that Plaintiff and his doctor relied on those misrepresentations in consuming and prescribing the ranitidine that caused Plaintiff's cancer and other injuries.

Cartee D.E. 19 ¶ 13. Significantly, Mr. Cartee's second amended SFC still purported to incorporate the allegations in the then-dismissed MPIC.

On the same day that he filed the second amended SFC, and without obtaining any further ruling from the district court, Mr. Cartee filed a notice of appeal. He cited the district court's innovator liability claims order and stated that the order "was made final with respect to Plaintiff Arthur Cartee on the 27th day of

January, 2021, when Plaintiff amended his Short Form Complaint to eliminate all claims for which repleading was permitted by the Court's Orders." Cartee D.E. 20. In his appeal, Mr. Cartee seeks reversal of the district court's rulings with respect to innovator liability under Illinois law.

Ms. Williams pursued a similar strategy with one additional wrinkle. First, she filed an amended SFC after the dismissal of the MPIC and before the filing of an amended MPIC. In her amended SFC, she only checked the box for the MPIC's strict products liability design defect claim and eliminated any suggestion that she might sue yet-unknown distributors and repackagers. She also added the following paragraph:

> Plaintiff's sole theory of liability is that the ranitidine she consumed was defectively designed under state law, and that these same design defects made ranitidine dangerous to health when used as instructed on the label such that it was misbranded under federal law. The ranitidine Plaintiff consumed was illegal to sell under federal law, and requires compensation under state design defect tort law.

Williams D.E. 12 at ¶ 13. Ms. Williams' amended SFC also incorporated the allegations in the then-dismissed MPIC.

On the same day that she filed her amended SFC, Ms. Williams voluntarily dismissed it without prejudice pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(i). Ms. Williams then filed a notice of

appeal, indicating that she wished to appeal the district court's orders granting the defendants' motions to dismiss "on preemption grounds," and asserted that "[t]hese [o]rders were made final with respect to Plaintiff Marilyn Williams on the 27th day of January, 2021, when Plaintiff amended her Short Form Complaint to eliminate all claims for which repleading was permitted by the Court's Orders." Williams D.E. 14 at 1. On appeal, Ms. Williams argues that where a plaintiff pleads a design defect in a drug based on post-approval scientific evidence never presented to the FDA, that state-law claim is not preempted by the FDCA.[2]

After Mr. Cartee and Ms. Williams filed their notices of appeal, the personal injury plaintiffs filed an amended MPIC. The district court has subsequently granted Rule 54(b) judgments in favor of some defendants on some or all of the claims against them, including Walgreens—the retailer Ms. Williams is suing. A second amended MPIC remains pending against the brand-name defendants.

II

Courts of appeals have subject-matter jurisdiction over "appeals from all final decisions of the district courts of the United States." 28 U.S.C. § 1291. Under § 1291, "[a] 'final decision' is one by which a district court disassociates itself from a case." *Gelboim v. Bank*

[2] The district court subsequently deconsolidated Ms. Williams' case from the MDL proceeding in light of her notice of voluntary dismissal.

of Am. Corp., 574 U.S. 405, 408 (2015) (internal quotation marks omitted). "[T]he statute's core application is to rulings that terminate an action." *Id.* at 409.

The defendants ask us to dismiss the appeals of Mr. Cartee and Ms. William for lack of appellate jurisdiction because the orders dismissing the MPIC—which they argue merged the personal injury cases against them—are non-final and non-appealable. Mr. Cartee and Ms. Williams respond that the personal injury plaintiffs' actions are merely consolidated and their individual rights to appeal are unaffected by the structure of this MDL.

A

We conclude that we lack jurisdiction to consider Mr. Cartee's appeal. Simply stated, there is no final decision in the district court against Mr. Cartee.

Under § 1291, "an order that disposes of fewer than all of the claims against all of the parties is not immediately appealable." *Commodores Ent. Corp. v. McClary*, 879 F.3d 1114, 1126 (11th Cir. 2018) (emphasis added). *See also* Fed. R. Civ. P. 54(b) (when an action involves multiple claims or parties, an order "that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties" ordinarily "does not end the action as to any of the claims or parties"). "[A]n order dismissing a complaint with leave to amend within a specified time becomes a final judgment if the time allowed for amendment expires without the plaintiff seeking an extension." *Auto.*

Alignment & Body Serv., Inc. v. State Farm Mut. Auto. Ins. Co., 953 F.3d 707, 719–20 (11th Cir. 2020). But if a plaintiff chooses to file an amended complaint, that party may not also appeal the dismissal order at that time. *See Fuller v. Carollo*, 977 F.3d 1012, 1014 (11th Cir. 2020) (dismissing appeal of qualified immunity order for lack of jurisdiction where the plaintiffs elected to file an amended complaint after the ruling); *Lobo v. Celebrity Cruises, Inc.*, 2009 WL 6353884, at *1 (11th Cir. Dec. 16, 2009) ("The district court's [dismissal order] is not final or immediately appealable because the plaintiffs elected to file an amended complaint prior to filing their . . . notice of appeal.").

As explained earlier, Mr. Cartee's operative complaint includes two documents: the MPIC and his SFC. After the MPIC was dismissed, Mr. Cartee filed a second amended SFC eliminating all but one of his claims and adding language clarifying the scope of his action. At the time he filed the second amended SFC, it purported to incorporate the allegations of the MPIC, but there was no operative MPIC to incorporate because the MPIC had been dismissed. The personal injury plaintiffs filed an amended MPIC, which restructured the claims and eliminated certain factual allegations, but they did so after Mr. Cartee filed a notice of appeal. A second amended MPIC remains pending in the district court today, as does Mr. Cartee's second amended SFC. Indeed, Mr. Cartee could file a third amended SFC today incorporating the second amended MPIC and selecting a new combination of claims to assert.

An individual plaintiff like Mr. Cartee does not necessarily need to wait for the resolution of the entire MDL to appeal. The district court could dismiss his amended SFC *sua sponte* (or on motion) in light of its rulings on the MPIC, but it has not done that. The district court could also enter a Rule 54(b) judgment against Mr. Cartee or in favor of the defendants Mr. Cartee is suing. But it has not done that either and Mr. Cartee has not asked for a such a judgment. *See Ryan v. Occidental Petroleum Corp.*, 577 F.2d 298, 302 (5th Cir. 1978) ("But where the claim is complete in itself and where the adjudication of that claim is also complete, Rule 54(b) certification is the appropriate channel for assuring appealability.").

Mr. Cartee claims that his individual case is "conclusively over." Cartee Jurisdictional Response at 9. He predicts that, if the district court looked at his second amended SFC, it would acknowledge that his remaining claim is due to be dismissed under its rulings on innovator liability claims outside of Massachusetts and California. *See id.* at 8–9. That prediction may turn out to be correct, but the district court had no opportunity to enter any final judgment because Mr. Cartee filed a notice of appeal the very day he filed the second amended SFC and at a time when there was no MPIC to incorporate. He cannot unilaterally declare his second amended SFC dead when the district court has not done so, and he cannot deny that this SFC is still alive and pending in the district court. *See*, *e.g.*, *Occidental Petroleum Corp.*, 577 F.2d at 302 ("[T]hese partial rulings on his complaint, considered together

with the purported voluntary dismissal of [one paragraph of the complaint], do not amount to a termination of the litigation between the parties."). Because there is no final ruling against his operative complaint—the combination of the MPIC and his SFC—to put the last nail in the coffin of his action, we lack jurisdiction to consider Mr. Cartee's appeal.

B

Ms. Williams' voluntary dismissal of her own amended SFC did not have the effect of creating a final judgment. We therefore also lack jurisdiction over her appeal.

A "Rule 41(a)(1) voluntary dismissal without prejudice is not ordinarily appealable." *Univ. of S. Ala. v. Am. Tobacco Co.*, 168 F.3d 405, 408 n.1 (11th Cir. 1999). *See also* 15A Charles Alan Wright & Arthur R. Miller, Fed. Prac. & Proc. § 3914.8 (2d ed. & April 2022 update) ("[A] voluntary dismissal without prejudice generally fails to achieve finality."). But "[o]ur precedent splinters in multiple directions on whether voluntary dismissals without prejudice are final." *Corley v. Long-Lewis, Inc.*, 965 F.3d 1222, 1228 (11th Cir. 2020). *Compare, e.g.*, *State Treasurer v. Barry*, 168 F.3d 8, 13 (11th Cir. 1999) ("[V]oluntary dismissals, granted without prejudice, are not final decisions themselves. . . ."), *with, e.g.*, *CSX Transp., Inc. v. City of Garden City*, 235 F.3d 1325, 1328–29 (11th Cir. 2000) (concluding that a voluntary dismissal without prejudice was final when "there was no attempt to manufacture jurisdiction"). In

Corley, we held that "an order granting a motion to voluntarily dismiss the remainder of a complaint under Rule 41(a)(2) 'qualifies as a final judgment for purposes of appeal.' " 965 F.3d at 1231 (citations omitted).

In this case, however, Ms. Williams is seeking to appeal matters related to the very claim she voluntarily dismissed through Rule 41(a)(1). She wants to challenge the district court's preemption ruling regarding the "misbranding" theory of design defect liability. And she argues that the district court's preemption orders "terminated her entire action." Williams Jurisdictional Response at 6. But there is no final order from the district court on Ms. Williams' design defect claim. There is also no final order dismissing the design defect claims in the later-filed second amended MPIC. That MPIC remains pending in the district court and includes two design defect claims—one based on the drug's warnings and precautions and another based on allegedly improper expiration dates. *See* MDL D.E. 3887 at 230–312.

Like Mr. Cartee, Ms. Williams filed an amended SFC incorporating allegations from the MPIC which had been dismissed. She then dismissed that very same amended SFC without any further action or acknowledgement from the district court. Because Ms. Williams' amended SFC was pending when she voluntarily dismissed it and because there was no operative MPIC in place to combine with the amended SFC, there was necessarily no final judgment against Ms. Williams. Ms. Williams' subjective belief that the district court would dismiss her amended SFC—which

merely checks the box for the dismissed MPIC's design defect claim and purports to base itself solely on the MPIC's misbranding theory—does not make a final judgment. We find it hard to classify Ms. Williams' voluntary dismissal of her amended SFC as anything other than an attempt to "manufacture jurisdiction." *See CSX Transp., Inc.*, 235 F.3d at 1328.

Ms. Williams also argues that her Rule 41 dismissal rendered the district court's preemption rulings final as against her because the district court placed "stringent conditions" on her ability to re-plead her only remaining theory at that time—a preempted design defect claim based on the "misbranding" theory of liability. *See* Williams Jurisdictional Response at 6–9. But the district court's order did not place conditions on Ms. Williams' filing of an amended SFC. It placed conditions only on the MPIC, which was in fact later amended and refiled. And, like Mr. Cartee, Ms. Williams—who voluntarily dismissed her amended SFC without prejudice—could file a second amended SFC today, checking the boxes for a different line-up of claims.

As the *Corley* concurrence explained, "Rule 41(a) is a poor mechanism to accelerate appellate review." *Corley*, 965 F.3d at 1236 (Pryor, C.J., concurring). It "contemplates the voluntary dismissal of 'an action,' which, we have explained, refers to 'the whole case' instead of particular claims." *Id.* (internal citations omitted). *See also Perry v. Schumacher Grp. of Louisiana*, 891 F.3d 954, 956 (11th Cir. 2018) ("Rule 41(a)(1), according to its plain text, permits voluntary dismissals

only of entire 'actions,' not claims. Thus, the invalid joint stipulation did not divest the District Court of jurisdiction over the case."). All of that is particularly true in the context of an MDL like this one where the parties have filed an operative master complaint. The rulings that Ms. Williams seeks to appeal impact not only her claims, but also the claims of many of her fellow personal injury plaintiffs.

Ms. Williams could seek and possibly obtain a tailored Rule 54(b) judgment to break away from those other plaintiffs with the district court's permission, but she has instead acted unilaterally to dismiss her own amended SFC. A Rule 41(a) voluntarily dismissal cannot manufacture finality under such circumstances. *See*, *e.g.*, *Microsoft Corp. v. Baker*, 137 S. Ct. 1702, 1715 (2 017) ("Plaintiffs in putative class actions cannot transform a tentative interlocutory order . . . into a final judgment within the meaning of § 1291 simply by dismissing their claims with prejudice—subject, no less, to the right to 'revive' those claims if the denial of class certification is reversed on appeal[.]"); *Perry*, 891 F.3d at 958 ("The existence of [other] procedural vehicles [like a Rule 15 amendment or a Rule 54(b) partial judgment] confirms that the purpose of Rule 41(a) is altogether different from that sought by the parties in this case.").

After these appeals were filed, the district court entered a final judgment in favor of all the retailer defendants, including Walgreens, under Rule 54(b). *See* MDL D.E. 4665 at 1 (entering a final judgment "on behalf of all Retailer/ Pharmacy . . . Defendants . . .

against any Plaintiff who has entered a claim against [them] as to Counts I through VI and Counts VIII through XII of the Master Personal Injury Complaint, . . . all previously dismissed by the Court . . . "). Ms. Williams argues that "[e]ven presuming a monolithic MDL action, [that] Rule 54(b) certification has rendered the district court's preemption order final against Walgreens." Williams Jurisdictional Response at 9.

We disagree. It is true that "a subsequent Rule 54(b) certification cures a premature notice of appeal from a non-final order dismissing claims or parties." *Nat'l Ass'n of Boards of Pharmacy v. Bd. of Regents of the Univ. Sys. Of Georgia*, 633 F.3d 1297, 1306 (11th Cir. 2011). But that does not mean that Ms. Williams' appeal against Walgreens has been perfected. This later Rule 54(b) judgment does not change the fact that Ms. Williams voluntarily dismissed her amended SFC (which could not be partnered with any viable and pending MPIC) against Walgreens. It does nothing to revive the amended SFC that Ms. Williams voluntarily dismissed.

III

Mr. Cartee and Ms. Williams argue that their actions are more or less dead given the district court's rulings dismissing certain claims from the MPIC. But "[t]here's a big difference between mostly dead and all dead. . . . Mostly dead is slightly alive." *The Princess Bride* (Act III Communications 1987). It may be that

the claims remaining in their amended SFCs—once paired with a viable and pending MPIC—have little hope of surviving given the district court's rulings. But at the moment there is no final ruling putting their operative complaints—the combination of the MPIC and their individual SFCs—to rest. For that reason, we lack jurisdiction to consider their appeals. The defendants' motions to dismiss these appeals are granted.

APPEALS DISMISSED.

UNITED STATES DISTRICT COURT
FOR THE 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**

THIS DOCUMENT RELATES TO: ALL CASES

FINAL JUDGMENT

(Filed Nov. 15, 2021)

Pursuant to the Court's Order of November 1, 2021, Dkt. No. 4595, for the reasons stated therein, and upon the Court's express determination that there is no just reason for delay, **FINAL JUDGMENT** under Federal Rule of Civil Procedure 54(b) is hereby entered on behalf of all Retailer/Pharmacy and Distributor Defendants (as identified in Appendix A)[1] against any

[1] The Retailer, Pharmacy and Distributor Defendants identified in Appendix A are Defendants named in the Master Personal Injury Complaint and the Amended Master Personal Injury Complaint. Appendix A also includes additional Retailer and Pharmacy Defendants named in individual complaints filed in or transferred to the MDL, but which are not named in the Master Complaints. The parties represent that the list of Defendants identified in Exhibit A may not be exhaustive and/or capture every Retailer and/or Pharmacy identified in all current and future individual complaints; the parties may move to amend or supplement this Appendix in the event additional Retailer, Pharmacy, and/or Distributor Defendant(s) are identified during the pendency of the MDL to which this Final Judgment would be applicable.

Plaintiff who has entered a claim against any Retailer/Pharmacy or Distributor Defendant, as to Counts I through VI and Counts VIII through XII of the Master Personal Injury Complaint, Dkt. No. 887 (the "MPIC"), all previously dismissed by the Court, *see* Dkt. No. 2513, and as further identified as follows in the MPIC:

> Count I: Strict Products Liability—Failure to Warn
>
> Count II: Strict Products Liability—Design Defect
>
> Count III: Strict Products Liability—Manufacturing Defect
>
> Count IV: Negligence—Failure to Warn
>
> Count V: Negligent Product Design
>
> Count VI: Negligent Manufacturing
>
> Count VIII: Negligent Misrepresentation
>
> Count IX: Breach of Express Warranties
>
> Count X: Breach of Implied Warranties
>
> Count XI: Violation of Consumer Protection and Deceptive Trade Practices Laws
>
> Count XII: Unjust Enrichment

The Court does not enter judgment as to Count VII, General Negligence. The Clerk of the Court shall file a copy of this judgment on the MDL docket.

DONE and **ORDERED** in Chambers, West Palm Beach, Florida, this 15th day of November, 2021.

/s/ Robin L. Rosenberg
ROBIN L. ROSENBERG
UNITED STATES
DISTRICT JUDGE

Copies furnished to: Counsel of Record

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION /	**MDL No. 2924** **No. 20-MD-2924** **JUDGE ROBIN L. ROSENBERG** **MAGISTRATE JUDGE BRUCE E. REINHART**

ORDER GRANTING IN PART AND DENYING IN PART THE DEFENDANTS' MOTIONS REQUESTING ENTRY OF FINAL JUDGMENT

(Filed Nov. 1, 2021)

The motions before the Court are the Distributor, Retailer, and Pharmacy Defendants' Motion for Entry of Final Judgment in all Cases Naming Distributor, Retailer, and Pharmacy Defendants [3934] (the "Retailers" and the "Retailers' Motion") and the Generic Manufacturers' Motion for Entry of Final Judgment in Mixed-Defendant Cases [3933] (the "Generics" and the "Generics' Motion").[1] Both Motions have been fully briefed. For the reasons set forth below, the Motions are granted in part and denied in part insofar as the Court will enter final judgment in favor of the Generics

[1] In addition to shorthand references to the movants, the Retailers and the Generics, the Court will also refer to Defendants Boehringer Ingelheim Pharmaceuticals, Inc., Chattem, Inc., Sanofi US Services Inc., Sanofi-Aventis U.S. LLC, Patheon Manufacturing Services, LLC, Pfizer Inc., and GlaxoSmithKline LLC as the "Brands."

and the Retailers, but the Court's entry of judgment is not as broad as the Retailers have requested.

This litigation arises from alleged defects in the formulation of the heartburn medication ranitidine, commonly known as Zantac.[2] In prior orders of dismissal, the Court dismissed all claims against the Generics (and most of the claims against the Retailers) with prejudice but permitted claims against the Brands to proceed. Because most of the Plaintiffs have brought claims against the Brands, most of the individual Plaintiffs' cases have survived the Defendants' motions to dismiss and are now at issue. Since most of the Plaintiffs' cases have survived, the dispute before the Court is whether the Court's partial dismissal of the Plaintiffs' claims may be appealed immediately through the Court's entry of final judgment and, if so, whether the judgment should be a full, unqualified final judgment (entered under Federal Rule of Civil Procedure 58), a partial final judgment (entered under Rule 54(b)), or both.

The parties' dispute focuses primarily on the process the Court should follow to perfect the Plaintiffs' appeals, not on whether the Plaintiffs are entitled to appeal. To explain the parties' dispute as to the appropriate process, however, the Court divides the individual cases at issue in the Motions into two categories. First, there are cases in which the Plaintiffs have named only the Generics—no other Defendants are

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[2] For the purposes of this Order, the Court presumes a certain level of general familiarity with the history of this MDL.

named. The Court refers to this category of cases as "Generic-Only" cases. Second, there are cases in which the Plaintiffs have named other Defendants in addition on the Generics. The Court refers to this category as "Mixed-Generic" cases.

Turning to specifics, despite their agreement on the ultimate result—the Plaintiffs' pending appeals, perfected—the parties' positions on *how* the Plaintiffs' appeals should be perfected could not be more varied or more confusing. As for the Plaintiffs, they have taken the position that the Court's orders of dismissal were final and appealable at the time of entry and that no further order of the Court is necessary to perfect their appeals.[3] In the alternative, the Plaintiffs argue that Rule 58 final judgment should be entered in the Generic-Only cases, but that no final judgment should be entered in any other case, including the Mixed-Generic cases. Most of the Generics agree that the Plaintiffs should receive final judgment in the Generic-Only cases,[4] but they argue that the Court should also enter partial final judgment under Rule 54(b) in the Mixed-Generic cases. Generic Defendant Apotex Corp. argues that only a single partial final judgment (under Rule 54(b)) should be entered in the MDL—not in any individual case. The Retailers seek entry of Rule 54(b) judgment in any case in which they are named as

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[3] "It is our belief that . . . the order itself standing on its own is clearly appealable as a final order." DE 3900 at 14.

[4] The Court construes Defendant Apotex's reply at docket entry 4143 as an objection to the entry of Rule 58 final judgment in any individual Plaintiff's case.

Defendants. Finally, the Brands argue that final judgment must be entered in order to perfect the Plaintiffs' appeals, but the Court should enter judgment without delving into why or how the judgment should be entered so as to permit the Eleventh Circuit to have the first say on the matter.[5] The Plaintiffs oppose the entry of a Rule 54(b) partial final judgment in any case.

Who, then, is correct and how is the Court to sort through the parties' varied, nuanced positions? The Court concludes that the answer to this question lies in how this MDL was organized and, more specifically, how the Court structured the Plaintiffs' master pleadings in Pretrial Order # 31. Accordingly, the Court first considers (A) the relevant procedural history of this MDL and the specifics of Pretrial Order # 31. Viewing all subsequent analysis through the prism of Pretrial Order # 31, the Court then addresses a disputed premise underpinning the parties' competing legal positions. That disputed premise is the threshold question of whether, consistent with the Pretrial Order # 31, the individual cases in this MDL have temporarily merged and lost their individual appellate rights for the duration of the MDL. This concept of merger and the corresponding loss of appellate rights frames the parties' competing legal positions, with some of the parties arguing that the individual cases in this MDL do not have a right to immediate appeal, and other parties

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[5] The Brands represent that the Eleventh Circuit will ultimately rule on the finality of the Plaintiffs' appeals when it decides the Brands' pending motion to dismiss the appeals. DE 3894.

arguing that the individual cases have retained their right to appeal. To resolve this dispute, the Court (B) summarizes the applicable law on the temporary merger of cases in an MDL and then (C) applies that law to Pretrial Order # 31 and the structure of this MDL. Because the Court ultimately concludes that the individual cases in this MDL *have not* lost their individual identities and corresponding appellate rights, the Court utilizes that premise in its subsequent analysis of (D) the parties' competing requests for entry of Rule 58 final judgment in the Generic-Only cases. The Court must also address the Mixed-Generic cases and cases involving the Retailers, and thus, the Court then turns to the question of whether a partial final judgment under Rule 54(b) should be entered in any case in the MDL. The Court's analysis on this topic is preceded by (E) a summary of the law applicable to the Retailers' and Generics' requests for entry of partial judgment under Rule 54(b) before finally turning to (F) the Generics' Motion for Entry of Judgment, (G) the Retailers' Motion for Entry of Judgment, and (H) the specifics of the Court's forthcoming entry of final judgment.

A. Relevant Procedural History and Pretrial Order # 31

The Court's Pretrial Order # 31

In mid-June 2020, a few months into the MDL, the parties submitted to the Court a proposed order, that they had negotiated and agreed upon, to address the filing of a master pleading on behalf of all individual Plaintiffs who assert personal injury claims in this

MDL. The Court entered the proposed order as Pretrial Order # 31.[6] DE 876. Pretrial Order # 31 explains that the parties agreed to the procedures in the Order due to the number of complaints filed, and likely to continue to be filed, in the MDL and due to the inefficiencies in drafting unique complaints and individual answers to those complaints. To avoid those inefficiencies, Pretrial Order # 31 required the Plaintiffs to file one Master Personal Injury Complaint on behalf of all Plaintiffs asserting personal injury claims related to the use of ranitidine. The Order states that, "All claims pleaded in the Master Personal Injury Complaint will supersede and replace all claims pleaded in any complaint previously filed in or transferred to MDL No. 2924, to the extent applicable under the procedural and substantive law that applies to previously filed actions, including this Order." *Id.* at 2. In addition to the filing of a Master Personal Injury Complaint, the Order required individual Plaintiffs to file "Short Form Complaints" to provide certain information specific to each Plaintiff. Among this information, each Plaintiff was required to list the Defendant(s) against whom he or she asserted claims and to specify the causes of action in the Master Personal Injury Complaint that the Plaintiff adopted. The Short Form Complaints also could contain "[a]dditional allegations or causes of action not pleaded in the Master Personal Injury Complaint." *Id.* at 3. The Order explained that, "For each

[6] The Court thereafter entered an Amended Pretrial Order # 31. *See* DE 1496. The differences between the original and the amended Pretrial Order # 31 are irrelevant for the purpose of this Order.

action directly filed in or transferred to MDL No. 2924 subject to this Order, the Master Personal Injury Complaint together with the Short Form Complaint shall be deemed the operative Complaint." *Id.*

Each of the three provisions in Pretrial Order # 31 are important to the Court's ultimate analysis of the Motions for Entry of Judgment, *infra.* First, consistent with the parties' agreement the master pleadings are, for the most part, the only operative pleadings for personal injury claims in this MDL—the master pleadings supersede all prior pleadings in individual cases. Second, the Short Form Complaints that each individual Plaintiff files are also operative pleadings insofar as the Short Form Complaints select (in each individual case) the various parts of the master complaints that an individual Plaintiff incorporates into his or her individual case. Third and finally, the Short Form Complaints are a theoretical vehicle[7] for an individual Plaintiff to plead claims not pled in the master complaints. These three provisions will be discussed below in the context of the Court's analysis of the Defendants' Motions, but the Court first summarizes in more detail its prior rulings and the parties' competing positions.

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[7] At this time, the Court is unaware of any individual case where a Plaintiff has exercised his or her right under Pretrial Order # 31 to plead a claim not pled in the master complaints.

The Court's Rulings on the Master Complaints and the Defendants' Motions to Dismiss

The Plaintiffs, thus far, have filed three rounds of master complaints in this MDL, including three versions of the Master Personal Injury Complaint. In the first round of master complaints, the Plaintiffs brought claims against brand-name manufacturers, generic manufacturers, retailers, and distributors of ranitidine that were premised on defective design and on inadequate labeling. *See* DEs 887, 888, 889. The Court then issued an Order setting a schedule for the filing and briefing of motions to dismiss directed to these master complaints,[8] and the various groups of Defendants filed motions to dismiss under that schedule. DE 1346. In their motion to dismiss, the Brands argued that the design-defect claims pled against them in the master complaints were pre-empted because federal law prohibited them from changing ranitidine's design absent the approval of the U.S. Food and Drug Administration ("FDA"). DE 1580. The Generics and Retailers filed motions to dismiss in which they argued that all of the claims brought against them in the master complaints were pre-empted because federal law prohibited them from changing ranitidine's design and its labeling. DEs 1582, 1583, 1584.

[8] Although the parties disagreed as to the precise timetable that would apply to the motions to dismiss, the parties were in agreement that the motions to dismiss would be directed to the consolidated master pleadings. As a result, no motions to dismiss were filed against the Plaintiffs' Short Form Complaints.

The Plaintiffs responded to all of these motions to dismiss by asserting, in part, that their design and labeling claims in the master complaints were not pre-empted because ranitidine was "misbranded" as that term is defined under federal law and because the claims asserted in the master complaints were "parallel" to—and therefore did not conflict with—federal law prohibiting the sale of misbranded drugs. DE 1976, 1977, 1978 (citing 21 U.S.C. §§ 331, 352). The Plaintiffs further responded that, despite the fact that the Retailers did not design or label ranitidine, state law could hold them absolutely liable for distributing and selling defective ranitidine products. DE 1977.

This Court rejected the Plaintiffs' misbranding argument as contrary to Supreme Court precedent. *See* DE 2512, 2513, 2532 (citing *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) and *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013)); *see also* DE 3715. The Court ruled that a claim is pre-empted if it is based on an alleged product defect that a defendant could not have remedied without FDA approval while remaining in compliance with federal law. *See*, *e.g.*, DE 2512. Thus, claims that the Brands should have changed ranitidine's FDA-approved design were pre-empted while, under Supreme Court precedent, claims that the Brands should have changed ranitidine's labeling were not necessarily pre-empted and could proceed through the pleading stage of the MDL. DE 2532 (citing *Wyeth v. Levine*, 555 U.S. 555 (2009)).

As to the claims against the Generics, the Court held that both design-defect and labeling claims were

pre-empted because federal law requires generic drug manufacturers to emulate the design and labeling of brand-name drugs, and therefore the Generics could not change ranitidine's design or labeling. DE 2512. The Court explained that the Generics could take certain actions with respect to generic ranitidine under federal law, such as printing a correct expiration date on a drug's packaging and properly storing a drug. The Court, therefore, granted the Plaintiffs leave to replead claims against the Generics that were based on alleged deficiencies they could have remedied while remaining compliant with federal law.

Finally, with respect to the Retailers, the Court rejected the Plaintiffs' argument about absolute liability as contrary to Supreme Court precedent. *See* DE 2513 (citing *Bartlett*, 570 U.S. 472). The Court ruled that both design-defect and labeling claims were pre-empted because drug retailers and distributors have no ability to alter drug design or labeling. However, the Court granted the Plaintiffs leave to replead claims against the Retailers that were based on alleged negligent storage of the ranitidine products in their possession.

Following these rulings, at least one individual Plaintiff appealed the Court's Orders on pre-emption. *See* Case No. 9:20-cv-80512 (S.D. Fla.). The Defendants named in the appeal moved to dismiss for lack of appellate jurisdiction. *See* Case No. 21-10306 (11th Cir.). That appeal, together with the motion to dismiss, remain pending before the Eleventh Circuit.

The Plaintiffs subsequently filed the second round of master complaints, including an Amended Master Personal Injury Complaint. *See* DE 2759, 2832-1, 2835. The Plaintiffs renewed their claims against the Brands that were based on inadequate labeling. The Plaintiffs also raised claims against both the Brands and Generics that were premised on failure to warn consumers through the FDA of ranitidine's alleged defects, inaccurate expiration dates, failure to appropriately package ranitidine pills, failure to store ranitidine under correct conditions, and failure to test ranitidine. The Plaintiffs raised claims against the Retailers that were premised on the storage and shipment of ranitidine products under excessively hot and humid conditions. The Court issued an Order setting a schedule for the filing and briefing of motions to dismiss directed at this round of master complaints. DE 2968. The Brands then moved to dismiss as pre-empted the claims in the master complaints for failure to warn consumers through the FDA; the Generics moved to dismiss as pre-empted all of the claims brought against them in the master complaints; and the Retailers moved to dismiss all of the claims raised against them in the master complaints as both pre-empted and implausibly pled. DE 3105, 3107, 3112, 3114.

The Court ruled that the claims against the Brands and Generics for failure to warn consumers through the FDA were pre-empted under Supreme Court and Eleventh Circuit precedent. DE 3715, 3750 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) and *Mink v. Smith & Nephew, Inc.*, 860

F.3d 1319 (11th Cir. 2017)). The Court further determined that, although the Plaintiffs purported to premise all of their remaining claims against the Generics on actions that they could have taken while remaining compliant with federal law, those remaining claims were pre-empted. DE 3750. The Court ruled as such because the legal claims pled against the Generics were based on failure to warn and negligence, and the Generics could not satisfy the legal duties for those claims—the duty to warn of the risks of ranitidine and the duty to use reasonable care—in accordance with federal law. Because the Plaintiffs alleged that the ranitidine molecule was inherently dangerous to consumers from the moment it was manufactured and that the Generics knew or should have known of the danger, the Generics could not satisfy the legal duties absent redesigning the molecule or relabeling ranitidine products, which federal law prohibited. The Court, therefore, dismissed all claims against the Generics without leave to amend.

The Court also ruled that the Plaintiffs' sole remaining claim against the Retailers—a negligence claim pertaining to storage and shipment—was implausibly pled. DE 3716. The Court's ruling was based on a number of reasons, including that (1) the claim was pled "upon information and belief" without supporting factual allegations; and (2) the Plaintiffs did not identify the incorrect condition(s), such as some high temperature or level of humidity for some period of time, to which any ranitidine products had been exposed. The Court, therefore, dismissed the negligence

claim against the Retailers without leave to amend and did not address the issue of whether the claim was pre-empted.[9]

Subsequent to these rulings, multiple individual Plaintiffs appealed the Court's Orders. The cases on appeal include Generic-Only cases. *See*, *e.g.*, Case Nos. 9:21-cv-80683, 9:21-cv-81169 (S.D. Fla.). The cases on appeal also include Mixed-Generic cases. *See*, *e.g.*, Case Nos. 9:20-cv-81204, 9:21-cv-80001 (S.D. Fla.). These appeals remain pending before the Eleventh Circuit. The Plaintiffs have filed the third and latest round of master complaints, which raise claims only against the Brands. *See* DE 3883, 3884, 3887. The third round of master complaints survived the Brands' motions to dismiss. DE 4487, 4488.

The Plaintiffs' Motion for Entry of Judgment

Following the Court's Orders on the second round of motions to dismiss, the Plaintiffs moved for entry of judgment in all cases wherein individual Plaintiffs named Generics and/or Retailers as the only Defendants in their Short Form Complaints. DE 3863. The Plaintiffs asserted in their motion that the individual Plaintiffs' cases retained their separate identities—

[9] The Court also did not rule on the question of whether a negligent storage and transportation claim against the Generics would be pre-empted, because the Court treated the Plaintiffs' count facially styled as a negligent storage and transportation claim (Count XI in the Amended Master Personal Injury Complaint) as a negligent manufacturing claim that was sourced in design defect. *See* DE 3750 at 40-42.

that is, that they had not "merged"—for the purpose of appeal. Among their arguments, the Plaintiffs maintained that (1) although the Master Personal Injury Complaints were filed on behalf of all Plaintiffs, the Short Form Complaints also remained operative complaints in the individual cases; (2) consolidation of cases for MDL purposes could not impair a Plaintiff's right to appeal when his or her own case had been fully resolved; and (3) merger would deprive this Court of subject matter jurisdiction by destroying diversity of citizenship. The Plaintiffs asserted that, because the Court had dismissed without leave to amend all claims against the Generics and Retailers in the master complaints, no claims remained pending in, and the Plaintiffs could therefore appeal, the individual cases with Short Form Complaints naming Generics and/or Retailers as the only Defendants. Therefore, the Plaintiffs sought entry of final judgments under Fed. R. Civ. P. 58(a) in those cases to remove any doubt about their appellate rights.

All but one of the Generics, together with all of the Retailers, responded by joining the Plaintiffs' request for entry of Rule 58 judgments in the individual cases with Short Form Complaints naming Generics and/or Retailers as the only Defendants. DE 3895. The remaining Generic, Apotex, responded that there had been a merger, as evidenced by the fact that, under Pretrial Order # 31, the Master Personal Injury Complaints superseded and replaced all claims pled in the individual cases. DE 3893. Apotex further asserted that, because of this merger and because claims

against the Brands remained pending in the merged proceeding, the proper procedural vehicle to secure any appeal was a certification and judgment under Fed. R. Civ. P. 54(b) as to all claims against the Generics and Retailers in the master complaints. Apotex argued in the alternative that, if the Court were to disagree that there had been merger and were to enter Rule 58 judgments in any individual cases, the Court should then enter Rule 54(b) judgments as to the claims against the Generics and Retailers in any cases with pending claims against the Brands. According to Apotex, either of these alternative procedures would ensure that the Court's rulings as to the Generics and Retailers would be reviewed once by one appellate court, avoiding piecemeal appeals.

The Brands argued that the Plaintiffs are not entitled to entry of Rule 58 judgments in any individual cases. DE 3894. The Brands maintained that this was so because there had been a merger and because the Court has not ruled on any Short Form Complaints, such that the Short Form Complaints, as operative complaints, remain pending in the individual cases. But the Brands suggested that it was unnecessary for the Court to resolve whether the Plaintiffs were entitled to entry of Rule 58 judgments because the Court could both enter final judgments and make a Rule 54(b) certification, to the extent it might be necessary, to ensure appellate jurisdiction in appropriate individual cases.

The Court denied the Plaintiffs' Motion for Rule 58 judgments. DE 3913. The Court explained that its

Order dismissing the claims against the Retailers without leave to amend had rejected as implausible the Plaintiffs' attempt, through the master complaints, to "impose *global* MDL liability on the [Retailers] without any concrete, particularized, or individualized allegation of negligence." *Id.* at 3. But the Court did not intend to preclude individual Plaintiffs, in their own cases, from seeking to plead "a negligence claim on case-specific facts, provided an individual Plaintiff has a factual basis to do so." *Id.* at 4. And the Court suggested that such case-specific claims could be addressed outside of this MDL. Thus, the Court determined that entry of Rule 58 judgments in individual cases naming the Retailers was inappropriate. As to Generic-Only cases, the Court explained that its dismissal of the claims in the master complaints against the Generics, unlike the Retailers, "had nothing to do with the need for individualized, case-specific facts" and that it was "the Court's intent that, at the proper time and upon proper motion, the Court could enter a final order of dismissal or a final judgment in an individual case" against one or more Generics. *Id.* at 5. The Court could not enter any such final orders, however, because the Plaintiffs had not provided a list of Generic-Only cases.[10] The Court stated that, "[s]hould the Plaintiffs identify all individual Plaintiffs who have named only a Generic Defendant and seek a final order of dismissal as to those cases, nothing in this Order

[10] Approximately 1,600 cases were filed in the MDL at the time of the Plaintiffs' Motion, and the Court could not easily identify the subset of Generic-Only cases.

shall preclude the Plaintiffs from filing a more specific renewed motion." *Id.* at 5-6. Of importance to the instant Order, the Court did not decide the question of whether the Plaintiffs' individual cases had merged through the usage of consolidated master pleadings. The Court decides that question in this Order in Section (C).

The Generics' and Retailers' Motions for Entry of Judgment

Two motions for entry of judgment are currently before the Court. One of the motions is brought by all of the Generics except Apotex and requests two forms of relief.[11] DE 3933. First, the Generics seek entry of judgments (without specifying whether the applicable Rule is 54(b) or 58) in the Generic-Only cases. The Generics provide a list of such cases and ask that Plaintiffs' Lead Counsel be ordered to identify any cases that should be added to the list. Second, the Generics seek entry of Rule 54(b) judgments in the Mixed-Generic cases. According to the Generics, granting both forms of relief in tandem will ensure that the Court's rulings as to the Generics will be reviewed once by one appellate court, avoiding piecemeal appeals. In the alternative to Rule 54(b) judgments, the Generics propose that the Court sever the claims against them from

[11] Apotex continues to maintain that there has been a merger and that the Court should enter one Rule 54(b) judgment as to all claims against the Generics in the master complaints. DE 4143.

the Mixed-Generic cases and enter Rule 58 judgments as to those severed claims.

The Retailers filed the second motion that is currently before the Court. DE 3934. The Retailers seek entry of Rule 54(b) judgments in all individual cases naming them among the Defendants. They argue that they are entitled to judgment because no claim remains pending against them in any Master or Short Form Complaint. Although the Court stated in its previous Order that it did not intend to preclude individual Plaintiffs from seeking to plead negligence claims based on case-specific facts, the Retailers argue that no such individualized claims have been pled.

The Plaintiffs oppose entry of Rule 54(b) judgments, asserting that a Rule 54(b) judgment is an extraordinary form of relief that is unwarranted here. DE 4092. The Plaintiffs argue that granting the Generics' and Retailers' motions would result in judgments in perhaps over one thousand cases and would burden the Plaintiffs by requiring them to pursue appeals in those cases now while continuing to litigate claims against the Brands that remain pending before this Court. The Plaintiffs contend that the filing fees alone for these appeals would be exorbitant. The Plaintiffs further argue that the judgments the Retailers seek are inappropriate for the additional reason that an individual Plaintiff may in the future choose to plead a case-specific negligence claim against a Retailer.

B. The Merger of Individual Cases in an MDL through Consolidated Master Pleadings

In *Gelboim v. Bank of America Corp.*, the Supreme Court considered an MDL in which the district court dismissed one of several complaints against some, but not all, of the Defendants—consolidated master pleadings were not utilized in the MDL. 574 U.S. 405, 411-12 (2015). The plaintiffs whose complaint had been dismissed appealed pursuant to 28 U.S.C. § 1291, reasoning that the district court's decision was final and therefore appealable. *Id.* Other, non-dismissed defendants were affected by the district court's legal conclusions supporting dismissal, even though they continued to face live claims in the MDL. *Id.* As to those defendants, the district court granted a Rule 54(b) final judgment so that they could participate in the pending appeal. *Id.* at 412.

The Second Circuit dismissed the § 1291 appeal, holding that the appeal was improper because the "orde[r] appealed from did not dispose of all claims in the consolidated action." *Id.*[12] The plaintiffs appealed the dismissal of their appeal to the Supreme Court, arguing that once their underlying claims were dismissed in their entirety, their action was no longer consolidated in the MDL and they did not need a Rule 54(b) certification. *Id.* at 413. The Supreme Court agreed with the plaintiffs and reversed the Second

[12] Subsequent to the Second Circuit's dismissal of the § 1291 appeal, the *Gelboim* district court withdrew its 54(b) certifications for the other defendants "given the reaction of the Second Circuit." 574 U.S. at 411-12.

Circuit's dismissal. *Id.* The Supreme Court's reasoning is of particular importance to the instant MDL. The Supreme Court contrasted the complaints in the *Gelboim* MDL—which were distinct and separate—with an MDL where the parties file one consolidated, master pleading:

> Parties may elect to file a "master complaint" and a corresponding "consolidated answer," which supersede prior individual pleadings. In such a case, the transferee court may treat the master pleadings as merging the discrete actions for the duration of the MDL pretrial proceedings. No merger occurs, however, when "the master complaint is not meant to be a pleading with legal effect but only an administrative summary of the claims brought by all the plaintiffs."

Id. n.3 (citations omitted) (hereinafter referred to as the "**merger doctrine**"). In addition to noting the possibility of such consolidation, the Supreme Court cited with approval the Sixth Circuit's decision in *In re Refrigerant Compressors Antitrust Litigation*, 731 F.3d 586, 590-92 (2013).

In *Refrigerant*, the Sixth Circuit considered the appealability of partial dismissals in MDL actions where the parties filed one consolidated master complaint. *Id.* The Sixth Circuit reasoned that under such a scenario a plaintiff *would* need a Rule 54(b) certification to appeal, even when all of a plaintiff's individual claims had been dismissed. *Id.* Important to the Sixth Circuit's decision was the difference between a master

complaint that serves as an administrative document and a master complaint that consolidates pleadings. As for the former—an administrative master complaint:

> In many cases, the master complaint is not meant to be a pleading with legal effect but only an administrative summary of the claims brought by all the plaintiffs. When plaintiffs file a master complaint of this variety, each individual complaint retains its separate legal existence. *See*, *e.g.*, *In re Nuvaring Prods. Liab. Litig.*, No. 4:08MD1964 RWS, 2009 WL 2425391, at *2 (E.D. Mo. Aug. 6, 2009) ("[T]he filing of the master consolidated complaint in this action was simply meant to be an administrative tool to place in one document all of the claims at issue in this litigation. Neither Plantiffs . . . nor I . . . contemplated that Rule 12(b) motion practice would be pursued . . . against the master complaint."); *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 142 (E.D. La. 2002) ("[T]he master complaint [filed in this case] should not be given the same effect as an ordinary complaint. Instead, it should be considered as only an administrative device to aid efficiency and economy.").

Id. at 590. Compared to an administrative summary of claims which would not have the effect of consolidation, the Sixth Circuit described a master complaint which *would* have the effect of consolidation and the application of the merger doctrine:

> But, in other cases, the court and the parties go further. They treat the master complaint as an operative pleading that supersedes the

> individual complaints. The master complaint, not the individual complaints, is served on defendants. The master complaint is used to calculate deadlines for defendants to file their answers. And the master complaint is examined for its sufficiency when the defendants file a motion to dismiss. *See*, *e.g.*, *In re Katrina Canal Breaches Litig.*, 309 F. App'x 836, 838 (5th Cir. 2009) ("[The plaintiff's] individual complaint was superseded, and . . . any arguments or claims that appear in [the] individual complaint but not in the Master Complaint were waived."); *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, No. MDL 2272, 2012 WL 3582708, at *4 (N.D. Ill. Aug. 16, 2012) ("MDL courts have entertained motions to dismiss 'master' or 'consolidated' complaints. . . ."); *see generally* Diana E. Murphy, *Unified and Consolidated Complaints in Multidistrict Litigation*, 132 F.R.D. 597 (1991).

Id. at 590-91.

Subsequent to *Refrigerant* and *Gelboim*, the Seventh Circuit in *Bell v. Publix Super Markets, Inc.*, 982 F.3d 468 (2020), endorsed the view that, pursuant to *Gelboim*, consolidated master pleadings in MDLs require a Rule 54(b) certification to appeal.[13] The Seventh Circuit noted that the default rule (absent master pleading consolidation) is that every individual case

[13] It is also arguable that the Tenth Circuit has recognized the validity of the merger doctrine as well. *See In re Cox Enter. Set-Top Cable Television Box Antitrust Litig.*, 835 F.3d 1195, 1208 n.4 (2016).

retains its separate identity and ability to appeal. *Id.* at 489. Yet in large MDLs, when "each transferred case comes with its own pleadings, a multidistrict transfer threatens to submerge the transferee district court in paper." *Refrigerant*, 731 F.3d at 590. As a result, "transferee courts and parties may choose to manage those cases in ways that can change that default rule and give up the separate identities of the original suits transferred to the MDL litigation." *Bell*, 982 F.3d at 489. When determining whether a master complaint was merely an administrative summary of claims or an actual consolidated pleading, the Seventh Circuit adopted a "pragmatic approach" that focuses on "the behavior of the district court and the parties to determine whether they treated the consolidated complaint as the 'operative pleading' or merely 'an administrative summary.'" *Id.* at 490. As explained by the Sixth Circuit in *Refrigerant*, to treat a consolidated master pleading as anything else simply makes no sense:

> What at any rate would be the alternative? The [plaintiffs] suggest looking at their original individual complaints rather than at the new consolidated complaint. But the new complaint superseded the old ones, and it makes little sense to ascertain appellate jurisdiction by looking at the ghosts of departed pleadings. Besides, when deciding whether the district court properly granted a motion to dismiss, we would have to look at the new complaint anyway. How odd it would be to write an opinion that talks about one complaint in the jurisdiction section and another in the merits section.

731 F.3d at 591. The *Bell* court, therefore, considered the following five factors to determine whether a master complaint was an administrative summary or a consolidated pleading: the label on the complaint, whether the complaint was served, whether key deadlines were set in relation to the complaint, whether the court entertained motions to dismiss the complaint, and whether the parties and the court looked solely to the allegations in the complaint when arguing and deciding motions to dismiss. *Bell*, 982 F.3d at 490. When the foregoing factors indicate the pleadings in a case have been consolidated, the parties forego "the default rule" and instead require Rule 54(b) certifications to appeal prior to the complete disposal of a complaint. *See id.*

C. The Application of the Merger Doctrine to this MDL

The *Bell* and *Refrigerant* factors are objective factors based upon the parties' actions and the Court's governance of the MDL. These objective factors favor the conclusion that the master pleadings were merged, consolidated pleadings, not mere administrative summaries of claims. The Court analyzes these objective factors below. In resisting the application of the merger doctrine, the Plaintiffs primarily rely upon their subjective intent to preserve their appellate rights. The Court considers the Plaintiffs' arguments regarding their subjective intent as well.

As to the objective *Bell* and *Refrigerant* factors, the Plaintiffs served the master pleadings. The key deadlines in this case were set in relation to the filing of the master pleadings. *E.g.*, DE 2968 (setting forth deadlines for motions to dismiss on the second round of master pleadings). The Court has entertained three rounds of motions to dismiss directed at the master pleadings—a total of twenty motions to dismiss. Finally, the Court looked solely to the allegations in the master complaints when ruling on the motions to dismiss, and the parties relied solely upon the master complaints when arguing the same. The Court's Pretrial Order # 31 which set forth the process for the filing of the master complaints clarified that they would be consolidated pleadings, not administrative summaries: "All claims pleaded in the Master Personal Injury Complaint will supersede and replace all claims pleaded in any complaint previously filed in or transferred to MDL No. 2924, to the extent applicable under the procedural and substantive law that applies to previously filed actions, including this Order." DE 876 at 2. The parties agreed to the Court's entry of Pretrial Order # 31. *Id.* at 1.

In response, the Plaintiffs make four arguments why the merger doctrine does not apply to this MDL. First, the Plaintiffs argue without citation to any authority that a consolidated master pleading would deprive this Court of subject matter jurisdiction by destroying diversity. DE 3904 at 8. The Court fails to see how this could be true. *See*, *e.g.*, *In re Bridgestone/Firestone, Inc. Tires Prod. Liab. Litig.*, 256

F. Supp. 2d 884, 890 (S.D. Ind. 2003) (finding that the filing of a master complaint had "no effect" on potential subject-matter jurisdiction arguments). The Court has not permanently merged the individual cases in this MDL—it has merely consolidated them, temporarily, for pretrial purposes consistent with its mandate under 28 U.S.C. § 1407. The temporary merger of pleadings through a master complaint was necessitated by the fact that there currently are over 1,800 individual cases in this MDL.

Second, the Plaintiffs' argument that the merger doctrine is inapposite with the Supreme Court case of *Hall v. Hall* is unavailing. 138 S. Ct. 1118 (2018). *Hall* stands for the proposition that cases consolidated under Rule 42(a) retain their individual identities for appellate purposes, *id.* at 1122, but the cases in this MDL were consolidated pursuant to § 1407. Further, *Hall* expressly does not apply to cases that have been merged; *Hall* does nothing to disturb the Supreme Court's prior decision in *Gelboim; Hall* does not address master consolidated pleadings; and, moreover, the individual cases in this MDL *do* ultimately retain their individual identities; they will eventually be remanded to their home districts. *See id.*

Third, the Plaintiffs point out that pursuant to Pretrial Order # 31, the master pleadings are not the only operative pleadings in this MDL—the Short Form Complaints are also operative pleadings. The Plaintiffs argue that the existence of a second type of operative pleading undercuts the idea that the master pleadings were intended to merge and consolidate the pleadings.

The primary purpose of the Short Form Complaints, however, is merely to provide a small amount of Plaintiff-specific information and incorporate select counts in the master pleadings. That is no barrier to the conclusion that, at least during the pendency of this MDL, the individual cases have merged through their usage of the master pleadings. Relatedly, while it is true that, at least in theory, a Short Form Complaint may bring a claim not brought in a master pleading, that too is no barrier to the merger and corresponding waiver of appellate rights for claims brought in the master complaints. In summary, the Plaintiff's argument that Short Form Complaints are operative pleadings, standing alone, is unpersuasive to resist the merger doctrine. However, the Plaintiffs' argument warrants greater consideration when the Court considers Pretrial Order # 31's usage of Short Form Complaints in conjunction with the Plaintiffs' fourth argument, as discussed below.

Fourth and finally, the Plaintiffs' best argument against the merger doctrine is that in lieu of focusing on the objective *Bell* and *Refrigerant* factors, the Court instead should focus on the Plaintiffs' subjective intent to preserve their individual appellate rights which, according to Plaintiffs, was memorialized in the following text in their master complaints:

> This SAMPIC does not necessarily include all claims asserted in all of the transferred actions to this Court, and it is not intended to consolidate for any purpose the separate claims of the individual Plaintiffs in this

> MDL. Each Plaintiff in this MDL will adopt this SAMPIC and specific causes of action alleged herein against specific Defendants through a separate Short Form Complaint—Version 3 ("SFC"), attached hereto as Exhibit A. Any individual facts, jurisdictional allegations, additional legal claims, and/or requests for relief of an individual Plaintiff may be set forth as necessary in the SFC filed by the respective Plaintiff.
>
> This SAMPIC does not constitute a waiver or dismissal of any actions or claims asserted in those individual actions, and no Plaintiff relinquishes the right to amend his or her individual claims to include additional claims as discovery proceeds and facts and other circumstances may warrant pursuant to PTO No. 31 or the appropriate Federal Rules of Civil Procedure.

E.g., DE 3887 at 2. This language cannot be squared with how the parties and the Court have conducted this litigation. Indeed, the Plaintiffs' assertion that the master complaints were "not intended to consolidate for any purpose the separate claims of the individual Plaintiffs in this MDL" is simply not true—that was the precise purpose of the master complaints and at all times the Court and the parties conducted themselves in accordance therewith.[14] Further, it is the Court's

[14] In *Bell*, the appellate court noted that the merger doctrine prevents the parties from "springing traps by treating a consolidated complaint as the operative complaint" in the district court but then, later, "denying its importance and effect" at the time of appeal. 982 F.3d at 490.

Pretrial Orders—entered with the Plaintiffs' consent—that govern the creation of the master pleadings and corresponding merger, not the Plaintiffs' unilaterally inserted language. Finally, any appellate review of the Court's decisions will necessarily turn on the master complaints and not the individual cases, which belies the assertion that the master pleadings were not intended to consolidate "**for any purpose**" the various claims of the individual Plaintiffs.

However, the Court believes that the merger doctrine is ultimately founded on the common-sense principle that if a party elects to waive an individual right, the party may do so. It is hornbook law that the waiver of a fundamental right must be knowing and intelligent, *Miranda v. Arizona*, 384 U.S. 436, 492 (1966), and the contractual waiver of a right must be knowing and voluntary, *Brookhart v. Janis*, 384 U.S. 1, 4-5 (1966). Thus, the *Bell* court "urge[d] district judges and MDL plaintiffs to indicate clearly whether a consolidated MDL complaint is to be treated as the operative pleading for purposes of judgment and appeal." *Bell*, 982 F.3d at 490. When the Court considers both the usage of Short Form Complaints in Pretrial Order # 31 and the Plaintiffs' express disavowal of the merger doctrine in their master pleadings, the Court concludes that there is room for doubt in this MDL as to the intent of the Plaintiffs to preserve their individual appellate rights. This doubt was not present in *Bell* and *Refrigerant*, as neither case utilized Short Form Complaints nor had an express disavowal of merger in the master pleadings.

The Court is therefore presented with the situation where the objective actions of the parties and the Court favor the application of the merger doctrine, but certain procedures (in the form of the Short Form Complaints) and subjective disclaimers by the Plaintiffs do not necessarily favor the application of the merger doctrine. In perfect hindsight, the undersigned, like other MDL judges who have entered agreed-upon pretrial orders,[15] wishes that she had a better appreciation of the significance of the language in Pretrial Order # 31 and the governing law as to the merger doctrine at the time the pretrial order was entered. The Court resolves this situation by concluding that, in the presence of doubt and the general presumption against a finding of waiver of individual rights, the Court should not find that any right to appeal was waived by a Plaintiff and, instead, the "default rule" applies. *Id.* at 489 ("The default rule is that separate actions transferred for . . . pretrial proceedings retain their separate identities, especially for purposes of entering final judgments and pursuing appeals."). As a result, the merger doctrine discussed in the *Gelboim* footnote does not apply to this MDL. The Court therefore analyzes the parties' Motions from the perspective that each individual Plaintiff in this MDL has not waived his or her right to appeal through the usage of the master pleadings.

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[15] "And to be candid, this Court did not adequately scrutinize lead counsel's proposal – the motion was unopposed at the time, and the Court was not very familiar with the nuances of MDL proceedings." *In re Roundup*, No. 16-MD-02741, 2021 WL 3161590, at *2 (N.D. Cal. June 22, 2021).

D. Rule 58 Final Judgment and the Generic-Only Cases

Under Rule 58, a Court must enter final judgment when all of the relief that a plaintiff seeks has been denied and, as set forth in Pretrial Order # 31, the Plaintiffs' master pleadings were to be the operative pleadings to determine whether they were entitled to relief as a matter of law. As to those master pleadings, the Court denied all relief against the Generic. Through that denial, the Plaintiffs are at least facially entitled to the entry of a Rule 58 final judgments in Generic-Only individual cases, but Pretrial Order # 31 clarifies that the master pleadings are not the *only* operative pleadings. Another operative pleading exists in the form of the Plaintiffs' Short Form Complaints, filed in their individual cases. True, Short Form Complaints choose which portions of the master complaints are incorporated into the individual cases and, through that incorporation, the Court's orders of dismissal of the master pleadings apply with full force to the individual cases and individual Plaintiffs. But it is also true that Pretrial Order # 31 permitted the Plaintiffs to bring claims not pled in the master complaints in their Short Form Complaints, and it is equally true that the deadline for the individual Plaintiffs to amend their Short Form Complaints has not passed.[16] As a result, the Court's orders of dismissal of the master complaints

[16] Under Pretrial Order # 31, the Plaintiffs possess the unilateral authority to amend their Short Form Complaints at any time, and there is no deadline for the Plaintiffs to exercise that authority.

did not necessarily deny all relief sought in the individual Short Form Complaints and individual cases—an individual Plaintiff could, in theory, bring other claims in the Short Form Complaint or could exercise his or her right to amend and incorporate a previously un-pled claim (such as a claim against a Brand Defendant) that was not dismissed by the Court's orders of dismissal.

An opportunity to amend, however, can be waived. Waiver occurs when a Plaintiff foregoes the opportunity to amend and proceeds directly to appeal. *E.g.*, *Van Poyck v. Singletary*, 11 F.3d 146, 148 (11th Cir. 1994). Once a plaintiff elects to appeal in lieu of amendment, the plaintiff waives the right to amend his or her pleading at a later time. *Briehler v. City of Miami*, 926 F.2d 1001, 1003 (11th Cir. 1991). Here, in some of the Generic-Only cases,[17] the Plaintiffs have filed notices of appeal and in some of the Generic-Only cases,[18] the Plaintiffs have not.

In Generic-Only cases where the Plaintiffs have declined to amend their Short Form Complaints and have instead proceeded directly to appeal, the standard for Rule 58 is met and the Court will enter Rule 58 final judgment. In Generic-Only cases where the Plaintiffs have not filed a notice of appeal, however, there is still a theoretical possibility that the individual Plaintiff could obtain relief in this MDL. The Court will not enter Rule 58 judgment in those cases until such time

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[17] 21-CV-80201; *see* 20-MD-2924, DE 3921.

[18] 21-CV-81169.

as it is clear (1) that all of the relief sought in the Short Form Complaint was addressed in the Court's orders of dismissal on the master complaints, and (2) that the Plaintiff foregoes the right to amend the Short Form Complaint. The Court leaves to the Plaintiffs' discretion how the foregoing may be accomplished, such as through a stipulation.

The Court now addresses the Mixed-Generic cases, cases involving the Retailers, and the parties' dispute about the applicability of Rule 54(b) to the Court's prior orders of dismissal. The Court therefore summarizes Rule 54(b) and federal law interpreting the same.

E. Rule 54(b) and Applicable Legal Standards

Federal Rule of Civil Procedure 54(b) provides:

> When more than one claim for relief is presented in an action, . . . or when multiple parties are involved, the [district] court may direct the entry of a final judgment as to one or more but fewer than all of the claims or parties only upon an express determination that there is no just reason for delay and upon an express direction for the entry of judgment.

The Rule provides an exception to the general principle that a final judgment is proper only after the rights and liabilities of all the parties to the action have been adjudicated. *Hogan v. Consol. Rail Corp.*, 961 F.2d 1021, 1024-25 (2d Cir. 1992).

"A district court must follow a two-step analysis in determining whether a partial final judgment may properly be certified under Rule 54(b)." *Lloyd Noland Found., Inc. v. Tenet Health Care Corp.*, 483 F.3d 773, 777 (11th Cir. 2007). "First, the court must determine that its final judgment is, in fact, both 'final' and a 'judgment.'" *Id.* "That is, the court's decision must be 'final' in the sense that it is an ultimate disposition of an individual claim entered in the course of a multiple claims action, and a 'judgment' in the sense that it is a decision upon a cognizable claim for relief." *Id.* (quotation marks omitted). "Second, having found that the decision was a final judgment, the district court must then determine that there is no 'just reason for delay' in certifying it as final and immediately appealable." *Id.* (quotation marks omitted). This question requires the district court to balance judicial administrative interests and relevant equitable concerns. *See id.* When weighing judicial administrative interests, courts may consider any judicial advantage that might be served through entry of judgment. *In re Fontainebleau Las Vegas Cont. Litig.*, No. 09-MD-2106, 2011 WL 13115470, at *3 (S.D. Fla. Jan. 13, 2011). Consideration of judicial administrative interests is necessary to ensure that application of the Rule effectively "preserves the historic federal policy against piecemeal appeals." *Sears, Roebuck & Co. v. Mackey*, 351 U.S. 427, 438 (1956). As for the second factor—consideration of equitable concerns—such a consideration is necessary to limit Rule 54(b) certification to instances in which immediate appeal would alleviate some danger of hardship or

injustice associated with delay. *Se. Banking Corp. v. Bassett*, 69 F.3d 1539, 1547 n.2 (11th Cir. 1995).

Rule 54(b) certifications "must be reserved for the unusual case in which the costs and risks of multiplying the number of proceedings and of overcrowding the appellate docket are outbalanced by pressing needs of the litigants for an early and separate judgment as to some claims or parties." *Morrison-Knudsen Co. v. Archer*, 655 F.2d 962, 965 (9th Cir. 1981). Recognizing that such circumstances will be encountered only rarely, the Eleventh Circuit has counseled district courts to exercise the limited discretion afforded by Rule 54(b) conservatively. *Se. Banking*, 69 F.3d at 1550; *see also Ebrahimi v. Huntsville Bd. of Educ.*, 114 F.3d 162, 165-66 (11th Cir. 1997) (collecting the cases cited above and below).

A district court's Rule 54(b) certification is not conclusive on an appellate court. *Se. Banking*, 69 F.3d at 1546. To the contrary, courts of appeals must review such determinations to ensure that they fit within the scope of the rule. *Id.* Consequently, although the decision to certify is committed to the sound judicial discretion of the district court, an appellate court must review the conclusion that there is "no just reason for delay" in the interest of sound judicial administration. *Curtiss-Wright Corp. v. Gen. Elec. Co.*, 446 U.S. 1, 10 (1980). The abuse of discretion standard reflects a recognition that "the task of weighing and balancing the contending factors is peculiarly one for the trial judge, who can explore all the facets of a case." *Id.* at 12.

When, after considering, the relevant factors, a district court is persuaded that Rule 54(b) certification is appropriate, the court should support that conclusion by clearly and cogently articulating its reasoning, together with the supporting factual and legal determinations. *Se. Banking*, 69 F.3d at 1546. The expression of clear and cogent findings of fact is crucial because it not only facilitates appellate review of a Rule 54(b) certification, but also assists the district court itself in analyzing the interrelatedness of the claims and the equities of the situation. *Id.*

F. The Court's Analysis and Conclusion as to the Generics' Request under Rule 54(b)

A concern for courts overseeing MDLs is the possibility that, upon remand, the court's various rulings will be appealed in piecemeal fashion to appellate courts across the federal judicial system. This precise concern is the reason that courts have entered Rule 54(b) judgments in MDLs, such as in the case of *In re: Fontainebleau Las Vegas Contract Litigation*.

In *Las Vegas Contract*, the district court faced a procedural question similar to the instant case. After a partial summary judgment ruling adverse to the plaintiffs, a bankruptcy trustee voluntarily dismissed certain claims in order to render the partial summary judgment ruling final and appealable. 2011 WL 13115470, at *2.[19] As a result of the dismissals, the

[19] The procedural posture of *Las Vegas Contract* is similar to the instant case insofar as the Plaintiffs have, during the course

court entered a Rule 58 final judgment, thereby permitting the trustee to appeal the summary judgment ruling. *Id.* Remaining in the MDL, however, were parties with a vested interest in the results of the appeal—the appeal by the trustee would resolve rulings on legal issues that were identical to the issues remaining in the active MDL. *Id.* at *3.

The district court decided in favor of entering Rule 54(b) judgment so that the active defendants in the MDL affected by the same ruling on appeal could join the appeal. *Id.* at *4. The court reasoned that if the Eleventh Circuit wanted to resolve the trustee's appeal at such time as the MDL concluded, the Eleventh Circuit do so, but by granting Rule 54(b) judgment, the district court would afford the Eleventh Circuit the option to rule upon the issue as soon as possible, should it elect to do so. *Id.* The district court further reasoned that by giving the Eleventh Circuit the option to resolve certain legal questions with all of the parties before it, the possibility of duplicative, piecemeal appeals was foreclosed—a primary purpose of Rule 54(b) certification. *Id.* In reaching its decision, the district court emphasized that the purpose of an MDL was to centralize proceedings and eliminate duplicative and inconsistent rulings. *Id.* Were the *Las Vegas Contract* district court to deny Rule 54(b) judgment, the legal

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of this MDL, also sought to perfect appeals through voluntary dismissals of claims subsequent to the Court's partially dispositive rulings. *E.g.*, 20-CV-80512, DE 12, 13, 14. In the event those appeals were properly taken then the possibility exists that, like *Las Vegas Contract*, not all of the cases impacted by the Court's legal rulings would be before the Eleventh Circuit.

rulings of the district court would have been disseminated to multiple circuits across the United States, thereby leading to the possibility of inconsistent rulings. *Id.* Concluding that such a result would be contrary to the goal and purposes of an MDL, the district court granted Rule 54(b) judgment. *Id.* at *5. The Eleventh Circuit accepted the Rule 54(b) certification[20] and affirmed the district court's decision.

Applying *Las Vegas Contract* to the instant case, the Plaintiffs have already filed an appeal of an important, dispositive legal issue in this MDL—the Court's conclusion that the Plaintiffs' claims against the Generics were pre-empted by federal law. Also like *Las Vegas Contract*, the Court's ruling was completely dispositive for a small portion of the cases consolidated in the MDL. However, despite the Court's ruling applying equally to all of the cases against the Generics in this MDL, only a small number of the cases brought against the Generics are on appeal—a subset of the Generic-Only cases.[21] Just as in *Las Vegas Contract*, should this Court deny Rule 54(b) certification, there

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[20] The Court's review of the appellate docket did not uncover an appellate decision that directly addressed the propriety of the district court's certification; however, the Eleventh Circuit consolidated the Rule 54(b) appeals with the Rule 58 appeal and affirmed the district court's summary judgment decision on the merits as to all of the appellants. *Ave. Clo Fund Ltd. v. Bank of Am., NA*, 709 F.3d 1072 (2013).

[21] While there are approximately fifty individual cases on appeal, there are likely over one thousand cases in the MDL in which Generics as well as some other Defendant are named in the case.

is a possibility that eventually the parties could receive different, inconsistent rulings on federal pre-emption in every circuit court in the United States. The Fourth Circuit Court of Appeals addressed such a problem in *In re Food Lion, Inc.*, 73 F.3d 528 (1996).

In *Food Lion*, an MDL court dismissed approximately half of the cases in the MDL at summary judgment. *Id.* at 530-31. Toward the conclusion of the MDL, the cases were remanded to the transferor courts. *Id.* at 531. Upon remand, some of the dismissed plaintiffs filed appeals of their dismissal. *Id.* The Fourth Circuit declined to consider the merits of the dismissal, and instead held that any consideration of the merits would frustrate the very purpose of an MDL:

> [I]t would be improper to permit a transferor judge to overturn orders of a transferee judge even though error in the latter might result in reversal of the final judgment of the transferor court. If transferor judges were permitted to upset rulings of transferee judges, the result would be an undermining of the purposes and usefulness of transfer under Section 1407 for coordinated or consolidated pretrial proceedings because those proceedings would then lack the finality (at the trial court level) requisite to the convenience of witnesses and parties and the efficient conduct of actions.

Id. (citing Weigle, S.A., The Judicial Panel on Multidistrict Litigation, Transferor Courts and Transferee Courts, 78 F.R.D. 575, 577 (1977)). The Fourth Circuit

held that, prior to remand, the dismissed defendants *should* have moved for Rule 54(b) certification in the MDL so that all of the dismissals could be heard by a single appellate court. *Id.* at 533. The Fourth Circuit transferred the cases back to the MDL district so that the plaintiffs could seek a Rule 54(b) certification. *Id.* The *Food Lion* court's reasoning applies with equal force in MDLs involving pharmaceuticals, such as *In re Fosamax*, 751 F.3d 150 (3d Cir. 2014).

In *Fosamax*, the district court dismissed claims against a generic drug manufacturer as pre-empted pursuant to the Supreme Court's decision in *Mensing*, much like the instant case. *Id.* at 155. The *Fosamax* MDL continued against the brand manufacturer, also like the instant case. *Id.* The plaintiffs appealed the district court's partial dismissal. *Id.* On appeal, the Third Circuit held that the plaintiffs should have sought a Rule 54(b) certification. *Id.* at 156. The plaintiffs thereafter sought and received a Rule 54(b) certification from the district court, and the Third Circuit proceeded to rule upon the merits of the district court's dismissal. *Id.*

In light of the possibility that, barring Rule 54(b) certification, there could be piecemeal, inconsistent appeals stemming from the Court's rulings on federal pre-emption, the instant case is similar to *Fosamax, Food Lion*, and *Las Vegas Contract*. The Plaintiffs have not made an argument that the foregoing cases are

distinguishable or are otherwise unpersuasive.[22] Just as a Rule 54(b) certification was appropriate in those cases, certification is appropriate here. The only question is *when* and *where*. As for when, should a 54(b) judgment be entered prior to the resolution of the claims brought against the Brands, who face claims very similar to the claims brought against the Generics? As for where, should Rule 54(b) final judgment be entered on the MDL docket or should it be entered in individual cases?

Addressing "when," the Court concludes that its rulings on federal pre-emption as to the Generics, Brands, and Retailers are of such great importance that the entry of partial judgment should not be delayed, even though other claims remain pending in this MDL. All of the parties affected by the Court's federal pre-emption rulings—not just a subset of the Generics—should have the opportunity to argue the propriety of that ruling in a single, binding appellate forum, consistent with the purpose of centralized MDL proceedings.

Addressing "where," the Court believes that it makes administrative sense to docket a single Rule 54(b) final judgment on the MDL docket, and believes that it is administratively unnecessary to docket more than one thousand separate Rule 54(b) judgments in the individual cases. In reaching this conclusion, the

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[22] Despite the Generics' reliance upon *Fosamax, Food Lion*, and *Las Vegas Contract* in their Motion, the Plaintiffs' Response does not cite or discuss the cases.

Court notes that the Plaintiffs filed their individual notices of appeal on the main MDL docket,[23] and that the active cases for which the judgment is intended remain consolidated in the MDL. Should any party disagree and seek the entry of over one thousand separate Rule 54(b) judgments, that party may move for the same and explain why it is administratively necessary to do so.

Finally, notwithstanding the Court's conclusion that the Brands would be entitled to Rule 54(b) judgment for claims dismissed with prejudice on federal pre-emption grounds,[24] the Brands have not yet moved for the same. Therefore, at this time the Court will not enter a Rule 54(b) judgment in favor of the Brands.

G. The Court's Analysis and Conclusion as to the Retailers' Motion

The Retailers request the entry of Rule 54(b) judgments in every individual case in the MDL where they are named as Defendants in a Short Form Complaint. The Court first addresses the Plaintiffs' general negligence claims against the Retailers and then turns to the Plaintiffs' other, non-negligence claims.

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[23] *E.g.*, DEs 3921-23, 26-29.

[24] Not every ruling on federal pre-emption as to the Generics and Retailers applied to the Brands, but many did, such as the Court's conclusions on the Plaintiffs' misbranding theory.

The Plaintiffs' General Negligence Claims Against the Retailers

The Retailers' request for entry of Rule 54(b) judgments as to the Plaintiffs' general negligence claims fails under the first prong of a Rule 54(b) analysis, wherein the Court must determine that it has rendered a final decision. *Lloyd Noland Found.*, 483 F.3d at 777. The Court has not done so. As the Court has already explained above in Section (A), the Court has not entered a final decision on the Plaintiffs' general negligence claims against the Retailers. True, there are no pending claims against the Retailers in any operative *master* pleading in this MDL, but that is because the Court previously dismissed without leave to amend the Plaintiffs' attempt to plead negligence claims against the Retailers without any supporting, concrete allegations of negligence by a particular Defendant.[25] DE 3716. Labeling the claims as "global" claims (for seeking to impose liability on all Retailers, for all sales of ranitidine, for all time), the Court dismissed the claims as implausibly pled due to the lack of supporting factual allegations and analogized the Plaintiffs' negligence claims to medical malpractice claims:

> The Plaintiffs sought to impose *global* MDL liability on the Defendants without any concrete, particularized, or individualized

[25] Prior to the Court's decision at docket entry 3716, the individual Plaintiffs would not have been on notice of the need to plead individualized negligence claims in their Short Form Complaints.

> allegation of negligence. The Court's dismissal rejected this global theory. Such a theory would be akin to Plaintiffs alleging medical malpractice claims against thousands of doctors who prescribed ranitidine. As with negligence claims, medical malpractice claims are highly individualized, highly case-specific claims that do not necessarily lend themselves easily to resolution in an MDL setting. The Court's dismissal of medical malpractice claims from a master pleading (just as the dismissal of Plaintiffs' negligence claims without leave to amend) would not preclude the individual Plaintiffs from *ever* bringing a medical malpractice claim—they simply could not press such a claim in the MDL.

DE 3913 at 3. The type of negligence claim that the Plaintiffs might be able to plead would, like a medical malpractice claim, be necessarily case-specific and Plaintiff-specific. As discussed by the Plaintiffs at the hearing on the first round of motions to dismiss:

> Thus, it is the Plaintiffs' contention that the Defendants should be held liable under state law because the Defendants should have used "cooled storage and transport." At the Hearing, the Court inquired about this allegation. . . . The Plaintiffs also responded by explaining that they believed a Defendant could be held liable for overheating a drug in its possession, such as "le[aving] Ranitidine on a hot truck in the Arizona desert during the summer for extensive periods of time

> creating temperature ranges that vastly exceeded those on the label."

DE 2513 at 35 (citations omitted). If a Plaintiff has a good faith basis to plead a "hot truck in the Arizona desert" negligence claim based upon the particulars of an individual Plaintiff's factual allegations, the Court previously explained that such a claim (like a medical malpractice claim) does not easily lend itself to adjudication in an MDL setting. Instead, the question of whether an individual Plaintiff has pled an individualized, case-specific negligence claim would ordinarily be resolved by a judge upon remand that can give individual cases individual attention:

> Upon remand, the individual Plaintiffs should have the option to seek through amendment a negligence claim on case-specific facts, provided an individual Plaintiff has a factual basis to do so. That is a matter for the judge upon remand, and in light of the fact that the Court has not dismissed any individual case, the Court declines to enter a final order of dismissal in individual cases as to claims against Retailer and Distributor Defendants.

DE 3913 at 4.

At present, the Court has not decided precisely when and how[26] individualized negligence claims against Retailers could be remanded, but the Retailers have requested clarification from the Court on this

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[26] The Court notes that it possesses the power to sever individualized negligence claims from this MDL pursuant to Rule 21.

issue. DE 4177 at 10 ("[C]larification from the Court about the intended effect of its suggestion that individual Plaintiffs may later re-file individualized negligence claims against the Distributors and Retailers would benefit all parties and promote the efficiencies that this MDL, like all MDLs, was created to accomplish."). Although the Court will not reach a final determination on this subject until the parties have had a chance to brief and argue the same, the Court provides clarification as follows.

Because the Court will not permit the Plaintiffs to bring a global negligence claim in the master complaints that is devoid of individualized allegations of negligence, the only operative pleading in this MDL for an individualized negligence claim to be pled is the Short Form Complaint, as discussed above in Sections (A), (C), and (D). Yet no Short Form Complaint, at this time, contains any individualized allegations of negligence.[27] And while the Court has noted that individualized negligence claims do not "easily" lend themselves to adjudication in an MDL setting, the Court will entertain discussion at a future status conference on how individualized negligence claims should be addressed in this MDL in light of this Court's

[27] The Retailers have represented that no Short Form Complaint contains an individualized claim of general negligence. *See* DE 4177 at 10 ("No individualized negligence claims are currently asserted against the Distributors or Retailers in this MDL."). The Court has not undertaken an independent review to verify the Retailers' representation.

mandate to complete pretrial proceedings. 28 U.S.C. § 1407.

At the forthcoming status conference, the Court has a number of questions that the parties may address on this topic. For example: Should the individual Plaintiffs plead an individualized negligence claim in their Short Form Complaint by a date certain? Such a claim has yet to be seen by this Court—a claim wherein an individual Plaintiff alleges that his or her cancer was proximately caused by a specific delivery truck or a specific warehouse utilizing temperatures that "vastly exceeded" the ranitidine label.[28] It may be that, once such claims are pled, the Court can decide whether case-specific negligence claims *can* be addressed in this MDL prior to remand through the same pretrial proceedings applicable to master complaints. As the Court previously explained:

> The Court does not mean to suggest that this MDL is no longer relevant to the negligence claims against the Retailer and Distributor Defendants. For example, the Court will adjudicate a common issue that is highly relevant to the Plaintiffs' negligence claims—general causation. If the Plaintiffs lose on general causation, they will necessarily lose on every claim, including any individualized negligence claim. Similarly, the Court's *Daubert* rulings may limit the number of cancers that

[28] Throughout the entirety of this MDL the Plaintiffs have represented to the Court that they have a good-faith basis to plead such claims.

> an individual Plaintiff may bring. Should only a subset of cancers survive *Daubert*, only some of the individual Plaintiffs could litigate an individualized negligence claim. Should the Plaintiffs survive the Defendants' *Daubert* challenges, then, at the proper time, an individual Plaintiff may seek to pursue his or her individualized negligence claim against a Retailer or Distributor Defendant. They simply cannot do so now for all of the reasons set forth in the Court's orders of dismissal.

Id. at 4-5.

In summary, the master complaints are not a procedural vehicle for individual Plaintiffs' individual allegations of negligence. The Court will hear from the parties at a forthcoming status conference whether individualized negligence claims should be pled in the Short Form Complaints, whether the Court should utilize a case management procedure to address individualized negligence claims, and how and when, if at all, the claims should be remanded. As for the Retailers' request for Rule 54(b) judgment on the Plaintiffs' negligence claims, the request is denied.

All Other Claims Brought Against the Retailers

In the Plaintiffs' initial master pleadings, the Retailers faced many claims besides negligence. By way of example, the Plaintiffs brought a strict liability failure to warn claim against the Retailers. DE 887 at 105.

The Court dismissed almost all[29] of the Plaintiffs' non-negligence claims with prejudice, utilizing a similar federal pre-emption analysis that the Court applied to the claims brought against the Generics. DE 2513. Therefore, for the same reason the Generics are entitled to a Rule 54(b) judgment—to avoid piecemeal appeals of the Court's prior rulings on federal pre-emption—the Retailers are also entitled to a Rule 54(b) judgment. Stated another way, because the Court's entry of Rule 58 judgments in favor of the Generics will permit the Plaintiffs to raise an issue on appeal that implicates the Court's pre-emption rulings as to the Retailers, the Retailers are granted Rule 54(b) judgment so that they may join and be heard in the appeal.

H. The Court's Entry of Judgment

For the reasons set forth above, the Court will enter Rule 58 judgments in Generic-Only cases with a notice of appeal. The Court will also enter Rule 54(b) partial final judgment as to the Generics and the Retailers on the main MDL docket. The Court clarifies its intent in entering Rule 54(b) judgment on three points. First, it is the Court's intent to perfect any appeal that the Plaintiffs may seek to bring against the Generics flowing from the Court's rulings on the master complaints. Second, it is the Court's intent to perfect any appeal that the Plaintiffs may seek to bring against

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[29] The Court dismissed certain derivative claims (such as loss of consortium) without prejudice. DE 2513 at 44.

the Retailers for claims the Court dismissed with prejudice, but the Court does not certify for 54(b) judgment the Plaintiffs' general negligence count against the Retailers. Third and finally, the Court does not certify any ruling specific to the class complaints because (1) it appears that no party has sought such a certification,[30] (2) the class complaints remain pending, and (3) any appellate ruling on conflict pre-emption or obstacle pre-emption in the context of the personal injury complaints would necessarily have the same effect in the context of the class action complaints.

Having clarified its intent, the Court will enter Rule 54(b) judgment as follows:

The Generics

The Court will enter Rule 54(b) judgment as to the Generics for all claims dismissed with prejudice from the master personal injury complaints.

The Retailers

As to the original Master Personal Injury Complaint at docket entry 887, the Court will enter Rule 54(b) final judgment as to the Retailers for Counts I though VI, and Counts VIII through XII, which the Court dismissed with prejudice on conflict pre-emption grounds at docket entry 2513.

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[30] *E.g.*, DE 3904 at 3 (Plaintiffs stating: "[T]he instant Motion is not about the class action complaints in this MDL.").

The Court addresses one final matter. A primary basis for the Plaintiffs' objection to Rule 54(b) judgment is that the entry of the judgment would require them to pay excessive appellate filing fees. If the Plaintiffs are correct, that is a ramification that flows from the way the Plaintiffs have prosecuted their appeals. First, the Plaintiffs have taken the position that, master pleadings notwithstanding, each individual case in this MDL has retained its full identity and corresponding appellate rights; were the Plaintiffs to adopt the opposite position and conclude that the more efficient merger doctrine applies, there would be no need to take many appeals from many individual cases. Second, the Plaintiffs have elected to take appeals and seek Rule 58 final judgments in only a very few, select cases. For the reasons set forth in this Order, the Plaintiffs' decision to seek individual appeals in this manner is the **reason** the Defendants are entitled to Rule 54(b) judgment; had the Plaintiffs sought to appeal through another avenue—such as through a 28 U.S.C. § 1292(b) interlocutory appeal—there would be no need to take many appeals from many individual cases.

In summary, the Plaintiffs' appellate filing fees are not grounds to deny the Defendants what they are entitled to—a Rule 54(b) judgment—particularly when the fees flow from the Plaintiffs' unilateral decisions. Even so, the Court stands ready to issue any order that the Plaintiffs may identify as a valid option to reduce or eliminate filing fees, such as the procedural avenues identified by the Generics at docket entry 4149.

For the foregoing reasons, it is **ORDERED AND ADJUDGED** that the Distributor, Retailer, and Pharmacy Defendants' Motion for Entry of Final Judgment in all Cases Naming Distributor, Retailer, and Pharmacy Defendants [3934] is **GRANTED IN PART AND DENIED IN PART** and the Generic Manufacturer's Motion for Entry of Final Judgment in Mixed-Defendant Cases [3933] is **GRANTED IN PART AND DENIED IN PART** as more fully set forth in this Order.

The parties shall confer and submit joint proposed final judgments that conforms to the Court's rulings herein. The proposed final judgment shall be sent to zantac_mdl@flsd.uscourts.gov in Microsoft Word format and shall be due within four (4) business days of the date of rendition of this Order.

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 1st day of November, 2021.

/s/ Robin L. Rosenberg
ROBIN L. ROSENBERG
UNITED STATES
DISTRICT JUDGE

Copies furnished to: Counsel of Record

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**

THIS DOCUMENT RELATES TO:
20-cv-80512-RLR
20-cv-81891-RLR

ORDER DECONSOLIDATING CASES

(Filed Mar. 17, 2021)

This matter comes before the Court on the Notices of Voluntary Dismissal filed for the above-referenced cases. In light of the fact that these cases have been dismissed, it is **ORDERED AND ADJUDGED** that:

1. The above-reference cases are **DECONSOLIDATED** from MDL proceeding 20-MD-2924.
2. The above-reference cases shall remain **CLOSED**.

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 17th day of March, 2021.

/s/ Robin L. Rosenberg
ROBIN L. ROSENBERG
UNITED STATES
DISTRICT JUDGE

UNITED STATES DISTRICT COURT
FOR THE 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**

ORDER GRANTING BRANDED DEFENDANTS' RULE 12 PARTIAL MOTION TO DISMISS PLAINTIFFS' THREE COMPLAINTS AS PREEMPTED BY FEDERAL LAW

(Filed Jan. 8, 2021)

This matter is before the Court on the Branded Defendants' ("Defendants") Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law ("Motion to Dismiss"). DE 1580. The Court held a hearing on the Motion to Dismiss on December 15, 2020 ("the Hearing"). *See* DE 2499. The Court has carefully considered the Motion to Dismiss, the Plaintiffs' Response [1976], the Defendants' Reply [DE 2134], the Plaintiffs' Notice of Supplemental Authority [DE 2159], the arguments that the parties made during the Hearing, and the record and is otherwise fully advised in the premises. For the reasons set forth below, the Motion to Dismiss is **GRANTED**.

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 1980's, 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. MPIC ¶¶ 226, 231, 432. GlaxoSmithKline ("GSK") first developed and patented Zantac. *Id.* ¶ 230. Zantac was a blockbuster—the first prescription drug in history to reach $1 billion in sales. ¶ 231.

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

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[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 Master Personal Injury Complaint ("MPIC"), the Consolidated Consumer Class Action Complaint ("CCCAC"), and the Consolidated Third Party Payor Class Complaint ("CTPPCC") (collectively "Master Complaints"). DE 887, 888, 889.

GSK retaining control over the sale of prescription Zantac in the United States. *Id.* ¶ 234. Pfizer acquired Warner-Lambert in 2000 and took control of the sale of OTC Zantac in the United States. *Id.* ¶ 235. The right to sell OTC Zantac in the United States later passed to Boehringer Ingelheim Pharmaceuticals and then to Sanofi. *Id.* ¶¶ 239-40, 242-44. 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.* ¶¶ 249-51.

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.* ¶¶ 253, 321, 324, 331. Studies have shown that these compounds increase the risk of cancer in humans and animals. *Id.* ¶¶ 253, 264-72. The FDA, the Environmental Protection Agency, and the International Agency for Research on Cancer consider NDMA to be a probable human carcinogen. *Id.* ¶¶ 254, 258. The FDA has set the acceptable daily intake level for NDMA at 96 nanograms. *Id.* ¶¶ 4, 263.

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.* ¶ 285. The FDA issued a statement on September 13 warning that some ranitidine products may contain NDMA. *Id.* ¶ 286. On November 1, the FDA announced that testing had revealed the presence of NDMA in

ranitidine products. *Id.* ¶ 296. The FDA recommended that drug manufacturers recall ranitidine products with NDMA levels above the acceptable daily intake level. *Id.* Six months later, on April 1, 2020, the FDA requested the voluntary withdrawal of all ranitidine products from the market. *Id.* ¶ 301.

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, hundreds of 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 thousands of claimants who have not filed lawsuits have registered their claims. *See* DE 547.

Plaintiffs filed three Master Complaints on June 22, 2020. DE 887, 888, 889. Plaintiffs contend 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. MPIC ¶¶ 1, 6, 19. Plaintiffs allege 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. Plaintiffs are pursuing federal claims and state claims under the laws of all 50 U.S. states, Puerto Rico, and the District of Columbia. *See generally* CCCAC. The entities named as defendants are alleged to have designed, manufactured, tested, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine products. MPIC ¶¶ 20, 225.

The Court has entered numerous Pretrial Orders to assist in the management of this MDL. In Pretrial Order # 30, the Court set a case management schedule that is intended to prepare the MDL for the filing of *Daubert* motions on general causation and class certification motions in December 2021. DE 875; *see generally Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). In Pretrial Order # 36, the Court set a schedule for the filing and briefing of motions to dismiss under Federal Rule of Civil Procedure 12 directed to the Master Complaints. DE 1346. Defendants filed the instant Motion to Dismiss pursuant to that schedule.

III. The Master Complaints

A. Master Personal Injury Complaint

All individuals who file a Short Form Complaint (collectively, the "MPIC Plaintiffs") adopt the MPIC.

MPIC at 2.[2] The MPIC Plaintiffs allege that they developed cancers from taking ranitidine products. *Id.* at 1. The MPIC "sets forth allegations of fact and law common to the personal-injury claims" within the MDL. *Id.* at 1. Each MPIC Plaintiff individually seeks compensatory damages, punitive damages, restitution, and all other available remedies. *Id.* at 1-2.

The defendants named in the MPIC (collectively, the "MPIC Defendants") are entities that "designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine." *Id.* ¶ 20. They are categorized by the MPIC Plaintiffs into five groups: (1) Brand-Name Manufacturer Defendants; (2) Generic Manufacturer Defendants; (3) Distributor Defendants; (4) Retailer Defendants; and (5) Repackager Defendants. Some MPIC Defendants belong to multiple categories.[3] Within each category, the MPIC combines distinct corporate entities, including parents, subsidiaries, and affiliates, into single named MPIC

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[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, AmerisourceBergen is named as both a Generic Manufacturer Defendant and a Distributor Defendant. MPIC at 15 n.3.

Defendants.[4] Certain allegations apply to MPIC Defendants across multiple groups.[5]

The MPIC contains 15 counts: Strict Products Liability—Failure to Warn (Count I), Strict Products Liability—Design Defect (Count II), Strict Products Liability—Manufacturing Defect (Count III), Negligence—Failure to Warn (Count IV), Negligence Product Design (Count V), Negligent Manufacturing (Count VI), General Negligence (Count VII), Negligent Misrepresentation (Count VIII), Breach of Express Warranties (Count IX), Breach of Implied Warranties (Count X), Violation of Consumer Protection and Deceptive Trade Practices Laws (Count XI), Unjust Enrichment (Count XII), Loss of Consortium (Count XIII), Survival Actions (Count XIV), and Wrongful Death (Count XV). Counts I, II, IV, VII, IX, X, XI, XII, XIII, XIV and XV are brought against every MPIC Defendant. Counts V and VIII are brought against every Brand-Name Manufacturer, Generic Manufacturer and Repackager Defendant. Counts III and VI are brought against every Brand-Name Manufacturer and Generic Manufacturer Defendant.

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[4] For example, CCCAC Defendant "Sanofi" refers to five entities: Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., Sanofi S.A., Patheon Manufacturing Services LLC, and Boehringer Ingelheim Promeco, S.A. de C.V. MPIC ¶ 36.

[5] *See*, *e.g.*, MPIC ¶ 44 (allegations referring to Repackager Defendants apply to Ajanta, a Generic Manufacturer Defendant).

B. Consolidated Consumer Class Action Complaint

One hundred and eighty-three named individuals (collectively, the "CCCAC Plaintiffs") bring the CCCAC on behalf of themselves and all others similarly situated.[6] The CCCAC Plaintiffs are citizens of nearly every state, the District of Columbia, and Puerto Rico. There are no CCCAC Plaintiffs who reside in or purchased ranitidine products from Delaware, Hawaii, Kansas, Maine, North Dakota, Rhode Island, or South Dakota. Each CCCAC Plaintiff asserts that he or she purchased and/or used a ranitidine product during an approximate timeframe.

The CCCAC Plaintiffs bring the action in their individual capacities and on behalf of numerous classes pursuant to Rule 23. Among the various classes are two nationwide classes: (1) the "RICO Class," comprised of "[a]ll residents of the United States or its territories who purchased for personal, family, or household use any of Brand-Name Manufacturer Defendants' Ranitidine-Containing Products in the United States or its territories"; and (2) the "Nationwide Class," comprised of "[a]ll residents of the United States or its territories who purchased and/or used for personal, family, or household use, any of the Defendants' Ranitidine-Containing Products in the United States or its territories." CCCAC ¶ 734. The CCCAC

[6] The CCCAC originally had 238 named plaintiffs, but 55 were subsequently dismissed without prejudice. *See* Order Granting Plaintiffs' Unopposed Motion to Drop Certain Plaintiffs from Consolidated Consumer Class Action Complaint, DE 2241.

alleges that as an alternative, and/or in addition to, the Nationwide Class, the CCCAC Plaintiffs bring the action in their individual capacities and on behalf of "State Classes" for all fifty states, the District of Columbia, and Puerto Rico. *Id.* ¶ 737. Each State Class is comprised of "[a]ll residents of [State or Territory] who purchased and/or used for personal, family, or household use, any of the Defendants' Ranitidine-Containing Products in the United States or its territories." *Id.*

The defendants named in the CCCAC are entities that "invented, manufactured, distributed, labeled, marketed, advertised, . . . stored, and sold ranitidine." *Id.* ¶ 259. They are categorized by the CCCAC Plaintiffs into five groups: (1) Brand-Name Manufacturer Defendants; (2) Generic Manufacturer Defendants; (3) Distributor Defendants; (4) Retailer Defendants; and (5) Repackager Defendants (collectively, the "CCCAC Defendants"). Some CCCAC Defendants belong to multiple categories. Within each category, the CCCAC combines distinct corporate entities, including parents, subsidiaries, and affiliates, into single named CCCAC Defendants. Certain allegations apply to CCCAC Defendants across multiple groups.

The CCCAC alleges 314 counts against the CCCAC Defendants. The CCCAC Plaintiffs allege Count 1 (RICO) on behalf of the RICO Class against the Brand-Name Manufacturer Defendants. *Id.* ¶ 750. The CCCAC Plaintiffs allege Count 2 (unjust enrichment) and Count 3 (Magnuson-Moss Warranty Act) on behalf of the Nationwide Class against all CCCAC Defendants. *Id.* ¶¶ 795, 804. Alternatively, they bring

Count 2 "on behalf of themselves under the laws of the state in which each [CCCAC] Plaintiff resides and/or purchased Ranitidine-Containing Products, and on behalf of a Class comprised of members from each [CCCAC] Plaintiff's respective state." *Id.* ¶ 795. The CCCAC Plaintiffs allege Count 4 (fraud) on behalf of the Nationwide Class against the Brand-Name Manufacturer Defendants, the Generic Manufacturer Defendants, and the Repackager Defendants. *Id.* ¶ 823. Alternatively, they bring Count 4 "on behalf of themselves under the laws of the state in which each [CCCAC] Plaintiff resides and/or purchased Ranitidine-Containing Products, and on behalf of each State Class." *Id.* The CCCAC Plaintiffs allege Count 5 (negligence) and Count 6 (battery) on behalf of numerous State Classes against all CCCAC Defendants. *Id.* ¶¶ 839, 886. Finally, the CCCAC Plaintiffs allege Counts 7 through 314 (including breach of express and implied warranties; failure to warn; manufacturing defects; design defects; state consumer protection violations; deceptive trade practices; and medical monitoring) on behalf of the various State Classes against some or all of the CCCAC Defendants. *Id.* ¶¶ 906-5899.

C. Consolidated Third-Party Payor Class Complaint

The NECA-IBEW Welfare Trust Fund, the Plumbers & Pipefitters Local Union 630, and the Indiana Laborers Welfare Fund (collectively, the "CTPPCC Plaintiffs") bring the CTPPCC on behalf of themselves

and all others similarly situated. CTPPCC at 8. The CTPPCC Plaintiffs are entities that provide eligible members with health and welfare benefits, such as paying and reimbursing for prescription drugs on behalf of their members and dependents. Each CTPPCC Plaintiff's members have filled prescriptions requiring reimbursement for ranitidine products in several states.

The CTPPCC Plaintiffs bring the action on behalf of a "Nationwide TPP Class" comprised of:

> All health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third party payors and any other health benefit provider, in the United States of America and its territories, which paid or incurred costs for prescription Zantac or the Generic Manufacturer Defendants' Ranitidine-Containing Products for purposes other than resale since their respective approval dates.

Id. ¶ 506. As an alternative and/or in addition to the Nationwide TPP Class, the CTPPCC Plaintiffs bring the action in their individual capacities and on behalf of state classes for all fifty states, the District of Columbia, and Puerto Rico ("State CTPPCC Classes"). *Id.* ¶ 508. Each State CTPPCC Class is comprised of:

> All health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third party payors and any other health benefit provider, in the United States

> of America and its territories, which paid or incurred costs for prescription Zantac or the Generic Manufacturer Defendants' Ranitidine-Containing Products for purposes other than resale since their respective approval dates.

Id. The Nationwide TPP Class and the State CTPPCC Classes are collectively referred to in the CTPPCC as the "TPP Class" or "Classes." *Id.* ¶ 511.

The defendants named in the CTPPCC are companies that "invented, made, distributed, labeled, marketed, advertised, . . . stored, and sold ranitidine." *Id.* ¶ 29. They are categorized by the CTPPCC Plaintiffs into two groups: (1) Brand-Name Manufacturer Defendants, and (2) Generic Manufacturer Defendants (collectively, the "CTPPCC Defendants"). Within each category, the CTPPCC combines distinct corporate entities, including parents, subsidiaries, and affiliates, into single named CTPPCC Defendants.

The CTPPCC Plaintiffs allege nine counts against the CTPPCC Defendants: Count 1 (RICO); Count 2 (breach of express warranties); Count 3 (breach of implied warranties); Count 4 (Magnuson-Moss Warranty Act); Count 5 (fraud); Count 6 (negligent misrepresentation and omission); Count 7 (violations of state consumer protection laws); Count 8 (unjust enrichment); and Count 9 (negligence). The CTPPCC Plaintiffs allege Count 1 on behalf of the TPP Class against the Brand-Name Manufacturer Defendants. The CTPPCC Plaintiffs allege Counts 2-9 on behalf of the TPP Class

against GSK and the Generic Manufacturer Defendants.[7]

IV. Summary of the Parties' Arguments

The Defendants contend in the Motion to Dismiss that the design-defect claims against them are pre-empted because they could not change the design of ranitidine products without FDA approval while remaining in compliance with federal law. And, 21 U.S.C. § 379r expressly pre-empts the Plaintiffs' claims that seek to recover refunds for the purchase of OTC ranitidine products.

The Plaintiffs respond that none of their claims against the Defendants are pre-empted. Their design-defect claims are not pre-empted because the claims are based on ranitidine products that were misbranded when sold, on labeling defects that the Defendants could have remedied without FDA approval, and on GSK's failure to propose a different drug formulation and/or different labeling to the FDA when seeking the initial approval to market ranitidine products. Section 379r does not expressly pre-empt the Plaintiffs' claims that seek to recover refunds for the purchase of OTC ranitidine products.

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[7] The Generic Manufacturer, Repackager, Retailer, and Distributor Defendants also brought motions to dismiss based on pre-emption that the Court has ruled upon by separate Orders. *See* DE 2512; DE 2513. The Court refers to all defendants named in this MDL collectively as "named defendants."

V. Summary of the Court's Rulings

Design-defect claims based on the FDA-approved formulation of ranitidine products are pre-empted, regardless of the Plaintiffs' allegations that the products were misbranded. The Plaintiffs' claims against Defendants based on allegations of failure to make changes to the FDA-approved design that the Defendants could not have made independently while remaining in compliance with federal law are dismissed with prejudice as pre-empted. Because all of the design-defect counts in the Master Complaints incorporate such allegations, all of the design-defect counts against the Defendants are dismissed. The Court grants the Plaintiffs leave to replead design-defect claims that are based on labeling defects and to plead pre-approval design-defect claims. The Plaintiffs' claims that seek a refund and are not premised upon a personal injury to a plaintiff's person or property are not saved from express pre-emption under 21 U.S.C. § 379r(e).

VI. Standard of Review

Defendants move to dismiss some of the claims against them under Federal Rule of Civil Procedure 12(b)(6) based on the affirmative defense of federal pre-emption. *See* DE 1580 at 1; DE 2499 at 145; *see also PLIVA, Inc. v. Mensing*, 564 U.S. 604, 619 (2011) (describing federal pre-emption as a drug manufacturer's affirmative defense). A court may grant a motion to dismiss a pleading if the pleading fails to state a claim upon which relief can be granted. Fed. R. Civ. P.

12(b)(6). A court ruling on a motion to dismiss accepts the well-pled factual allegations as true and views the facts in the light most favorable to the plaintiff. *Jones v. Fransen*, 857 F.3d 843, 850 (11th Cir. 2017). But the court 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). A "complaint may be dismissed under Rule 12(b)(6) when its own allegations indicate the existence of an affirmative defense, so long as the defense clearly appears on the face of the complaint." *Quiller v. Barclays Am./Credit, Inc.*, 727 F.2d 1067, 1069 (11th Cir. 1984), *aff'd en banc*, 764 F.2d 1400 (11th Cir. 1985).

VII. Analysis

An understanding of the law that applies to drugs approved by the FDA is necessary to understand the arguments that the parties make in briefing the Motion to Dismiss. Before turning to the parties' arguments, the Court (A) discusses key statutes and regulations that govern the FDA's regulation of drugs. The Court next addresses impossibility pre-emption and significant cases that have addressed impossibility pre-emption in the drug context. The Court then turns to the issues raised in the briefing: (B) impossibility pre-emption for design-defect claims, and (C)

express pre-emption under 21 U.S.C. § 379r. For each issue, the Court reviews the arguments of the parties, any relevant allegations in the Master Complaints, and additional, issue-specific law before providing the Court's analysis and conclusion on the issue.

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); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 477 (2013) (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. . . .").

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* 21 C.F.R. §§ 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," and 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." *Id.* § 314.70(b)(2)(i), (iv), (v). 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, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 923 (6th Cir. 2014).

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).

4. 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.

a. *Wyeth v. Levine*

In *Wyeth v. Levine*, a consumer of a brand-name drug sued the brand-name drug manufacturer on

negligence and strict-liability theories under Vermont law for failure to provide an adequate warning on the drug's labeling. 555 U.S. 555, 559-60 (2009). The Supreme Court held that the consumer's labeling claims were not pre-empted because the CBE process permitted the brand-name drug manufacturer to "unilaterally strengthen" the warning on the labeling, without waiting for FDA approval. *Id.* at 56869, 571, 573. The Court stated that it could not conclude that it was impossible for the brand-name drug manufacturer to comply with both its federal-law and state-law duties "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.

b. *PLIVA, Inc. v. Mensing*

In *PLIVA, Inc. v. Mensing*, consumers of generic drugs sued the generic drug manufacturers under Minnesota and Louisiana tort law for failure to provide adequate warnings on the drugs' labeling. 564 U.S. at 610. The Supreme Court held that the consumers' labeling claims were pre-empted because the generic drug manufacturers could not "independently" change the labeling while remaining in compliance with federal law. *Id.* at 618-20, 623-24. The generic drug manufacturers' "duty of 'sameness'" under federal law required them to use labeling identical to the labeling of the equivalent brand-name drug. *Id.* at 613. Thus,

the CBE process was unavailable to the generic drug manufacturers to change labeling absent a change to the brand-name drug's labeling. *Id.* at 61415. Because any change that the generic drug manufacturers made to the drugs' labeling to comply with duties arising under state tort law would have violated federal law, the state tort claims were pre-empted. *Id.* at 618, 623-24.

The consumers argued, and the FDA asserted in an amicus brief, that even if the generic drug manufacturers could not have used the CBE process to change the labeling, the manufacturers could have "asked the FDA for help" by proposing a labeling change to the FDA. *Id.* at 616, 619. The consumers further argued that their state-law claims would not be pre-empted unless the generic drug manufacturers demonstrated that the FDA would have rejected a proposed labeling change. *Id.* at 620. The generic drug manufacturers conceded that they could have asked the FDA for help. *Id.* at 619.

The Supreme Court rejected the argument that the ability to ask the FDA for help defeated impossibility pre-emption. *Id.* at 620-21. The Court stated that the "question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Id.* at 620 (citing *Wyeth*, 555 U.S. at 573). "[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. Asking the FDA for

help "would have started a Mouse Trap game" that eventually may have led to a labeling change, "depending on the actions of the FDA and the brand-name manufacturer." *Id.* at 619-20. But, the Court stated, pre-emption analysis that was dependent on what a third party or the federal government might do would render impossibility pre-emption "all but meaningless." *Id.* at 620-21 ("If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force.").

c. *Mutual Pharmaceutical Co. v. Bartlett*

In *Mutual Pharmaceutical Co. v. Bartlett*, a consumer of a generic drug brought a design In *Mutual Pharmaceutical Co. v. Bartlett*, a consumer of a generic drug brought a design defect claim under New Hampshire law against a generic drug manufacturer for failure to ensure that the drug was reasonably safe. 570 U.S. at 475. Under New Hampshire law, a drug manufacturer could satisfy its duty to ensure that its drug was reasonably safe "either by changing a drug's design or by changing its labeling." *Id.* at 482, 492. However, because the generic drug manufacturer was unable to change the drug's composition "as a matter of both federal law and basic chemistry," the only way for the manufacturer to fulfill its state-law duty and "escape liability" was by changing the labeling. *Id.* at 475, 483-84 (citing 21 U.S.C. § 355(j) for the proposition that "the FDCA requires a generic drug to have the

same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based"). The Supreme Court concluded that, under *Mensing*, federal law prohibited the generic drug manufacturer "from taking the remedial action required to avoid liability" under state law, that is, changing the labeling, and therefore the consumer's design-defect claim was pre-empted. *Id.* at 475, 486-87 (citing *Mensing*, 564 U.S. 604).

The First Circuit Court of Appeals had ruled that the generic drug manufacturer could comply with both federal and state law by removing the drug from the market. *Id.* at 475, 479. The Supreme Court stated that this was "no solution" because adopting this "stop-selling rationale would render impossibility pre-emption a dead letter and work a revolution in th[e] Court's pre-emption case law." *Id.* at 475, 488-90 (rejecting the stop-selling rationale as "incompatible" with pre-emption jurisprudence because, 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 "presume[s] 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.

B. Impossibility Pre-emption and Design-Defect Claims

1. Arguments and Allegations

The Defendants seek dismissal of Counts II and V of the MPIC and of the 47 design-defect counts in the CCCAC listed in Appendix A to the Motion to Dismiss. DE 1580 at 27, 32-35. The Defendants argue that these design-defect claims are premised on the theory that they should have designed ranitidine products to be safer. *Id.* at 7-8, 22, 24-25. Such claims are pre-empted because the Defendants could not change the design of ranitidine products without FDA approval while remaining in compliance with federal law, and therefore it was impossible for them to independently fulfill any duties under state design-defect causes of action. *Id.* at 7-8, 22-27.

The Plaintiffs concede that the Defendants could not independently redesign the FDA-approved formulation of ranitidine products while remaining in compliance with federal law. DE 1976 at 16 (citing 21 C.F.R. § 314.70(b)(2)(i) for the proposition that "[c]hanging the formulation of an approved medication is a major change requiring FDA preapproval"). The Plaintiffs contend, however, that their design-defect claims should not be dismissed as pre-empted for two reasons. *Id.* at 7, 16. First, they have alleged in the Master Complaints that ranitidine products were "misbranded" as that term is defined in 21 U.S.C. § 352(a)(1) and (j). *Id.* at 20-21, 24. The U.S. Code prohibits the introduction of misbranded drugs into

interstate commerce. *Id.* at 11, 21. And state laws prohibit the sale of defectively designed drugs. *Id.* at 21. Therefore, because federal law and state laws "parallel" to prohibit the same action, the sale of drugs that are misbranded and dangerous, there is no conflict between federal and state law and no impossibility in complying with both federal and state law. *Id.* at 17, 21-23. The Defendants can be held liable under state design-defect causes of action for failing to stop selling misbranded ranitidine products. *Id.* at 7, 17.

Second, the Plaintiffs assert that some states consider a drug's labeling to be part of the drug's design, and therefore they may pursue design-defect claims against the Defendants under the laws of those states. *Id.* at 7, 16-20. The Supreme Court ruled in *Wyeth v. Levine* that labeling claims against brand-name drug manufacturers are not necessarily pre-empted. *Id.* at 15-16; *see Wyeth*, 555 U.S. at 571-73.

The Plaintiffs maintain that, as to design-defect claims against GSK, there is a third reason that the claims should not be dismissed as pre-empted. DE 1976 at 17. That is, GSK could have proposed a different drug formulation and/or different labeling to the FDA when seeking approval of the initial NDA for a ranitidine product. *Id.* The Plaintiffs may pursue a pre-approval design-defect claim against GSK. *Id.*

The Plaintiffs allege in each Master Complaint that ranitidine products were misbranded because the named defendants "did not disclose NDMA as an ingredient" in the products, "did not disclose the proper

directions for storage" of the products, and "did not disclose the proper directions for expiration" of the products. MPIC ¶¶ 421-23; CCCAC ¶¶ 601-03; CTPPCC ¶¶ 338-40. The Plaintiffs allege in the MPIC that ranitidine products "were defective in design and formulation in that . . . they were unreasonably dangerous" because they were susceptible to breaking down into NDMA. MPIC ¶¶ 478-79, 481(a)-(b), 523(a)-(c). The named defendants "could have designed ranitidine-containing products to make them less dangerous" and "could have employed safer alternative designs and formulations." *Id.* ¶¶ 481(k), 485, 523(j). The Defendants, as well as the Generic Manufacturer and Repackager Defendants, breached their duty to use reasonable care in designing ranitidine products because the products had "an inherent susceptibility to form NDMA" and "exposed users to unsafe levels" of NDMA. *Id.* ¶¶ 521-22, 525. Plaintiffs make similar allegations in the CCCAC. The CTPPCC does not contain a design-defect count.

2. Law on Design Defects

A change "in the qualitative or quantitative formulation of the drug product, including inactive ingredients" is a major change that requires the submission of a Prior Approval Supplement to the FDA and FDA approval. 21 C.F.R. § 314.70(b)(2)(i); *see also Bartlett*, 570 U.S. at 477 (citing § 314.70(b)(2)(i) for the proposition that "[o]nce a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the qualitative or

quantitative formulation or the drug product" (quotation marks omitted)). A claim that a brand-name drug manufacturer should have changed a drug's FDA-approved formulation is a pre-empted claim because the manufacturer cannot make such a change independently and while remaining in compliance with federal law. *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298-99 (6th Cir. 2015); *see Epstein v. Gilead Scis., Inc.*, No. 19-81474-CIV, 2020 WL 4333011, at *2 (S.D. Fla. July 27, 2020) (holding that a claim that a brand-name drug manufacturer should have designed drugs with different ingredients was pre-empted because the FDA had approved the drugs' formulas and "any changes would have required further approval"); *see also Mensing*, 564 U.S. at 620 ("The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it.").

Federal courts are split on the issue of whether a design-defect claim against a brand-name drug manufacturer is pre-empted if based on an allegation that the manufacturer should have proposed a safer drug to the FDA for initial approval. The Sixth Circuit Court of Appeals held in *Yates* that such a pre-approval design-defect claim was pre-empted. 808 F.3d at 299-300. The court reasoned that the claim was "too attenuated" and "speculative" because it would require a court or jury to assume that the FDA would have approved an alternative design for a drug, that the plaintiff would have selected the alternatively designed drug for use, and that the alternatively designed drug would have

been safer. *Id.* at 299. The court further reasoned that, under *Mensing*, impossibility pre-emption existed because any initial alternative design would have required FDA approval before being marketed. *Id.* at 300 ("Defendants could not have complied with whatever pre-approval duty might exist without ultimately seeking the FDA's approval prior to marketing [the drug], and certainly prior to Yates's use of the drug."). Finally, the court stated that a pre-approval design-defect claim was similar to a stop-selling argument, which the Supreme Court rejected in *Bartlett*. *Id.* ("In contending that defendants' pre-approval duty would have resulted in a birth control patch with a different formulation, Yates essentially argues that defendants should never have sold the FDA-approved formulation . . . in the first place. We reject this never-start selling rationale for the same reasons the Supreme Court in *Bartlett* rejected the stop-selling rationale of the First Circuit.").

Some district courts have likewise ruled that pre-approval design-defect claims are pre-empted. *See*, *e.g.*, *Gustavsen v. Alcon Lab'ys, Inc.*, 272 F. Supp. 3d 241, 254-55 (D. Mass. 2017) (acknowledging the split among federal courts, finding "the Sixth Circuit's conclusion in *Yates* more consistent with" *Mensing* and *Bartlett*, and stating that "defendants here could not have marketed [eye] droppers . . . in the manner plaintiffs advocate without the FDA's prior approval" and that it was "irrelevant that the defendants could have designed an entirely different product before they sought approval, which may never have been granted"), *aff'd*, 903 F.3d

1 (1st Cir. 2018); *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 185-86 (S.D.N.Y. 2016) (concluding that a negligent design-defect claim was pre-empted where plaintiffs asserted "that the defendants had a pre-approval duty to submit a differently designed drug for FDA approval"); *Brazil v. Janssen Rsch. & Dev. LLC*, 196 F. Supp. 3d 1351, 1364 (N.D. Ga. 2016) (concluding that a plaintiff's "original design theory of liability makes little sense in the face of the Supreme Court's precedents" such as *Mensing* and *Bartlett*).

Other district courts have held that pre-approval design-defect claims are not pre-empted. Courts have reasoned that it is not impossible for a manufacturer to design a drug differently before seeking FDA approval. *See*, *e.g.*, *Holley v. Gilead Scis., Inc.*, 379 F. Supp. 3d 809, 824 (N.D. Cal. 2019) (concluding that pre-approval design-defect claims were not pre-empted where there was no evidence "that the FDA would not have approved the allegedly safer versions of the drugs" that the plaintiffs contended would have complied with state law); *Guidry v. Janssen Pharms., Inc.*, 206 F. Supp. 3d 1187, 1208 (E.D. La. 2016) ("[T]he dispositive question presented here is simply: Can a drug manufacturer independently design a reasonably safe drug in compliance with its state-law duties before seeking FDA approval? The answer is yes."); *Trahan v. Sandoz, Inc.*, No. 3:13-cv-350-J-34MCR, 2015 WL 2365502, at *6 (M.D. Fla. Mar. 26, 2015) (ruling that, "because there is no basis to find that Sandoz was required under federal law to choose the purportedly substandard glass vial in the first place, the fact that

Sandoz could not later change the vial without FDA approval does not establish impossibility preemption"); *Est. of Cassel v. Alza Corp.*, No. 12-cv-771-WMC, 2014 WL 856023, at *6 (W.D. Wis. Mar. 5, 2014) (rejecting a defense of impossibility pre-emption where "[n]o federal law prohibited defendants from submitting a different design" and where the defendants offered no "evidence that the FDA would have exercised its authority to prohibit defendants from creating and submitting such a design for approval").

Courts that have rejected pre-emption of pre-approval design-defect claims have also refused to accept that there may be no way for a consumer to hold any drug manufacturer—either brand-name or generic—liable for a defective drug formulation. *See*, *e.g.*, *Guidry*, 206 F. Supp. 3d at 1206-07 (stating that, if the court were to rule that "the plaintiff's defective design claim is preempted, even under a pre-FDA approval theory, the result is that a Louisiana plaintiff can *never* bring a defective design claim against a drug manufacturer"); *Est. of Cassel*, 2014 WL 856023, at *5 (explaining that, "[s]ince defendants would find preemption wherever a manufacturer needs to ask for FDA approval before marketing, and since *all* new drugs require FDA approval before marketing, no drug manufacturer could *ever* be liable for a defectively designed product under defendants' interpretation" and rejecting that interpretation because "[n]one of the impossibility preemption cases to date contemplates this wholesale preemption of state product liability claims, at least in the drug context").

3. Analysis and Conclusion

The Court discusses the Plaintiffs' misbranding theory at length in the Order Granting Generic Manufacturers' and Repackagers' Rule 12 Motion to Dismiss on the Ground of Preemption. DE 2512 at 20-30. There, the Court explains that no court has adopted the theory that impossibility pre-emption can be avoided by showing that a drug is misbranded under federal law. *Id.* at 27. The Court further explains why *Mensing* and *Bartlett* dictate a contrary result. *Id.* at 22-28. As with generic drugs, a claim based on an allegation that a brand-name drug's FDA-approved formulation renders the drug misbranded is a pre-empted claim because the drug's manufacturer cannot independently and lawfully change a drug formulation that the FDA has approved. The Plaintiffs' claims against the Defendants based on allegations of failure to make changes to the FDA-approved design that they could not have made independently while remaining in compliance with federal law are dismissed with prejudice as pre-empted. Because all of the Plaintiffs' design-defect counts in the Master Complaints incorporate these allegations, all of the design-defect counts against the Defendants are dismissed. The Plaintiffs should omit such allegations from claims against the Defendants when repleading the Master Complaints.

The Plaintiffs are correct that some states address the adequacy of drug labeling as part of a design-defect claim. *See*, *e.g.*, *Bartlett*, 570 U.S. at 482-84 (analyzing the requirements of a design-defect claim under New Hampshire law and explaining that the duty to ensure

that a drug's design is not unreasonably dangerous "can be satisfied either by changing a drug's design or by changing its labeling"). Because the CBE process enables brand-name drug manufacturers to strengthen warnings on labeling without waiting for FDA approval, a labeling claim against a brand-name drug manufacturer is not necessarily pre-empted. *Wyeth*, 555 U.S. at 568-73 (concluding that claims against a brand-name drug manufacturer for inadequate warnings on labeling were not pre-empted where the manufacturer offered no "clear evidence that the FDA would not have approved" a labeling change). Therefore, the Plaintiffs are granted leave to replead design-defect claims against the Defendants that are based on the labeling of ranitidine products.

The Court declines to determine at this juncture whether a pre-approval design-defect claim is pre-empted. This is because the Plaintiffs have not pled a pre-approval design-defect claim. The design-defect counts in the Master Complaints do not differentiate between GSK—the entity alleged to have initially designed the ranitidine molecule—and any other named defendant. The Plaintiffs instead allege that all of the named defendants could have designed safer ranitidine products. *See*, *e.g.*, MPIC ¶¶ 481(k), 485. The Plaintiffs have not identified which, if any, states recognize a pre-approval duty that drug manufacturers owe to consumers.

Moreover, the parties' briefing on whether a pre-approval design-defect claim is pre-empted is inadequate in informing the Court of the parties' positions.

The Defendants devote only one paragraph to this issue, and the Plaintiffs devote only one footnote to the issue. *See* DE 1580 at 26-27; DE 1976 at 17. Neither side acknowledges that this is an issue on which federal courts are split; neither side provides substantive legal analysis; and neither side addressed the matter at the Hearing. Should the Plaintiffs raise a pre-approval design-defect claim or claims upon repleading, and should the Defendants challenge the claim(s) on the ground of pre-emption in a future motion, the parties shall meaningfully brief this matter.

Accordingly, Counts II and V of the MPIC and the 47 design-defect counts in the CCCAC listed in Appendix A to the Motion to Dismiss are dismissed against the Defendants without prejudice and with leave to amend, consistent with this Order. *See* DE 1580 at 32-35. Upon repleading, the Plaintiffs should bring all claims arising under separate states' laws in separate counts in each of the Master Complaints. The Plaintiffs should also bring any pre-approval design-defect claims in separate counts from any post-approval design-defect claims that are based on labeling. *See* Fed. R. Civ. P. 10(b) ("If doing so would promote clarity, each claim founded on a separate transaction or occurrence . . . must be stated in a separate count or defense.").

C. Express Pre-emption under 21 U.S.C. § 379r

The Defendants move to dismiss all 320 state-law claims to recover alleged monetary losses from the purchase of OTC ranitidine. The basis for the Defendants'

requested dismissal is that 21 U.S.C. § 379r expressly pre-empts these state-law claims. In response, the Plaintiffs argue that their claims are not pre-empted for two reasons. First, the Plaintiffs characterize their claims as parallel to federal claims because they have alleged that ranitidine products were misbranded under federal law. Second, the Plaintiffs invoke the savings clause in § 379r, which exempts from pre-emption any claim arising under the product liability law of a state. The Court briefly addresses the Plaintiffs' argument about misbranding before analyzing the § 379r savings clause.

Although the Plaintiffs argue that their state-law claims parallel federal misbranding law, this argument cannot be squared with their pleadings. First, the Plaintiffs have not pled any standalone state-law count for misbranding, nor have the Plaintiffs pled the jurisdictions where, according to the Plaintiffs, state causes of action impose requirements identical to federal misbranding law. Second, only 14 of the Plaintiffs' 323 counts in the CCCAC and CTPPCC explicitly reference misbranding at all. *See* CCCAC, Counts 2, 5, 33, 97, 99, 208, 264, and 266; CTPPCC, Counts 2, 3, 5, 7, 8, and 9.[8] Third, federal misbranding law arguably applies only to labeling, *see* 21 U.S.C. § 352(a)-(j), but the Plaintiffs' claims encompass more than just labeling. By way of example, the Plaintiffs allege that the

[8] Each of the Plaintiffs' counts incorporate every factual allegation. For this reason, as well as others, the Court concluded that all of the Master Complaints are shotgun pleadings that must be repled. *See* DE 2515 at 18, 22-23.

Defendants could have complied with state law through disclosures in advertisements and public service announcements. CCCAC ¶ 2367. Fourth, the Court has ruled that the Master Complaints are shotgun pleadings that must be amended. *See* DE 2515. Fifth, any analysis of state misbranding claims requires a careful consideration of whether state-law requirements are greater than federal requirements. *E.g.*, *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447 (2005) (remanding for the circuit court to consider whether state-law duties are equivalent to federal misbranding requirements). As the Master Complaints are currently pled, the Court cannot undertake a careful, state-by-state analysis of state-law-based misbranding claims. Sixth and finally, the Court has found that the Plaintiffs' allegations of misbranding lack clarity and must be repled. *See* DE 2515 at 43. For all of these reasons, the Court rejects the Plaintiffs' misbranding-based arguments as an exception to § 379r pre-emption but will permit the Plaintiffs, in an amended and clarified pleading, to raise the exception anew.[9]

The Court turns to the Plaintiffs' remaining argument that the savings clause in § 379r preserves their claims. To analyze this argument, the Court considers (1) the facial applicability of § 379r to the Plaintiffs' claims, (2) the appropriate body of authority to

[9] This issue should also receive additional attention and discussion in future briefing.

consider the scope of the § 379r savings clause, and (3) the scope of the § 379r savings clause.

1. The Facial Applicability of § 379r to the Plaintiffs' Claims

a. Arguments

The Defendants cite to 21 U.S.C. § 379r(a) and argue that the express pre-emption provision contained therein bars the Plaintiffs' claims for refunds.[10] In response, the Plaintiffs do not argue that their claims are outside of the scope of § 379r(a).[11] Instead, the Plaintiffs rely upon the proposition that the savings clause in § 379r permits their claims to proceed because their claims sound in product liability law. Before examining the specifics of the Plaintiffs' position, however, the Court examines the law generally applicable to federal pre-emption under § 379r.

b. Applicable Law as to § 379r Pre-emption, Generally

Congress has explicitly mandated that federal law pre-empts nearly all state-law claims relating to OTC medications. *See* 21 U.S.C. § 379r(a). Specifically,

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[10] The Defendants do not argue § 379r pre-emption for claims premised upon personal injury.

[11] The Plaintiffs did make one related argument; the Plaintiffs argued that, because ranitidine was misbranded, their claims were parallel to federal requirements. The Court has already rejected that argument.

consumers may not bring any state-law claims that would impose duties on companies marketing OTC products that are "different from," "in addition to," or "otherwise not identical with" a federal requirement under the FDCA. *Id.*

Courts interpret § 379r's "federal requirement" pre-emption broadly, applying § 379r to federal regulations. *See Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 793-95 (2002) (finding that a federal regulation for OTC head lice products established federal "requirements"); *see also Mills v. Warner-Lambert Co.*, 581 F. Supp. 2d 772, 785-87 (E.D. Tex. 2008). Courts find that § 379r pre-empts even state-law advertising claims, provided the advertisements are based upon content approved by the FDA for a drug's labeling, *Andrus v. AgrEvo USA Co.*, 178 F.3d 395, 400 (5th Cir. 1999), in addition to claims that would require additional warnings on labeling or in an advertisement. *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1282 (C.D. Cal. 2008) ("A reasonable reading of § 379r(c)(2) is that it expands the universe of potentially pre-empted state law claims to include those that require additional warnings in the advertising for nonprescription drugs, and not only on the labeling."). Finally, § 379r pre-empts not only state legislation and regulations, but also common-law duties. *Cf. Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324-25 (2008) (holding that common-law causes of action were pre-empted under the express pre-emption provision of the Medical Device Amendments of 1976).

Courts, therefore, find claims that are founded in FDA-approved labeling to be pre-empted under § 379r, regardless of how those claims are styled. For example, in *Carter v. Novartis Consumer Health, Inc.*, consumers filed class actions against manufacturers of OTC cough and cold medicines, claiming that the manufacturers knew or should have known that their medications were unsafe for children. 582 F. Supp. 2d at 1276-77. The plaintiff-consumers brought causes of action that included fraud, unjust enrichment, false and misleading advertising, fraudulent concealment, unfair and deceptive business practices, and breach of express and implied warranties. *Id.* at 1277. The court dismissed all claims, finding § 379r pre-emption. *See id.* at 1284 ("[T]he analysis under § 379r depends not on the theory upon which the claim is brought, but its ultimate outcome: would a finding of liability impose requirements that are different from or in addition to FDA requirements?"), 1290 ("Defendants' Motion to Dismiss is GRANTED as to all claims pursuant to express pre-emption under 21 U.S.C. § 379r."). Similarly, in *Kanter v. Warner-Lambert Co.*, consumers brought a class action against three manufactures of OTC head lice medication under causes of action including breach of warranty, fraud and deceit, false advertising, and unfair competition. 99 Cal. App. 4th at 788, 796. The California state court found each cause of action pre-empted under § 379r because, although "the legal theories underlying these causes of action . . . differ[ed], each [was] bottomed on the assertion that th[e] approved label [was] no longer accurate or

adequate and that the label should be changed or the product banned." *Id.* at 796.

c. Analysis and Conclusion as to § 379r Pre-emption, Generally

The Court agrees with the Defendants that, at least as a facial matter, caselaw establishes that all of the Plaintiffs' state-law claims against the Defendants are pre-empted to the extent those claims are premised upon the adequacy of OTC ranitidine products' design or label and are limited to injuries stemming from the purchase of ranitidine. In response, the Plaintiffs have provided neither argument nor caselaw to the contrary—the Plaintiffs do not argue, for example, that some of their claims are not premised upon the adequacy of ranitidine products' design or label; the Plaintiffs rest upon their misbranding argument which the Court rejected, *supra.* The Court therefore turns to the Plaintiffs' argument that their claims satisfy the savings clause in § 379r.[12]

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[12] The parties dispute whether the Plaintiffs have the burden to show that their claims survive pre-emption under the § 379r savings clause. The Court notes that there is caselaw to support the Defendants' argument that Plaintiffs do carry such a burden, *see Carter*, 582 F. Supp. 2d at 1288, but the Court need not resolve this dispute, as the Court's conclusions are not based upon any allocation of burden.

2. The Appropriate Body of Authority to Consider the Scope of the § 379r Savings Clause

a. Arguments on the Appropriate Body of Authority

The Plaintiffs cite to 21 U.S.C. § 379r(e), which reads as follows: "Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." Because the Plaintiffs contend that their claims sound in state product liability law, they argue that their claims are saved under § 379r(e), and because the Defendants have not made a state-by-state argument that the Plaintiffs' claims fail under state product liability law, the Motion to Dismiss must be denied. The Defendants reply that the Court must look to federal law—not state law—to define the phrase "product liability law" as used in § 379r(e) because, while the states may have been granted some leeway under § 379r(e) to expand or contract product liability law, there is a limit on just how much leeway § 379r(e) grants to the states. Put another way, it is the Defendants' position that, when Congress saved causes of action sounding in product liability law, Congress had a certain intent as to what type of claims could be saved on a state-by-state basis.

The phrase at issue in § 379r(e) is "the product liability law of any State." The Defendants argue that the appropriate body of authority to consult in the interpretation of a phrase in a federal statute is federal law, not state law. The Plaintiffs argue that state law

should be consulted because of the wording in § 379r(e): "Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." If Congress had intended federal law to govern the scope of the § 379r savings clause, the Plaintiffs argue, the statute would have saved "product liability claims," not the "product liability law of any State."

b. Applicable Law, the Appropriate Body of Authority

Federal law generally governs terms used in federal statutes. *See Johnson v. United States*, 559 U.S. 133, 138 (2010) (holding that the meaning of "physical force" is a question of federal law, not state law); *Dickerson v. New Banner Inst., Inc.*, 460 U.S. 103, 111-12 (1983) (holding that the meaning of "convicted" is a question of federal law, not state law, despite the fact "that the predicate offense and its punishment are defined by the law of the State"), *superseded by* 18 U.S.C. § 921(a)(20); *United States v. Alexander*, 802 F.3d 1134, 1139 (10th Cir. 2015) (holding that the meaning of "consensual" is a question of federal law, not state law). It is undisputed that the phrase "product liability law" in § 379r is an undefined term, and "where a federal statute contains a term with settled meaning under the common law, courts must presume Congress meant to import that meaning unless the statute says otherwise." *Garcia-Celestino v. Ruiz Harvesting, Inc.*, 898 F.3d 1110, 1118 (11th Cir. 2018).

In response, the Plaintiffs provide no authority for the proposition that the Court should consult state law to interpret phrases in federal statutes. Instead, the Plaintiffs cite to two cases where courts considered the boundaries of the § 379r savings clause and, in each case, the court consulted state law, not federal law.

The Plaintiffs' first citation is to *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d at 1271. In *Carter*, the defendant argued that because the plaintiff was seeking only economic damages—not damages for personal injury—the plaintiff's claims could not arise under the product liability law of California and, as a result, § 379r did not save the plaintiff's claims from pre-emption. *Id.* The *Carter* court agreed with the defendant because California law supported the defendant's position. *Id.* The *Carter* court was not called upon to consult federal law or the law of any other state because whether other states were at issue was "unclear." *Id.* ("[B]ut the extent to which the four Complaints at issue are brought under the laws of other states is unclear.").

The Plaintiffs' second citation is to *In re Tylenol (Acetaminophen) Mktg.*, No. 2:13-md-02436, 2015 WL 7076012, at *6 n.20 (E.D. Pa. Nov. 13, 2015). In *Tylenol*, the defendant argued that the plaintiff's state-law fraud claims did not qualify as product liability claims. *Id.* The court cited Alabama law—the state the claims were brought under—and concluded that Alabama law *did* classify the claims at issue as falling under the more general umbrella of "product liability" claims. *Id.* Nothing in the *Tylenol* decision suggests that the court

was asked to consider federal law on the scope of § 379r.

c. Analysis and Conclusion, the Appropriate Body of Authority

The Defendants have cited a plethora of authority for the proposition that federal law should be consulted to determine the meaning of phrases in federal statutes—authority that the Plaintiffs have not refuted. The caselaw is binding. *E.g.*, *Stein v. Paradigm Mirasol, LLC*, 586 F.3d 849, 854 (11th Cir. 2009) ("Because the Disclosure Act is a federal statute its interpretation is a matter of federal law."). Of course, this is not to suggest that state law is irrelevant—just as a claim under § 379r could be foreclosed by federal law, state law could foreclose the very same claim. This is precisely what happened in *Carter*—the court in *Carter* had no need to consult federal law when state law foreclosed a claim from the § 379r savings clause. And while it is true that the *Tylenol* court found that state law permitted a claim under § 379r, the *Tylenol* court did not reach the question of whether federal law foreclosed the same claim. In conclusion, the Court must consult federal law to determine the meaning of the phrase "product liability law" in § 379r(e).

3. The Scope of the § 379r(e) Savings Clause

a. Arguments as to the Scope of § 379r(e)

The Defendants only move to dismiss claims that seek monetary losses stemming from the purchase of

ranitidine products themselves—the Defendants do not seek to dismiss any claims where the Plaintiffs have suffered a personal injury.[13] Limiting their requested relief as such, the Defendants argue that Congress did not intend for certain claims to be saved as product liability claims when the injury supporting those claims was limited to the purchase of a product and did not include any injury to a plaintiff's person or property. In response, the Plaintiffs make two arguments. First, the Plaintiffs argue that *remedies* cannot be pre-empted—only *claims* can be—and a request for a refund is a remedy, not a claim. Second, the Plaintiffs argue that the definition of product liability under federal common law is unsettled and, as a result, cannot bar their claims.

b. Applicable Law, the Scope of § 379r(e)

Although Congress did not expressly define "product liability" in § 379r, if the term has certain meanings under the common law then the Court must presume that Congress intended to utilize those meanings. *See Garcia-Celestino*, 898 F.3d 1110 at 1118. In *Home Warranty Corp. v. Caldwell*, the Eleventh Circuit Court of Appeals was called upon to conduct an exhaustive, comprehensive analysis of the history of product liability law, together with common-law definitions of the same and congressional understanding of

[13] The Defendants move to dismiss Count 2 and Counts 4-314 from the CCCAC, Count 12 from the MPIC, and Counts 2, 3, 5, and 9 from the CTPPCC.

those definitions. 777 F.2d 1455, 1457-62 (11th [Cir.] 1985). Based upon its review, the *Caldwell* court concluded that "[i]t is a traditional concept of products liability law that the products liability risk does not include the loss of or damage to the product itself." *Id.* at 1486. Instead, the general scope of product liability law encompasses injuries to a person or a person's property. *See id.* at 1457-59. Federal regulations comport with this general definition. *See* 26 C.F.R. § 1.172-13(b)(2)(i) (federal regulation defining "product liability" to "mean[] the liability . . . for damages resulting from physical injury or emotional harm to individuals, or damage to or loss of the use of property"). The Restatement also comports with this definition. Restatement (Third) of Torts: Products Liability § 21 (Am. L. Inst. 1998) (providing that the only economic losses recoverable in product liability are those involving personal injury or property damage other than damage to the defective product itself). State law generally conforms to this definition as well. *See E. River S.S. Corp. v. Transam. Delaval, Inc.*, 476 U.S. 858, 868-69 (1986) (explaining that the majority of states preclude tort liability for pure economic loss); *Carter*, 582 F. Supp. 2d at 1288 ("In fact, Plaintiffs have not demonstrated that product liability law in *any* state omits a requirement for injury to one's person or property.").

In response to the foregoing authority, the Plaintiffs have not provided a citation to any federal case holding that a product liability claim may be pursued where the plaintiff has not suffered a *personal* injury.

c. Analysis, the Scope of § 379r(e)

The Court rejects the Plaintiffs' argument that the Defendants have focused on the pre-emption of a remedy in lieu of the pre-emption of a claim. The Defendants' argument is not that the Plaintiffs' claims are pre-empted because of the remedy (a refund) that the Plaintiffs seek; the Defendants' argument is that the Plaintiffs have not suffered a personal *injury* that, under federal law, is required for a claim to qualify as a product liability claim.

The Plaintiffs contend that there is no settled meaning of product liability law in either the federal common law or the common law of the states, and the Plaintiffs' proposition is adequately supported with citations to authority. *E.g.*, *E. River S.S. Corp.*, 476 U.S. at 868-69. Even so, the Defendants do not necessarily dispute that, in the general sense, there is uncertainty as to the *precise* common-law definition of "product liability law." Ultimately, however, this Court need not define the precise boundaries of product liability law, nor does the Court need to define everything that Congress intended when it enacted § 379r. What is before this Court is whether Congress intended to permit state-law causes of action when no plaintiff suffered a *personal injury* to their person or to their property—when a plaintiff's damages are limited solely to the purchase of the product itself. As to this specific boundary, as to this specific question, the Defendants have the more persuasive argument. The Court concludes that Congress did not intend for any state to have the authority, under the § 379r(e) savings clause, to

classify a claim as a product liability claim when the plaintiff did not suffer a personal injury. Thus, any claim for a refund for the purchase of OTC ranitidine products that is premised upon the allegation that Plaintiffs suffered no personal injury—to themselves or to their property—is not saved under the § 379r savings clause.[14]

VIII. Conclusion

For the foregoing reasons, it is **ORDERED AND ADJUDGED** that Branded Defendants' Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law [DE 1580] is **GRANTED** consistent with this Order.

1. Counts II and V of the MPIC and the 47 design-defect counts in the CCCAC listed in Appendix A to the Motion to Dismiss as against Defendants are **DISMISSED WITHOUT PREJUDICE AND WITH LEAVE TO AMEND**, consistent with this Order.

2. The Plaintiffs' amended pleadings are due within 30 days of the date of this Order.

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[14] Although the CCCAC alleged personal injury in the form of cellular and sub-cellular damage, the Court struck those allegations from the CCCAC at docket entry 2515, permitting the Plaintiffs to seek leave of Court for an alternative pleading to allege their class physical injury and/or medical monitoring claims.

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

/s/ Robin L. Rosenberg
ROBIN L. ROSENBERG
UNITED STATES
DISTRICT JUDGE

Copies furnished to Counsel of Record

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION /	**MDL No. 2924** **No. 20-MD-2924** **JUDGE ROBIN L. ROSENBERG** **MAGISTRATE JUDGE BRUCE E. REINHART**

ORDER GRANTING RETAILER AND PHARMACY DEFENDANTS' RULE 12 MOTION TO DISMISS ON THE GROUND OF PREEMPTION, GRANTING DISTRIBUTOR DEFENDANTS' RULE 12 MOTION TO DISMISS ON THE GROUND OF PREEMPTION, DENYING AS MOOT RETAILER AND PHARMACY DEFENDANTS' RULE 12 MOTION TO DISMISS ON STATE LAW GROUNDS, AND DENYING AS MOOT DISTRIBUTOR DEFENDANTS' RULE 12 MOTION TO DISMISS ON VARIOUS GROUP-SPECIFIC GROUNDS

(Filed Dec. 31, 2020)

This matter is before the Court on the Defendant Retailers' ("Retailer Defendants") Rule 12 Motion to Dismiss on the Grounds of Preemption [DE 1584], the Defendant Distributors' ("Distributor Defendants") (when referencing both Defendants, collectively "Defendants") Rule 12 Motion to Dismiss on the Ground of Preemption [DE 1583] (collectively, "Defendants' First Round Motions to Dismiss"), the Retailers' Rule 12 Motion to Dismiss on State Law Grounds [DE 2044], and

the Distributors' Rule 12 Motion to Dismiss on Various Group-Specific Grounds [DE 2045] (collectively, "Defendants' Second Round Motions to Dismiss"). The Court held a hearing on the Motions to Dismiss on December 15, 2020 ("the Hearing"). The Court has carefully considered the Motions, the Responses [DE 1977,[1] 2243, 2244], the Replies [DE 2128, 2131, 2323, 2326], the Notice of Supplemental Authority [DE 2488], 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' First Round Motions to Dismiss are **GRANTED**, the Plaintiffs' claims are **DISMISSED**, and the Defendants' Second Round Motions to Dismiss are **DENIED AS MOOT**; the Plaintiffs shall have leave to amend a subset of their claims.[2]

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[1] The Plaintiffs filed a consolidated Response to the Defendants' First Round Motions to Dismiss.

[2] To the extent the Defendants have requested any relief through incorporation of the Generic Defendants' Motion to Dismiss at docket entry 1582, the Court's ruling in its Order Granting Generic Manufacturers' and Repackagers' Rule 12 Motion to Dismiss on the Ground of Preemption applies. To the extent the Defendants have requested any relief through incorporation of the Brand Defendants' Motion to Dismiss at docket entry 1580, the Court's forthcoming order on that Motion applies.

I. Factual Background[3]

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 1980's, first by prescription and later as an over-the-counter medication ("OTC"). In 1983, the U.S. Food and Drug Administration ("FDA") approved the sale of prescription Zantac. MPIC ¶¶ 226, 231, 432. GlaxoSmithKline ("GSK") first developed and patented Zantac. *Id.* ¶ 230. Zantac was a blockbuster—the first prescription drug in history to reach $1 billion in sales. ¶ 231.

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

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[3] 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 Master Personal Injury Complaint ("MPIC"), the Consolidated Consumer Class Action Complaint ("CCCAC"), and the Consolidated Third Party Payor Class Complaint ("CTPPCC") (collectively "Master Complaints"). DE 887, 888, 889.

GSK retaining control over the sale of prescription Zantac in the United States. *Id.* ¶ 234. Pfizer acquired Warner-Lambert in 2000 and took control of the sale of OTC Zantac in the United States. *Id.* ¶ 235. The right to sell OTC Zantac in the United States later passed to Boehringer Ingelheim Pharmaceuticals and then to Sanofi. *Id.* ¶¶ 239-40, 242-44. 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.* ¶¶ 249-51.

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.* ¶¶ 253, 321, 324, 331. Studies have shown that these compounds increase the risk of cancer in humans and animals. *Id.* ¶¶ 253, 264-72. The FDA, the Environmental Protection Agency, and the International Agency for Research on Cancer consider NDMA to be a probable human carcinogen. *Id.* ¶¶ 254, 258. The FDA has set the acceptable daily intake level for NDMA at 96 nanograms. *Id.* ¶¶ 4, 263.

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.* ¶ 285. The FDA issued a statement on September 13 warning that some ranitidine products may contain NDMA. *Id.* ¶ 286. On November 1, the FDA announced that testing had revealed the presence of NDMA in

ranitidine products. *Id.* ¶ 296. The FDA recommended that drug manufacturers recall ranitidine products with NDMA levels above the acceptable daily intake level. *Id.* Six months later, on April 1, 2020, the FDA requested the voluntary withdrawal of all ranitidine products from the market. *Id.* ¶ 301.

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, hundreds of 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 thousands of claimants who have not filed lawsuits have registered their claims. *See* DE 547.

Plaintiffs filed three Master Complaints on June 22, 2020. DE 887, 888, 889. Plaintiffs contend 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. MPIC ¶¶ 1, 6, 19. Plaintiffs allege 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. Plaintiffs are pursuing federal claims and state claims under the laws of all 50 U.S. states, Puerto Rico, and the District of Columbia. *See generally* Consolidated Consumer Class Action Complaint ("CCCAC"). The entities named as defendants are alleged to have designed, manufactured, tested, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine products. MPIC ¶¶ 20, 225.

The Court has entered numerous Pretrial Orders to assist in the management of this MDL. In Pretrial Order # 30, the Court set a case management schedule that is intended to prepare the MDL for the filing of *Daubert* motions on general causation and class certification motions in December 2021. DE 875; *see generally Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). In Pretrial Order # 36, the Court set a schedule for the filing and briefing of motions to dismiss under Federal Rule of Civil Procedure 12 directed to the Master Complaints. DE 1346. Defendants filed the instant Motions to Dismiss pursuant to that schedule.

III. The Master Complaints

A. Master Personal Injury Complaint

All individuals who file a Short Form Complaint (collectively, the "MPIC Plaintiffs") adopt the MPIC.

MPIC at 2.[4] The MPIC Plaintiffs allege that they developed cancers from taking the Defendants' ranitidine products. *Id.* at 1. The MPIC "sets forth allegations of fact and law common to the personal-injury claims" within the MDL. *Id.* at 1. Each MPIC Plaintiff individually seeks compensatory damages, punitive damages, restitution, and all other available remedies. *Id.* at 1-2.

The MPIC Defendants are entities that "designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine." *Id.* ¶ 20. They are categorized by the MPIC Plaintiffs into five groups: (1) Brand-Name Manufacturer Defendants; (2) Generic Manufacturer Defendants; (3) Distributor Defendants; (4) Retailer Defendants; and (5) Repackager Defendants. Some MPIC Defendants belong to multiple categories.[5] Within each category, the MPIC combines distinct corporate entities, including parents, subsidiaries, and affiliates, into single named MPIC

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

[5] For example, AmerisourceBergen is named as both a Generic Manufacturer Defendant and a Distributor Defendant. MPIC at 15 n.3.

Defendants.[6] Certain allegations apply to MPIC Defendants across multiple groups.[7]

The MPIC contains 15 counts: Strict Products Liability—Failure to Warn (Count I), Strict Products Liability—Design Defect (Count II), Strict Products Liability—Manufacturing Defect (Count III), Negligence—Failure to Warn (Count IV), Negligence Product Design (Count V), Negligent Manufacturing (Count VI), General Negligence (Count VII), Negligent Misrepresentation (Count VIII), Breach of Express Warranties (Count IX), Breach of Implied Warranties (Count X), Violation of Consumer Protection and Deceptive Trade Practices Laws (Count XI), Unjust Enrichment (Count XII), Loss of Consortium (Count XIII), Survival Actions (Count XIV), and Wrongful Death (Count XV). Counts I, II, IV, VII, IX, X, XI, XII, XIII, XIV and XV are brought against every MPIC Defendant. Counts V and VIII are brought against every Brand-Name Manufacturer, Generic Manufacturer and Repackager Defendant. Counts III and VI are brought against every Brand-Name Manufacturer and Generic Manufacturer Defendant.

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[6] For example, CCCAC Defendant "Sanofi" refers to five entities: Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., Sanofi S.A., Patheon Manufacturing Services LLC, and Boehringer Ingelheim Promeco, S.A. de C.V. MPIC ¶ 36.

[7] *See*, *e.g.*, MPIC ¶ 44 (allegations referring to Repackager Defendants apply to Ajanta, a Generic Manufacturer Defendant).

B. Consolidated Consumer Class Action Complaint

One hundred and eighty-three named individuals (collectively, the "CCCAC Plaintiffs") bring the CCCAC on behalf of themselves and all others similarly situated.[8] The CCCAC Plaintiffs are citizens of nearly every state, the District of Columbia, and Puerto Rico. There are no CCCAC Plaintiffs who reside in or purchased ranitidine products from Delaware, Hawaii, Kansas, Maine, North Dakota, Rhode Island, or South Dakota. Each CCCAC Plaintiff asserts that he or she purchased and/or used a ranitidine product during an approximate timeframe.

The CCCAC Plaintiffs bring the action in their individual capacities and on behalf of numerous classes pursuant to Rule 23. Among the various classes are two nationwide classes: (1) the "RICO Class," comprised of "[a]ll residents of the United States or its territories who purchased for personal, family, or household use any of Brand-Name Manufacturer Defendants' Ranitidine-Containing Products in the United States or its territories"; and (2) the "Nationwide Class," comprised of "[a]ll residents of the United States or its territories who purchased and/or used for personal, family, or household use, any of the Defendants' Ranitidine-Containing Products in the United States or its territories." CCCAC ¶ 734. The CCCAC

[8] The CCCAC originally had 238 named plaintiffs, but 55 were subsequently dismissed without prejudice. *See* Order Granting Plaintiffs' Unopposed Motion to Drop Certain Plaintiffs from Consolidated Consumer Class Action Complaint, DE 2241.

alleges that as an alternative, and/or in addition to, the Nationwide Class, the CCCAC Plaintiffs bring the action in their individual capacities and on behalf of "State Classes" for all fifty states, the District of Columbia, and Puerto Rico. *Id.* ¶ 737. Each State Class is comprised of "[a]ll residents of [State or Territory] who purchased and/or used for personal, family, or household use, any of the Defendants' Ranitidine-Containing Products in the United States or its territories." *Id.*

The defendants named in the CCCAC are entities that "invented, manufactured, distributed, labeled, marketed, advertised, . . . stored, and sold ranitidine." *Id.* ¶ 259. They are categorized by the CCCAC Plaintiffs into five groups: (1) Brand-Name Manufacturer Defendants; (2) Generic Manufacturer Defendants; (3) Distributor Defendants; (4) Retailer Defendants; and (5) Repackager Defendants (collectively, the "CCCAC Defendants"). Some CCCAC Defendants belong to multiple categories. Within each category, the CCCAC combines distinct corporate entities, including parents, subsidiaries, and affiliates, into single named CCCAC Defendants. Certain allegations apply to CCCAC Defendants across multiple groups.

The CCCAC alleges 314 counts against the CCCAC Defendants. The CCCAC Plaintiffs allege Count 1 (RICO) on behalf of the RICO Class against the Brand-Name Manufacturer Defendants. *Id.* ¶ 750. The CCCAC Plaintiffs allege Count 2 (unjust enrichment) and Count 3 (Magnuson-Moss Warranty Act) on behalf of the Nationwide Class against all CCCAC Defendants. *Id.* ¶¶ 795, 804. Alternatively, they bring

Count 2 "on behalf of themselves under the laws of the state in which each [CCCAC] Plaintiff resides and/or purchased Ranitidine-Containing Products, and on behalf of a Class comprised of members from each [CCCAC] Plaintiff's respective state." *Id.* ¶ 795. The CCCAC Plaintiffs allege Count 4 (fraud) on behalf of the Nationwide Class against the Brand-Name Manufacturer Defendants, the Generic Manufacturer Defendants, and the Repackager Defendants. *Id.* ¶ 823. Alternatively, they bring Count 4 "on behalf of themselves under the laws of the state in which each [CCCAC] Plaintiff resides and/or purchased Ranitidine-Containing Products, and on behalf of each State Class." *Id.* The CCCAC Plaintiffs allege Count 5 (negligence) and Count 6 (battery) on behalf of numerous State Classes against all CCCAC Defendants. *Id.* ¶¶ 839, 886. Finally, the CCCAC Plaintiffs allege Counts 7 through 314 (including breach of express and implied warranties; failure to warn; manufacturing defects; design defects; state consumer protection violations; deceptive trade practices; and medical monitoring) on behalf of the various State Classes against some or all of the CCCAC Defendants. *Id.* ¶¶ 906-5899.

IV. Summary of the Parties' Arguments

As to the Defendants' First Round Motions to Dismiss, the Defendants argue that all of the Plaintiffs' claims must be dismissed. They must be dismissed because the Plaintiffs' state-law claims are pre-empted by federal law and the Plaintiffs' sole federal claim

must be dismissed without a state-law claim to support it. In Response, the Plaintiffs argue that their state-law claims are not pre-empted by federal law for two reasons. First, Supreme Court precedent supports the proposition that their claims are not pre-empted. Second, their claims are parallel with federal law—there is no conflict (and therefore no pre-emption) with federal law.

As to the Defendants' Second Round Motions to Dismiss, the Defendants argue that a subset of the Plaintiffs' claims must be dismissed because they are precluded by state law. In Response, the Plaintiffs argue that exceptions in state law permit their claims to go forward.

V. Summary of the Court's Rulings

The Court concludes that all of the Plaintiffs' state-law claims against the Defendants are pre-empted by federal law and, as a result, are dismissed. Without a state-law claim to support it, the Plaintiffs' sole federal claim is dismissed as well. The Court will permit the Plaintiffs to re-plead a general negligence claim, subject to certain rulings contained in this Order. Because the Court concludes that the Plaintiffs' claims are dismissed, the Defendants' Second Round Motions to Dismiss are moot.

VI. Standard of Review

Defendants move to dismiss all of the claims against them under Federal Rule of Civil Procedure

12(b)(6) based on the affirmative defense of federal pre-emption. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 619 (2011) (describing federal pre-emption as a drug manufacturer's affirmative defense). A court may grant a motion to dismiss a pleading if the pleading fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A court ruling on a motion to dismiss accepts the well-pled factual allegations as true and views the facts in the light most favorable to the plaintiff. *Jones v. Fransen*, 857 F.3d 843, 850 (11th Cir. 2017). But the court 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). A "complaint may be dismissed under Rule 12(b)(6) when its own allegations indicate the existence of an affirmative defense, so long as the defense clearly appears on the face of the complaint." *Quiller v. Barclays Am./Credit, Inc.*, 727 F.2d 1067, 1069 (11th Cir. 1984), *aff'd en banc*, 764 F.2d 1400 (11th Cir. 1985).

VII. Analysis of the Defendants' First Round Motions to Dismiss

An understanding of the law that applies to drugs approved by the FDA is necessary to understand the arguments that the parties make in briefing the Motions to Dismiss. Before turning to the parties'

arguments, the Court discusses key statutes and regulations that govern the FDA's regulation of drugs. The Court next addresses impossibility pre-emption and significant cases that have addressed impossibility pre-emption in the drug context. The Court then turns to the issues raised in the briefing: absolute liability, misbranding, negligence, and federal regulation of drug supply chains. For each issue, the Court reviews the arguments of the parties, any relevant allegations in the Master Complaints, and any additional, issue-specific law before providing the Court's analysis and conclusion on the issue.

A. Federal Regulation of Drug Products

The FDA regulates prescription and over-the-counter ("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); *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 477 (2013) (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. However, despite the availability of these processes to make changes, "generic drug manufacturers have an ongoing federal duty of 'sameness' " that requires "that the warning labels of a brand-name drug and its generic copy must always be the same."

Mensing, 564 U.S. at 613; *see also* 21 C.F.R. § 314.150(b)(10) (explaining that approval for an ANDA may be withdrawn if the FDA finds that the drug product's labeling "is no longer consistent with that for the listed drug"). Thus, the Changes Being Effected ("CBE") process allows "changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions." *Mensing*, 564 U.S. at 614.

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*, a consumer of a brand-name drug sued the brand-name drug manufacturer on negligence and strict-liability theories under Vermont law for failure to provide an adequate warning on the drug's labeling. 555 U.S. 555, 559-60 (2009). The Supreme Court held that the consumer's labeling claims were not pre-empted because the CBE process permitted the brand-name drug manufacturer to "unilaterally strengthen" the warning on the labeling, without waiting for FDA approval. *Id.* at 568-69, 571, 573. The Court stated that it could not conclude that it was impossible for the brand-name drug manufacturer to comply with both its federal-law and state-law duties "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.

2. *PLIVA, Inc. v. Mensing*

In *PLIVA, Inc. v. Mensing*, consumers of generic drugs sued the generic drug manufacturers under Minnesota and Louisiana tort law for failure to provide adequate warnings on the drugs' labeling. 564 U.S. at 610. The Supreme Court held that the consumers' labeling claims were preempted because the generic drug manufacturers could not "independently" change the labeling while remaining in compliance with federal law. *Id.* at 618-20, 623-24. The generic drug manufacturers' "duty of 'sameness'" under federal law required them to use labeling identical to the labeling of the equivalent brand-name drug. *Id.* at 613. Thus, the CBE process was unavailable to the generic drug manufacturers to change labeling absent a change to the brand-name drug's labeling. *Id.* at 614-15. Because any change that the generic drug manufacturers made to the drugs' labeling to comply with duties arising under state tort law would have violated federal law, the state tort claims were pre-empted. *Id.* at 618, 623-24.

The consumers argued, and the FDA asserted in an amicus brief, that even if the generic drug manufacturers could not have used the CBE process to change the labeling, the manufacturers could have "asked the FDA for help" by proposing a labeling change to the FDA. *Id.* at 616, 619. The consumers further argued that their state-law claims would not be pre-empted unless the generic drug manufacturers demonstrated that the FDA would have rejected a proposed labeling change. *Id.* at 620. The generic drug manufacturers

conceded that they could have asked the FDA for help. *Id.* at 619.

The Supreme Court rejected the argument that the ability to ask the FDA for help defeated impossibility pre-emption. *Id.* at 620-21. The Court stated that the "question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Id.* at 620 (citing *Wyeth*, 555 U.S. at 573). "[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 preemption purposes." *Id.* at 623-24. Asking the FDA for help "would have started a Mouse Trap game" that eventually may have led to a labeling change, "depending on the actions of the FDA and the brand-name manufacturer." *Id.* at 619-20. But, the Court stated, pre-emption analysis that was dependent on what a third party or the federal government might do would render impossibility pre-emption "all but meaningless." *Id.* at 620-21 ("If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force.").

3. *Mutual Pharmaceutical Co. v. Bartlett*

In *Mutual Pharmaceutical Co. v. Bartlett*, a consumer of a generic drug brought a design defect claim

under New Hampshire law against a generic drug manufacturer for failure to ensure that the drug was reasonably safe. 570 U.S. at 475. Under New Hampshire law, a drug manufacturer could satisfy its duty to ensure that its drug was reasonably safe "either by changing a drug's design or by changing its labeling." *Id.* at 482, 492. However, because the generic drug manufacturer was unable to change the drug's composition "as a matter of both federal law and basic chemistry," the only way for the manufacturer to fulfill its state-law duty and "escape liability" was by changing the labeling. *Id.* at 475, 483-84 (citing 21 U.S.C. § 355(j) for the proposition that "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based"). The Supreme Court concluded that, under *Mensing*, federal law prohibited the generic drug manufacturer "from taking the remedial action required to avoid liability" under state law, that is, changing the labeling, and therefore the consumer's design-defect claim was pre-empted. *Id.* at 475, 486-87 (citing *Mensing*, 564 U.S. 604).

The First Circuit Court of Appeals had ruled that the generic drug manufacturer could comply with both federal and state law by removing the drug from the market. *Id.* at 475, 479. The Supreme Court stated that this was "no solution" because adopting this "stop-selling rationale would render impossibility pre-emption a dead letter and work a revolution in th[e] Court's preemption case law." *Id.* at 475, 488-90 (rejecting the

stop-selling rationale as "incompatible" with pre-emption jurisprudence because, 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 "presume[s] 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.

4. Application of *Mensing* and *Bartlett*

Based on the *Mensing* and *Bartlett* opinions, federal courts have held that numerous categories of claims against generic drug manufacturers are pre-empted, even where plaintiffs do not couch their claims as design defect or failure to warn. For example, courts have held that claims against generic drug manufacturers for failure to communicate information to consumers or medical providers, where the manufacturers of the listed brand-name drugs have not done so, are pre-empted. *See*, *e.g.*, *In re Darvocet*, 756 F.3d 917, 932-33 (6th Cir. 2014) (concluding that a claim that generic drug manufacturers should have sent letters explaining safety risks to medical providers was pre-empted because, "if 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" (quotation marks omitted)); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 474-75 (5th Cir. 2014) (concluding that a claim that generic drug

manufacturers should have communicated information consistent with the brand-name drug labeling was pre-empted because "the duty of sameness prohibits the generic manufacturers from taking such action unilaterally, they are dependent on brand-names taking the lead" (quotation omitted)); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (concluding that a claim that generic drug manufacturers should have communicated that a labeling change had been made was pre-empted because the manufacturers "were not at liberty" to communicate such information where "no brand-name manufacturer sent a warning based on the . . . label change").

Courts similarly have held that claims against generic drug manufacturers for failure to conduct testing of their drug products are pre-empted. *See*, *e.g.*, *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 476-77 (4th Cir. 2014) (concluding that a claim that a generic drug manufacturer was negligent in the "testing, inspection, and post-market surveillance" of its drug product was pre-empted because any duty to perform such acts fell within the "general duty to protect consumers from injury based on the negligent marketing and sale of a product," and the manufacturer "whose product is unreasonably dangerous as sold could not satisfy that [general] duty without changing its warnings, changing its formulation, exiting the market, or accepting tort liability"); *Morris*, 713 F.3d at 778 (concluding that a claim that generic drug manufacturers failed to test and inspect their products was pre-empted, in part, because "any 'useful' reporting [of testing results]—at

least from the standpoint of those injured—would ostensibly consist of some sort of warning," which the manufacturer could not give).

Courts also have held that claims against generic drug manufacturers for misrepresentation, fraud, and violation of consumer-protection statutes are preempted. *See*, *e.g.*, *In re Darvocet*, 756 F.3d at 935-36 (concluding that fraud, misrepresentation, and consumer-protection claims against generic manufacturers were preempted because the claims "all challenge[d] label content," the plaintiffs did "not identify any representations made other than those contained in the FDA-approved labeling," and the manufacturers "could not have corrected any alleged misrepresentation without violating federal law because they were required to conform their labeling to that of the brand-name drugs"); *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 680 (5th Cir. 2014) (concluding that consumer-protection claims against generic manufacturers were pre-empted because the claims were based on allegations that the manufacturers failed to sufficiently warn consumers, and federal law forbade the manufacturers from making any changes to their FDA-approved warnings); *Drager*, 741 F.3d at 479 (concluding that negligent misrepresentation and fraudulent concealment claims against a generic drug manufacturer were pre-empted because they were premised on the content of the labeling, the manufacturer had "no authority to add or remove information from its materials or to change the formulation of the product to make its representations complete or

truthful," and the manufacturer's "only remaining options [were] to leave the market or accept tort liability").

As one final example, courts have held that claims against generic drug manufacturers for breaches of express and implied warranties are pre-empted. *See*, *e.g.*, *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1288 (10th Cir. 2013) (concluding that an express-warranty claim against a generic drug manufacturer was pre-empted because the plaintiffs did not identify a mechanism through which the manufacturer "could have modified or supplemented the warranties allegedly breached without running afoul of the duty of sameness" and that claims for breach of the implied warranties of merchantability and fitness for intended use were pre-empted because the manufacturer "could not have altered the composition of the [drug] it manufactured without violating federal law"); *Drager*, 741 F.3d at 478-79 (concluding that claims that a generic drug manufacturer had breached an express warranty and the implied warranties of merchantability and fitness for a particular purpose were pre-empted because the manufacturer could not have changed its warnings or drug formulation to comply with the warranties and therefore could avoid liability only by leaving the market).

C. Issues in the Defendants' First Round Motion to Dismiss

The Defendants contend that, under *Mensing* and *Bartlett*, all of the non-derivative claims against them in the MPIC and the CCCAC are pre-empted and must be dismissed. For their part, the Plaintiffs maintain that none of their claims are preempted. The parties' arguments revolve around four separate legal issues raised in the briefing: (1) absolute liability, (2) federal misbranding, (3) general negligence, and (4) the law applicable to prescription drug supply chains. The Court addresses each in turn before turning to (5) the Plaintiffs' federal claim and state-law derivative claims.

1. Absolute Liability

a. Arguments and Allegations

The Defendants argue that they do not have authority under federal law to alter a drug's design or label; all of the Plaintiffs' state-law claims are preempted under *Bartlett* and *Mensing* because, at their core, all of the Plaintiffs' state-law claims are based upon either an allegation of a faulty design or a faulty label. The Defendants cite to cases which found preemption where claims were based upon improper labeling and defective design—cases where the defendant had no ability to alter a label or alter a design. *E.g.*, *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 2:14-mn-02502-RMG, 2016 WL 7368203, at *2 (D.S.C. Nov. 1,

2016) ("a pharmacy also has no authority to unilaterally change a drug's label" and thus, any claims against the pharmacy based on the label are pre-empted); *Greager v. McNeil-PPC, Inc.*, 414 F. Supp. 3d 1137, 1142 (N.D. Ill. 2019) (dismissing claims against retail seller of OTC drug on pre-emption grounds). Indeed, courts have even found that claims against *brand manufacturers* were pre-empted when the manufacturer lost the ability to alter a label. *See In re Darvocet*, 756 F.3d at 940 (affirming dismissal of state claims against brand manufacturer as pre-empted because, once that defendant divested its NDA prior to plaintiff's use of the drug, that defendant had "no more power to change the [brand] label than did [the generic manufacturer]"); *see also Smith v. Teva Pharm. USA, Inc.*, 437 F. Supp. 3d 1159, 1165-66 (S.D. Fla. 2020) ("The FDA's regulations nowhere contemplate a distributor of a brand drug, albeit a distributor closely affiliated with the NDA holder, initiating changes to an approved NDA . . . Fatal to Plaintiff's claims is that Defendant is not [the drug's] NDA holder.").

In contrast to the foregoing authority, the Plaintiffs have provided no citation to a case where similar claims against retailers (or distributors) survived a pre-emption analysis. Similarly, the Plaintiffs have provided no authority in direct opposition to the foregoing authority. Rather, the Plaintiffs respond that neither *Bartlett* nor *Mensing* apply to their claims because their claims are sourced in a theory of absolute liability under state law, while *Bartlett* and *Mensing* addressed only strict liability under state law. As the Plaintiffs

argue that their claims impose absolute liability on the Defendants, they reference the first footnote in the *Bartlett* opinion: "We can thus save for another day the question whether a true absolute-liability state-law system could give rise to impossibility pre-emption." *Bartlett*, 570 U.S. at 482 n.1. Because *Bartlett* expressly declined to hold that absolute liability claims are pre-empted and since all of the Plaintiffs' claims allege absolute liability against the Defendants, the Plaintiffs argue that their claims survive under the *Bartlett* footnote. For their part, the Defendants argue that the Plaintiffs have not pled any absolute liability claims, nor could they as no state has recognized such a claim.

The Plaintiffs have not pled absolute liability claims. The word "absolute" does not appear once in the 1,523 pages of the MPIC and the CCCAC. At the Hearing, the Plaintiffs clarified that their position is that the Court should treat their strict liability claims as functionally equivalent to absolute liability claims. DE 2499 at 95 ("We think that all of these causes of action . . . sound in strict liability. . . . There is no such thing under state law so far as we know as a cause of action titled absolute liability. . . .").

b. Law on Absolute Liability

The Supreme Court in *Bartlett* squarely rejected the plaintiff-respondent's attempt to recast her strict lability claims as absolute liability claims:

> [R]espondent's argument conflates what we will call a "strict-liability" regime (in which

liability does not depend on negligence, **but still signals the breach of a duty**) with what we will call an "absolute-liability" regime (**in which liability does not reflect the breach of any duties at all**, but merely serves to spread risk). New Hampshire has adopted the former, not the latter. Indeed, the New Hampshire Supreme Court has consistently held that the manufacturer of a product has a "duty to design his product reasonably safely for the uses which he can foresee." *Thibault v. Sears, Roebuck & Co.*, 118 N.H. 802, 809, 395 A.2d 843, 847 (1978). See also *Reid v. Spadone Mach. Co.*, 119 N.H. 457, 465, 404 A.2d 1094, 1099 (1979) ("In New Hampshire, the manufacturer is under a general duty to design his product reasonably safely for the uses which he can foresee" (internal quotation marks omitted)); *Chellman v. Saab-Scania AB*, 138 N.H. 73, 78, 637 A.2d 148, 150 (1993) ("The duty to warn is part of the general duty to design, manufacture and sell products that are reasonably safe for their foreseeable uses"); *cf. Simoneau v. South Bend Lathe, Inc.*, 130 N.H. 466, 469, 543 A.2d 407, 409 (1988) ("We limit the application of strict tort liability in this jurisdiction by continuing to emphasize that liability without negligence is not liability without fault"); *Price v. BIC Corp.*, 142 N.H. 386, 390, 702 A.2d 330, 333 (1997) (cautioning "that the term 'unreasonably dangerous' should not be interpreted so broadly as to impose absolute liability on manufacturers or make them insurers of their products"). Accordingly, respondent is incorrect in arguing

> that New Hampshire's strict-liability system "imposes no substantive duties on manufacturers." Brief for Respondent 19.

Bartlett, 570 U.S. at 481-82 (emphases added). The Supreme Court rejected the plaintiff's contention that her strict liability claim imposed no duty on the defendant (serving instead only to spread risk) and instead found that the defendant did owe a duty—there was no absolute liability, independent of a duty owed to a consumer. *Id.* at 485-86. Because the defendant's duty was to either redesign the drug or alter the label, and because both of those actions were prohibited by federal law, the Supreme Court held that the plaintiff's design defect claim was pre-empted. *Id.* at 486-87. Important to the instant case (and as bolded above), the Supreme Court clarified that an absolute liability theory is one that imposes no duties on a defendant. *Id.* at 481.

The Supreme Court's state-specific analysis in *Bartlett* considered the duties a generic manufacturer in New Hampshire owed to the consumers of its products. *Id.* at 481-82. In the abstract, the range of possible duties a state could impose upon a retailer (that merely sells a packaged product) is logically more constrained than the duties a state could conceivably impose upon a manufacturer that designs, produces, *and* sells a product. Unlike a manufacturer, a retailer's more limited duty is, essentially, not to sell a defective product—under such a duty, "[i]t is not enough to show that the product caused the plaintiff's injury or was involved in it. The plaintiff must show that there was

something wrong with the product." *E.g.*, *Tatum v. Cordis Corp.*, 758 F. Supp. 457, 461 (M.D. Tenn. 1991). The Supreme Court expressly expounded upon this concept in *Bartlett* when it refused to permit the plaintiff to equate strict liability with absolute liability. For authority in reaching its conclusion, the Court cited to the Restatement (Second) of Torts, Section 402A. The Restatement explains that a seller's duty under a strict liability regime is not to "sell[] any product in a defective condition." RESTATEMENT (SECOND) OF TORTS § 402A (Am. L. Inst. 1965).

The Plaintiffs have provided no authority for the proposition that the Defendants can be held liable in strict liability regardless of whether there was something wrong with a product or the product's label. At the Hearing, the Court asked Plaintiffs' counsel whether Plaintiffs were aware of any state which would permit a jury trial without the Plaintiff having the burden of proof to show that something was wrong with ranitidine's design or label—the Plaintiffs answered in the negative. DE 2499 at 109-10.

Though strict liability "means liability without negligence, it does not mean liability without some type of fault. . . . There must be such a defect in the product as to render it unreasonably dangerous to the user." *Oregon Farm Bureau Ins. Co. v. E.L. Caldwell & Sons, Inc.*, 306 F. Supp. 835, 838 (D. Or. 1969). In the absence of fault—in the absence of a duty not to sell a *defective* product—a retailer would be relegated to the role of an insurer for each sale it makes and, for this

reason, courts have refused to impose an absolute liability system under the auspices of strict liability. *See*, *e.g.*, *Peterson v. Superior Ct.*, 899 P.2d 905, 919 (1995) (rejecting "the function of loss spreading" as the sole rationale for imposing strict liability); *see also Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 559 (1991) ("[I]t was never the intention of the drafters of the [strict liability] doctrine to make the manufacturer or distributor the insurer of the safety of their products. It was never their intention to impose *absolute* liability."); *Woodill v. Parke Davis & Co.*, 402 N.E.2d 194, 199 (1980) ("Strict liability is not the equivalent of absolute liability."); *Daly v. Gen. Motors Corp.*, 575 P.2d 1162, 1166 (1978) ("From its inception, . . . strict liability has never been, and is not now, *absolute* liability.") (emphasis added); *McHargue v. Stokes Div. of Pennwalt*, 686 F. Supp. 1428, 1434 (D. Colo. 1988) ("Strict liability, however, is not the equivalent of absolute liability. . . .").

The Plaintiffs cite to two trial court decisions in Pennsylvania[9] decided by the same judge on the same day: *Hassett v. Dafoe*, 74 A.3d 202 (Pa. Super. Ct. 2013) and *In re Reglan/Metoclopramide Litig.*, 81 A.3d 80 (Pa. Super. Ct. 2013). The Plaintiffs' citation is for the proposition that Pennsylvania strict liability causes of action are not pre-empted under *Bartlett.* The cases, however, do not support the Plaintiffs' proposition. In

[9] The Plaintiffs also analogize absolute liability to vicarious liability; these doctrines are plainly distinct, and vicarious liability is irrelevant to the issues before the Court.

contrast to the Plaintiffs' representation that *Hassett* held that *Bartlett* does not pre-empt strict liability claims against retailers under Pennsylvania law, the quote cited by the Plaintiffs merely sets forth what the plaintiffs' *argument* was in *Hassett*—the plaintiffs *argued* that *Bartlett* did not pre-empt Pennsylvania strict liability claims. The best support that can be found for the Plaintiffs in *Hassett* is that the trial court made a reference that the argument "appear[ed] to have some vitality." 74 A.3d at 213. What the *Hassett* court held, however, was that while the plaintiffs' claims "may be of the type held to be pre-empted in *Bartlett,*" the court could not reach a conclusion "without a careful analysis of the applicable state law." *Id.* at 217. And, without that analysis, any conclusion on *Bartlett* pre-emption would be "premature." *Id.*

c. Analysis and Conclusion

The Court first considers whether *Bartlett* and *Mensing* facially apply and therefore preclude the Plaintiffs' claims. The Defendants' first point—any state-law claim based upon a faulty label is pre-empted—is supported by a plain reading of *Mensing*:

> To summarize, the relevant state and federal requirements are these: State tort law places a duty directly on all drug manufacturers to adequately and safely label their products. . . . [T]his duty required the Manufacturers to use a different, stronger label than the label they actually used. Federal drug regulations, as interpreted by the FDA, prevented the

> Manufacturers from independently changing their generic drugs' safety labels. . . . We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them.

564 U.S. at 617-18. Similarly, the Defendants' second point—any claim based upon drug design is pre-empted—is also supported by a plain reading of *Bartlett*:

> In the present case, however, redesign was not possible. . . . [T]he FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based. 21 U.S.C. §§ 355(j)(2)(A)(ii)-(v) and (8)(B); 21 C.F.R. § 320.1(c). Consequently, the Court of Appeals was correct to recognize that "Mutual cannot legally make sulindac in another composition." [*Bartlett v. Mutual Pharmaceutical Co.,*] 678 F.3d [30] at 37 [(1st Cir. 2012)]. Indeed, were Mutual to change the composition of its sulindac, the altered chemical would be a new drug that would require its own NDA to be marketed in interstate commerce. See 21 C.F.R. § 310.3(h) (giving examples of when the FDA considers a drug to be new, including cases involving "newness for drug use of any substance which composes such drug, in whole or in part").

Bartlett, 570 U.S. at 483-84. Finally, the Defendants' third point—preemption cannot be avoided by arguing that a party could have ceased to sell a product—is

squarely addressed in *Bartlett*. *Id.* The Court next considers whether the Plaintiffs' claims against the Defendants, as alleged, are indeed based upon a faulty label or design.

The Plaintiffs' first count in the MPIC, Failure to Warn (Strict Liability), alleges that the Defendants failed to warn the Plaintiffs of dangerous risks because the Defendants knew of dangerous risks and did not warn the Plaintiffs about the same. MPIC ¶ 460. The Plaintiffs allege that the labels were inadequate. *Id.* ¶ 467.

The Plaintiffs' second count, Design Defect (Strict Liability), alleges that the Defendants designed a defective product, the ranitidine molecule, and failed to provide proper warnings concerning the design defect. *Id.* ¶¶ 474, 486.

The Plaintiffs' fourth count, Negligence—Failure to Warn, alleges that the Defendants could have, at the time of manufacture, "provided warnings or instructions regarding the full and complete risks" of ranitidine because they knew that the product was dangerous. *Id.* ¶ 505.

The Plaintiffs' seventh count, General Negligence, alleges that the Defendants did not provide the public with accurate information about ranitidine, and that the Defendants did not provide appropriate warnings about the potential effects of ranitidine consumption. *Id.* ¶ 545.

The Plaintiffs' ninth count, Breach of Express Warranties, alleges that no Plaintiff would have consumed ranitidine, had the Defendants properly disclosed the risks associated with consumption. *Id.* ¶ 583.

The Plaintiffs' tenth count, Breach of Implied Warranties, alleges that ranitidine was not adequately tested or researched and that the ranitidine sold by the Defendants was not safe or fit for consumption. *Id.* ¶ 596.

The Plaintiffs' eleventh count, Deceptive Acts, alleges that the Defendants represented ranitidine to have benefits and qualities that it did not have. *Id.* ¶ 608. Plaintiffs further allege that ranitidine was deceptively designed, manufactured, distributed, and sold. *Id.* ¶ 610.

The Plaintiffs' twelfth count, Unjust Enrichment, alleges that the Defendants omitted disclosures that ranitidine consumption presented an unreasonable risk. *Id.* ¶ 631.

As for the CCCAC, the Plaintiffs' allegations mirror the allegations in the MPIC, and the CCCAC brings essentially the same counts (*see* CCCAC at 8-35) with one deviation—the CCCAC brings a federal claim against the Defendants, a claim under the Magnuson-Moss Warranty Act.[10]

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[10] The Plaintiffs' Magnuson-Moss Warranty Act claim is addressed in Section 5, *infra*. The CCCAC also raises a state-law battery claim that alleges the Defendants improperly promoted,

The Court concludes that all of the Plaintiffs' state-law claims against the Defendants are based upon ranitidine's allegedly defective design and inadequate labels/warnings. This Court cannot disregard the holdings in *Bartlett* and *Mensing*. The Defendants have no ability to alter a label or alter a drug's design; thus, claims against them premised on labeling and design are preempted. Courts have routinely reached this conclusion over the years since *Bartlett* and *Mensing* were decided, and the Plaintiffs provide no authority to the contrary.

A Defendant can take only limited steps to comply with state-law duties stemming from the sale of a federally-approved drug; it can (1) modify the label, (2) issue a non-label warning, (3) redesign the drug, or (4) stop selling the product. The Plaintiffs do not dispute that the Defendants would be powerless to cure a design defect in a drug, to make changes to the drug's label, or to issue other warnings without FDA approval. The Defendants would therefore have no recourse to avoid liability except to stop selling the drug altogether. But one thing that *Bartlett* made clear is that a "stop-selling" theory cannot be the basis on which a state law claim survives preemption. 570 U.S. at 488-91. For this reason, as well as others, courts dismiss design and label-based claims against any defendant that is powerless to alter a design or alter a label. *E.g.*, *Smith*, 437 F. Supp. 3d at 1165 ("Whether Plaintiff's state-law claims as to [the defendant] are

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advertised, marketed, distributed, and sold ranitidine. CCCAC ¶ 894.

preempted is wholly dependent on whether Defendant had the authority to 'unilaterally' initiate changes to [the drug's] labels.").

The Plaintiffs have provided no citation to post-*Bartlett* authority where a court reached a different conclusion, nor have the Plaintiffs cited to a case where a court held that strict liability is equivalent to absolute liability—a proposition that *Bartlett* squarely rejected. Instead, the Plaintiffs rely upon Section 402A of the Restatement of Torts, quoting the provision of 402A that notes that a seller may exercise all possible care, but still be found liable under a strict liability claim. But the Supreme Court in *Bartlett* utilized 402A in reaching its conclusion that strict liability is *not* equivalent to absolute liability because strict liability, unlike absolute liability, still imposes a duty upon a seller—the duty not to sell a defective product. At the Hearing, the Court asked the Plaintiffs' counsel if the Plaintiffs were aware of any pharmaceutical case or MDL subsequent to *Bartlett* and *Mensing* that found a state-law strict liability claim had been stated against a retailer or distributor—the Plaintiffs were unable to provide any citation. DE 2499 at 123-24. In summary, all of the caselaw weighs in favor of a conclusion that the Plaintiffs' claims are pre-empted. For these reasons, and because all of the Plaintiffs' state-law claims against the Defendants are premised upon the contention that ranitidine's design or label were deficient, all of the Plaintiffs' state-law claims against the Defendants are pre-empted and therefore dismissed.

The Court's dismissal is with prejudice and without leave to amend. The Court may deny leave to amend when further amendment would be futile. *E.g.*, *Hall v. United Ins. Co. of Am*, 367 F.3d 1255, 1263 (11th Cir. 2004). The Defendants represent to the Court that there is no state that has imposed upon retailers or distributors a faultless, absolute-liability system wherein Defendants *do* function as insurers for damages flowing from the products that they sell. The Court's own research has similarly revealed no such state. At the Hearing, Plaintiffs' counsel conceded that he was not aware of any state that permitted a claim for absolute liability against a retailer or distributor. DE 2499 at 94-95. Instead, counsel affirmed that it was the Plaintiffs' position that their strict liability claims were equivalent (sounded in) absolute liability. *See id.* The Court therefore concludes that further amendment of claims predicated on design defect or an improper label would be futile and denies leave to amend for that reason; however, the Court will permit amendment as to Count VII, general negligence, for the reasons discussed below in subsection (3).

2. Federal Misbranding

a. Arguments and Allegations

The Plaintiffs argue that their claims are not preempted under *Bartlett* and *Mensing* because their claims are parallel to federal law—that is, there is no conflict between federal duties and state duties because the duties are, essentially, the same. They argue

that (i) federal law prohibits the sale of misbranded drugs; (ii) the Plaintiffs have alleged that the Defendants sold misbranded drugs; and (iii) such misbranding is prohibited by state law. Thus, the Plaintiffs' "misbranding" claim is a parallel claim—not a conflicting claim. The Defendants contend that the Plaintiffs' misbranding argument has never been accepted by a court and, if it were, such an argument would invalidate all existing Supreme Court precedent on impossibility pre-emption.

The Plaintiffs have not pled a standalone state-law misbranding claim. Rather, the Plaintiffs have incorporated the allegation that ranitidine was misbranded under federal misbranding law into each of their counts. *E.g.*, MPIC ¶ 418. The Plaintiffs allege that ranitidine products were misbranded because the Defendants "did not disclose NDMA as an ingredient" in the products, "did not disclose the proper directions for storage" of the products, and "did not disclose the proper directions for expiration" of the products. *Id.* ¶¶ 421-23; CCCAC ¶¶ 601-03.

b. Federal Statutes on Misbranding

The U.S. Code prohibits the "introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded," the "adulteration or misbranding of any . . . drug . . . in interstate commerce," the "receipt in interstate commerce of any . . . drug . . . that is adulterated or misbranded," and the "manufacture within any Territory of any . . .

drug . . . that is adulterated or misbranded." 21 U.S.C. § 331(a)-(c), (g). The Plaintiffs do not have a private cause of action to enforce this statute. *Id.* § 337(a) (providing that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States"); *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002) (explaining that "no private right of action exists for a violation of the FDCA"). Section 352 of the U.S. Code contains several sub-sections delineating the circumstances under which a drug "shall be deemed to be misbranded." 21 U.S.C. § 352. As relevant here, a drug is misbranded if "its labeling is false or misleading in any particular" or if "it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." *Id.* § 352(a)(1), (j).

c. Analysis and Conclusion

As a threshold matter, the Plaintiffs have not provided specific authority for the proposition that any of their state-law claims are parallel to federal misbranding law. Plaintiffs' theory of misbranding is that ranitidine's labeling was false and misleading (in violation of 21 U.S.C. § 352(a)(1)) and was dangerous to health when used in conformity with its labeling (in violation of 21 U.S.C. § 352(j)). The Plaintiffs' misbranding argument fails for several independent reasons.

First, as previously discussed, the Defendants could not correct the alleged misbranding by altering the composition of the drug, nor could the Defendants alter the drug's label. The Defendants would have no recourse but to stop selling the drug altogether which they are not required to do to comply with a state law duty. *Bartlett*, 570 U.S. at 488-91. The Plaintiffs' argument that federal law would require the Defendants to stop selling misbranded drugs is of no moment because the Plaintiffs have not plausibly alleged that the Defendants *knew* that the drugs were misbranded or otherwise could have detected the alleged defects in the ranitidine molecule.

Second, in the aftermath of *Bartlett*, courts have only entertained the possibility of misbranding-based claims when the claims were "pure design-defect claims." *E.g.*, *In re Yasmin and Yaz (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2015 WL 7272766, at *4 (S.D. Ill. Nov. 18, 2015) (determining that the plaintiff could not "assert a 'pure' design defect claim under Illinois law."). By definition, however, such a claim could only be brought against a manufacturer—not a retailer or a distributor. *E.g.*, *In re Darvocet*, 756 F.3d at 929-30. Furthermore, the Plaintiffs have provided no authority for the proposition that pre-emption can be avoided by showing that a drug is misbranded under federal law.

Third, a finding that Plaintiffs can avoid pre-emption by alleging that defects in ranitidine products made the products misbranded under 21 U.S.C. § 352 would render the vast body of pre-emption caselaw in

the drug context, including binding Supreme Court decisions, meaningless. If Plaintiffs' position were accepted, a plaintiff could avoid pre-emption simply by asserting, for example, that a drug's labeling was "false or misleading in any particular" or that the drug was "dangerous to health when used" as prescribed. *See* 21 U.S.C. § 352(a)(1), (j). The Court cannot adopt a position that would render pre-emption caselaw meaningless. *Cf. Bartlett*, 570 U.S. at 488-90 (rejecting the stop-selling rationale because it was "incompatible with our pre-emption jurisprudence," would mean that the vast majority or all "of the cases in which the Court has found impossibility pre-emption, were wrongly decided," and would make impossibility pre-emption "all but meaningless" (quotation marks omitted)); *Mensing*, 564 U.S. at 620-21 (rejecting the proposition that pre-emption analysis could be dependent on what a third party or the federal government might do because such a position would "render conflict pre-emption largely meaningless").[11] This is a topic addressed in the Court's Order Granting Generic Manufacturers'

[11] The Defendants raised an additional argument in support of their contention that the Plaintiffs' claims are preempted, an argument premised upon a good-faith exception contained in the federal misbranding statute, 21 U.S.C. § 333 ("No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith. . . ."). At the Hearing, the Plaintiffs made a counter-argument that the good-faith exception does not apply in this case. DE 2499 at 75. Because the Court concludes that the Plaintiffs' misbranding argument does not apply for other, independent reasons, the Court need not address the Defendants' good-faith exception argument.

and Repackagers' Rule 12 Motion to Dismiss on the Ground of Preemption. The Court adopts and incorporates herein the Court's analysis and conclusions contained in that Order.

Fourth, there is no private right of action to enforce federal misbranding law—a statute that imposes criminal penalties. *Ellis*, 311 F.3d at 1284 n.10. The Plaintiffs cannot create a private right of action to enforce federal misbranding rules by disguising it as a state-law strict-liability claim. Indeed, the Plaintiffs have represented that there *are no* state-law duties as to the Retailer Defendants.[12] DE 1977 at 12 (Section II.A. titled: "Retailers Have no Legal Duties Under State Law."). State tort claims that rely solely upon federal law for the source of a duty are preempted. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

For the reasons set forth above, the Plaintiffs' state-law claims, other than the general negligence claim, against the Defendants are pre-empted and, therefore, dismissed with prejudice. The Court's dismissal is without leave to amend as further amendment would be futile; however, the Court will permit amendment as to Count VII, general negligence.

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[12] Because the Plaintiffs filed a consolidated Response to both the Retailer and the Distributor Defendants, it may easily be inferred from the Plaintiffs' argument on this point that it is their contention that state law imposes no duties on *both* the Retailer Defendants and the Distributor Defendants.

3. General Negligence

a. Arguments and Allegations

The Court concluded, in Section VII. C.1.c, that the Plaintiffs' general negligence claim, Count VII in the MPIC, was based upon the adequacy of ranitidine's design and label and, as a result, Count VII was dismissed as pre-empted. The Court's dismissal was without leave to amend; however, the Plaintiffs have separately argued (outside of the arguments contained in Section VII.C.1) that Count VII is unique—that it is not based upon the adequacy of a label or drug design. Thus, the Plaintiffs argue that Count VII is not pre-empted under *Bartlett* or *Mensing*. For their part, the Defendants contend that Count VII is not based upon any legally viable theory.

As pled, the General Negligence count is very broad. By way of example, the Plaintiffs have facially alleged that all of the Defendants *designed* ranitidine because neither the Retailer Defendants nor the Distributor Defendants are delineated from "Defendants" in Count VII. MPIC ¶ 543 ("Defendants, directly or indirectly, designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products that were used by the Plaintiffs."). Thus, the Plaintiffs allege that every Defendant in this MDL engaged in every possible action—designing, marketing, testing, labeling, packaging, and manufacturing—regardless of the individual Defendant's role or purpose in this case. *Id.* Additionally, not only is Count VII styled against all

Defendants without delineation by any one Defendant's role, but the Count applies across every possible timeframe, running from the early 1980's to the present. *E.g.*, *id.* ¶ 542.

b. Analysis and Conclusion

The Court is required to view all factual allegations in the light most favorable to the Plaintiffs, *Bryant v. Avado Brands, Inc.*, 187 F.3d 1271, 1273 n.1 (11th Cir. 1999), but because of the Plaintiffs' shotgun-style pleading of Count VII, the Court cannot discern the precise factual grounds upon which Count VII is based. The Court has therefore relied upon the Plaintiffs' representations in their Response as to the underlying factual premise for Count VII to discern what the Count is intended to allege. The Plaintiffs devote only two paragraphs in their Response to explain the basis for Count VII as follows:

> The Complaints allege negligence against all Defendants. For example, the MPIC includes negligent failure to warn (Count IV) and general negligence (Count VII). The MPIC details a variety of ways in which temperature, light, and other factors relating to storage and handling can hasten ranitidine's breakdown into NDMA, and alleges that "[n]othing prevented any Defendant from, on their own, taking actions to prevent accumulation of NDMA in ranitidine-containing products by ensuring cooled storage and transport. Such actions would not have required FDA approval, nor would they have violated any regulatory

> decisions or laws." MPIC ¶ 408. The FDA in fact requires that storage conditions be appropriate. *See* 21 C.F.R. § 211.142(b) (requiring "Storage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected").
>
> Defendants entirely ignore these negligence allegations. Instead, they mischaracterize all the claims as sounding entirely in failure to warn and design defect. *See* Retailer Mot. At 6 (glossing Count VII as entirely about warnings and marketing). Defendants have provided no basis to dismiss the negligence counts.

DE 1977 at 21-22.[13]

The Court draws two conclusions from the Plaintiffs' representation of the factual premise for Count VII. First, the Plaintiffs did intend for Count VII to be based, at least in part, on the adequacy of the ranitidine label and the alleged defective design of the drug. *See id.* at 22 ("Instead, [the Retailer Defendants] mischaracterize all of the claims as sounding *entirely* in failure to warn and design defect.") (emphasis added). The Court infers from the word "entirely" that, at least in part, Count VII sounded in failure to warn (a label-based claim) and design defect. This is why, in Section VII.C.1.c, the Court found Count VII to be pre-

[13] Because Count IV, negligent failure to warn, turns on the adequacy of the ranitidine label, that count is pre-empted for the reasons set forth in this Order.

empted and dismissed the Count pursuant to *Bartlett* and *Mensing*.

The second conclusion that the Court draws is that the Plaintiffs also intended to premise Count VII on the concept of temperature, alleging that nothing "prevented any Defendant from, on their own, taking actions to prevent accumulation of NDMA in ranitidine-containing products by ensuring cooled storage and transport." *Id.* The Court therefore addresses this temperature-based negligence theory.

The Plaintiffs have alleged that heat can cause the ranitidine molecule to rapidly break down into cancer-causing NDMA. MPIC ¶¶ 340-45. The Plaintiffs further allege:

> Testing conducted by the FDA confirms that improper storage of ranitidine has resulted in extremely high levels of NDMA. FDA has also concluded that NDMA can increase in ranitidine even under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also showed that the level of NDMA in ranitidine-containing products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency

> sought to withdraw ranitidine-containing products altogether.
>
> Nothing prevented any Defendant from, on their own, taking actions to prevent accumulation of NDMA in ranitidine-containing products by ensuring cooled storage and transport. Such actions would not have required FDA approval, nor would they have violated any regulatory decisions or laws.

Id. ¶¶ 407-08 (footnote omitted). Thus, it is the Plaintiffs' contention that the Defendants should be held liable under state law because the Defendants should have used "cooled storage and transport." *Id.* ¶ 408. At the Hearing, the Court inquired about this allegation. *See* DE 2499 at 40-50. Plaintiffs' counsel responded that the Defendants could be held liable for not cooling ranitidine to a low-end-of-the-range temperature permitted by the ranitidine label. *Id.* at 47. Such an action, the Plaintiffs argued, would be consistent with federal regulation and therefore would impose no impossibility pre-emption on a Defendant.[14] The Plaintiffs also responded by explaining that they believed a Defendant could be held liable for overheating a drug in its possession, such as "le[aving] Ranitidine on a hot truck in the Arizona desert during the summer for extensive periods of time creating temperature ranges that

[14] At the Hearing, the Plaintiffs conceded that if a state law required a party to store ranitidine at a temperature *below* federally-approved storage conditions, impossibility pre-emption would apply. DE 2499 at 112.

vastly exceeded those on the label." *Id.* at 77. Neither of these theories is pled in the Master Complaints.

With respect to the "heating" theory—that the Defendants should be held liable for storing ranitidine at an elevated temperature prohibited by *both* federal law and state law—the Plaintiffs have leave in an amended complaint to plead this theory because, at this juncture, the Court is not prepared to conclude it would be futile for the Plaintiffs to so plead; this theory also received minimal discussion in the parties' briefing. Nonetheless, should the Plaintiffs proceed with this theory, the Plaintiffs should address the Court's concerns.

Can the Plaintiffs plead in good faith that any Defendant had a *policy* to store ranitidine products at temperatures above those approved by the FDA? The Court has serious reservations as to whether the Plaintiffs can plead that the Defendants had a global policy or practice to do so because, presumably, that would mean that the Defendants stored *all* drugs—not just the drugs that are the subject of this MDL—at temperatures that could subject the Defendants to litigation from complications arising from all of the stored drugs in their possession. The more reasonable inference from the Plaintiffs' allegations in this regard is that, perhaps, individual stores or warehouses or trucks negligently stored ranitidine, but this leads the Court to additional concerns.

If *individual* stores negligently stored ranitidine at unsafe, heated temperatures, how is that a global,

MDL-based issue? This scenario was implicated in the Plaintiffs' hypothetical, discussed at the Hearing, of a rogue truck overheating ranitidine in a desert. *Id.* That hypothetical appears to the Court to be both individualized and fact-specific and likely would have little, if any, bearing on the broader, more global questions in this MDL. This raises a question as to whether, if a specific truck overheated ranitidine in a desert, such a claim is appropriate in this MDL or should it be severed from the MDL. By way of example, medical malpractice actions are sometimes severed from MDL suits against pharmaceutical companies[15] because the individual questions posed by such claims are best addressed outside of an MDL. This MDL was created for the purposes of efficiency, and there is efficiency in adjudicating the common questions of law and fact stemming from the Plaintiffs' allegations that ranitidine was defectively designed and defectively labeled, together with the related causes of actions that flow from that allegation. DE 1 at 2. However, whether or not a specific truck broke down in a desert, contaminating the drugs contained in the truck, would not appear to be a common question of fact in this MDL.

Furthermore, do the causation questions inherent in a high-temperature allegation further suggest that severance would be appropriate? Suppose a plaintiff alleged that a specific store did not use appropriate air conditioning and, as a result, the ranitidine in the store generated NDMA which caused the plaintiff cancer. A

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[15] *E.g.*, *Joseph v. Baxter Int'l Inc.*, 614 F. Supp. 2d 868, 870 (N.D. Ohio 2009).

natural, logical defense by the store may be that the overheating occurred prior to the store's receipt of the drug—perhaps by an overheated delivery truck or a manufacturer's overheated storage facility. Investigation where, in a supply chain, overheating occurred appears to the Court to be an individualized, fact-intensive discovery challenge. Each supply chain, perhaps even each shipment of ranitidine, could pose different fact-intensive questions—none of which concern global, MDL-based matters.

Finally, how is a high-temperature allegation consistent with the Plaintiffs' core theory of the case? At present, the central premise of this MDL is that ranitidine was defectively designed and that the problems with the ranitidine molecule were concealed from the FDA—the FDA did not know about the potential problems of the ranitidine molecule when the drug was approved for sale. Viewed in that light, how are high-temperature allegations to be squared with the Plaintiffs' theory of the case? Stated differently, it is the Plaintiffs' theory that the Plaintiffs' harm was caused at the very moment ranitidine was manufactured—the Plaintiffs have not alleged that, for some period of time, the ranitidine molecule was safe to consume but, because the Defendants negligently overheated the drug, the drug became unsafe to consume and therefore caused injury to a Plaintiff. This matter is also addressed in the Court's Order Granting Generic Manufacturers' and Repackagers' Rule 12 Motion to Dismiss on the Ground of Preemption. Should the Plaintiffs proceed with a high-temperature theory, the

Plaintiffs must explain how that *specific* theory of liability is compatible with the Plaintiffs' *global* theory of liability.[16]

With respect to the Plaintiffs' "cooling" theory—that to the extent it is the Plaintiffs' intent to hold the Defendants liable for not storing ranitidine at the low-end of a federally-approved range—the Plaintiffs have leave to plead this theory in an amended complaint because, at this juncture, the Court is not prepared to conclude that it would be futile for the Plaintiffs to so plead; this theory received minimal discussion in the parties' briefing. Nonetheless, should the Plaintiffs proceed with this theory, the Plaintiffs should address the Court's additional concerns. How can a Defendant be found liable for storing a drug in accordance with a drug's label? The FDA drug approval process is what determines the appropriate storage temperature for a drug and, as conceded by the Plaintiffs, it is the manufacturer that determines proper storage procedures—not the Defendants. MPIC ¶ 412 (citing USP Ch. 1079). The Plaintiffs should provide authority for the proposition that (i) if a federally-approved label permits a party to store a drug at a specific temperature, nonetheless (ii) a state may impose liability for storing a drug at that temperature.

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[16] As explained in the Court's Order Granting Generic Manufacturers' and Repackagers Rule 12 Motion to Dismiss on the Ground of Preemption, the Plaintiffs may plead inconsistent, incompatible theories in the alternative, but the Plaintiffs have not yet done so.

How were the Defendants to arrive at the conclusion that they should store ranitidine at the low-end of a federally-approved range? As the Plaintiffs concede in the MPIC, the duty to conduct scientific testing on drugs belongs to manufacturers, not retailers. *Id.* ¶ 370 (citing 21 C.F.R. § 211.166(a)). The Plaintiffs have provided no authority for the proposition that Defendants had a duty under state law to hire independent scientists to determine where, in a federally-approved temperature range, a drug should be stored. Finally, if the Plaintiffs challenge the appropriateness of the upper-range of a federally-approved label, does that amount to the charge that Defendants may have a burden, imposed by state law, to deviate from the conditions *permitted* on a federally-approved label?

In conclusion, although the Court in Section VII.C.1.c dismissed all of the Plaintiffs' state-law claims without leave to amend on pre-emption grounds, the Court carves out one exception from its ruling for Count VII, general negligence. The Plaintiffs may amend Count VII, provided the amended claim is not based upon (i) the adequacy of an FDA-approved label or (ii) the design of ranitidine, as more fully discussed in this Order. The Plaintiffs may also amend any general negligence claims raised in the CCCAC. However, to the extent it is possible to do so, the Plaintiffs' amendment and future briefing on this subject should be responsive to the Court's concerns outlined above.

4. Prescription Drug Supply Chain

a. Arguments and Allegations

In addition to arguing impossibility pre-emption under *Bartlett* and *Mensing*, the Defendants argue an express pre-emption affirmative defense that applies to the Defendants that functioned as pharmacies and/or sold prescription-strength ranitidine. The Defendants argue that the Drug Supply Chain Security Act (the "Security Act" or "Act"), 21 U.S.C. §§ 360eee to 360eee-4, expressly pre-empts the Plaintiffs' claims. The Plaintiffs argue the Act is inapplicable to their claims because the Act only concerns product tracing, not product safety.

b. The Drug Supply Chain Security Act

In 2013, Congress passed the Security Act in an effort to secure the supply chain for prescription pharmaceutical drugs. The Act is intentionally broad and comprehensive, governing all trading partners (whether manufacturers, repackagers, distributors, or pharmacies) in the supply chain for prescription drugs and establishing a framework for the critical steps necessary to enable the eventual electronic identification and traceability of prescription drugs. For example, since 2015, trading partners have been required to include specific transaction information for most transfers to other trading partners in the supply chain. *See id.* § 360eee-1.

The Act also imposes specific obligations on pharmacies, called "dispensers" in the Act's text. First,

pharmacies may not accept ownership of a prescription drug unless the previous owner provides specific information about that drug, including its name, its strength and dose, and the manufacturer's confirmation that the drug is what it purports to be and is fit for distribution. *Id.* §§ 360eee(26)-(27), 360eee-1(d)(1)(A)(i). A pharmacy must reject any shipment that is missing this information. Second, the Act requires that pharmacies capture various information "as necessary to investigate a suspect product." *Id.* § 360eee-1(d)(1)(A)(iii) (requiring capture of, among other things, transaction history, product name and dose, and manufacturer's verification of product legitimacy). Suspect products include any drug that a pharmacy has reason to believe is adulterated or otherwise unfit for distribution. *Id.* § 360eee(21). Finally, pharmacies must implement a system for quarantining suspect products and determining whether they are unfit for distribution. *Id.* § 360eee-1(d)(4). Through this web of requirements for pharmacies and others in the supply chain, the Act creates a comprehensive, national framework that sets pharmacies' requirements for identifying, tracing, and isolating adulterated or misbranded drugs.

To give the Act effect, Congress included an express pre-emption provision that precludes imposition of any state requirement that is "inconsistent with, more stringent than, or in addition to" requirements under the Act, including investigation relating to systems for tracing misbranded or adulterated drugs. *Id.* § 360eee-4(a). The pre-emption provision provides

uniformity so that trading partners are not subjected to different rules for identifying, tracing, and quarantining suspect products. It reads, in relevant part:

> *[N]o State or political subdivision of a State may establish or continue in effect any requirements* for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) *which are inconsistent with, more stringent than, or in addition to, any requirements applicable under [the Act].*

Id. (emphases added). Unlike other express pre-emption provisions, which pre-empt only those state requirements that are "inconsistent" with federal standards, the Drug Security Act additionally pre-empts any state requirements for product tracing that are "more stringent than, or in addition to" federal requirements. *Cf. Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 459-60 (2012) (Federal Meat Inspection Act's pre-emption clause that prevents a state from imposing any additional or different requirements "sweeps widely").

c. Analysis and Conclusion

For authority that the Act only concerns itself with drug tracing, the Plaintiffs rely upon the following block-quote in the Act focusing particularly on the bolded section of the quote:

> Beginning on November 27, 2013 [date of enactment], no State or political subdivision of a State may establish or continue in effect any requirements **for tracing products through the distribution system** (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable [by regulation or this statute].

DE 1977 at 18 (quoting 21 U.S.C. § 360-eee(4)(a)). The Plaintiffs ignore, however, additional text in the statute. The Act also pre-empts requirements pertaining to transaction statements, verification, *investigation*, or record keeping, as follows:

> Beginning on November 27, 2013 [date of enactment], no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through

> the distribution system (**including any requirements with respect to statements** of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, **or verification, investigation, disposition, notification, or recordkeeping relating to such systems**, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) **which are inconsistent with, more stringent than, or in addition to, any requirements applicable** [by regulation or this statute].

21 U.S.C. § 360-eee(4)(a) (emphases added). Thus, not only does the Act pre-empt state requirements that pertain to investigation or verification of drugs in the supply chain, but also any state law requirement that is inconsistent with, more stringent than, or in addition to, the requirements of the Act. As to these words—verification and investigation—the Plaintiffs' Response is silent.

The Act prohibits a pharmacy from accepting drugs unless certain criteria are met. *Id.* § 360eee-1(d)(1)(A)(i). But the Plaintiffs' theory of the case is that the Defendants that operated as pharmacies[17]

[17] The Plaintiffs' Master Complaints do not contain a category for "Pharmacy Defendants." Nonetheless, the Defendants who have operated as pharmacies (at any point in time) have moved for dismissal to the extent any claim is premised upon the sale of prescription ranitidine. *See* Section VII.C.3 (discussing how the Plaintiffs have alleged that every Defendant in this MDL is liable for every action at every point in time).

should have refused to accept ranitidine on grounds in addition to—not contained in—the Act. The Plaintiffs contend that the Defendants should not have accepted ranitidine because it was defectively designed, the warning label was insufficient, and the drug may have produced NDMA during transport. The Plaintiffs respond to the Defendants' arguments that, even if there were a duty by the pharmacies to reject shipments of ranitidine, that duty has nothing to do with "tracing products through the distribution system." DE 1977 at 18-19.

In a Notice of Supplemental Authority, the Plaintiffs cite to a recent decision in an MDL wherein the Act was found not to pre-empt certain claims. DE [2488] (citing *In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.*, No. 19-MD-02875, 2020 WL 7418006, at *10-11 (D.N.J. Dec. 17, 2020)). In *Valsartan*, the district court found that both the plaintiffs and the defendants had valid arguments in favor and against pre-emption under the Act, but the court ultimately held in favor of a finding of no pre-emption. 2020 WL 7418006, at *10-11. Unlike the instant case, however, in *Valsartan* the allegation was that the drug became contaminated *before* it entered the supply chain, not *within* the supply chain. *Id.* at 11.[18] Here, the Court declines to rule on pre-emption under the Act for two reasons.

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[18] The Plaintiffs have alleged that NDMA formed in ranitidine during normal, routine transport of the drug. *See* MPIC ¶¶ 407-08.

First, the Court finds that it is unnecessary to decide whether the Act pre-empts claims against Defendants that operated as pharmacies and/or sold prescription-strength ranitidine where the Court has already found pre-emption as to *all* Defendants. Second, the Court declines to decide whether the Act applies to the Plaintiffs' claims when it does not, at this juncture, have clarity as to the precise scope of some of the Plaintiffs' claims. As discussed above in subsection (3) on general negligence, the Plaintiffs advanced a theory at the Hearing that the Defendants should be held liable for failing to cool ranitidine to temperatures at the low-end of the federally-approved range. If Plaintiffs plead and proceed with such a theory, it may be that the Plaintiffs' claims *are* based upon product tracing and are therefore pre-empted.

5. The Plaintiffs' Remaining Claims

The Plaintiffs' sole federal claim, a claim under the Magnuson-Moss Warranty Act, requires a valid state-law anchor breach of warranty claim, however, all of the Plaintiffs' state-law warranty claims have been dismissed. *Cardenas v. Toyota Motor Corp.*, 418 F. Supp. 3d 1090, 1110-11 (S.D. Fla. 2019); *Hernandez v. Johnson & Johnson Consumer, Inc.*, No. 3:19-cv-15679-BRM-TJB, 2020 WL 2537633, at *5 (D.N.J. May 19, 2020). As a result, the Plaintiffs' federal warranty claim is dismissed without prejudice as to the Defendants.

Counts XIII, XIV, and XV of the MPIC are claims for loss of consortium, damages to be paid to the estates of deceased ranitidine-product consumers, and wrongful death. MPIC ¶¶ 637-56. Defendants refer to these three counts as "derivative" claims and contend that these claims must be dismissed if all of the other claims against them are dismissed. Plaintiffs do not dispute that the derivative claims must be dismissed if no other claims remain against Defendants, but Plaintiffs assert again that they can proceed with all of their claims against Defendants. *See 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"). Because the Court is dismissing all underlying claims against Defendants for the reasons given herein, the derivative claims raised against Defendants in Counts XIII, XIV, and XV of the MPIC and any identical claims in the CCCAC are dismissed without prejudice.

VIII. Defendants' Second Round Motions to Dismiss

Pursuant to the Court's schedule in Pretrial Order # 36, the Defendants were permitted to file a second round of motions to dismiss, provided the second-round motions were limited to certain topics out-lined in the Pretrial Order. The Defendants elected to file

additional motions to dismiss that complied with Pretrial Order # 36. Defendants argue in those motions that, in the alternative to a finding by the Court that the Plaintiffs' claims are pre-empted by federal law, the Court should find that certain states have liability shields that insulate the Defendants from the Plaintiffs' claims. Because the Court has granted the Defendants' First Round Motions to Dismiss on pre-emption grounds, the Court denies the Defendants' Second Round Motions to Dismiss as moot,[19] however, the Court addresses one specific point raised in the parties' briefing on the motions.

Both Second Round Motions to Dismiss argued that *some* states shield the Defendants from liability, but the Defendants' arguments were not broken out state-by-state. The Plaintiffs, in their Responses, argued that the Defendants had not met their burden to dismiss the claims in their entirety because the Defendants had not addressed the laws of each state. The Court recognizes that the Defendants' ability to make a state-by-state argument was impaired by the Plaintiffs' shotgun-style pleading. Plaintiffs shall clearly specify, in any future amended pleading, which states' laws their claims are brought under and, as a result, any future motions to dismiss raising the arguments in the second round of motions to dismiss should

[19] At the Hearing, the Defendants agreed that these motions would be moot, provided the Court granted their earlier motions on pre-emption grounds. DE 2499 at 124.

address the law applicable to the Plaintiffs' claims on a state-by-state basis.

IX. Conclusion

For the foregoing reasons, it is **ORDERED AND ADJUDGED** that the Retailer Defendants' Motion to Dismiss at docket entry 1584 is **GRANTED** and the Distributor Defendants' Motion to Dismiss at docket entry 1583 is **GRANTED**. All of the Plaintiffs' claims against the Retailer and the Distributor Defendants are **DISMISSED**. The Court's dismissal is with prejudice except as to the Plaintiffs' general negligence and derivative counts, and as to the Plaintiffs' Magnuson-Moss Warranty Act count, all of which may be repled in accordance with the rulings in this Order. The Retailer Defendants' Motion to Dismiss at docket entry 2044 and the Distributor Defendants' Motion to Dismiss at docket entry 2045 are **DENIED AS MOOT**.

Under Pretrial Order # 36, the Plaintiffs' repled Master Complaints are due 30 days after the Court issues its Order on Article III standing. DE 1346 at 4. The Court **AMENDS** that requirement in Pretrial Order # 36. The Plaintiffs' repled Master Complaints are due 30 days after the Court issues its forthcoming Order on the Branded Defendants' Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law. DE 1580. All other requirements in Pretrial Order # 36 remain in place.

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 31st day of December, 2020.

/s/ Robin L. Rosenberg
ROBIN L. ROSENBERG
UNITED STATES
DISTRICT JUDGE

Copies furnished to: Counsel of Record

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 21-10306-JJ

IN RE: ZANTAC (RANITIDINE)
PRODUCTS LIABILITY
LITIGATION

9:20-cv-80512-RLR

MARILYN WILLIAMS,

Plaintiff - Appellant,

versus

BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC.,
BOEHRINGER INGELHEIM
USA CORPORATION,
WALGREENS BOOT
ALLIANCE, INC.,

Defendants - Appellees.

Appeal from the United States District Court
for the Southern District of Florida

ON PETITION(S) FOR REHEARING AND
PETITION(S) FOR REHEARING EN BANC

(Filed May 18, 2023)

BEFORE: JORDAN and LAGOA, Circuit Judges.*

PER CURIAM:

The Petition for Rehearing En Banc is DENIED, no judge in regular active service on the Court having requested that the Court be polled on rehearing en banc. (FRAP 35) The Petition for Panel Rehearing is also denied. (FRAP 40)

* This order is being entered by a quorum pursuant to 28 U.S.C. § 46(d) due to Judge Luck being recused from this case.

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 REINHART**

THIS DOCUMENT RELATES TO:
MARILYN WILLIAMS
CASE NO. 9:20-CV-80512

JURY TRIAL DEMANDED

AMENDED SHORT-FORM COMPLAINT

(Filed Jan. 27, 2021)

The Plaintiff named below, by counsel, files this Amended Short Form Complaint against Defendants named below. Plaintiff incorporates by reference the allegations contained in the Master Personal Injury Complaint ("MPIC") in *In re: Zantac (Ranitidine) Products Lability Litigation*, MDL No. 2924 (S.D. Fla), Docket Entry 887. Plaintiff files this Amended Short-Form Complaint as permitted by Pretrial Order No. 31.

Plaintiff selects and indicates by completing where requested, the Parties and Causes of Actions specific to this case. Where certain claims require additional pleading or case specific facts and individual information, Plaintiff shall add and include them herein.

Plaintiff, by counsel, alleges as follows:

I. PARTIES, JURISDICTION, AND VENUE

A. PLAINTIFF

1. Plaintiff Marilyn Williams ("Plaintiff") brings this action (check the applicable designation):

   ☒ On behalf of herself;

   ☐ In representative capacity as the _____, on behalf of the injured party, (Injured Party's Name) _____.

2. Injured Party is currently a resident and citizen of Montgomery, Alabama and claims damages as set forth below.

   —OR—

   Decedent died on (Month, Day, Year) _____. At the time of Decedent's death, Decedent was a resident and citizen of (City, State) _____.

If any party claims loss of consortium,

3. _____ ("Consortium Plaintiff") alleges damages for loss of consortium.

4. At the time of the filing of this Short Form Complaint, Consortium Plaintiff is a citizen and resident of (City, State) _____.

5. At the time the alleged injury occurred, Consortium Plaintiff resided in (City, State) _____.

B. DEFENDANT(S)

6. Plaintiff names the following Defendants from the Master Personal Injury Complaint in this action:

   a. Brand Manufacturers: Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim USA Corporation

   b. Generic Manufacturers: None.

   c. Distributors: None.

   d. Retailers: Walgreens Boots Alliance, Inc.

   e. Repackagers: None.

   f. Others Not Named in the MPIC: None.

C. JURISDICTION AND VENUE

7. Identify the Federal District Court in which Plaintiff(s) would have filed this action in the absence of Pretrial Order No. 11 (direct filing) [or, if applicable, the District Court to which their original action was removed]:

   United States District Court
   Middle District of Alabama
   Northern Division
   (Where the case was pending before being transferred to the MDL.)

8. Jurisdiction is proper upon diversity of citizenship.

II. PRODUCT USE

9. The Injured Party used Zantac: [*Check all that apply*]

    ☐ By prescription

    ☒ Over the counter

10. The Injured Party used Zantac from approximately January 2011 to December 2016.

III. PHYSICAL INJURY

11. As a result of the Injured Party's use of the medications specified above, [*he/she*] was diagnosed with the following specific type of cancer (check all that apply):

Check all that apply	Cancer Type	Approximate Date of Diagnosis
☐	BLADDER CANCER	
☐	BRAIN CANCER	
☐	BREAST CANCER	
☐	COLORECTAL CANCER	
☐	ESOPHAGEAL/THROAT/ NASAL CANCER	
☐	INTESTINAL CANCER	
☐	KIDNEY CANCER	
☐	LIVER CANCER	
☐	LUNG CANCER	
☒	OVARIAN CANCER	August 2016
☐	PANCREATIC CANCER	
☐	PROSTATE CANCER	
☐	STOMACH CANCER	

☐	TESTICULAR CANCER	
☐	THYROID CANCER	
☐	UTERINE CANCER	
☒	OTHER CANCER: Abdominal	August 2016
☐	DEATH (CAUSED BY CANCER)	

12. Defendants, by their actions or inactions, proximately caused the injuries to Plaintiff.

IV. CAUSES OF ACTION ASSERTED

13. Plaintiff's sole theory of liability is that the ranitidine she consumed was defectively designed under state law, and that these same design defects made ranitidine dangerous to health when used as instructed on the label such that it was misbranded under federal law. The ranitidine Plaintiff consumed was illegal to sell under federal law, and requires compensation under state design defect tort law.

14. The following Causes of Action asserted in the Master Personal Injury Complaint are asserted against the specified defendants in each class of Defendants enumerated therein, and the allegations with regard thereto are adopted in this Amended Short Form Complaint by reference.

Check if Applicable	COUNT	Cause of Action
☐	I	STRICT PRODUCTS LIABILITY – FAILURE TO WARN
☒	II	STRICT PRODUCTS LIABILITY – DESIGN DEFECT
☐	III	STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT
☐	IV	NEGLIGENCE – FAILURE TO WARN
☐	V	NEGLIGENT PRODUCT DESIGN
☐	VI	NEGLIGENT MANUFACTURING
☐	VII	GENERAL NEGLIGENCE
☐	VIII	NEGLIGENT MISREPRESENTATION
☐	IX	BREACH OF EXPRESS WARRANTIES
☐	X	BREACH OF IMPLIED WARRANTIES

☐	XI	VIOLATION OF CONSUMER PROTECTION AND DECEPTIVE TRADE PRACTICES LAWS and specify the state's statute below: _____
☐	XII	UNJUST ENRICHMENT
☐	XIII	LOSS OF CONSORTIUM
☐	XIV	SURVIVAL ACTION
☐	XV	WRONGFUL DEATH
☐	XVI	OTHER:
☐	XVII	OTHER:

If Count XVI or Count XVII is alleged, additional facts supporting the claim(s):

_____

_____

_____

V. JURY DEMAND

15. Plaintiff hereby demands a trial by jury as to all claims in this action.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff has been damaged as a result of Defendants' actions or inactions and demands

judgment against Defendants on the above-referenced causes of action, jointly and severally to the full extent available in law or equity, as requested in the Master Personal Injury Complaint.

Dated: January 27, 2021

/s/ Michael L. McGlamry
Michael L. McGlamry
(GA Bar No. 492515)
N. Kirkland Pope
(GA Bar No. 584255)
Caroline G. McGlamry
(GA Bar No. 230832)
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ATTORNEYS FOR PLAINTIFF

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 REINHART**

THIS DOCUMENT RELATES TO:
MARILYN WILLIAMS
CASE NO. 9:20-CV-80512

NOTICE OF VOLUNTARY DISMISSAL *WITHOUT* PREJUDICE

(Filed Jan. 27, 2021)

Pursuant to Pretrial Order # 39, Plaintiff Marilyn Williams, who instituted the above-captioned action, a member case in *In Re Zantac Products Liability Litigation*, MDL. No. 2924 (S.D. Fla.), hereby provides notice pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(i) that the case is **DISMISSED *WITHOUT* PREJUDICE**.

By filing this notice, undersigned counsel certifies that no answer or motion for summary judgment has previously been served in response to the Short-Form Complaint or Individual Long-Form Complaint to which this notice applies.

DATED: January 27, 2021.

/s/ Michael L. McGlamry
Michael L. McGlamry
(GA Bar No. 492515)
N. Kirkland Pope
(GA Bar No. 584255)
Caroline G. McGlamry
(GA Bar No. 230832)
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ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

I hereby certify that on January 27, 2021, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and that the foregoing document is being served on all counsel of record or parties registered to receive CM/ECF Electronic Filings.

/s/ *Michael L. McGlamry*
Michael L. McGlamry

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 REINHART**

THIS DOCUMENT RELATES TO:
MARILYN WILLIAMS
CASE NO. 9:20-CV-80512

Marilyn Williams, Plaintiff

v.

Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim USA Corporation, Walgreens Boot Alliance, Inc., Defendants

Notice of Appeal

(Filed Jan. 27, 2021)

Notice is hereby given that Marilyn Williams, plaintiff in the above named case, hereby appeals to the United States Court of Appeals for the Eleventh Circuit from D.E. 2532, 2512, and 2513, Orders granting Defendants' Motions to Dismiss on preemption grounds, the last of which was entered in this action on the 8th day of January, 2021.

These Orders were made final with respect to Plaintiff Marilyn Williams on the 27th day of January, 2021, when Plaintiff amended her Short Form

Complaint to eliminate all claims for which repleading was permitted by the Court's Orders.

DATED: January 27, 2021.

Respectfully submitted,

/s/Ashley Keller
Ashley Keller
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Counsel for Plaintiff–Appellant

CERTIFICATE OF SERVICE

I hereby certify that on January 27, 2021, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and that the foregoing document is being served on all counsel of record or parties registered to receive CM/ECF Electronic Filings.

/s/Ashley Keller
Ashley Keller