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

DEFENDANTS' MOTION TO DISMISS AMENDED CONSOLIDATED MEDICAL MONITORING CLASS ACTION COMPLAINT, AND INCORPORATED MEMORANDUM OF LAW

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INTRODUCTION

As the Court held when dismissing the Consolidated Medical Monitoring Class Action Complaint ("MMC")—and as Plaintiffs concede—Plaintiffs "are not entitled to medical monitoring for just *any* exposure." Dkt. 3720 ("Order") at 21. Instead, Plaintiffs must plead plausible allegations that their "exposure to NDMA [was] ***significant***," and that they are at a "***significant*** increase in their risk of cancer" as a result. *Id.* at 21–22 (emphasis added).

In the MMC, Plaintiffs failed to plead adequate facts alleging either the level of NDMA that places them at a significantly increased risk of cancer or the level of NDMA to which they were exposed. Addressing this failure head-on in dismissing the MMC, the Court identified three allegations that if "clearly" pleaded would satisfy Plaintiffs' pleading burden: (1) "how much NDMA is necessary to cause a significantly increased risk of cancer," (2) "the amount of NDMA each Plaintiff received per dose," and (3) "the number of doses of ranitidine the Plaintiffs consumed." *Id.* at 32–33. The Court was clear that Plaintiffs were required to rectify these failures through re-pleading. *Id.* at 22. But despite this Court's detailed instruction, Plaintiffs ***again*** failed to plead facts in the Amended Medical Monitoring Complaint ("AMMC"): nowhere in the AMMC do Plaintiffs allege the amount of NDMA necessary to cause, in their view, a significantly increased risk of cancer, the amount of NDMA that each Plaintiff received per dose of ranitidine, or even the number of doses consumed by Plaintiffs. Instead, Plaintiffs attempt to string together a series of vague allegations, which do not plead a significant increased cancer risk even when accepted as true. Indeed, this Court already has rejected or questioned the adequacy of the allegations on which Plaintiffs' claims rely. Yet the AMMC does not address the Court's numerous concerns.

Plaintiffs have not pleaded, and cannot plead, exposure to a level of NDMA that placed them at a significantly increased risk of cancer. The AMMC should be dismissed with prejudice.

BACKGROUND

A. The MMC

On February 22, 2021, fifty-two Plaintiffs filed the MMC. *See* Dkt. 2832 ("MMC"). Plaintiffs alleged that, though they had no present physical injuries, their ingestion of Defendants' ranitidine products increased their risk of injury and sought relief in the form of unspecified, ongoing medical monitoring. *Id*. at 3–4. Plaintiffs sought medical monitoring under the laws of 14 states based on their alleged increased risk of developing certain "Subject Cancers."[1] *Id.* at 4–5.

B. The Court's Order Dismissing the MMC

Defendants moved to dismiss the MMC. Dkt. 3116. On June 30, 2021, this Court dismissed with prejudice the medical monitoring claims asserted under Montana law, and dismissed the claims without prejudice as to the remaining 13 states. Order at 58. The Court found Plaintiffs' allegations insufficient to support several elements of their medical monitoring claims, and the Court was explicit about what was needed to properly replead them. *Id.* at 21–36.

First, Plaintiffs failed to plead (1) individual levels of exposure to NDMA and (2) the threshold amount of exposure needed to significantly increase the risk of cancer. *Id.* at 22–23. More specifically, the Court concluded that Plaintiffs failed to allege "(i) the number of doses of ranitidine the Plaintiff consumed, (ii) the amount of NDMA each Plaintiff received per dose, and (iii) how much NDMA is necessary to cause a significantly increased risk of cancer for each of the Subject Cancers alleged." *Id.* at 32–33. Due to these deficiencies, the Court concluded that

[1] The "Subject Cancers" included "bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancers." MMC at 3.

Plaintiffs did not plausibly allege a substantial increase in the risk of cancer from ingestion of Defendants' ranitidine products. *Id.* at 33.

Second, the Court held that Plaintiffs "failed to plausibly allege that diagnostic tests exist for early detection of the Subject Cancers" or that their proposed monitoring regime differed "from what is recommended to the public at large." *Id.* at 33, 36. Plaintiffs did not allege "that any tests and exams exist, much less specify what they are." *Id.* at 33. Further, as an element of medical monitoring, Plaintiffs were required to allege that their monitoring regime is "different from that normally recommended in the absence of exposure." *Id.* at 35. Instead, Plaintiffs' allegations merely recited this required element and provided no factual support. *Id.*

C. The AMMC

Twenty-seven Plaintiffs filed the AMMC on August 2, 2021. *See* Dkt. 3884 ("AMMC"). Again, Plaintiffs alleged that "as a direct and proximate result of consuming Defendants' Ranitidine-Containing Products for years, Plaintiffs are at a significantly increased risk of contracting a Subject Cancer" and that "Plaintiffs' lengthy duration of exposure to NDMA from Defendants' products warrants additional medical testing not routinely provided to the public at large." *Id.* ¶ 386. Plaintiffs included a handful of new allegations in response to this Court's Order but as explained below, Plaintiffs' new pleading failed to cure the deficiencies that this Court identified.

LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, 'to state a claim to relief that is plausible on its face."' *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). To determine "facial plausibility," bare legal conclusions unsupported by factual allegations must be disregarded because they are "not entitled to the assumption of truth." *Id.* at 678–79. "Threadbare

recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 678. As to any remaining "factual content," it must be sufficient to "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

Moreover, while the Court "must assume that [the plaintiffs] can prove the facts alleged," it is "not . . . proper [for the Court] to assume that [the plaintiffs] can prove facts that [they have] not alleged." *Associated Gen. Contractors of Cal. Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983).

ARGUMENT

Plaintiffs still do not make any attempt to allege—with anything approaching the factual specificity that this Court's Order demanded—the amount of NDMA that substantially increases the risk of cancer or the amount of NDMA to which Plaintiffs were exposed in each dose. The vague allegations that Plaintiffs do plead either were already rejected by the Court as insufficient to support their medical monitoring claims or they suffer from the same or similar defects. Finally, Plaintiffs' amended dosage allegations remain inadequate and confirm that Plaintiffs have not alleged and cannot plausibly allege a substantially increased risk of cancer.

I. The AMMC Does Not Allege the Amount of NDMA Needed to Significantly Increase the Risk of Each of the Subject Cancers.

To adequately plead medical monitoring, Plaintiffs must plead, among other things, that their "exposure to NDMA [was] significant." Order at 21; *see also Riva v. Pepsico, Inc.*, 82 F. Supp. 3d 1045, 1057 (N.D. Cal. 2015) (holding that plaintiff must "demonstrate sufficient severity of exposure" that requires "future monitoring" (quotation marks and citations omitted)). The significance of Plaintiffs' exposure, however, cannot be analyzed without "context" as to what "level of exposure creates [an] increased risk." *Riva v*, 82 F. Supp. 3d at 1057. As the Court observed, it is not enough for Plaintiffs to allege that NDMA is a carcinogen; they must also allege

"the amount of NDMA the Plaintiffs contend would equate to a significant increase in the risk of cancer." Order at 25.

Despite this clear direction from the Court, the AMMC fails to affirmatively and unequivocally allege the amount of NDMA exposure needed to significantly increase the risk of developing the Subject Cancers.

A. The FDA's Acceptable Daily Intake for NDMA Is Not the Amount of NDMA That Significantly Increases the Risk of Cancer.

Plaintiffs appear to suggest—but never clearly allege—that the FDA's acceptable daily intake ("ADI") for NDMA of 96 ng per day is an amount of NDMA that significantly increases the risk of cancer. *See* AMMC ¶¶ 390–92. As Plaintiffs acknowledge, FDA's ADI means that, from the FDA's perspective, consumption of 96 ng of NDMA every day for 70 years results in only a .001% increase in the risk of cancer. *Id.* ¶ 390; Order at 23.

In its prior order, the Court instructed Plaintiffs that if they decided to replead, they should "clearly" state whether they "equate a .001% increased risk with a significantly increased risk" of cancer. Order at 24. Plaintiffs did not comply with that directive. Instead, Plaintiffs simply allege that exposure to more than 96 ng per day "is unacceptable and harmful by definition." AMMC ¶ 392. Plaintiffs then claim—in a footnote—that "[e]xpert testimony will explain the significance of this exposure [to NDMA in excess of the ADI] and the concomitant risk of cancer." *Id.* ¶ 400 n.172.

That is not a "clear" allegation of anything. Plaintiffs' reliance on the FDA's ADI as "unacceptable and harmful" is insufficient to plead a factual basis for medical monitoring claims. Rather, at "the pleadings stage," a plaintiff must "allege that she was exposed to a quantifiable 'harmful' level" of exposure"; it is insufficient to rely on a regulatory "threshold" baldly alleged to be "unsafe" because the "Court cannot apply [that] as a legal standard." *Butler v. Denka*

Performance Elastomer, LLC, 2020 WL 2747276, at *14 n.21 (E.D. La. May 27, 2020); *see also Riva*, 82 F. Supp. 3d at 1057 (granting Rule 12 motion where plaintiffs alleged "that increased risk occurs 'at or above threshold levels' of exposure, but [did] not allege what threshold level of exposure creates the increased risk" (citations omitted)).

It is no surprise that Plaintiffs avoid clearly pleading that a .001% increase constitutes a significantly increased risk of cancer. Courts have concluded such an incremental increased risk is insufficient to support a medical monitoring claim. In *Riva*, the plaintiffs alleged the same threshold exposure level: "one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question"—or a .001% increased risk of cancer. 82 F. Supp. 3d at 1061 (quotation marks and citation omitted). The *Riva* court concluded that plaintiffs seeking medical monitoring must demonstrate "a higher level of proof of health risk" than a .001% increase in cancer "[b]ecause the burden on a defendant to fund medical screening for thousands, potentially millions, of people is so substantial." *Id.*

The holding in *Riva* is consistent with the Eleventh Circuit's recognition that "regulatory levels generally overestimate potential toxicity levels for nearly all individuals," and therefore "the theoretical risks from exposure at the guideline range level is likely to be substantially over-estimated for the large majority of individuals in the population." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1249 (11th Cir. 2005) (citation omitted). As the Court in *Williams v. Mosaic Fertilizer, LLC*, 889 F.3d 1239 (11th Cir. 2018) carefully explained, regulatory standards do not "establish the dose threshold above which [a plaintiff's] condition [is] likely [to] result from her exposure." *Id*. at 1246. That is because "regulatory standards often build in considerable cushion in order to account for the most sensitive members of the population and prophylactically protect the public) (in other words, they are protective), while dose-response calculations aim to identify

the exposure levels that actually cause harm (in other words, they are predictive)." *Id*. at 1247. Indeed, courts have rejected that a regulatory threshold establishes a "danger point" and that "extra levels above [the threshold] are significantly harmful." *Gates v. Rohm & Haas Co.*, 265 F.R.D. 208, 226 (E.D. Pa. 2010), *aff'd*, 655 F.3d 255 (3d Cir. 2011). More specifically, courts have held that regulatory "thresholds of proof" are "reasonably lower than that appropriate in tort law," and therefore insufficient to establish the required causal "link" between "exposure" and "cancer." *Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 198 (5th Cir. 1996); *see also Rhodes v. E.I. du Pont de Nemours & Co.*, 253 F.R.D. 365, 377 (S.D.W. Va. 2008) ("Medical monitoring, as a common law tort, requires more certainty than that provided by [regulatory thresholds].")[2]

Plaintiffs' bare assertion that "[e]xpert testimony will explain the significance of this exposure [to NDMA above the ADI] and the concomitant risk of cancer," AMMC ¶ 400 n.172, cannot save their improperly pleaded claims, and is precisely the type of "speculative" allegation that *Twombly* and *Iqbal* reject. *Twombly*, 550 U.S. at 555; *accord Iqbal*, 556 U.S. at 680–81. Courts have expressly recognized that under federal pleading standards, "[i]t is insufficient to allege . . . that expert testimony will substantiate . . . claims at trial." *Rodriguez v. Sec'y of Pa. Dep't of Env't Prot. of Pa.*, 604 F. App'x 113, 115 (3d Cir. 2015).

Plaintiffs "must allege a significant increase in their risk of cancer" caused by their Zantac ingestion, by reference to an amount of exposure that leads to such a significant increase in risk. Order at 22. Their mention in the AMMC of the FDA's ADI does not do so.

[2] Similarly, it is baseless for Plaintiffs to suggest that the FDA's request to voluntarily withdraw ranitidine from the market is sufficient to plausibly allege an increased risk of cancer. *See* AMMC ¶ 400–01. As courts have recognized, FDA's decision to recall a medication "is unreliable proof of medical causation . . . because the FDA employs a reduced standard (vis-a-vis tort liability) for gauging causation when it decides to rescind drug approval." *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001).

B. The Studies Cited by Plaintiffs Do Not Identify the Amount of NDMA that Significantly Increases the Risk of Each of the Subject Cancers.

Plaintiffs cite to "numerous studies" that they claim "support the conclusion that NDMA and, specifically, NDMA in ranitidine, causes cancer in humans, including the Subject Cancers." AMMC ¶¶ 402. Even accepting Plaintiffs' characterizations of their selected studies, the studies do not plausibly establish any specific ***amount*** of NDMA in ranitidine that significantly increases the risk of ***each*** Subject Cancer.

As an initial matter, most of the studies Plaintiffs cite that report an increased risk of cancer associated with ranitidine or other H_2RA blockers ***do not even mention NDMA***, and in none of those studies was there an effort to quantify any level of NDMA in ranitidine that resulted in the increased risk of cancer reported. *See id*. ¶¶ 403–08. Thus, the studies provide no basis to plausibly identify the level of NDMA exposure that creates a significant increase in the risk of cancer.[3]

Even as to the handful of cited NDMA studies that reported an increased risk of cancer associated with certain levels of NDMA, Plaintiffs fail to allege whether those amounts—ranging from 130 ng/day to 270 ng/day—create a ***significantly*** increased risk of each of the Subject Cancers, as required to satisfy the Court's Order. Nor could Plaintiffs. First, those studies relate to only three of the Subject Cancers (gastric, lung, and rectal), *see* AMMC ¶ 409, and consequently are insufficient to plead an amount of NDMA that significantly increases the risk of the other Subject Cancers (bladder, breast, esophageal, kidney, liver, pancreatic, colon/intestinal, and prostate). *See* AMMC at 26 n.13. Indeed, one of Plaintiffs' cited studies found "no significant associations" between NDMA exposure and colon, breast, prostate, and lung cancers. Yet Hua

[3] Moreover, the FDA's own study recently concluded that "studies with comparison to active controls found ***no association between ranitidine and overall or specific cancer risk***." Jeffrey Florian et al., *Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA)*, JAMA at 8 (June 28, 2021) (emphasis added).

Loh et al., *N-nitroso Compounds and Cancer Incidence: The European Prospective Investigation into Cancer and Nutrition (EPIC)–Norfolk Study*, 93 AM. J. CLINICAL NUTRITION 1053, 1057 (2011).[4]

Second, in each of those studies, there was no ranitidine use at issue; rather, the NDMA was present because of diet. *See* AMMC ¶ 409. As the Court previously noted, these studies assess "*lifetime diet habits* and then conclude, based upon a lifetime of eating or not eating NDMA-rich foods, the relative risk of a consumer's cancer." Order at 24. These studies do not and cannot support any conclusion about the amount of NDMA needed to create a significantly increased cancer risk.

Third, these studies based on dietary habits highlight yet another glaring omission previously identified by the Court, which Plaintiffs failed to address as directed: the AMMC does not allege "how much NDMA a typical Plaintiff consumes (outside of ranitidine consumption)." *Id*. at 25. As the Court unambiguously stated, "this is a number that matters." *Id*. Without that number, it is "implausible to conclude that any alleged increased risk of cancer is 'more likely than not' caused by" ingesting ranitidine given the "many alternative sources" of NDMA. *Riva*, 82 F. Supp. 3d at 1062.

In sum, because Plaintiffs fail to plead "the amount of NDMA the Plaintiffs contend would equate to a significant increase in the risk of cancer," the AMMC should be dismissed. Order at 25.

[4] In addition to the Loh study, Plaintiffs cite the Song and De Stefani studies in support of their allegation of a significantly increased risk of cancer associated with NDMA. *See* AMMC ¶ 210 & nn. 138–40). Notably, the Song study was a meta-analysis that included the results of De Stefani. Peng Song et al., *Dietary Nitrates, Nitrites, and Nitrosamines Intake and the Risk of Gastric Cancer: A Meta-Analysis*, 7 NUTRIENTS 9872–95 (2015). The Song study authors determined that the De Stefani study skewed the meta-analysis, and when De Stefani was removed, the overall results were no longer statistically significant. *See id.* at 9890.

II. The AMMC Does Not Plead the Amount of NDMA in Each Zantac Dose.

Even if Plaintiffs had pleaded the amount of NDMA that causes an increased risk of cancer (they do not), the AMMC would still fail to plead a significantly increased risk of cancer as to Plaintiffs because it says nothing about the "levels [to which] Plaintiffs were actually exposed." *Lafferty v. Sherwin-Williams Co.*, 2018 WL 3993448, at *5 (D.N.J. Aug. 21, 2018). In its Order, the Court found that Plaintiffs had not plausibly pleaded a significant increase in cancer risk because it was "unclear . . . how much NDMA exposure the Plaintiffs have alleged is caused through ranitidine ingestion." Order at 30. The Court could not "clearly ascertain from the MMC . . . the amount of NDMA each Plaintiff received per dose." *Id*. at 32. Again, despite the Court's direction to Plaintiffs that they should explicitly plead the amount of NDMA in ***each*** dose of Zantac, that allegation appears nowhere in the AMMC.

A. The FDA's Testing of Zantac Does Not Give Plaintiffs a Basis to Plausibly Plead the Amount of NDMA in Each Dose.

In the AMMC, Plaintiffs have abandoned many of the theories and allegations that the Court previously held were insufficient to plead the amount of NDMA in each Zantac dose. They no longer claim that each dose contains over 3000 ng of NDMA, which, as the Court found, was a number unsupported by any plausible factual allegation in the MMC. Order at 26. They do not rely on testing results from a study that the Court noted was retracted due to "flawed" and "unreliable" NDMA measurements. *Id*. at 26 & n.13.[5] And they likewise do not rely on the Valisure testing after the Court appropriately questioned the relevance of the results of a study conducted under conditions simply not present in the human body. *Id*. at 27–29.

[5] Plaintiffs cannot object to the Court's consideration of the underlying documents cited in the AMMC. As the Court noted in its prior Order, "Plaintiffs should omit [such] citations in any future pleading" if they "believe that the cited documents and studies should not be considered by the Court." Order at 24 n.10.

Plaintiffs do, however, continue to allege that "[t]he FDA's own testing found that the ranitidine sold by Defendant Sanofi contained ***up to*** 360 ng per 150 mg tablet—3 times the ADI in just one dose." AMMC ¶ 397 (emphasis added). But these allegations are not sufficient to plead the amount of NDMA in each dose of ranitidine that Plaintiffs consumed, for all the same reasons the Court previously cited in rejecting and dismissing the MMC.

First, the FDA did not test products manufactured by each Defendant. Sanofi is the only Defendant whose product FDA tested, and even as to Sanofi, the results range from 10 ng/dose—well below the ADI level of 96 ng/day—to 360 ng/dose. These results therefore do not plausibly support that every dose—or even any significant percentage of doses—of Zantac manufactured by Sanofi contained an amount of NDMA above the ADI.[6]

Second, as the Court previously noted, other manufacturers' ranitidine samples tested by the FDA were below the ADI for NDMA or contained no NDMA at all. Order at 29. Thus, based on the FDA's findings, it is not plausible to conclude that any other Defendant's Zantac contained NDMA or amounts of NDMA above the ADI.

Third, the AMMC is silent as to the Court's critical question of "why the statements of the FDA about the low levels of danger of ranitidine . . . should be disregarded or otherwise not impact the Court's decision on plausibility." *Id*. at 30. As the Court noted, the FDA specifically stated that the NDMA levels detected in its testing of Zantac "are similar to the levels a consumer would expect to be exposed when eating common foods like grilled and smoked meats." *Id*. at 29. The AMMC cites the FDA's testing, yet fails to address—as the Court directed—how these findings support the "plausibility" of Plaintiffs' allegations.

[6] FDA, Laboratory analysis of ranitidine and nizatidine products (Nov. 1, 2019), *available at* https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine.

B. Plaintiffs Cannot Plausibly Plead the Amount of NDMA in Zantac Based on Defendants' Testing.

Plaintiffs' allegations about certain Defendants' own testing of their Zantac products do not sufficiently allege any amount of NDMA that can be found in each dose. Similar to the FDA's testing, both GSK's and Sanofi's testing show significant variation across the products, and in many instances, showed that NDMA in the tested Zantac products was ***below*** the ADI. *See* GSKZAN0000883508; SANOFI_ZAN_MDL_0000038689. Based on these results, no specific or even estimated amount of NDMA can be said to exist in each dose of Zantac manufactured by GSK or Sanofi. And these results say nothing about Zantac that was manufactured or sold by Pfizer, BI, or Patheon.

III. Plaintiffs Fail to Plead Significant Exposure to NDMA as a Result of Zantac Ingestion.

Even if every dose of Zantac contained the highest amounts of NDMA detected for that Defendant's product as alleged by Plaintiffs in the AMMC, Plaintiffs still have not plausibly pleaded a significant increased risk of cancer. This is because without knowing "the frequency" with "which the Plaintiffs . . . allege[] they consumed ranitidine," it is impossible to tell from the face of the pleading "the amount of NDMA to which the Plaintiffs have alleged they were exposed." Order at 31. "Without that information, the Court cannot ascertain whether the Plaintiffs have alleged they have a significantly increased risk of cancer." *Id.* Plaintiffs attempt to address their pleading deficiency in the AMMC by adding allegations concerning the dosage and duration of use for each putative class representative. But Plaintiffs still have not pleaded how much NDMA ***any Plaintiff allegedly received***, either per dose of ranitidine or over the entire course of her or his usage history. *See* AMMC ¶¶ 26–52. This failure, alone, dooms the AMMC.

Plaintiffs' new individual treatment allegations fall far short of demonstrating even how much of Defendants' brand-name ***Zantac*** a particular Plaintiff consumed.[7] As a result of these pleading failures, Plaintiffs cannot plausibly allege a claim against Defendants for medical monitoring. Defendants attach a chart at Exhibit A summarizing the usage allegations of each named Plaintiff. A review of this chart confirms that Plaintiffs have failed to plead the amount of Zantac consumed by each Plaintiff, let alone the amount of NDMA allegedly consumed.

For example, Plaintiff Golbenaz Bakhtiar alleges she used generic ranitidine from 2000 to 2019, but alleges she used prescription Zantac for only one year in 2000 and OTC Zantac "when she needed an extra dose or ran out of her prescription." AMMC ¶ 28. Plaintiff Michael Tomlinson alleges only that he used prescription Zantac for two years—more than 18 years ago—and only ever used OTC Zantac "when he ran out of or did not have access to his prescription." *Id*. ¶ 48. Plaintiff Felicia Ball alleges she took prescription Zantac in 2000, but then alleges that as to years 2000 through 2020, she ingested generic prescription ranitidine "when her insurance would not pay for brand Zantac." *Id*. ¶ 29. Plaintiff Alberta Griffin alleges she used prescription Zantac in 2000, but then alleges that as to years 2013 through 2020, she ingested generic prescription ranitidine "when her insurance would not pay for brand." *Id*. ¶ 35. She further alleges she used OTC Zantac "when she ran out of her prescription." *Id*. Plaintiff Marva McCall alleges she only took OTC Zantac from 2007 to 2015 "when her [generic] prescription ran out." AMMC ¶ 38. And Plaintiff Gustavo Velasquez alleges he took Zantac "two to six times per week from approximately 2000 to 2016, and thereafter until 2020 on an as-needed basis, approximately once a month." *Id*. ¶ 50. Based on these allegations, it is impossible to determine how often these Plaintiffs ingested Zantac in the last two decades.

[7] "Zantac" as used in this section refers to brand-name Zantac products.

Moreover, many Plaintiffs allege only limited or long-ago use of the Brand Defendants' products and have not plausibly alleged that their consumption of ***Brand Defendants' Zantac*** caused a significant increased risk of cancer. Plaintiff Ronda Lockett alleges she has not ingested prescription Zantac since 1995, and has not ingested OTC Zantac since 2000, and thereafter ingested generic ranitidine for the next twenty years until 2020. *Id.* ¶ 37. Plaintiff Clifton McKinnon alleges he ingested ranitidine from 2008 to 2020 but took OTC Zantac for only two years—from 2008 to 2010—before switching to generic prescription ranitidine, which he took for the next decade. *Id.* ¶ 39. Laura Monger and Alexander Monger—represented by Plaintiff Kristen Monger—have not ingested prescription Zantac since 1998 and 1999, respectively, and thereafter ingested generic ranitidine for more than ten years until 2020. *Id.* ¶¶ 40–41. And Plaintiff Karen Foster alleges only that she used OTC Zantac "a dozen times over the years from 2013 to 2017," but took generic prescription ranitidine at unknown frequencies during this same time period. *Id.* ¶ 33.

In sum, it is impossible for the Court to conclude that any of these Plaintiffs ingested Zantac with sufficient frequency, at sufficient dosage, to significantly increase their risk of cancer.

CONCLUSION

For the foregoing reasons, the AMMC should be dismissed with prejudice.

Dated: August 23, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was filed on August 23, 2021 using the Court's CM/ECF system, which will provide automatic notification to all counsel of record.

/s/ Mark Cheffo
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EXHIBIT A

Plaintiff	Alleged Frequency of Use	Alleged Dosage(s) and Time Periods Of Use
Ida Adams (AMMC ¶ 26)	"once to three times daily depending on her condition"	"(a) OTC 150 mg Zantac tablets and capsules from approximately 2000 to 2005 in West Virginia while a citizen of West Virginia, manufactured by Pfizer and BI; (b) OTC 150 mg Zantac tablets and capsules from approximately 2005 to 2017 in Maryland while a citizen of Maryland, manufactured by Pfizer, BI and Sanofi; and (c) OTC 150 mg Zantac tablets and capsules from approximately 2010 to 2012 in West Virginia while a citizen of Maryland, manufactured by BI."
Virginia Aragon (AMMC ¶ 27)	"daily"	"(a) OTC Zantac tablets and capsules of 75 mg and/or 150 mg from approximately 2006 to 2020 manufactured by Pfizer, BI, and Sanofi; and (b) prescription 300 mg generic ranitidine tablets and capsules from approximately 2006 to 2020."
Golbenaz Bakhtiar (AMMC ¶ 28)	"up to twice daily, depending on her condition, with occasional gaps of no longer than a week"	"(a)150 mg prescription Zantac tablets and capsules beginning in approximately 2000, manufactured by GSK; (b) prescription 150 mg generic ranitidine tablets and capsules from approximately 2000 to 2019 that were used interchangeably throughout the time period with the brand; (c) 150 mg OTC Zantac tablets and capsules from approximately 2000 until 2019, manufactured by Pfizer, BI, and Sanofi, when she needed an extra dose or ran out of her prescription; and (d) OTC 150 mg generic ranitidine tablets and capsules from approximately 2005 to 2019, when she needed an extra dose or ran out of her prescription."
Felicia Ball (AMMC ¶ 29)	"at least once per day"	"(a) prescription Zantac in 150 mg and/or 300 mg manufactured by GSK beginning in 2000; and (b) prescription 150 mg and 300 mg generic ranitidine tablets and capsules when her insurance would not pay for brand Zantac."
Antrenise Campbell (AMMC ¶ 30)	"twice daily"	"(a) prescription 150 mg generic ranitidine tablets and capsules from approximately 1998 to 2008; and (b) OTC 150 mg Zantac tablets and capsules from approximately 2008 to 2013, manufactured by BI."

Plaintiff	Alleged Frequency of Use	Alleged Dosage(s) and Time Periods Of Use
Teresa Dowler (AMMC ¶ 31)	"daily"	"(a) prescription 150 mg Zantac tablets and capsules from approximately 2011 to 2013, manufactured by GSK; (b) OTC 150 mg Zantac tablets and capsules from approximately 2013 to 2018 manufactured by BI and Sanofi; and (c) prescription 150 mg generic ranitidine tablets and capsules from approximately 2018 to December 2019."
Jonathan Ferguson (AMMC ¶ 32)	"daily"	"(a) OTC Zantac tablets and capsules in approximately 1996 and 1999 in Nevada while a citizen of Nevada, manufactured by GSK and Pfizer; (b) OTC Zantac tablets and capsules from approximately 2007 to 2012 in California while a citizen of California, manufactured by BI; and (c) OTC ranitidine tablets from 2010 to 2012 in California while a citizen of California."
Karen Foster (AMMC ¶ 33)	Unknown	"(a) OTC 150 mg Zantac tablets and capsules that she purchased approximately a dozen times over the years from 2013 to 2017 in Florida while a citizen of Florida, manufactured by BI and Sanofi; and (b) prescription 150 mg generic ranitidine tablets and capsules in Florida while a citizen of Florida from approximately 2013 to 2017."

Plaintiff	Alleged Frequency of Use	Alleged Dosage(s) and Time Periods Of Use
Michael Galloway (AMMC ¶ 34)	"up to three times daily"	"(a) prescription 150 mg Zantac tablets and capsules from approximately 1997 through 1999 in Florida while a citizen of Florida, manufactured by GSK; (b) prescription 150 mg generic ranitidine tablets and capsules from approximately 1997 through 1999 in Florida while a citizen of Florida; (c) OTC Zantac tablets and capsules from approximately 1997 through 1999 in Florida while a citizen of Florida manufactured by GSK and Pfizer; (d) prescription 150 mg generic ranitidine tablets and capsules from approximately 1999 through October 2019 in Ohio while a citizen of Ohio; (e) OTC Zantac tablets and capsules from approximately 1999 through October 2019 in Ohio while a citizen of Ohio manufactured by Pfizer, BI, and Sanofi; and (f) prescription 150 mg Zantac tablets and capsules, beginning in approximately 1999 in Ohio, manufactured by GSK."
Alberta Griffin (AMMC ¶ 35)	"up to three times a day depending on her condition"	"(a) prescription Zantac tablets and capsules in increasing dosages beginning in approximately 2000, manufactured by GSK; (b) prescription 150 mg generic ranitidine tablets and capsules from approximately 2013 to March 2020 when her insurance would not pay for brand; and (c) OTC 150 mg Zantac tablets and capsules from approximately 2000 to March 2020, manufactured by Pfizer, BI, and Sanofi when she ran out of her prescription."
Lorie Kendall-Songer (AMMC ¶ 36)	"once or twice per day"	"OTC 150 mg Zantac tablets and capsules . . . from approximately 2012 to 2020, which were manufactured by BI and Sanofi."
Ronda Lockett (AMMC ¶ 37)	"Once" or "twice" daily	"(a) prescription Zantac tablets and capsules consumed twice daily from approximately 1990 to 1995, which were manufactured by GSK; and (b) OTC Zantac tablets and capsules consumed once daily from approximately 1996 to 2000, which were manufactured by GSK and Pfizer."

Plaintiff	Alleged Frequency of Use	Alleged Dosage(s) and Time Periods Of Use
Marva Mccall (AMMC ¶ 38)	"once per day"	"(a) 300 mg OTC Zantac tablets and capsules . . . from approximately 2007 to 2015 when her prescription ran out, which were manufactured by BI; and (b) prescription 150 mg and 300 mg generic ranitidine tablets and capsules from approximately 2011 to 2019."
Clifton McKinnon (AMMC ¶ 39)	"twice per day"	"(a) OTC 75 and 150 mg Zantac tablets and capsules consumed twice per day from approximately 2008 to 2010, which were manufactured by BI; and (b) prescription 150 mg generic ranitidine tablets and capsules from approximately 2010 to 2020."
Alexander Monger (AMMC ¶ 40)	"twice per day"	"(a) prescription 10, 15, 65, and 75 mg/ml Zantac syrup consumed twice per day beginning in approximately 1999, which was manufactured by GSK; (b) prescription Zantac tablets and capsules consumed for approximately a six-month period during a hiatus from taking syrup; and (c) prescription 15 and 75 mg/ml and 65ml/5ml generic ranitidine syrup, consumed twice per day from approximately 1999 to 2020."
Laura Monger (AMMC ¶ 41)	"twice per day"	"(a) prescription 15, 25 mg/ml and 75mg/5ml Zantac syrup consumed twice per day, which was manufactured by GSK from approximately 1997 to 1998; and (b) prescription generic ranitidine syrup in various dosages based on Plaintiff's weight consumed twice per day from approximately 1998 to 2020."
Ricardo Moron (AMMC ¶ 42)	"three to four times a week"	"150 mg OTC Zantac tablets and capsules . . . from approximately 1996 to 2020, which were manufactured by GSK, Pfizer, BI, and Sanofi."
Richard O'Brien (AMMC ¶ 43)	"twice per day from approximately 1998 to 2008, and . . . once per day from approximately 2008 to 2019"	"(a) OTC 150 mg Zantac tablets and capsules manufactured by GSK, Pfizer, BI, and Sanofi; and (b) OTC 150 mg generic ranitidine tablets and capsules when he occasionally ran out of Zantac brand."
Cesar Pinon (AMMC ¶ 44)	"two or three times per day after meals"	"OTC 75 mg and 150 mg Zantac tablets and capsules . . . from approximately 2009 to 2015, and manufactured by BI."

Plaintiff	Alleged Frequency of Use	Alleged Dosage(s) and Time Periods Of Use
Jeffrey Pisano (AMMC ¶ 45)	"twice per day but later consumed as needed"	"(a) OTC 150 mg Zantac tablets and capsules from approximately 2012 to 2019, which were manufactured by BI and Sanofi; (b) prescription 150 mg Zantac tablets and capsules from approximately 1998 to 2003, which were manufactured by GSK; and (c) prescription 150 mg generic ranitidine tablets and capsules from approximately 1998 to 2003."
Ronald Ragan (AMMC ¶ 46)	"two times per day"	"(a) OTC 150 mg Zantac tablets and capsules from approximately 2012 to 2019, which were manufactured by BI and Sanofi; and (b) OTC 150 mg generic ranitidine tablets and capsules from approximately 2012 to 2019."
Tangie Sims (AMMC ¶ 47)	"one to two times per day"	"(a) OTC 150 mg Zantac tablets and capsules from approximately 2007 to 2020, which were manufactured by BI and Sanofi; and (b) OTC generic ranitidine tablets and capsules from approximately 2010 to 2020."
Michael Tomlinson (AMMC ¶ 48)	"twice daily"	"(a) prescription 300 mg Zantac tablets and capsules beginning in 2000 and continuing through at least 2002, manufactured by GSK; (b) prescription 150 mg and 300 mg generic ranitidine tablets and capsules at some point thereafter until 2019; and (c) OTC 150 mg Zantac tablets and capsules from approximately 2000 to 2019, manufactured by Pfizer, BI, and Sanofi when he ran out of or did not have access to his prescription."
Chris Troyan (AMMC ¶ 49)	"three to four times per week"	"(a) 75 mg and 150 mg OTC Zantac tablets and capsules beginning in approximately 2002, manufactured by Pfizer, BI, and Sanofi; and (b) OTC generic ranitidine tablets and capsules from approximately 2011 to 2020."
Gustavo Velasquez (AMMC ¶ 50)	"two to six times per week from approximately 2000 to 2016, and thereafter until 2020 on as-needed basis, approximately once a month"	"OTC 75 mg and 150 mg Zantac tablets and capsules manufactured by Pfizer, BI, and Sanofi [from approximately 2000 to 2020]."

Plaintiff	Alleged Frequency of Use	Alleged Dosage(s) and Time Periods Of Use
Teresa Waters (AMMC ¶ 51)	"daily"	"(a) OTC 150 mg Zantac tablets and capsules from approximately 2017 to 2020 manufactured by BI and Sanofi; and (b) prescription 150 mg generic ranitidine tablets and capsules from approximately 2017 to 2020."
Joshua Winans (AMMC ¶ 52)	"daily"	"OTC 75 and 150 mg Zantac tablets and capsules . . . from approximately 2000 to 2019, manufactured by Pfizer, BI, and Sanofi."