REDACTED

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

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS AMENDED CONSOLIDATED MEDICAL MONITORING CLASS ACTION COMPLAINT

DATED: September 9, 2021

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rules

Other

Plaintiffs submit this opposition to Defendants' Motion to Dismiss Amended Consolidated Medical Monitoring Class Action Complaint ("Motion") [DE 4106]. The Amended Consolidated Medical Monitoring Complaint ("AMMC") [DE 3884] properly pleads medical monitoring claims in those jurisdictions where this Court has permitted such claims and otherwise fully complies with Fed. R. Civ. P. ("Rule") 12. The Motion should be denied.

I. INTRODUCTION

"The Plaintiffs *may*, of course, plead a substantial increase in the risk of cancer *in whatever way they deem best*, including through avenues other than NDMA exposure and NDMA frequency." Order[1] at 33 (emphasis added). In the AMMC, Plaintiffs painstakingly revised their exposure and risk allegations to more explicitly plead the facts underlying their "significantly increased risk of harm." Plaintiffs did so by explaining the frequency, duration, and dosage of their ranitidine consumption and the medical conditions for which they consumed the drug. They explained why Plaintiffs were exposed to significant levels of NDMA: the FDA's Acceptable Daily Intake for NDMA ("ADI") is a safety threshold, Defendants' ranitidine contained NDMA at levels well in excess of the ADI, even more NDMA formed in the pills during storage and transport and post-ingestion, and even without quantifying exposure, the FDA recognized the drug was dangerous and directed full market withdrawal. Plaintiffs clearly link ranitidine and high levels of NDMA to an increased risk of the Subject Cancers by referencing the FDA's market withdrawal, explaining that for decades NDMA has been recognized as a genotoxic and mutagenic carcinogen, and identifying numerous exemplary scientific studies demonstrating causation. These allegations are substantially more than enough to "barely nudge" Plaintiffs' claims "past the plausibility threshold." *Montoya v. PNC Bank, N.A.*, 94 F. Supp. 3d 1293, 1309 (S.D. Fla. 2015).

The only issue before the Court is whether Plaintiffs plausibly allege a "significantly increased risk."[2] Defendants make four primary errors when arguing for dismissal. *First*, they

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[1] *See* Order Granting in Part and Denying in Part the Defendants' Omnibus Motion to Dismiss and/or Strike Consolidated Medical Monitoring Class Action Complaint and Consolidated Amended Consumer Economic Loss Class Action Complaint [DE 3720] ("Order").

[2] Generally, medical monitoring requires proof of:

> (1) exposure greater than normal background levels; (2) to a proven hazardous substance; (3) caused by the defendant's negligence; (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease; (5) a monitoring procedure exists that makes the early detection of the disease possible; (6) the prescribed monitoring regime is different from that

assume the only way Plaintiffs can plead a significantly increased risk is by quantifying exposure and risk of harm. That distorts the law and the relevant pleading standard. *Second*, contrary to established law, Defendants argue that the FDA's ADI is irrelevant to the Court's evaluation of plausibility. But established precedent reflects that courts regularly consider regulatory benchmarks when assessing the plausibility of a medical monitoring claim. *Third*, they improperly seek to have this Court make factual findings on disputed interpretations of scientific studies cited in the AMCC. That request confuses a battle of the experts for a motion to dismiss. *Fourth,* for the first time, Defendants claim that Plaintiffs must connect brand usage to risk without regard to any generic usage, seeking to impose a burden of proof well beyond the bounds of Rule 12(b)(6) and distorting black-letter tort law.

From the AMMC's allegations of exposure, use, and harm, Plaintiffs have plausibly alleged a "significantly increased risk." In effect, Defendants want this Court to require improper, preliminary disclosure of Plaintiffs' expert opinions in service of a heightened Rule 12(b)(6) standard that is unsupported by any law. The Motion should be denied.

II. RELEVANT FACTS

Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold OTC and prescription ranitidine under the brand Zantac. ¶ 53.[3] Plaintiffs regularly consumed ranitidine containing products, including Defendants' Zantac, for years. AMMC at Intro, ¶¶ 383-386. Plaintiffs identify the years they consumed brand and generic ranitidine, dosage, frequency, and their underlying medical conditions. ¶¶ 25-52. The average duration of Plaintiffs' usage is 17.7 years. *See* Exhibit 1 (477 years total / 27 plaintiffs).

Ranitidine contains the constituent molecules to form NDMA. ¶ 147. It has long been known that ranitidine's degradation into NDMA occurs with heat, humidity, and time, and in the human body after ingestion, particularly if consumed with nitrates. ¶¶ 147 – 202, 399. Defendants urged consumers to take Zantac after eating nitrate-rich foods. ¶ 177.

> normally recommended in the absence of the exposure; and (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles.

(Order at 20) (quoting *Petito v. A.H. Robins Co., Inc.*, 750 So. 2d 103, 106-07 (Fla. 3d DCA 1999)). The only element at issue here is "significantly increased risk." *See* Motion at 1 (limiting challenge to "significantly increased risk").

[3] All paragraph citations hereafter refer to the AMMC, unless otherwise stated.

NDMA is a mutagenic and genotoxic carcinogen used only to cause cancer in lab rats: its dangerous propensities are well-established. ¶¶ 81- 126, 387. The Environmental Protection Agency, International Agency for Research on Cancer, American Conference of Governmental Industrial Hygienists, Department of Health and Human Services, FDA, World Health Organization, European Medicines Agency, Agency for Toxic Substances and Disease Registry, International Register of Potentially Toxic Chemicals, and Occupational Safety and Health Administration all classify NDMA as a "probable human carcinogen," "reasonably anticipated . . . human carcinogen," a chemical that causes cancer in all human species tested, and/or a "highly potent mutagenic carcinogen[]." ¶¶ 81- 92. Defendants' internal documents and the medical and scientific literature demonstrate that NDMA's toxic and carcinogenic nature has been known for over 40 years. ¶¶ 93-101.

To protect consumers from harm, the FDA established an ADI for NDMA of 96 ng per day (.32ppm for ranitidine), or 2,452 µg total, the amount by which the FDA concluded the risk of cancer increases by 0.001%. ¶¶ 388-392. However, the risk continues to increase as exposure increases, and the FDA expects that pharmaceuticals which exceed 96 ng of NDMA will be recalled. ¶ 393-394. The ranitidine Plaintiffs consumed contained NDMA at levels many times greater than the ADI. ¶ 395.

After independent lab Valisure reported that significant levels of NDMA form in ranitidine, the FDA warned that some ranitidine medications might contain NDMA. ¶¶ 127-128, 172-179. In September 2019, it recommended that manufacturers undertake additional testing and indicated it was evaluating the risk to consumers. *Id.* Concerned their ranitidine products might contain carcinogenic NDMA, Non-Parties Sandoz, Apotex, Walgreens, Walmart, and Rite Aid removed it from the shelves. ¶¶ 129-131. [redacted] ¶ 133, 398. Thereafter, Defendant Sanofi, defined in the AMMC to include Pantheon (¶¶ 18-24), and generic manufacturers Perrigo and Dr. Reddy's, voluntarily withdrew their product from the shelves. ¶¶ 134-136. [redacted] ¶ 398. Plaintiffs typically took more than one dose a day. ¶ 397.

The FDA's testing also found unacceptable levels of NDMA in ranitidine-containing products—for example, up to 360 ng of NDMA per 150 mg tablet in Sanofi's product—3 times

the ADI. ¶ 137. It requested a voluntary recall and advised consumers who wished to continue using ranitidine to limit their intake of nitrate-containing food, which mirrored admonitions by scientists dating back to 1981 who found that consuming ranitidine with nitrates increases NDMA formation. ¶ 137-138. More generic manufacturers withdrew their products from the shelves, citing NDMA concerns. ¶ 139.

Then, in January 2020, research laboratory Emery Pharma showed the FDA how ranitidine is unstable and breaks down into NDMA under higher temperatures, such as during storage and transport. ¶¶ 140-141, 396. At this point, the FDA recognized that time, temperature, and humidity increase ranitidine's degradation into NDMA. ¶¶ 142-143. It realized that regardless of product testing results, it could not confirm that *any* ranitidine containing product that consumers ingested was safe from heightened levels of NDMA. ¶¶ 142-143, 401. It concluded that ranitidine "presents a serious health risk" and that a full market withdrawal was necessary to "protect the public health from products that present a risk of injury." ¶¶ 142-143, 401. The FDA's action was consistent with regulatory action taken across the world. ¶¶ 145-146.

Multiple studies, including epidemiological studies, support the conclusion that NDMA, including NDMA in ranitidine, causes cancer in humans, including the Subject Cancers. For example, Plaintiffs allege that ranitidine creates at least a 22% increased risk of bladder cancer; double risk of breast cancer; an increased risk of prostate, lung, esophageal, liver, stomach, colorectal/intestinal, gastric, and kidney cancer; double the risk of pancreatic cancer; and, if the patient is over 60, five times the risk of prostate cancer. ¶¶ 403-409 (citing exemplary studies).

Additional studies show that consuming 190ng to 270ng of NDMA a day causes a 34% increase in the risk of gastric cancer, ¶ 409; consuming 270ng of NDMA significantly increases the risk of lung cancer, ¶ 409; and consuming 130 ng of NDMA a day increases the risk of rectal cancer by 46%, ¶ 409. Defendants' ranitidine exposed Plaintiffs to more than this amount of NDMA over a long period of time. *See, e.g.*, ¶¶ 295, 397-399.

In sum, Plaintiffs' ranitidine consumption exposed them to significant levels of NDMA over a lengthy period of time that plausibly supports specialized testing (with resultant treatment) that is not generally given to the public at large as a part of routine medical care. ¶ 414.

III. ARGUMENT

A. The standard for pleading "significantly increased risk" does not require quantification.

The ultimate issue in a medical monitoring case is whether "the defendant's wrongful acts increased the plaintiff's incremental risk of incurring the harm produced by the toxic substance *enough to warrant a change* in the medical monitoring that otherwise would be prescribed" for the plaintiff. *Hansen v. Mountain Fuel Supply Co.,* 858 P.2d 970, 980 (Utah 1993) (emphasis added). Each of the claim's elements, including whether the plaintiff has sustained a "significantly increased risk" of harm, is intended to serve this inquiry and must be evaluated holistically, and ultimately supported by expert testimony. *See also* Order at 22 ("Plaintiffs must allege . . . a risk [of cancer] significant enough that a treating physician would prescribe a monitoring regime.") Plaintiffs do not have to prove probability of harm, nor do they have to quantify the risk of harm—even at summary judgment. *See, e.g., In re Paoli R.R. Yard Pcb Litig.,* 35 F.3d 717, 787 (3d Cir. 1994) (citations and quotations omitted) ("[T]he appropriate inquiry is not whether it is reasonably probable that plaintiffs will suffer harm in the future but rather whether medical monitoring is, to a reasonable degree of medical certainty, necessary in order to diagnose properly the warning signs of disease.") (citations and quotations omitted); *Burns v. Jaquays Mining Corp.,* 752 P.2d 28 (Ariz. Ct. App. 1987) (same); *Bower v. Westinghouse Elec. Corp.,* 522 S.E.2d 424, 433 (W. Va. 1999) ("All that must be demonstrated is that the plaintiff has a significantly increased risk of contracting a particular disease relative to what would be the case in the absence of exposure. Importantly, no particular level of quantification is necessary to satisfy this requirement.") (citations and quotations omitted); *Hansen,* 858 P.2d at 979 ("No particular level of quantification is necessary to satisfy this requirement of significantly increased risk."). *See also, e.g., Petito,* 750 So. 2d at 108, n.5 (favorably citing *Hansen, Bower,* and *In re Paoli*); *Redland Soccer Club v. Dep't of the Army,* 696 A.2d 137, 190-95 (Pa. 1997) (favorably citing *Hansen* and *In re Paoli*). It is enough that the expert testifies through a well-supported opinion that the risk is significant. *See In re Paoli,* 35 F.3d at 788. In fact, "[e]ven if the likelihood that these plaintiffs would contract cancer were only slightly higher than the national average, medical intervention may be completely appropriate in view of the attendant circumstances." *Ayers v. Jackson,* 525 A.2d 287, 312 (N.J. 1987).[4]

[4] *Ayers* is relied upon and/or cited favorably in *Burns,* 752 P.2d 28; *Potter v. Firestone Tire & Rubber Co.,* 863 P.2d 795 (Cal. 1993); *Cook v. Rockwell Int'l Corp.,* 755 F. Supp. 1468 (D.

At this juncture, the operative question is this: Have the Plaintiffs alleged enough facts to plausibly conclude that Plaintiffs have a significantly increased risk of harm which warrants medical monitoring? The answer is unequivocally yes.

Even if the Court believes "that actual proof of [these] facts is improbable, and that a recovery is very remote and unlikely," the AMMC must proceed. *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 556 (2007) (citations and quotations omitted); *see also Marabella v. NCL (Bahamas), Ltd.,* 437 F. Supp. 3d 1221, 1229 (S.D. Fla. 2020) ("[A]t the motion to dismiss stage, it is enough if one can reasonably infer actual and proximate causation for Plaintiff's injuries . . . ."). Plaintiffs need only "***barely*** nudge their [] claims past the plausibility threshold." *Montoya,* 94 F. Supp. 3d at 1309 (emphasis added); *see also Prisua Eng'g Corp. v. Samsung Elecs. Co.,* No. 1:16-cv-21761-KMM, 2017 WL 1041571, at *3 (S.D. Fla. Mar. 9, 2017) (dismissal is appropriate only if "*no construction* of the factual allegations will support the cause of action") (emphasis added) (citations omitted). Plaintiffs' additional allegations have done far more than nudge their claims past the threshold, and the Motion should be denied.

B. Plaintiffs allege facts to support their medical monitoring claims, which the Court must accept as true pursuant to Rule 12(b)(6).

1. Plaintiffs plausibly allege that Defendants' ranitidine exposed Plaintiffs to NDMA at levels much greater than the Acceptable Daily Intake.

The Court already concluded that each Plaintiff plausibly alleged exposure to NDMA. Order at 21. Plaintiffs further alleged the years during which they consumed brand and generic ranitidine, including dosage, frequency, and the underlying medical conditions. *See* ¶¶ 25-52; *see also* Exhibit 1 (concisely setting forth Plaintiffs' usage allegations). On average, Plaintiffs regularly consumed ranitidine for 17.7 years.[5] Plaintiffs' usage is substantial.[6]

Colo. 1991); *Petito,* 750 So.2d 103; *Allgood v. GMC,* Case No. 1:02-cv-1077-DFH-TAB, 2005 WL 2218371 (S.D. Ind. Sept. 12, 2005); *Exxon Mobil Corp. v. Albright,* 71 A.3d 30 (Md. 2013); *Sadler v. PacifiCare of Nev., Inc.,* 340 P.3d 1264 (Nev. 2014); *Hansen,* 858 P.2d 970; *Bower,* 522 S.E.2d 424. It also favorably cites *Friends for All Children v. Lockheed Aircraft Corp.,* 587 F. Supp. 180 (D.D.C. 1984).

[5] Many Plaintiffs used the medication for more than 20 years. *See* Exhibit 1.

[6] Defendants' claim that it is "impossible to determine" Plaintiffs' consumption is belied by the AMMC itself. Taking some of Defendants' self-serving examples: Golbenaz Bakhtiar took ranitidine up to twice daily for 20 years, with occasional gaps of up a week. Even assuming consumption only once a day, that is 7,300 doses. Felicia Ball took ranitidine at least once a day from 2000 to recall, or approximately 7,665 doses. Gustavo Velasquez took Zantac two to six times a week for 17 years and once a month after that, totaling 1,768 to 5,304 doses. Karen Foster

The FDA determined that 96ng of NDMA per day, or 2,952ng in total, increases the risk of cancer by 0.001%. ¶¶ 388-393. It established that level as an ADI so as to protect consumers from harm, but the risk of cancer increases as NDMA exposure increases. *Id.* The FDA's product testing found that Sanofi's ranitidine contained up to 360 ng of NDMA per 150 mg tablet—three times the ADI (and Plaintiffs may take many tablets a day). ¶ 397. [redacted]. ¶ 398. And [redacted]. ¶ 398.

But product testing is only part of the picture. Additional NDMA accumulated in ranitidine during storage, transport, and post-ingestion. *See, e.g.,* ¶¶147-187 (generally, ranitidine forms NDMA in the body); ¶¶188-196 (generally, ranitidine forms NDMA under heat, humidity, and time); ¶¶196, 395-401 (product testing data and its FDA-recognized limitations). Thus, testing results significantly underestimate the amount of NDMA to which consumers—including Plaintiffs—were exposed. *Id.* The totality of NDMA exposure explains why the FDA deemed the product dangerous and directed a market withdrawal. *Id.* All of these facts, coupled with Plaintiffs' substantial ranitidine usage, plausibly allege that Plaintiffs were exposed to NDMA at levels *many times greater* than the FDA's ADI of 96 ng. ¶ 295.

Defendants spill significant ink arguing that the FDA's ADI for NDMA "Is Not the Amount of NDMA That Significantly Increases the Risk of Cancer." Motion at 5. But Plaintiffs never pled that it was. They allege exposure at many times more than the ADI: the ADI itself is merely a touchstone.

Next, Defendants violate Rule 12(b)(6) parameters by asking this Court to ignore the ADI entirely as a matter of law.[7] Motion at 5-7. Unsurprisingly, there is no support for their assertion: Defendants merely cite cases that were decided post-pleadings, at the *Daubert,* summary

purchased OTC Zantac at least a dozen times. A bottle could contain 24-200 pills; she consumed at least 288 to 2,400 doses. *See, e.g.*, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-ranitidine-tablets-75mg-and-150mg-all-pack-sizes-and (last accessed September 1, 2021). *See* Exhibit 1.

[7] Defendants disingenuously cite the ADI to suit their own purposes—that 96ng represents "only" a 1:100,000 chance of cancer—but would deny Plaintiffs' proper use of the ADI when it contradicts their misleading narrative.

judgment, and class certification stages, and seek to graft those standards of review into the pleadings phase.[8]

Defense counsel in this case made an identical argument in *Bell v. 3M Co.*, also on a Rule 12(b)(6) motion, relying upon similar case law. That court aptly explained why defendants were wrong:

> [t]he fact that a regulatory standard was deemed not to be a measure of causation and thus not to provide support for the expert's opinion . . . is inapposite in the motion to dismiss context in the present case in which the plaintiffs need only plausibly plead significant exposure. Defendants' reliance on *Rhodes* . . . is similarly misplaced, since that opinion dealt with the use of such evidence at the class certification stage rather than at the motion to dismiss phase currently at issue before this Court.

344 F. Supp. 3d 1207, 1226 (D. Colo. 2018). The *Bell* court further observed that even if the EPA's health advisory was ultimately inadequate to *prove* exposure, it was sufficient to *plausibly allege* it: "[w]hile plaintiffs have not yet proven what a significant level of exposure is, they need not do so at this stage, but with the assistance of the EPA guidance they have met their requirement to plausibly plead significant exposure." *Id.* Similarly, the ADI is relevant to whether Plaintiffs have plausibly alleged a significantly increased risk of significant exposure and is properly considered. *See, e.g., Exxon Mobil Corp.,* 71 A.3d at 83-84 (using state action levels for MTBE and benzene water contamination to distinguish between plaintiffs who had a significantly increased risk of disease and those who did not).

Finally, the Court asked how it was to interpret the FDA's initial assertion that the NDMA levels it found during its initial ranitidine product testing were "low." Order at 30. The FDA's statement was merely an initial impression that was quickly proven wrong and, in any event, presents a disputed fact. *See infra,* Section III.D. Its subsequent testing and evaluation

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[8] *See McClain v. Metabolife Int'l, Inc.,* 401 F.3d 1233 (11th Cir. 2005) (*Daubert*); *Williams v. Mosaic Fertilizer, L.L.C.,* 889 F.3d 1239 (11th Cir. 2018) (summary judgment); *Gates v. Rohm & Haas Co.,* 265 F.R.D. 208 (E.D. Pa. 2010), *aff'd,* 655 F.3d 255 (3d Cir. 2011) (class certification); *Allen v. Pa. Eng'g Corp.,* 102 F.3d 194 (5th Cir. 1996) (*Daubert* and post-trial motion for judgment as a matter of law); *Rhodes v. E.I. Du Pont de Nemours & Co.,* 253 F.R.D. 365 (S.D.W. Va. 2008) (class certification). Notably, even the Federal Judicial Center's REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, 413 (2d Ed. 2000) recognizes that "risk assessment information about a chemical can be somewhat useful in a toxic tort case, at least in terms of setting reasonable boundaries as to the likelihood of causation," even though the regulatory process has different goals.

demonstrated that because ranitidine's NDMA levels continue to increase during storage and transport and with the passage of time, regardless of product testing results it could not confirm that the products were safe, how much NDMA was in them, or how much NDMA consumers would be exposed to after taking them. ¶ 401; FDA Letter, Woodcock.[9] The product was too dangerous and full market withdrawal was required. ¶ 401. Notably, the FDA did not quantify the amount of NDMA to which consumers or Plaintiffs were exposed before reaching these conclusions. *Id.* And because the risk of harm is associated with *ranitidine itself,* the FDA sensibly did not distinguish between manufacturers.[10]

2. Plaintiffs plausibly allege that NDMA significantly increases the risk of the Subject Cancers.

There can be no dispute that NDMA is a genotoxic and mutagenic carcinogen used to cause cancer in lab rats, or that the risk of cancer increases as the level of NDMA exposure increases. ¶¶ 387, 393. Plaintiffs' AMMC references numerous scientific studies so that the Court understands that the allegation that NDMA, including NDMA in ranitidine,[11] increases the risk of the Subject Cancers is not conclusory, but instead is plausible, supported by scientific research, and will be the subject of expert testimony.[12] *Id.* at ¶¶ 81-126 (studies cited for the general proposition that NDMA is carcinogenic); ¶¶ 402-410 (specific studies connecting NDMA and NDMA in ranitidine to specific cancer risks). For example, Plaintiffs allege that:

- People who take ranitidine have at least a 22% increased risk of bladder cancer. ¶ 403.
- Ranitidine doubles the risk of breast cancer. ¶ 404.

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[9] Letter of Janet Woodcock, U.S. Food & Drug Admin., Docket No. FDA-2020-P-0042 (Apr. 1, 2020), *available at* https://emerypharma.com/wp-content/uploads/2020/04/FDA-2020-P-0042-CP-Response-4-1-2020.pdf.

[10] Plaintiffs allege product testing data for GSK, BI, and Sanofi (defined to include Pantheon), as well as numerous non-party manufacturers. The hazard and concomitant risk originates from ranitidine-containing products themselves (including storage, transport, and/or post-ingestion processes). Thus, Plaintiffs plausibly allege exposure and significantly increased risk for *all* Defendants' products.

[11] Because ranitidine degrades to form NDMA, both ranitidine studies and NDMA studies are relevant to plausibility.

[12] Defendants do not challenge that the Subject Cancers are serious, potentially fatal diseases for which early detection is beneficial.

- Ranitidine increases the risk of prostate, lung, esophageal, pancreatic, and kidney cancer. ¶ 405. In particular, ranitidine users have a doubled risk of pancreatic cancer, and ranitidine users over 60 have five times the risk of prostate cancer. ¶ 405.
- Ranitidine increases the risk of liver cancer. ¶¶ 406, 407.
- Studies support the causal connection between ranitidine use and breast, gastric, pancreatic, stomach, colorectal/intestinal, kidney, liver, lung, and prostate cancer. ¶ 408.
- Consuming 190ng to 270ng of NDMA a day causes a 34% increase in the risk of gastric cancer. ¶ 409. Defendants' ranitidine exposed Plaintiffs to more than 270ng of NDMA for extended periods of time. *See, e.g.,* ¶¶ 295, 397-399.
- Consuming 270ng of NDMA significantly increases the risk of lung cancer. ¶ 409.
- Consuming 130 ng of NDMA a day increases the risk of rectal cancer by 46%. ¶ 409.

Viewing the allegations as a whole, Plaintiffs have plausibly alleged that they are at a significantly increased risk of the Subject Cancers and require medical monitoring. And the facts they have employed to do so are consistent with Fed. R. Civ. P. 8's notice pleading standard and other toxic exposure cases denying similar motions to dismiss. *See infra,* Section III.C.

C. Plaintiffs' allegations are consistent with bedrock medical monitoring precedent.

Medical monitoring law originated in toxic tort cases where plaintiffs were typically exposed to contaminants through air and water. Those plaintiffs alleged air and water was contaminated, that they spent time in the affected geographic area, and that they consumed the contaminated air and water. They do not and were not required to allege how much of the *contaminant* they consumed: practically speaking, that measurement would be the subject of proof at trial.[13] And the harm resulting from the exposure is routinely described with reference to regulatory standards.

At the June 3, 2021 hearing on Defendants' prior motions to dismiss, defense counsel relied upon *Bell,* 344 F. Supp. 3d 1207.[14] There, plaintiffs alleged that the municipal wells serving their water system were contaminated with PFCs[15] at levels exceeding the EPA's 70 ppt health advisory

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13 *See, e.g., supra* Section III.A.

14 June 3, 2021 Hearing Transcript at 208.

15 Perfluorinated compounds, also referred to as "forever chemicals," are toxic and likely carcinogenic.

limit. Second Amended Complaint at 4-5, *Bell v. 3M Co.,* Case No. 1:16-cv-02351-RBJ (DE 126). One well's concentration reached levels nearly 20 times more than the EPA health advisory. *Id.* The EPA recommended that pregnant women and small children not drink the water.[16] *Id.*

Plaintiffs alleged "[y]ears of ingestion and dermal absorption of contaminated water" from the affected water districts, *id.* at 10, but they did not identify the amount of PFCs found in their neighborhoods' or homes' water and did not quantify the amount of PFCs they consumed. On direct challenge by defendants, the court found that plaintiffs' allegations were sufficient to plausibly allege exposure, a significantly increased risk of disease, and medical monitoring. *Bell,* 344 F. Supp. 3d at 1225-1226.

Similarly, plaintiffs in *Grayson v. Lockheed Martin Corp.,* Case No. 6:20-cv-1770-RBD-GJK, 2021 WL 2873465 (M.D. Fla. May 13, 2021), alleged they were exposed to air and soil contamination caused by defendants. They did not specify the amount of contaminant in their air or soil: at most, they alleged groundwater contamination "as high as" 386,000 ppb and 213,600 ppb for only two of the chemicals (TCE and methylene chloride, respectively) in the *groundwater* at the defendants' *facility.*[17] Neither did they quantify the increase in risk posed by their exposure.[18] Nonetheless, the court found that plaintiffs plausibly alleged a significantly increased risk of disease sufficient to support medical monitoring. *Id.* at *2-3.

The same principles apply in cases involving other types of contamination. For example, in *Vavak v. Abbott Labs., Inc.*, No. SACV 10-1995, 2011 WL 10550065 (C.D. Cal. June 17, 2011), plaintiffs alleged that their child had a significantly increased risk of harm from consuming beetle-laden infant formula manufactured by Abbott. Abbott recalled approximately five million units of the infant formula, even though the FDA initially said the beetles posed no immediate health risk. Defendants' Memorandum of Law in Support of Their Motion to Dismiss Plaintiff's First Amended Class Action Complaint at 3, *Vavak v. Abbott Lab., Inc.,* 8:10-cv-01995-JVS-RZ (C.D. Cal.) (DE 29). Plaintiffs did not allege the specific amount of beetle parts their child consumed or quantify the child's increased risk of harm. The court held that plaintiffs plausibly alleged

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16 Here the FDA went further by demanding ranitidine's full market withdrawal.

17 *See* Second Amended Complaint at 2, *Grayson v. Lockheed Martin Corp*., Case No. 6:20-cv-01770-RBD-GJK (DE 60).

18 *See e.g.*, *id.* at 3-6 (describing "extreme risks" and "increased risk"); 14-43 (generally describing unquantified health risks posed by "dangerous levels" of the chemicals).

exposure and significantly increased risk and denied defendants' motion to dismiss on that basis.[19] *Vavak*, 2011 WL 10550065, at *3-4.

In *Baker v. Deutschland GmbH*, 240 F. Supp. 3d 341 (M.D. Pa. 2016), plaintiffs were exposed to a potentially fatal bacteria from a heater-cooler system used during open heart surgery. They alleged that the bacteria was naturally-occurring, that it aerosolized into the operating room during invasive surgery, and that defendants recalled the heater-cooler system and issued exposure notices.[20] *Id.* at 347-348. Plaintiffs did not quantify the degree of bacteria or exposure or the increase in their risk of disease; their allegations were nonetheless sufficient to plausibly allege exposure, substantially increased risk, and medical monitoring. *Id.* at 347-348. The court noted: anything more "go[es] to the veracity of the claims rather than the plausibility, and are more appropriately raised at the summary judgment or trial stages of the litigation. . . . To require the Plaintiffs to allege more facts to show exposure would effectively bar medical monitoring claims altogether." *Id.* The case law is clear: quantification of exposure and risk are not required to be pleaded with specificity. *See also supra,* Section III.A.

Thus, as reflected in these cases, Plaintiffs do not have to plead a particular level of exposure, quantify the amount of contaminant needed to increase their risk, or quantify their risk of harm. The AMMC's factual allegations connect Plaintiffs' exposure to their risk of harm such that such that it plausibly alleges a "significantly increased risk." Although this Court had many questions following the last round of briefing, its Order properly recognized that Plaintiffs do not have to answer each of them to plausibly allege a significantly increased risk. Defendants ignore this guidepost, instead claiming that Plaintiffs must identify the exact levels of NDMA each

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[19] This Court's conclusion that *Vavak* did not address "significantly increased risk" (Order at 32, n.17) is at odds with the record in that case. *See* Defendants' Memorandum of Law in Support of Their Motion to Dismiss Plaintiff's First Amended Class Action Complaint, *Vavak v. Abbott Lab., Inc.*, 8:10-cv-01995-JVS-RZ (C.D. Cal.) (DE 29) (arguing plaintiffs did not adequately allege there were beetle parts in their formula or that the contamination caused harm); Plaintiff Vavak's Response in Opposition to Defendants' Motion to Dismiss First Amended Class Action Complaint at 8-10, *Vavak v. Abbott Lab., Inc.*, 8:10-cv-01995-JVS-RZ (C.D. Cal.) (DE 41) (arguing plaintiff plausibly alleged medical monitoring relief, including exposure and significantly increased risk); Defendants' Reply Memorandum of Law in Further Support of Their Motion to Dismiss Plaintiff's First Amended Class Action Complaint at 7-10, *Vavak v. Abbott Lab., Inc.*, 8:10-cv-01995-JVS-RZ (C.D. Cal.) (DE 42) (arguing plaintiff did not plausibly allege a significant risk of serious disease and other elements of medical monitoring relief).

[20] The CDC connected use of the heater-cooler machine to bacteria exposure. Here, the FDA causally related ranitidine consumption with exposure to dangerous levels of NDMA.

Plaintiff consumed,[21] the amount of NDMA necessary to "significantly increase" the risk ("threshold level") and must quantify the increased risk of harm in order to overcome their Rule 12(b)(6) challenge. They are wrong.

Defendants' sole authority is *Riva v. Pepsico, Inc.*, 82 F. Supp. 3d 1045 (N.D. Cal. 2015). Plaintiffs recognize that the Order evaluated their claims under the framework employed by *Riva.* But *Riva* is a distinguishable outlier. It is a single case from one of the 13 jurisdictions at issue in this litigation. This Court recognized that "significantly increased risk" can be plausibly alleged in different ways: unlike here, the *Riva* plaintiffs chose to do so using threshold levels. Their definition of "risk" was "at or above threshold levels," but they failed to identify that level or allege that their consumption exceeded it. Neither did their complaint explain why a study that found a causal relationship between the chemical and cancer in mice was enough to plausibly allege a causal connection between the chemical and lung cancer in humans. These deficiencies are demonstrably different than this case, where the exposure, toxicity, regulatory activity, product testing, variety of scientific studies (including human studies), and chemical nature of ranitidine together demonstrate a significantly increased risk of harm. *See supra*, Section III.B. And not even *Riva* required *quantification* of harm. The court there said that plaintiffs had not presented "the quantitative (*or even qualitative*) increased risk to individuals"—signaling that it found either acceptable. *Riva*, 82 F. Supp. 3d at 1062 (emphasis added) (citations and quotations omitted).[22] More recently, courts in the same district have reached contrary determinations. *See In re JUUL Labs, Inc., Mktg. Sales Prac. & Prod. Liab. Litig.*, No. 19-md-02913-WHO, 2021 WL 3112460, at *16 (N.D. Cal. July 22, 2021) ("Those claims have been sufficiently alleged. Whether plaintiffs meet their evidentiary burdens for them can be tested on summary judgment and at trial.").

In sum, *Riva* is readily distinguishable from this case, and relying on it to require that Plaintiffs plead a quantifiable amount of NDMA consumption, a quantifiable amount of NDMA

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[21] The Court already found that exposure is plausibly alleged. Order at 22-23.

[22] The case *Riva* cited in support of that statement did not require quantification either. *Abuan v. General Elec. Co.*, 3 F.3d 329 (9th Cir. 1993) was a pre-*Potter* summary judgment case in which plaintiffs' experts "amorphously" testified that *any* exposure increased the risk of harm and provided no testimony on the nature of the risk. *Abuan* relied on *In re Paoli* for the standard of proof, but the Third Circuit criticized *Abuan*'s approach and explicitly disavowed a quantification requirement. *In re Paoli*, 35 F.3d at 788.

that significantly increases risk, or a specific quantified risk, is contrary to the case law that established medical monitoring and Rule 12(b)(6). *See supra*, Sections III.A.[23]

D. This Court cannot resolve the parties' competing factual interpretations of the documents and studies cited in the AMMC on Rule 12(b)(6).

The Court incorporated by reference into the AMMC the governmental documents and scientific studies Plaintiffs cited in their complaint based on Defendants' assertion that the documents were "undisputed." Order at 24, n.10; *see Horsley v. Feldt*, 304 F.3d 1125, 1134 (11th Cir. 2002) (a document may be incorporated by reference to the complaint if it is central to plaintiffs' claims and authenticity is undisputed). Defendants now ask the Court to use these documents to resolve factual disputes between the parties regarding core issues like causation—which requires expert testimony—at the pleading stage. This is improper.

It is axiomatic that on a motion to dismiss, the court cannot resolve factual disputes, disregard well-pleaded factual allegations, or require the complaint to "prove" scientific facts. *Michel v. NYP Holdings, Inc.*, 816 F.3d 686, 707 (11th Cir. 2016) (Questions of fact "ought not to be determined on a motion to dismiss absent some extraordinary factor."); *Hi-Tech Pharms., Inc. v. HBS Int'l Corp.*, 910 F.3d 1186, 1197 (11th Cir. 2018) (Twombly-Iqbal does not require plaintiff to provide evidence for allegations of scientific fact at the motion to dismiss stage; such assertions are "entitled to the assumption of truth"); *Aguila v. Corp. Caterers II, Inc.*, 199 F. Supp. 3d 1358, 1359 (S.D. Fla. 2016) ("[A] motion to dismiss for failure to state a claim merely tests the sufficiency of the complaint; it does not decide the merits of the case."). Rather, the court must accept factual allegations as true and read the complaint in the light most favorable to the plaintiffs. *Michel*, 816 F.3d at 707.

It follows that a document which is incorporated by reference into a complaint can only be considered for what it contains, *not* to prove the truth of the matter asserted. *See Davis v. Group Homes for Children, Inc.*, No. 2:09cv415-WHA, 2009 WL 2905767, at *2 (M.D. Ala. Sept. 8, 2009) (citing *Bryant v. Avado Brands, Inc.*, 187 F.3d 1271, 1278 & n.10 (11th Cir. 1999) (holding

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[23] Defendants' insistence that Plaintiffs quantify the amount of NDMA in each ranitidine pill at the pleading stage is particularly disingenuous given Defendants' superior knowledge on this issue. This is *Defendants'* pharmaceutical product, manufactured, stored, transported, and distributed by or at *Defendants'* direction, pursuant to their technical specifications, and tested by *Defendants* before sale to the layperson Plaintiffs. Defendants still have not provided Plaintiffs with product to test.

that it is permissible for courts to take judicial notice of SEC filings at the 12(b)(6) stage in securities fraud cases "for the purpose of determining what statements the documents contain")); *see also Lake v. Aetna Life Ins. Co.*, No. 8:20-cv-3010-VMC-TGW, 2021 WL 2649234, at *3 (M.D. Fla. June 28, 2021) (An "attempt to disprove" the plaintiff's factual "allegations" with documents incorporated by reference "is premature at the motion-to-dismiss stage.") (citations omitted); *Morgan v. Ocwen Loan Servicing, LLC*, 795 F. Supp. 2d 1370, 1374 n.4 (N.D. Ga. 2011) (same). Stated differently, "it is improper to assume the truth of an incorporated document *if such assumptions only serve to dispute facts stated in a wellpleaded complaint.* This admonition is, of course, consistent with the prohibition against resolving factual disputes at the pleading stage." *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1003 (9th Cir. 2018) (emphasis added).[24] At the pleading stage, the court is not in the business of truth, only plausibility.

Yet announcing facts is precisely what Defendants would have this Court do. For example, Defendants argue that the *Loh* study, which Plaintiffs cite for the proposition that 130 ng of NDMA a day causes a 46% increased risk of *rectal* cancer, found "no significant associations between NDMA exposure and *colon*, *breast*, *prostate* and *lung* cancers"—even though Plaintiffs allege (and identify other studies) indicating that NDMA in ranitidine causes these cancers. Motion at 8; AMMC at ¶¶ 403-408. The parties dispute whether ranitidine causes or significantly increases the risk of colon, breast, prostate and lung cancer; they will offer competing expert testimony on that issue and *Loh* cannot be used on a Rule 12(b)(6) motion to prove or disprove Plaintiffs' allegation as to these cancers.[25]

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[24] This is consistent with Eleventh Circuit cases, where an exhibit to the complaint and central to plaintiffs' claims may be used to verify a demonstrably false allegation, but that is all. *See Leones v. Rushmore Loan Mgmt. Servs. LLC*, 749 F. App'x 897, 902 (11th Cir. 2018) (allegation that mortgage agreement prohibited additional payments was directly contradicted by the agreement itself, which was not in dispute); *Caldwell v. Nationstar Mortgage, LLC,* --- F. App'x ---, 2021 WL 1229754, at *2 (11th Cir. 2021) (allegation that, pursuant to the mortgage agreement, mortgagor should have rescinded foreclosure was directly contradicted by mortgage agreement and correspondence that were not in dispute).

[25] Defendants also cite a June 28, 2021 FDA publication in a footnote (without affirmatively requesting judicial notice) in furtherance of their attempt to disprove Plaintiffs' causation allegations. Motion at 8, n. 3. Judicial notice is only proper if the fact "is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b), (d). Causation is, undoubtedly, a disputed fact that does not meet these requirements. Defendants' citation must be disregarded.

Similarly, Defendants claim Plaintiffs do not address the FDA's statement that the levels of NDMA it found in ranitidine were "low." Motion at 11. Defendants are wrong: this issue was addressed in the AMMC at n.172 and is further discussed *supra,* Sections II, III.B.1 (explaining that the FDA reversed course thereafter and requested a full market withdrawal, and that Plaintiffs were exposed to NDMA far beyond the amounts found through product testing because of endogenous and exogenous formation). Regardless, the FDA's statement stands for the proposition that at that point in time, the FDA thought NDMA levels were low. Whether or not the levels of NDMA the FDA found in Defendants' ranitidine actually *were* "low," what "low" means, the significance of the FDA's statement, the relationship between these NDMA levels and Plaintiffs' exposure, and the significance of the NDMA values, are all factual disputes that will be the subject to expert opinion. The FDA's statement cannot be used to prove or disprove those issues, causation, exposure, or increased risk.

Further, Defendants argue that studies addressing "lifetime diet habits… do not and cannot support any conclusion about the amount of NDMA needed to create a significantly increased cancer risk." Motion at 9. First, the referenced studies were cited merely for the general proposition that NDMA causes cancer, under the heading "NDMA is a Carcinogen Whose Dangerous Propensities are Well Established." *See* AMMC at ¶¶ 81 *et seq.* & n.59-61. More importantly, the parties dispute whether NDMA, including NDMA in ranitidine, increases the risk of or causes cancer; the amount of NDMA a typical person consumes in a day outside of ranitidine; and the relevance of that number to any risk analysis.[26] Thus, Defendants cannot use the studies to disprove any of these questions.

Defendants' approach is not only wrong—it's dangerous. It urges judicial adjudication of central, disputed issues like causation and risk of harm at the Rule 12 pleadings stage, without the necessary expert testimony. This is not the Court's proper role now —nor at *Daubert* and summary judgment stage – competing expert opinions interpreting the scientific evidence differently are par for the course. Experts use a variety of methodologies to demonstrate causation, including dose-response relationship, epidemiological studies and the Bradford Hill factors, background risk of the disease, biological plausibility, case studies and adverse event reports, *in vivo* and *in vitro* studies, analogous drugs, and weight of the evidence—none of which are available to the Court at

[26] For example, information from dietary studies may provide evidence of background NDMA exposure, as contrasted to *increased* exposure through NDMA in ranitidine.

the pleading stage. *See, e.g.*, *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1306-12 (N.D. Fla. 2018) (describing different types of methodologies employed by causation experts). Defendants' attempt to disprove Plaintiffs' factual allegations by interpreting scientific studies incorporated into the complaint is well outside the bounds of the incorporation by reference doctrine and Rule 12(b)(6). And Plaintiffs' citation to scientific studies as a matter of good form does not change the pleading standard.

E. Defendants are precluded from parsing "significantly increased risk" in terms of brand versus generic usage; nonetheless, its Defendants' burden to apportion blame if Plaintiffs' risk was caused by both brand and generic products.

This Court gave Defendants leave to brief only those issues raised in prior motions to dismiss; only the sufficiency of the edits Plaintiffs made in response to the Court's Order are properly at issue. *See* DE 3751 at 2. Nevertheless, in disregard for the Order, Defendants argue for the first time that Plaintiffs must (but fail to) plausibly allege significant exposure to *brand Zantac* that—on its own, without any consideration of *generic* usage—significantly increases the risk of the Subject Cancers. Motion at 13-14. Defendants could have previously raised this argument but did not. They should be precluded from doing so now.

Even if this Court considers the argument, it fails on the merits, which Defendants do not even pretend to address. Defendants are liable to Plaintiffs for the increased risk of harm proximately caused by their products, even if Plaintiffs' exposure to NDMA through *generic* ranitidine renders the injury Defendants' brand product inflicted "greater" than was otherwise foreseeable. Restatement (Second) of Torts § 461 (Am. Law Inst. 1965). This is the so-called "eggshell plaintiff" rule. To employ a different aspect of black-letter tort law, if Plaintiffs' increased risk of harm was caused by both brand and generic product, it is *Defendants'* burden—not Plaintiffs'—to apportion that harm. *See, e.g.*, Restatement (Second) of Torts § 433B(2) (Am. Law Inst. 1965) ("Where the tortious conduct of two or more actors has combined to bring about harm to the plaintiff, and one or more of the actors seeks to limit his liability on the ground that the harm is capable of apportionment among them, the burden of proof as to the apportionment is upon each such actor."). It is irrelevant that the generic manufacturers are no longer defendants. *Id.* at cmt. c.

F. Plaintiffs' general causation expert reports will provide additional scientific detail regarding increased risk.

Defendants urge dismissal with prejudice of the AMMC because Plaintiffs have not specifically alleged even greater scientific detail regarding the increased risk, including the amount of NDMA that causes an increased risk of cancer or the amount of NDMA Plaintiffs were exposed to via ranitidine. Decisions from the Eleventh Circuit and elsewhere demonstrate that pleading this level of scientific detail is not required for purposes of the Rule 12 analysis. *See, e.g. Hi-Tech Pharms., Inc.*, 910 F.3d at 1197; *see also supra*, Section III.A.

As this Court is well aware, it recently revised its scheduling order as a result of Defendants' delays in producing voluminous scientific studies, product for testing, and other discovery that are critical to Plaintiffs' ongoing analysis and development of expert reports. *See* Pretrial Order # 65 [DE 3624]. To that end, Plaintiffs' general causation expert reports are not due until December 20, 2021 (the same day fact discovery closes).[27] Plaintiffs' experts have not yet completed their analysis of the critical issues nor prepared their general causation reports.

Given the status of discovery and the expert deadline set forth in PTO # 65, Plaintiffs are not able to allege greater scientific detail regarding the increased risk. To the extent the Court requires Plaintiffs to plead greater scientific detail than currently set forth in the AMMC, Plaintiffs will be in a position to supplement the AMMC after submission of their general causation expert reports in late December 2021. For these reasons, under the existing scheduling order, dismissal would be unfair and unwarranted.

IV. CONCLUSION

Defendants' Motion to Dismiss the AMMC should be denied.

Dated: September 9, 2021

Respectfully submitted,

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[27] The Court also deferred class certification proceedings until after *Daubert* general causation issues are resolved. PTO # 65 [DE 3624]. This thoughtful approach ensures that class issues are evaluated efficiently and within the necessary scientific context.

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CERTIFICATE OF SERVICE

I hereby certify that on September 9, 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/ Mark J. Dearman
Mark J. Dearman

EXHIBIT 1

PLAINTIFFS' ALLEGATIONS OF RANITIDINE USAGE

Plaintiff	Frequency of Use	Dosage(s) and Time Periods Of Use	Total Years Used
Ida Adams (MD, WV) (AAMC, ¶ 26)	"once to three times daily"	"Plaintiff purchased and used Ranitidine-Containing Products from approximately 2000 to 2019 for heartburn and gastroesophageal reflux disease ("GERD"). The Ranitidine-Containing Products purchased and used by Plaintiff specifically included the following, consumed 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."	20
Virginia Aragon (CA) (AAMC, ¶ 27)	"daily"	"Plaintiff purchased and used Ranitidine-Containing Products in California while a citizen of California from approximately 2006 to 2020 for heartburn. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included the following, consumed 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."	14

Plaintiff	Frequency of Use	Dosage(s) and Time Periods Of Use	Total Years Used
Golbenaz Bakhtiar (CA) (AAMC, ¶ 28)	"up to twice daily ... with occasional gaps of no longer than a week"	"Plaintiff purchased and used Ranitidine-Containing Products in California while a citizen of California from approximately 2000 to December 2019 for acid reflux and GERD. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included the following, consumed 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."	20
Felicia Ball (PA) (AAMC, ¶ 29)	"at least once per day"	"Plaintiff purchased and used Ranitidine-Containing Products in Pennsylvania while a citizen of Pennsylvania from approximately 2000 to 2020 for irritable bowel syndrome. The Ranitidine-Containing Products purchased and used by Plaintiff during that time specifically included the following, consumed 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."	20
Antrenise Campbell (MO) (AAMC, ¶ 30)	"twice daily"	"Plaintiff purchased and used Ranitidine-Containing Products in Missouri while a citizen of Missouri from approximately 1998 to 2015 for heartburn and acid reflux. The Ranitidine-Containing Products purchased and used by Plaintiff and consumed twice daily specifically included (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."	18

Plaintiff	Frequency of Use	Dosage(s) and Time Periods Of Use	Total Years Used
Teresa Dowler (IN) (AAMC, ¶ 31)	"daily"	"Plaintiff purchased and used Ranitidine-Containing Products from approximately 2011 to December 2019 in Indiana while a citizen of Indiana for GERD. The Ranitidine-Containing Products Plaintiff purchased and used daily specifically included (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."	9
Jonathan Ferguson (NV, CA) (AAMC, ¶ 32)	"daily"	"Plaintiff purchased and used Ranitidine-Containing Products from approximately 1996 to 2017 for heartburn and GERD. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included the following, consumed 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."	22
Karen Foster (FL) (AAMC, ¶ 33)	regularly	"Plaintiff purchased and used Ranitidine-Containing Products from approximately 2013 to 2020 for hernia, heartburn, reflux, sour stomach, and GERD. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included the following: (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."	8

Plaintiff	Frequency of Use	Dosage(s) and Time Periods Of Use	Total Years Used
Michael Galloway (OH, FL) (AAMC, ¶ 34)	"up to three times daily"	"Plaintiff purchased and used Ranitidine-Containing Products from approximately 1989 through October 2019 for acid reflux. The Ranitidine-Containing Products purchased and used by Plaintiff and consumed up to three times daily specifically included (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."	31
Alberta Griffin (MD) (AAMC, ¶ 35)	"up to three times a day"	"Plaintiff purchased and used Ranitidine-Containing Products in Maryland while a citizen of Maryland from approximately 2000 to March 2020 for acid reflux. The Ranitidine-Containing Products purchased and used by Plaintiff, consumed up to three times a day depending on her condition specifically included the following: (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."	20
Lorie Kendall-Songer (MO) (AAMC, ¶ 36)	"once or twice per day"	"Plaintiff purchased and used Ranitidine-Containing Products from approximately 2012 to 2020 in Missouri while a citizen of Missouri for acid reflux and heartburn. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included OTC 150 mg Zantac tablets and capsules, consumed once or twice per day, from approximately 2012 to 2020, which were manufactured by BI and Sanofi."	8

Plaintiff	Frequency of Use	Dosage(s) and Time Periods Of Use	Total Years Used
Ronda Lockett (MO) (AAMC, ¶ 37)	"Once" or "twice" daily	"Plaintiff purchased and used Ranitidine-Containing Products from approximately 1983 to March 2020 for heartburn, acid reflux, and ulcers. The Ranitidine-Containing Products Plaintiff purchased and used in Missouri while a citizen of Missouri specifically included (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."	37
Marva Mccall (FL) (AAMC, ¶ 38)	"once per day"	"Plaintiff purchased and used Ranitidine-Containing Products in Florida while a citizen of Florida from approximately 2007 to December 2019 for heartburn, acid reflux, and GERD. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (a) 300 mg OTC Zantac tablets and capsules consumed once per day 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."	13
Clifton McKinnon (FL) (AAMC, ¶ 39)	"twice per day"	"Plaintiff purchased and used Ranitidine-Containing Products in Florida while a citizen of Florida from approximately 2008 to 2020 for acid reflux and GERD. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (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."	12
Alexander Monger (FL) (AAMC, ¶ 40)	"twice per day"	"Plaintiff purchased and used Ranitidine-Containing Products in Florida while a citizen of Florida from approximately 1999 to 2020 for acid reflux. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (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."	21

Plaintiff	Frequency of Use	Dosage(s) and Time Periods Of Use	Total Years Used
Laura Monger (FL) (AAMC, ¶ 41)	"twice per day"	"Plaintiff purchased and used Ranitidine-Containing Products in Florida while a citizen of Florida from approximately 1997 to 2020 for acid reflux, heartburn, GERD, and aspiration. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included (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."	23
Ricardo Moròn (FL) (AAMC, ¶ 42)	"three to four times a week"	"Plaintiff purchased and used Ranitidine-Containing Products in Florida while a citizen of Florida from approximately 1996 to 2020 for heartburn, acid reflux, and stomach discomfort. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included 150 mg OTC Zantac tablets and capsules consumed approximately three to four times a week from approximately 1996 to 2020, which were manufactured by GSK, Pfizer, BI, and Sanofi."	24
Richard Obrien (CA) (AAMC, ¶ 43)	"twice per day from approximately 1998 to 2008, and . . . once per day from approximately 2008 to 2019"	"Plaintiff purchased and used Ranitidine-Containing Products in California while a citizen of California from approximately 1998 to November 2019 for gastritis and GERD. The Ranitidine-Containing Products purchased and used by Plaintiff, consumed twice per day from approximately 1998 to 2008, and consumed once per day from approximately 2008 to 2019, specifically included: (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."	22
Cesar Pinon (NV) (AAMC, ¶ 44)	"two or three times per day"	"Plaintiff purchased and used Ranitidine-Containing Products in Nevada while a citizen of Nevada from approximately 2009 to 2019 for acid reflux. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included OTC 75 mg and 150 mg Zantac tablets and capsules consumed two or three times per day after meals from approximately 2009 to 2015, and manufactured by BI."	11

Plaintiff	Frequency of Use	Dosage(s) and Time Periods Of Use	Total Years Used
Jeffrey Pisano (CO) (AAMC, ¶ 45)	"twice per day but later consumed as needed"	"Plaintiff purchased and used Ranitidine-Containing Products in Colorado while a citizen of Colorado from approximately 1998 to February 2020 for heartburn. The Ranitidine-Containing Products purchased and used by Plaintiff and consumed twice per day but later consumed as needed specifically included (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."	22
Ronald Ragan (CO) (AAMC, ¶ 46)	"two times per day"	"Plaintiff purchased and used Ranitidine-Containing Products from approximately 2012 to 2019 in Colorado while a citizen of Colorado for acid reflux, heartburn, and GERD. The Ranitidine-Containing Products purchased and used by Plaintiff and consumed two times per day specifically included (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."	8
Tangie Sims (AZ) (AAMC, ¶ 47)	"one to two times per day"	"Plaintiff purchased and used Ranitidine-Containing Products in Arizona while a citizen of Arizona from approximately 2007 to 2020 for heartburn. The Ranitidine-Containing Products purchased and used by Plaintiff and consumed one to two times per day specifically included: (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."	13

Plaintiff	Frequency of Use	Dosage(s) and Time Periods Of Use	Total Years Used
Michael Tomlinson (FL) (AAMC, ¶ 48)	"twice daily"	"Plaintiff purchased and used Ranitidine-Containing Products in Florida while a citizen of Florida from approximately 2000 to November 2019 for acid reflux. The Ranitidine-Containing Products purchased and used by Plaintiff and consumed twice daily specifically included the following: (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."	20
Chris Troyan (OH) (AAMC, ¶ 49)	"three to four times per week"	"Plaintiff purchased and used Ranitidine-Containing Products in Ohio while a citizen of Ohio from approximately 2002 to 2020 for heartburn and acid reflux. The Ranitidine-Containing Products purchased and used by Plaintiff and consumed three to four times per week specifically included (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."	18
Gustavo Velasquez (FL) (AAMC, ¶ 50)	"two to six times per week from approximately 2000 to 2016, and thereafter until 2020 on as- needed basis, approximately once a month"	"Plaintiff purchased and used Ranitidine-Containing Products in Florida while a citizen of Florida from approximately 2000 to February 2020 for acid reflux. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included OTC 75 mg and 150 mg Zantac tablets and capsules manufactured by Pfizer, BI, and Sanofi. Plaintiff consumed these Zantac tablets two to six times per week from approximately 2000 to 2016, and thereafter until 2020 on an as-needed basis, approximately once a month."	20
Teresa Waters (UT) (AAMC, ¶ 51)	"daily"	"Plaintiff purchased and used Ranitidine-Containing Products in Utah while a citizen of Utah from approximately 2017 to March 2020 for acid reflux. The Ranitidine-Containing Products purchased and used by Plaintiff and consumed daily specifically included the following: (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."	3

Plaintiff	Frequency of Use	Dosage(s) and Time Periods Of Use	Total Years Used
Joshua Winans (FL) (AAMC, ¶ 52)	"daily"	"Plaintiff purchased and used Ranitidine-Containing Products in Florida while a citizen of Florida from approximately 2000 to 2019 for GERD, dyspepsia, heartburn, upset stomach, and erosive esophagitis. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included OTC 75 and 150 mg Zantac tablets and capsules, consumed daily from approximately 2000 to 2019, manufactured by Pfizer, BI, and Sanofi."	20
TOTAL YEARS OF COLLECTIVE USAGE			**477**