UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

MDL NO. 2924
20-MD-2924

JUDGE ROBIN L. ROSENBERG
MAGISTRATE JUDGE BRUCE E. REINHART

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THIS DOCUMENT RELATES TO: ALL CASES

ORDER ENTERING SUMMARY JUDGMENT PURSUANT TO RULE 56(F)

This matter is before the Court on the Retailers' and Distributors' Motion for Summary Judgment at docket entry 6233, the Generic Defendants' Motion for Entry of Final Judgment at docket entry 6236, the Generic Defendants' Motion for Entry of Judgment at docket entry 6237, the Brand Defendants' Memorandum of Law Addressing Entry of Final Judgment at docket entry 6235, and the Plaintiffs' Memorandum Addressing Final Judgment at docket entry 6234. The Motions have been fully briefed, and each matter is ripe for adjudication.

Each of the filings referenced above either seeks entry of final judgment or opposes entry of final judgment. After careful consideration, the Court previously concluded that its decision to enter final judgment or to decline the entry of final judgment had to await certain threshold determinations. DE 6303. One such threshold determination was whether certain Defendants were entitled to summary judgment because, if they were, summary judgment would in turn entitle those Defendants to the entry of final judgment. The purpose of this Order is to resolve the question of summary judgment, and, once the question of summary judgment is resolved, the Court will turn to the question of which Defendants are entitled to final judgment and how final judgment will be entered. The Court begins its analysis with (**I**) a summary of the background and procedural history underpinning the Court's summary judgment decision.

I. Background and Procedural History

On December 6, 2022, the Court entered summary judgment in favor of the Defendants that manufactured brand-name ranitidine (the "Brand Defendants") for all Designated Cancers.[1] DE 6120. The basis for the Court's entry of summary judgment was that the Plaintiffs had no reliable evidence that ranitidine could cause cancer—reliable evidence of general causation. The Plaintiffs had no reliable evidence because, in the same order, the Court granted the Brand Defendants' *Daubert* motions and excluded the opinions of the Plaintiffs' general causation experts.

One month after the Court's entry of summary judgment, on January 5, 2023, the Court held a status conference. At the status conference, the Court questioned the parties on what matters in the MDL still required adjudication. Broadly summarized, the parties informed the Court that three matters remained before the Court. First, the parties disagreed over whether the class action cases (which allege economic injuries and also seek medical monitoring) could proceed in light of the Court's *Daubert* decision. The Court addresses that issue in a separate forthcoming order. Second, the parties disagreed over whether the Court's ruling on general causation at summary judgment for the Brand Defendants was dispositive of general causation for non-Brand Defendants, such as the manufacturers of generic ranitidine (the "Generic Defendants"), distributors of ranitidine (the "Distributor Defendants"), and resellers of ranitidine (the "Retailer Defendants"). Third, the parties disagreed over whether the Court's ruling applied to cases filed after December 6, 2022. This Order addresses the latter two issues.

After the parties briefed their various positions, the Court entered two orders to show cause. One order to show cause required the Plaintiffs to explain why summary judgment should not be

1 Designated Cancers are bladder, esophageal, pancreatic, stomach, and liver cancer.

entered against all Plaintiffs in the MDL, regardless of the date upon which the Plaintiffs' cases were filed. DE 6444. The other order to show cause required the Plaintiffs to explain why summary judgment should not be entered for the non-Brand Defendants for the same reasons summary judgment was entered in favor of the Brand Defendants. DE 6303. The Plaintiffs filed a single response to both orders to show cause. DE 6540. The Brand Defendants filed a reply to the Plaintiffs' response. DE 6592. The Non-Brand Defendants also filed a reply to the Plaintiffs' response. DE 6590, 6591. Below, the Court (**II**) first addresses the issue of cases filed after December 6, 2022, and then (**III**) addresses the non-Brand Defendants. Finally, the Court (**IV**) creates a process for its eventual entry of final judgment.

II. The Court's Entry of Summary Judgment in Cases Filed After December 6, 2022

At a status conference on the Court's entry of final judgment, the Plaintiffs took the position that cases filed after December 6, 2022, did not qualify for the immediate entry of final judgment because the Plaintiffs in those cases had a due process right to be heard and, if judgment was entered immediately, the Plaintiffs would be deprived of their due process rights. *E.g.,* DE 6274 at 25. The Plaintiffs initially took no position on cases filed prior to December 6, such as a case filed on December 5. *Id.* at 24 ("The December 5th example is an interesting one, it is one I would like to think about more. Let's put a pin in that."). In subsequent briefing, however, the Plaintiffs chose a date of August 1, 2022. DE 6234 at 1. The Plaintiffs argued that cases filed on or after that date did not qualify for the immediate entry of final judgment because the Plaintiffs' response to the Brand Defendant's *Daubert* motions was filed on the same day, and that the Court could only enter final judgment if it first gave the Plaintiffs an opportunity to be heard, such as through an order to show cause process. *Id.* For their part, the Brand Defendants argued the relevant date was December 6, not August 1, and that Plaintiffs who filed after December 6 needed an opportunity

to be heard before final judgment count be entered, such as through an order to show cause process. DE 6235 at 2.

The Court's subsequent order to show cause, issued following the status conference and after the benefit of the parties' input, was not limited to any particular date. The Court ordered the Plaintiffs to show cause why summary judgment should not be entered in *all* of the Plaintiffs' cases, without regard to dates:

> This Order serves as a Rule 56(f) notice, through an order to show cause process, and grants the Plaintiffs the opportunity to address why the Court should not enter summary judgment as to ***every*** Designated Cancer personal injury case in the MDL, ***regardless*** of the date the case was first filed, ***including*** cases filed on or after August 1, 2022, for of all the reasons the Brand Defendants were previously found to be entitled to summary judgment.

DE 6444 at 8 (emphasis added). The Court's order to show cause was premised on Rule 56(f) of the Federal Rules of Civil Procedure. Pursuant to that Rule, after giving notice and an opportunity to respond, a court may grant summary judgment to a non-movant, or it may consider summary judgment on its own. Consistent with the Plaintiffs' request, the Court therefore ordered individual Plaintiffs to show cause why it should not enter summary judgment in any individual case, regardless of the date upon which the case may have been filed.

In response to the Court's order to show cause, Plaintiffs' leadership did not provide a reason why any *specific* individual case should not, because of the date the case was filed, receive entry of summary judgment under Rule 56(f). Instead, Plaintiffs' leadership argued more generally that individual Plaintiffs had not had the opportunity to retain their own experts and individual Plaintiffs should have the opportunity to "out-out" of leadership's previously chosen (and stricken) experts. DE 6540 at 1-3. Plaintiffs' leadership's argument was premised on the case of *Home Depot USA, Inc. v. Lafarge N. Am., Inc.*, 59 F.4th 55 (3d Cir. 2023), a case decided shortly before the Court's order to show cause.

In *Home Depot*, the district court certified an appeal under 28 U.S.C. § 1292(b). The district court sought appellate guidance on how earlier-entered orders in an MDL may be applied to later-arriving plaintiffs, just like the instant question before this Court. *Id.* at 60-62. The Third Circuit provided the district court with the guidance it requested:

> [A] court may rely on its prior decisions as persuasive, and demand good reasons to change its mind. Both parties here agree that this procedure is appropriate.
>
> A judge may formalize this process through the use of case management orders. This practice is regularly employed in MDLs—a judge may enter an order with respect to one party and then provide that it will be automatically extended to other parties if they do not come forward and show cause why it should not be applicable. *See, e.g.*, Order of Jan. 24, 2018, *In re Terrorist Attacks on Sept. 11, 2001*, No. 03-MD-1570, at 2 (S.D.N.Y. Jan. 24, 2018) ("Any order entered into, or decision rendered, in this MDL that relates to all actions shall apply to all Tag-Along Actions without the need for separate motions and orders, unless counsel in a Tag-Along Action show good cause why the order should not apply to that Tag-Along Action."); Order to Show Cause as to the B3 Claims Against the Clean-Up Responder Defendants, *In re Oil Spill by the Oil Rig Deepwater Horizon*, No. 10-MD-2179 (E.D. La. Jan. 7, 2016) (similar); Order No. 50, *In re Gen. Motors LLC Ignition Switch Litig.*, No. 14-MD-02543, at 8 (S.D.N.Y. Apr. 24, 2015) (implementing a show-cause procedure for applying rulings made on the basis of consolidated pleadings to non-consolidated actions).
>
> This is a technique that we have approved.

Id. at 65-66 (citations partially omitted). The Third Circuit therefore endorsed an order to show cause process, just like the order to show cause process in the instant case.

With respect to the Third Circuit's observation that "a court may rely on its prior decisions as persuasive, and demand good reasons to change its mind," the Court's order to show cause in this MDL detailed various "reasons" or issues that an individual Plaintiff should address, if the Plaintiff were to seek to change the Court's mind. By way of example, the Court explained its own understanding, based upon what it learned at the *Daubert* stage of these proceedings, that the theoretical potential of ranitidine to cause cancer would be the same for every Plaintiff, regardless of the date upon which a Plaintiff filed his or her case. DE 6444 at 8. The Court's order to show

cause explained why its *Daubert* decision would apply to every Plaintiff unless a Plaintiff came "forward and show[ed] cause why it should not be applicable" to the individual Plaintiff, the very process that the Third Circuit endorsed in *Home Depot*.

Just as Plaintiffs' leadership requested, the Court provided a show cause process for individual Plaintiffs to be heard: "Individual Plaintiffs who elect to file a response to this Order to Show Cause that differs from the response filed by Plaintiffs' leadership may file a motion for leave to file a response by May 5, 2023." *Id.* at 16. The Court's deadline of May 5, 2023, has passed, but no individual Plaintiff has filed a response to the Court's order to show cause or requested leave to file a response to the Court's order to show cause. Therefore, the Court finding its prior *Daubert* and summary judgment decision persuasive, the Court seeing no good reason to depart from its decision or to otherwise not apply the decision to any individual Plaintiff's case, and for all of the reasons set forth in the Court's order to show cause, the Court's prior summary judgment ruling applies to every Designated Cancer case in this MDL filed prior to May 5, 2023. Summary judgment in turn entitles certain Defendants to the entry of final judgment, the next topic to which the Court now turns.

III. The Court's Entry of Summary Judgment as to Non-Brand Defendants

At the *Daubert* stage of these proceedings, only the Brand Defendants were named Defendants in the Plaintiffs' master pleadings.[2] For this reason, only the Brand Defendants moved for the Plaintiffs' general causation experts to be excluded and only the Brand Defendants moved for summary judgment. Yet other, non-Brand Defendants (previously named in the master complaints) have never completely exited from this MDL because those non-Brand Defendants have repeatedly been named as Defendants in individual Plaintiff's cases. For that reason (as well

2 The non-Brand Defendants were dismissed from the master pleadings in the summer of 2021. *E.g.,* DE 3718.

as others) the non-Brand Defendants seek the entry of summary judgment for the same reasons that the Brand Defendants previously received summary judgment. Because of the unusual procedural posture the non-Brand Defendants find themselves in, (**A**) a discussion of that procedural posture is warranted. After that discussion, the Court (**B**) discusses and analyzes its prior order to show cause on the non-Brand Defendants' request for entry of summary judgment before (**C**) entering its final ruling.

A. The Procedural Posture of the Non-Brand Defendants

1. The Structure of the Pleadings in this MDL

In Pretrial Order 31, this Court created a structure for personal injury pleadings. That structure consists of two operative pleadings. The first operative pleading is a master complaint, drafted by Plaintiffs' leadership counsel and filed on the main MDL docket. The second operative pleading is a Short Form Complaint, drafted by each individual Plaintiff's counsel (or *pro se* Plaintiff) and filed in each Plaintiff's individual case.

The master complaint contains many claims arising under the laws of many jurisdictions, and the large number of claims stems from the fact that the master complaint is brought by Plaintiffs' leadership on behalf of *every* individual Plaintiff in this MDL. Because individual Plaintiffs may elect to pursue only some of the claims in the master complaint, the individual Short Form Complaints are the vehicle by which individual Plaintiffs choose the claims in the master complaint that they are pursuing. For example, each Short Form Complaint contains checkboxes for the claims pled in the master complaint. An individual Plaintiff selects claims from the master complaint by checking the boxes for the appropriate claims, as shown in the following excerpt from a recently-filed[3] Short Form Complaint:

3 This example is taken from case 23-CV-11202.

[X]	IX	Negligent Product Containers: (Against Brand-Name and Generic Manufacturers of pills)	All States and Territories
[]	X	Negligent Storage and Transportation Outside the Labeled Range (Against All Retailer and Distributor Defendants)	All States and Territories
[X]	XI	Negligent Storage and Transportation Outside the Labeled Range (Against All Brand-Name and Generic Manufacturer Defendants)	All States and Territories
[]	XII	Negligent Misrepresentation (Against Brand-Name Manufacturers by Generic Consumers in California)	CA only
[]	XIII	Reckless Misrepresentation (Against Brand-Name Manufacturers by Generic Consumers in Massachusetts)	MA only
[X]	XIV	Unjust Enrichment (Against All Defendants)	All States and Territories

In this example, the individual Plaintiff has elected to bring Count IX in the master complaint, a negligence claim against Brand Defendants and Generic Defendants, but has not elected to bring Count X, a negligence claim against Retailer Defendants or Distributor Defendants. The individual Plaintiff in this example also elected to bring Count XIV, an unjust enrichment claim against all Defendants. These elections by the Plaintiffs do not name the *specific* Defendants they are suing; rather, the Plaintiffs merely check the box in the Short Form Complaint for the claim(s) they wish to bring against a *category* of Defendants.

To show how individual Plaintiffs specify the Defendants in their Short Form Complaint, the Court sets forth below another example.[4] In this example, the Plaintiff brought claims against the following Defendants:

4 This example is taken from case 23-CV-10154.

6. Plaintiff(s) name(s) the following Defendants from the Amended Master Personal Injury Complaint in this action:

a. Brand-Name Manufacturers:
Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim Corporation; Boehringer Ingelheim USA Corporation; Boehringer Ingelheim International GmbH; Boehringer Ingelheim Promeco, S.A. de C.V.; GLAXOSMITHKLINE LLC; GLAXOSMITHKLINE HOLDINGS (AMERICAS) INC.; GlaxoSmithKline PLC; PFIZER INC.

b. Generic Manufacturers:
Amneal Pharmaceuticals of New York, LLC; Amneal Pharmaceuticals LLC; Apotex Corp.; Apotex Inc.; Dr. Reddy's Laboratories, Inc.; Dr. Reddy's Laboratories, Ltd.; Dr. Reddy's Laboratories LOUISIANA LLC; Dr. Reddy's Laboratories SA; Glenmark Pharmaceuticals, Inc. USA; L. Perrigo Co; Perrigo Company; Perrigo Research & Development Company; Sandoz, Inc.; Strides Pharma, Inc.; Ranbaxy, Inc.; Sun Pharmaceutical Industries, Inc.; Sun Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc.; Actavis Mid Atlantic LLC; Watson Laboratories, Inc.; Wockhardt Ltd.; Wockhardt USA LLC; Wockhardt USA, Inc

d. Retailers:

John Doe

e. Others Not Named in the AMPIC:

John Doe

(The Short Form Complaint's reference to the Amended Master Personal Injury Complaint corresponds to the master complaint at docket entry 2759). Important to this Order, the individual Plaintiff in the immediately preceding example brings claims against many Brand Defendants, many Generic Defendants, and certain unidentified Retailer and Distributor Defendants. This fact—the naming of non-Brand Defendants in the Short Form Complaints—is important because of the Court's prior rulings on motions to dismiss, as discussed below.

2. The Court's Prior Rulings on the Master Complaints

The first master personal injury complaint, the Master Personal Injury Complaint at docket entry 887, brought many different counts against Retailer and Distributor Defendants. In

December of 2020, the Court ruled on several motions to dismiss, and one of the Court's key rulings was the conclusion that most of the Plaintiffs' claims against Retailer and Distributor Defendants were pre-empted under federal law and were therefore dismissed. However, one claim against the Retailer and Distributor Defendants, a claim for negligence, survived the Court's initial rulings and the Court permitted the Plaintiffs to replead the claim in a future master pleading.

Consistent with the Court's ruling on the initial motions to dismiss, Plaintiffs' leadership filed an Amended Master Personal Injury Complaint at docket entry 2759. That master pleading contained one count against the Retailer and Distributor Defendants, a negligence count. After a second round of motions to dismiss in July of 2021, however, the Court dismissed the negligence count without leave to amend in the *master* complaint, but the Court permitted the count to be repled in Short Form Complaints. DE 3716. The Court also dismissed with prejudice all claims against the Generic Defendants on pre-emption grounds. DE 3718. Plaintiffs' leadership filed a Second Amended Master Personal Injury Complaint at docket entry at 3887 which, consistent with the Court's rulings, no longer contained any claim against the Generic, Retailer, or Distributor Defendants. It is this pleading, the second amended pleading filed in August of 2021, which is the operative master personal injury complaint in this MDL.

This brings the Court to a confusing pleading issue. The Court's Short Form Complaint examples above were filed very recently—February of 2023. Yet they bring claims against Generic, Retailer, and Distributor Defendants who were dismissed from the master complaints in July of 2021. In doing so, many of the Plaintiffs do not incorporate or rely upon the current, operative master pleading. Instead, many Short Form Complaints utilize and incorporate claims from an earlier, interim pleading, the Amended Master Personal Injury Complaint at docket entry 2759.

The Court does not fully undertsand the decision of many Plaintiffs to rely upon outdated, non-operative pleadings with claims that were previously dismissed. For example, in one of the individual cases cited above (23-CV-10154), in February of 2023, the Plaintiff brought a negligence claim against a Retailer Defendant that the Court dismissed in July of 2021:

		Name and Generic Manufacturers of pills)	Territories
X	X	Negligent Storage and Transportation Outside the Labeled Range (Against All Retailer and Distributor Defendants)	All States and Territories
	XI	Negligent Storage and Transportation Outside the	All States and

The Plaintiffs' reliance upon non-operative pleadings in their Short Form Complaints conflicts with Pretrial Order 31, the pretrial order governing Short Form Complaints. Pursuant to Pretrial Order 31, all claims in a master complaint "supersede and replace all claims pleaded in any complaint previously filed" in this MDL. Thus, when Plaintiffs' leadership filed the operative master pleading, it superseded and replaced all prior master complaints and all prior pled claims. This Court is not alone in struggling with some individual Plaintiffs' reliance upon dismissed, non-operative pleadings. In an earlier appeal in this MDL, the Eleventh Circuit puzzled:

> At the time he filed the second amended [Short Form Complaint], it purported to incorporate the allegations of the [Master Personal Injury Complaint], but there was no operative [Master Personal Injury Complaint] to incorporate because the [Master Personal Injury Complaint] had been dismissed.
>
> . . .
>
> [T]he district court had no opportunity to enter any final judgment because [Plaintiff] filed a notice of appeal the very day he filed the second amended [Short Form Complaint] and at a time when there was no MPIC to incorporate.

DE 6146 at 12, 13.

The Court's best guess is that individual Plaintiffs have relied upon non-operative pleadings to preserve their right to appeal the Court's prior dismissal of certain claims in the master complaints. But Pretrial Order 31 contains a procedure that would, if invoked, permit a Plaintiff

to preserve his or her right to appeal. Pursuant to Pretrial Order 31, individual Plaintiffs may include "additional allegations or causes of action not pleaded" in the master personal injury complaints. Thus, because the current operative master pleading does not contain any causes of action against Retailer, Distributor, or Generic Defendants, Pretrial Order 31 permits Plaintiffs to separately plead those causes of action. At the appropriate time, such claims could be adjudicated upon motion. For example, if applicable, the Court could dismiss claims in Short Form Complaints for all of the reasons set forth in its prior rulings on identical claims in the master complaints. This brings the Court to another topic generating confusion in the context of the entry of final judgment: how the Court's rulings on the master complaints apply to individual cases.

3. How the Court's Prior Rulings Apply to Individual Cases

The Plaintiffs previously maintained that the Court's rulings on the master complaints applied in each individual case without the need for any further action from the Court. In other words, the Plaintiffs took the position that case-specific adjudication of Short Form Complaints was unnecessary. *E.g.,* DE 6223 (referencing a prior appeal taken without a final judgment). Based upon that belief, the Plaintiffs previously appealed many of the Court's prior rulings, arguing to the Eleventh Circuit that their appeals were both perfected and timely.

The Eleventh Circuit disagreed, finding that the Plaintiffs' prior appeals were improper for at least two reasons.[5] First, at any time a Plaintiff could seek to amend a Short Form Complaint. As explained by the Eleventh Circuit: "Indeed, [Plaintiff] could file a third amended [Short Form Complaint] today incorporating the second amended [Master Personal Injury Complaint] and selecting a new combination of claims to assert." *Id.* at 12. Second, because each individual

5 The Court's interpretation of Pretrial Order 31 and the need for case-specific adjudication of its rulings on the master pleadings matched the Eleventh Circuit's interpretation of the same.

personal injury case has *two* operative pleadings, the Court's ruling on a master complaint was not sufficient—the Court had to adjudicate both a Short Form Complaint and the master complaint that the Short Form Complaint utilized. As explained by the Eleventh Circuit:

> [The Plaintiff] cannot unilaterally declare his second amended [Short Form Complaint] dead when the district court has not done so, and he cannot deny that this [Short Form Complaint] is still alive and pending in the district court.
>
> . . .
>
> Because there is no final ruling against his operative complaint—the combination of the [Master Personal Injury Complaint] and his [Short Form Complaint]—to put the last nail in the coffin of his action, we lack jurisdiction to consider [the Plaintiff's] appeal.

Id. at 13.

What is clear from the Eleventh Circuit's discussion on this topic, and from Pretrial Order 31's requirements, is that if an individual case is to be dismissed or to receive final judgment, a Defendant must move for dismissal of the case or for entry of final judgment. All of the Defendants have now done so. The Brand Defendants, as active Defendants in the master complaints, clearly have standing to request the entry of final judgment (and they have), citing the Court's prior entry of summary judgment in their favor. As to the non-Brand Defendants, while they are no longer named in the master complaints, they continue to be named as Defendants in individual cases in Short Form Complaints, and it would therefore be incorrect to suggest (as the Plaintiffs have done from time to time) that the non-Brand Defendants are no longer parties to this MDL. The Court concludes for all of the reasons set forth above that the non-Brand Defendants also have standing to seek entry of final judgment in individual cases in which they are named in the Short Form Complaint. And they have now done so, requesting that summary judgment be entered in their favor for all of the same reasons summary judgment was entered in the Brand Defendants' favor.

4. The Non-Brand Claims that Remain Pending in this MDL

The Court is uncertain what claims against non-Brand Defendants remain in this MDL.[6] The Court's uncertainty arises from how individual Plaintiffs have drafted their Short Form Complaints, as detailed above. By way of example, when an individual Short Form Complaint asserts a negligence claim against a non-Brand Defendant, perhaps it is the Plaintiff's intent to allege a negligence claim in the Short Form Complaint because, in its prior rulings at the motion to dismiss stage, the Court permitted individual Plaintiffs to do just that. Alternatively, perhaps it is the Plaintiff's intent merely to preserve an appeal of the Court's prior rulings on negligence claims in the master complaints.

What the Court *can* say for certain is regardless of the breadth of the claims that remain in the Short Form Complaints, those claims would necessarily fail if the Court entered summary judgment in all of the Defendants' favor on general causation. For that reason, the question of whether non-Brand Defendants are entitled to summary judgment is a question that has the potential to dispose of every remaining Designated Cancer claim in the MDL, and it is to this question that the Court now turns.

B. The Court's Order to Show Cause as to the Non-Brand Defendants

The Court previously entered an order to show cause as follows:

> Rule 56(f) of the Federal Rules of Civil Procedure allows for the entry of summary judgment in a non-movant's favor. Pursuant to that rule, after giving notice and an opportunity to respond, a court may grant summary judgment to a non-movant. . . .
>
> This Order serves as a Rule 56(f) notice and grants the Plaintiffs the opportunity to address why the Non-Brand Defendants are not entitled to summary judgment for all the reasons the Brand Defendants were entitled to summary judgment. To aid

6 Because there are approximately 14,000 active individual cases in this MDL, it is not possible for the Court to review and analyze the claims in each Short Form Complaint.

> in the clarity and structure of the parties' briefing as to this Order to Show Cause, the Court will detail its current thinking as to the following seven salient points: (1) the case management structure of this MDL always provided for the Court's general causation rulings to apply to all of the Plaintiffs' claims; (2) the Plaintiffs were free to take discovery from Non-Brand Defendants, if the Plaintiffs believed it would assist them to prove general causation; (3) the theoretical capability of ranitidine to cause cancer is the same across all Defendants; (4) the Court's ruling at *Daubert* would have been the same, regardless of discovery from Non-Brand Defendants; (5) the Court's application of its general causation ruling to Non-Brand Defendants should come as no surprise to the Plaintiffs; (6) the Court's ruling applies equally to both the Defendants and to the Plaintiffs; and (7) the Court's ruling results in efficiency and streamlines case management of the MDL.

DE 6303 at 10-11. No individual Plaintiff responded to the Court's order to show cause or sought leave to do so. *See* Pretrial Order 24 (creating a process for individual Plaintiffs to file motions); DE 6444 at 16-17 (creating a process for individual Plaintiffs to file responses to the Court's orders to show cause). Plaintiffs' leadership did file a response, however, and the Court addresses the Plaintiffs' responses to the first four points[7] in the order to show cause.

1. The Case Management Structure of this MDL

In its order to show cause, the Court explained how it was always the intent of the parties and the Court that the question of general causation would be adjudicated expeditiously. DE 6303 at 12. This was a logical case management structure for the Court to implement because the theoretical potential of ranitidine to cause cancer was a threshold issue that applied to every claim in the master personal injury complaint. *Id.* Lacking such a broad application, the Court doubts it would have focused its case management efforts on the expeditious resolution of *Daubert* challenges to general causation evidence.

In response to this point, the Plaintiffs make no argument as to whether the case management structure of the MDL should weigh on the decision to extend the Court's Brand

7 Based upon the Court's reading of *Home Depot USA, Inc. v. Lafarge N. Am., Inc.*, 59 F.4th 55, 61 (3d Cir. 2023), the Court does not enter summary judgment in favor of a non-Brand Defendant on the basis of the fifth, sixth, or seventh topics outlined in its order to show cause.

Defendant ruling to non-Brands; instead, the Plaintiffs argue that the case management structure should not impact the Court's decision as to which individual cases, in terms of a filing date, fall within its prior rulings. The Court has already addressed the Plaintiffs' date-based arguments above in Section **I**. The Plaintiffs' lack of a response on non-Brand Defendants notwithstanding, the Court assigns minimal weight to this issue in reaching its ultimate decision.

2. The Plaintiffs were Free to Take Evidence from Non-Brand Defendants

In its order to show cause, the Court pointed out that the Plaintiffs were free to take discovery from non-Brand Defendants to prove general causation, should they have elected to do so. *E.g.,* DE 6591 at 7 (referencing millions of pages of discovery produced by the Generic Defendants in this MDL). In response, the Plaintiffs contend, without an evidentiary citation, that generic ranitidine is different from brand ranitidine and, for this reason, discovery on generic ranitidine would "have been futile and (if it mattered) unavailable." DE 6540 at 9.

As a threshold matter, there is no difference between the generic ranitidine and brand ranitidine molecules—an undisputed fact in this case. *E.g.,* DE 6591 at 9. Indeed, federal law requires generic ranitidine to copy and mimic ranitidine's design—something that is also undisputed in the case. *E.g., PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612-13 (2011). Moreover, the Plaintiffs *did* use generic ranitidine evidence in furtherance of their general causation burden. Generic ranitidine's propensity to form a carcinogen was studied by the FDA—which the Plaintiffs' experts relied upon—and the propensity of ranitidine not manufactured or handled by the Brand Defendants to cause cancer was studied in epidemiology—which the Plaintiffs' experts relied upon. *E.g.,* Najafi Report at 57-58 (discussing FDA test results, which included generic ranitidine); McTiernan Report at 14 (relying upon FDA test results); McTiernan Supplemental Report at 12 (relying upon the Wang study); Chun-Hsiang Wang et al., *Pharmacoepidemiological*

Research on N-nitrosodimethylamine-Contaminated Ranitidine Use and Long-Term Cancer Risk: A Population-Based Longitudinal Cohort Study, 19 Int'l J. Env't Rsch. & Pub. Health 1, 1 (2022) (analyzing ranitidine consumption between 2000 and 2018 without differentiating the source or supply chain of the ranitidine).[8] Furthermore, the Plaintiffs' experts relied upon evidence far more attenuated from brand ranitidine than generic ranitidine; the Plaintiffs' experts relied upon studies of food, water, and fumes to form their general causation opinions. *E.g.,* McTiernan Report at 170 (relying on a study of food); 200 (relying on studies of fumes and water). If, as the Plaintiffs previously posited, studies of food, water, and fumes were relevant to general causation, the Court fails to see how generic ranitidine evidence was, as the Plaintiffs now put it, "irrelevant to any claims in the case." DE 6540 at 9. In sum, the Plaintiffs have failed to provide any persuasive reason why they would have been prevented, had they chosen to do so, from taking discovery from non-Brand Defendants to prove general causation.[9]

3. The Theoretical Capability of the Ranitidine Molecule to Cause Cancer, Across Multiple Defendants

In its order to show cause, the Court observed that its *Daubert* ruling was based upon the Plaintiffs' evidence that was in turn premised on the ranitidine molecule, and that the molecule's design was not specific or unique to the Brand Defendants. The Court therefore gave the Plaintiffs

8 Consistent with the Court's citation to the Wang study, a common theme throughout the ranitidine epidemiology is that the researchers did not care (or did not have the data) about the *manufacturing source* of ranitidine, or which supply chain was used to transport ranitidine. Instead, the ranitidine epidemiology analyzes the propensity of ranitidine to cause cancer, regardless of which company made the ranitidine and regardless of which company transported or resold the ranitidine. In light of the fact that the ranitidine epidemiology analyzed millions of ranitidine users, and given that many of those users consumed ranitidine for more than a decade, the Court cannot fathom how the ranitidine epidemiology did not include analysis of ranitidine that was manufactured and handled by companies other than the Brand Defendants, including generic ranitidine. *E.g.,* Yeseong D. Kim et al., *No Association Between Chronic Use of Ranitidine, Compared with Omeprazole or Famotodine, and Gastrointestinal Malignancies*, 54 Alimentary Pharmacology & Therapeutics 606, 609 (2021) (analyzing 581,028 ranitidine users between 2009 and 2018). And the Plaintiffs, through their silence, have not argued that the ranitidine epidemiology did not attempt to quantify the potential of non-Brand Defendant ranitidine to cause cancer.

9 As the Court understands it, the Plaintiffs *did* pursue discovery from non-Brand Defendants, including discovery after non-Brands were dismissed from the master complaints. *See* DE 6591 at 7 (discussing discovery sought from a Generic Defendant in September of 2021).

the opportunity in its order to show cause to explain how the various Defendants' ranitidine could have different theoretical potentials to cause cancer. As best as the Court is able to discern,[10] the Plaintiffs' response on this topic is that: "an expert opinion that the brand manufacturers' ranitidine in general can cause cancer is not the same thing as an opinion that ranitidine that is mishandled in a specific manner can cause cancer." DE 6263 at 3. In other words, the Court takes the Plaintiffs to mean that although the ranitidine *molecule* is the same—be it brand or generic—if a ranitidine *product* is mishandled, post-manufacture, the potential of that ranitidine to cause cancer could be different from a product that was properly handled. Implicit in this argument is the contention that non-Brand Defendants may have mishandled ranitidine to a greater extent than the Brand Defendants. This argument is unpersuasive.

The Plaintiffs' position on mishandled ranitidine is encompassed in their general causation expert opinions. The Plaintiffs certainly had evidence at the *Daubert* stage that the more severely ranitidine was mishandled—such as subjecting it to high temperatures—the more carcinogens would be formed. The problem with the Plaintiffs' argument, however, is that it was fully and adequately addressed at the *Daubert* stage.

Mishandled ranitidine is merely a subset of ranitidine, generally. The Plaintiffs' burden at *Daubert* was to prove that ranitidine could cause cancer, regardless of how the ranitidine was handled in its supply chain. Could ranitidine, if properly handled, cause cancer? Could ranitidine, if not properly handled, cause cancer? Both questions were subsumed within the general causation question at *Daubert*.

10 The Plaintiffs' response on this topic is difficult to parse as the Plaintiffs request the Court clarify the scope of its earlier *Daubert* ruling. The Court's *Daubert* ruling speaks for itself, and the Court declines to clarify it. The Court merely afforded the Plaintiffs the opportunity to explain how a general causation analysis could be different between the Brand Defendants and the non-Brand Defendants.

Moreover, in full recognition that "mishandled" ranitidine has a theoretically greater potential to cause cancer, the Plaintiffs' expert chemist (Dr. Najafi) thoroughly explored the potential of ranitidine to produce a carcinogen in "mishandled" conditions. In Dr. Najafi's own words: "The drug product may be subject to various environmental conditions at the wholesalers' facility, pharmacy, during transport, and in the patient's possession." Najafi Report at 72. To test the properties of "mishandled" ranitidine in a supply chain to produce a carcinogen, Dr. Najafi studied ranitidine exposed to 60-degree Celsius heat and 95% humidity in various combinations at various levels. *Id.* at 75-82. Indeed, Dr. Najafi subjected ranitidine to extreme conditions (at varying levels) for as long as 180 days. *Id.* at 81. To put these parameters into context, 60 degrees Celsius is 140 degrees Fahrenheit. The "feels like" temperature for 140-degree Fahrenheit heat, combined with 95% humidity, is around 600 degrees Fahrenheit. *Heat Index Calculator*, Nat'l Weather Serv., https://weather.gov/epz/wxcalc_heatindex (last visited Feb. 23, 2023). Yet Dr. Najafi was stricken for many different reasons (most of them unrelated to "mishandling"), and the Plaintiffs "mishandled" theory of cancer causation did not survive summary judgment.

Finally, the Plaintiffs' epidemiological experts relied upon epidemiology that was necessarily based upon ranitidine that traveled through a supply chain. The ranitidine consumed by participants in the epidemiology studies that the experts reviewed was handled by Brand Defendants, Generic Defendants, Distributor Defendants, and Retailer Defendants. Stated differently, if "mishandled" ranitidine had the ability to cause cancer, the ranitidine epidemiology attempted to detect that ability. Indeed, much of the ranitidine studied in the ranitidine epidemiology was not even manufactured by the named Brand Defendants in this case. The Plaintiffs therefore attempted to use large amounts of evidence from sources other than the Brand Defendants to prove that ranitidine could cause cancer, and it would be fair to say that the Plaintiffs

relied upon evidence from non-Brand sources from all over the world across several decades of time. In sum, the Plaintiffs have failed to persuade the Court that there could be any meaningful general causation difference between Brand Defendants' ranitidine and non-Brand Defendants' ranitidine.

4. The Court's *Daubert* Ruling Would Not Have Been Altered with Theoretical Non-Brand Discovery

In the Court's order to show cause, the Court pointed out that its *Daubert* decision was not a close question:

> Yet Dr. Najafi was not stricken as an expert witness because of insufficient data. Instead, he was stricken for many other reasons, none of which would have been affected by theoretical discovery from Non-Brand Defendants. Dr. Najafi was stricken, *inter alia*, because of his poor documentation of experiments and because of his excessive reliance upon assistants that exercised their own independent judgment. Suffice it to say that if Dr. Najafi had performed additional experiments on Non-Brand Defendant discovery, those experiments would have been performed in the same laboratory, with the same protocols, and with the same assistants.
>
> Additionally, the Plaintiffs' epidemiological experts, who were also stricken at the *Daubert* stage of the proceedings, would have been similarly unaffected by Non-Brand Defendant discovery. As a threshold matter, the Plaintiffs' epidemiological experts did not even rely upon the Plaintiffs' testing of the Defendants' product for their opinions—they relied upon data from the Food and Drug Administration. *E.g.*, McTiernan Report at 15 ("The Emery Lab testing results strengthen my causation opinions, but my opinions are not predicated on these higher levels.").
>
> . . . .
>
> Finally, the Plaintiffs' epidemiologists even relied in great part (and quite possibly for the most part) on studies that had absolutely nothing to do with ranitidine or Non-Brand Defendants; they relied upon studies about rubber production, meat consumption, and well water.
>
> The Court struck the Plaintiffs' epidemiological experts for many reasons, none of which had anything to do with Non-Brand Defendant discovery. By way of example, the Plaintiffs' epidemiological experts were stricken because they failed to adequately explain their methodologies and because they relied upon "cherry picked" data from studies to support their conclusions, conclusions that differed from the study authors' interpretation of the very same data. In short, Non-Brand

> Defendant discovery would have had no bearing on the Plaintiffs' epidemiological experts or the Court's *Daubert* decision.

DE 6303 at 15-16. Because the Court struck the Plaintiffs' general causation experts on so many alternative and independent grounds, it gave the Plaintiffs the opportunity to explain how non-Brand discovery could have altered the Court's *Daubert* decision, given that so many of the Court's independent reasons had nothing to do with Defendant-specific discovery. The Plaintiffs' response to the order to show cause is silent on this topic; the Plaintiffs have therefore provided no persuasive reason how the Court's *Daubert* decision could have been different or should be different for non-Brand Defendants.

C. Ruling as to Non-Brand Defendants

For all of the reasons set forth above, the Plaintiffs have provided no persuasive reason why the Court's *Daubert* and summary judgment rulings should not apply to every non-Brand Defendant. Pursuant to Rule 56(f) and the order to show cause process endorsed in cases such as *Home Depot*, the Court enters summary judgment in favor of every Defendant in the MDL, Brand or non-Brand, in every active[11] Designated Cancer case filed prior to May 5, 2023. The Court's summary judgment and *Daubert* rulings, however, shall have no application to any claim or case premised upon a cancer other than a Designated Cancer.

IV. Procedure for the Entry of Final Judgment

Because the Court's entry of summary judgment disposes of every Designated Cancer personal injury claim in the MDL,[12] every Defendant in those cases is entitled to the entry of final judgment. The Court's entry of final judgment is retrospective, insofar as it applies to every active

11 Unless a Designated Cancer case was previously dismissed through a voluntary dismissal, a stipulation of dismissal, or the Court's entry of a Rule 58 final judgment, the Court considers the case to be active. Designated Cancer cases that previously received the entry of a Rule 54(b) judgment—but not a Rule 58 judgment—are active cases subject to the Court's summary judgment ruling.

12 To the best of the Court's knowledge, no case in the MDL was filed on or after May 5, 2023.

Designated Cancer case and every pled Designated Cancer claim. The Court's entry of final judgment also serves a prospective purpose, however, insofar as certain claims[13] in this MDL are currently on appeal, and the Court lacks jurisdiction to enter final judgment as to those claims. Prospectively, if the Eleventh Circuit remands MDL claims the Court will, after a show cause process, likely enter summary judgment and final judgment on the remanded claims and cases for all of the reasons set forth in this Order and in the Court's orders to show cause.[14]

The Court will, through separate order, provide the parties with a proposed final judgment to be entered in each active Designated Cancer case in this MDL. The Court will allow the parties to object to the form of the proposed final judgment and to suggest changes. In preparation for the Court's drafting of the final judgment, the Defendants **SHALL** prepare and file a list of individual Designated Cancer cases as follows: (i) a list of every active case filed prior to the Court's entry of Rule 54(b) judgment on November 15, 2021, that qualified for the entry of 54(b) judgment in favor of the Distributor and Retailer Defendants that has not been appealed, (ii) a list of every active case filed prior to the Court's entry of Rule 54(b) judgment on November 15, 2021, that qualified for the entry of Rule 54(b) judgment in favor of the Generic Defendants that has not been appealed, (iii) a list of every active case filed prior to the Court's entry of Rule 54(b) judgment on November 15, 2021, that qualified for the entry of Rule 54(b) judgment in favor of Distributor, Retailer, and Generic Defendants that was not appealed, (iv) a list of every active case filed prior to the Court's entry of Rule 54(b) judgment on November 15, 2021, that qualified for the entry of 54(b) judgment in favor of the Distributor and Retailer Defendants that was appealed, (v) a list of every active case filed prior to the Court's entry of Rule 54(b) judgment on November 15, 2021,

13 The Court previously entered a Rule 54(b) judgment allowing an interlocutory appeal on certain claims. DE 4665.
14 The Court previously entered an indicative ruling informing the Eleventh Circuit of the actions it would take, should the Eleventh Circuit return jurisdiction to the district court. DE 6310.

that qualified for the entry of Rule 54(b) judgment in favor of the Generic Defendants that was appealed, (vi) a list of every active case filed prior to the Court's entry of Rule 54(b) judgment on November 15, 2021, that qualified for the entry of Rule 54(b) judgment in favor of Distributor, Retailer, and Generic Defendants that was appealed, (vii) a list of every active Designated Cancer case filed after the Court's entry of Rule 54(b) judgment on November 15, 2021, and prior to the deadline for the individual Plaintiffs to respond to the Court's orders to show cause of May 5, 2023, and (viii) a list of every active Designated Cancer case filed prior to the deadline for the individual Plaintiffs to respond to the Court's orders to show cause of May 5, 2023, not contained on any preceding list, that the Defendants contend qualifies for the entry of final judgment, together with an explanation for the Defendants' position.

The Defendants **SHALL** also prepare and file a list of every Defendant[15] named in active Designated Cancer Short Form Complaints filed prior to May 5, 2023. The Defendants **SHALL** file the lists as soon as reasonably practical (with a targeted goal of May 31, 2023), and the Plaintiffs **SHALL** assist the Defendants in their efforts to prepare the lists. If the Defendants require assistance from the Clerk of the Court, the Defendants should make the Court aware of that fact immediately. At the time that these lists are filed with the Court by the Defendants, the parties shall indicate whether any of the information on the lists are in dispute and the nature of the dispute, with particularity.

The Court will enter a pretrial order that establishes a prospective order to show cause process for any Designated Cancer case or claim filed on or after May 5, 2023, including any case or claim remanded by the Eleventh Circuit.

15 The Court does not necessarily expect that the Defendants will be able to locate every Defendant named in every Short Form Complaint, given the sheer volume of Short Form Complaints in this MDL. Rather, the Court expects that the Defendants will make an earnest effort to capture most of the named Defendants in their filed list.

In the Court's prior orders of dismissal, the Court left open the possibility that individual Plaintiffs could continue to amend their Short Form Complaints and add, for example, certain claims dismissed from the master complaints. The Court also left open the possibility, in Pretrial Order 78, that individual Plaintiffs could, upon motion, continue to seek leave from the Court to amend Short Form Complaints. For all of the reasons set forth in this Order, in the Court's orders to show cause, and in the Court's *Daubert* ruling, the Court **DENIES** further leave to amend Short Form Complaints in Designated Cancer cases. *See Burger King Corp. v. Weaver*, 169 F.3d 1310, 1319 (11th Cir. 1999) (holding leave to amend may be denied when amendment would be futile). The Court will continue to permit technical amendments to Short Form Complaints. *E.g.,* Pretrial Order 82 (permitting amendment to remove Defendant Par due to Par's bankruptcy).

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 15th day of May, 2023.

ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

Copies furnished to Counsel of Record