UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

MDL NO. 2924
20-MD-2924

JUDGE ROBIN L. ROSENBERG
MAGISTRATE JUDGE BRUCE E. REINHART

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ORDER DENYING DEFENDANTS' MOTION TO DISMISS AMENDED CONSOLIDATED MEDICAL MONITORING CLASS ACTION COMPLAINT

This matter is before the Court on the Defendants' Motion to Dismiss Amended Consolidated Medical Monitoring Class Action Complaint [DE 4106] (the "Motion"). The Court held a hearing on the Motion to Dismiss on October 4, 2021 (the "Hearing"). The Court has carefully considered the Motion, the Response [DE 4241], the Reply [DE 4320], the arguments made during the Hearing, and the record, and is otherwise fully advised in the premises. For the reasons set forth below, the Defendants' Motion is **DENIED**.

Twenty-seven named Plaintiffs bring the Amended Consolidated Medical Monitoring Class Action Complaint ("AMMC") on behalf of themselves and various proposed classes. AMMC ¶¶ 26-52, 463. The Plaintiffs are individuals who purchased and used Defendants' ranitidine products. *Id.* ¶ 25. Each Plaintiff alleges how frequently he or she used ranitidine, the duration of use, the dosages used, whether the ranitidine was OTC or prescription, the manufacturers of the ranitidine used, the medical conditions for which he or she used ranitidine, and the jurisdictions in which he or she purchased and used ranitidine. *Id.* ¶¶ 26-52. The Plaintiffs allege 98 counts in the AMMC. Each count falls within one of four general causes of action: (1)

Failure to Warn through Warnings and Precautions; (2) Failure to Warn through Proper Expiration Dates; (3) Negligent Product Containers; and (4) Negligent Storage and Transportation.

The Plaintiffs propose several state- and defendant-specific classes. There are eight prescription medical monitoring classes, each of which alleges claims against only Defendant GlaxoSmithKline ("GSK") (*e.g.*, California GSK Prescription Medical Monitoring Class). AMMC ¶ 464. The remainder are over-the-counter ("OTC") medical monitoring classes that allege claims against one of the Defendants (*e.g.*, Arizona Sanofi OTC Medical Monitoring Class). AMMC ¶¶ 465-68. The various classes are comprised of individuals who used one of the Defendants' prescription or OTC ranitidine products while residing in a particular state and who have not been diagnosed with a Subject Cancer. The Plaintiffs allege that the Subject Cancers "include serious and potentially fatal bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancers." *Id.* at 13.[1]

The Defendants named in the AMMC are "entities that designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold OTC Zantac." *Id.* ¶ 6. There are four Defendants: GSK, Pfizer, Boehringer Ingelheim, and Sanofi. *Id.* ¶¶ 7-24.[2]

The Defendants now move to dismiss all of the claims in the AMMC. Below, the Court (A) reviews legal authority relevant to the Motion, (B) describes the parties' arguments, and (C) provides its analysis and conclusion.

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

[2] A more detailed procedural and factual background of the case is set forth in the Court's prior Order dismissing the Plaintiffs' medical monitoring claims. *See* DE 3720 at 2-5.

A. Relevant Law

1. Rule 12(b)(6)

A court may grant a motion to dismiss a pleading if the pleading fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A Rule 12(b)(6) motion to dismiss should be granted only when the pleading fails to contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The pleading must contain more than labels, conclusions, a formulaic recitation of the elements of a cause of action, and naked assertions devoid of further factual enhancement. *Id.* The "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555; *see also Iqbal*, 556 U.S. at 678 (explaining that the plausibility standard "asks for more than a sheer possibility that a defendant has acted unlawfully").

A court ruling on a motion to dismiss accepts the well-pled factual allegations as true and views the facts in the light most favorable to the plaintiff. *Jones v. Fransen*, 857 F.3d 843, 850 (11th Cir. 2017). But the court need not accept as true allegations upon information and belief that lack sufficient facts to make the allegations plausible. *Mann v. Palmer*, 713 F.3d 1306, 1315 (11th Cir. 2013) (citing *Twombly*, 550 U.S. at 551, 557); *see also In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 931 (6th Cir. 2014) ("The mere fact that someone believes something to be true does not create a plausible inference that it is true."). The court also need not accept legal conclusions couched as factual allegations. *Diverse Power, Inc. v. City of LaGrange, Ga.*, 934 F.3d 1270, 1273 (11th Cir. 2019). "Under Rule 12(b)(6), dismissal is proper when, on the basis of a dispositive issue of law, no construction of the factual allegations will

support the cause of action." *Allen v. USAA Cas. Ins. Co.*, 790 F.3d 1274, 1278 (11th Cir. 2015) (quotation marks omitted).

2. Medical Monitoring; Significantly Increased Risk

Medical monitoring claims are non-traditional torts, through which individuals "seek to recover the anticipated costs of long-term diagnostic testing necessary to detect latent diseases that may develop as a result of tortious exposure." *In re Nat'l Hockey League Players' Concussion Inj. Litig.*, 327 F.R.D. 245, 259-60 (D. Minn. 2018) (quotation marks omitted). Medical monitoring claims "evolved from the realization that widely recognized tort law concepts premised upon a present physical injury are ill-equipped to deal with cases involving latent injury." *Id.* at 260 (quotation marks omitted). "[A]n action for medical monitoring seeks to recover only the quantifiable costs of periodic medical examinations necessary to detect the onset of physical harm . . . ." *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 850 (3d Cir. 1990).

The Plaintiffs here seek medical monitoring in states where they allege that proof of present physical injury is not required. AMMC at 14. The elements to obtain medical monitoring under Florida law illustrate what some of these jurisdictions require:

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

Petito v. A.H. Robins Co., Inc., 750 So. 2d 103, 106-07 (Fla. Dist. Ct. App. 1999).

At issue in the present Motion is whether the Plaintiffs have plausibly alleged that they are at a significantly increased risk of a Subject Cancer due to ingesting ranitidine. In some states, the requirement for significantly increased risk is an express element of the medical monitoring claim.

Id. at 106 (requiring a plaintiff to plead a "significantly increased risk of contracting a serious latent disease"). In other states, the requirement for a significant exposure exists in the form of a reasonable treating physician's diagnosis. *Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 980 (Utah 1993) (requiring a plaintiff to show that because of an exposure to a toxic substance, "a reasonable physician would prescribe for her or him a monitoring regime different than the one that would have been prescribed in the absence of that particular exposure"); *Cook v. Rockwell Int'l Corp.*, 755 F. Supp. 1468, 1477 (D. Colo. 1991) (requiring a plaintiff to show that because of an exposure, "periodic diagnostic medical examinations" are reasonably necessary). Regardless of these variations, the parties agree that the Plaintiffs must allege a significant increase in their risk of cancer—a risk significant enough that a treating physician would prescribe a monitoring regime.

B. The Parties' Arguments

The Defendants first argue that the Plaintiffs do not allege a threshold level of NDMA exposure that creates a significantly increased risk of the Subject Cancers. DE 4106 at 8. While the Plaintiffs reference the FDA's acceptable daily limit ("ADI") of 96 nanograms (ng), they do not equate that with the threshold level; they instead call it "unacceptable and harmful by definition." *Id.* at 9 (quotation marks omitted). But regulatory thresholds do not constitute the levels at which individuals are subject to significantly increased risks of health conditions. *Id.* at 10. Additionally, the various studies cited by the Plaintiffs do not indicate a threshold level of NDMA exposure. *Id.* at 12. Second, the Plaintiffs do not plead the amount of NDMA in each Zantac dose. *Id.* at 14. While the Plaintiffs rely on the FDA's testing of Sanofi's products, the results revealed NDMA levels above and below the ADI, and which cannot be imputed to other Defendants. *Id.* at 15. The same issues are true of the testing conducted by GSK and Sanofi

themselves. *Id.* at 16. Third, the Plaintiffs do not allege how frequently each Plaintiff consumed branded Zantac versus generic ranitidine. *Id.* at 17. Allegations of significant generic ranitidine use but sparse brand Zantac use from many years ago impacts whether the Plaintiffs have pled a significantly increased risk of cancer based on the Defendants' products. *Id.* at 17-18.

The Plaintiffs first respond that they do not need to quantify the threshold level of NDMA exposure that triggers a significantly increased risk of a Subject Cancer. DE 4241 at 11. Rather, their allegations about "exposure, toxicity, regulatory activity, product testing, [a] variety of scientific studies (including human studies), and [the] chemical nature of ranitidine together demonstrate a significantly increased risk of harm." *Id.* at 19. Second, the Plaintiffs do not need to quantify the amount of NDMA in each dose of ranitidine. *Id.* at 20 n.23. Doing so is not required based on medical monitoring precedent, and the Defendants' argument is disingenuous given that they have not provided the Plaintiffs any product to test. *Id.* Third, the Defendants' argument regarding the Plaintiffs' brand versus generic use fails on its merits. *Id.* at 23. Pursuant to the "eggshell plaintiff" rule, if the Defendants' branded products proximately caused the Plaintiffs' increased risk of Subject Cancers, the Defendants are liable even if the generic ranitidine products exacerbated the Plaintiffs' injuries beyond what was foreseeable. *Id.* It is the Defendants' burden to apportion the harm caused to the Plaintiffs. *Id.* Finally, the Plaintiffs' general causation experts will eventually provide scientific detail to support the allegations of significantly increased risk. *Id.* at 24.

C. Analysis and Conclusion

In the prior round of motions to dismiss, the Defendants made the same argument that they make now—that the Plaintiffs had failed to plausibly plead a significant increase in the risk of cancer. DE 3116 at 23. The Plaintiffs' response on this point was a single paragraph:

> [T]he MMC alleges that exposure to NDMA above 96 ng is unacceptable and increases the risk of cancer, that one ranitidine dose exposes the user to over 3000 ng of NDMA, that doses of NDMA even lower than that significantly increase the risk of cancer, that certain Defendants' testing showed NDMA in all batches of ranitidine, and that MM Plaintiffs took therapeutic doses of ranitidine for years. MM Plaintiffs need only show that it is plausible that they were exposed to excessive and unsafe levels of NDMA. They have.

DE 3429 at 28 (citations omitted). The Court ultimately concluded that it:

> [could not] clearly ascertain from the MMC: (i) the number of doses of ranitidine the Plaintiffs 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 in the MMC.

DE 3720 at 32-33. The Court did not, however, conclude that the Plaintiffs could only plead a significant increase in the risk of cancer through precise responses to the Court's points quoted above. Instead, the Court expressly recognized that the Plaintiffs could plead their medical monitoring claims in an amended complaint however they saw fit:

> The Court does not mean to suggest that the only way that the Plaintiffs may plausibly plead a substantial increase in the risk of cancer is by answering in detail, through their allegations, the questions the Court has posed or by dispelling all of the uncertainty that the Court has highlighted in this Order. 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. The Court's ruling is merely that, as pled, the Court cannot conclude that the Plaintiffs have plausibly alleged a substantial increase in the risk of cancer.

Id. at 33; *see id.* at 23 n.9 ("The Court's focus is not on whether the Plaintiffs have alleged a threshold exposure, but rather whether the Plaintiffs have plausibly alleged an undisputed element of medical monitoring—a substantial increase in the risk of disease.").

In the Motion before the Court, the Defendants read the Court's prior Order of dismissal to say that the Plaintiffs *must* quantify a particular level of NDMA that is necessary to cause a significantly increased risk, the amount of NDMA per dose, and the frequency of the Plaintiffs'

ranitidine use. DE 4106 at 5 ("The Court was clear that Plaintiffs were required to rectify these failures through re-pleading."). This premise underpins their arguments in the Motion.

The Plaintiffs do not need to quantify a particular level of NDMA to satisfy plausibility. The caselaw cited by the Plaintiffs is illustrative. *See, e.g.*, *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 . . . . Importantly, no particular level of quantification is necessary to satisfy this element.") (quotation marks omitted); *see also Hansen*, 858 P.2d at 979 ("No particular level of quantification is necessary to satisfy this requirement of significantly increased risk."). The case the Defendants rely upon—*Riva v. Pepsico, Inc.*, 82 F. Supp. 3d 1045 (N.D. Cal. 2015)—does not stand for the proposition that a plaintiff must quantify levels of exposure to survive a motion to dismiss. Although the *Riva* court equated the plaintiffs' failure to plead a threshold level of exposure with a failure to plausibly plead a significant increase in the risk of cancer, the court's dismissal was based upon the plaintiffs' decision to plead and rely upon exposure "at or above threshold levels." *Id.* at 1057 (quotation marks omitted).

Unlike the Plaintiffs' response in the prior round of motions to dismiss, the Plaintiffs have now provided the Court with argument to refute the Defendants' Motion that is supported by ample citations to their complaint. They allege that NDMA is a known human carcinogen. AMMC ¶ 81-126. They identify the frequency and dosage of each Plaintiff's ranitidine use and the medical conditions for which they used ranitidine, AMMC ¶¶ 25-52, as well as levels of NDMA in ranitidine (as detected by the FDA) that were above the FDA's acceptable daily limit. AMMC ¶ 199. Although the Plaintiffs acknowledge that the FDA initially concluded that the levels of NDMA detected in ranitidine were relatively low, at the motion to dismiss stage, they are entitled to the inference that the FDA subsequently changed its mind about the levels of NDMA in

ranitidine (and corresponding risk of cancer) because the FDA called for a voluntary nationwide recall of ranitidine. AMMC at 54 n.69. Finally, the Plaintiffs identify several studies linking ranitidine to the Subject Cancers. AMMC ¶¶ 203-11. The Court must accept all of these allegations as true and view all reasonable inferences in favor of the Plaintiffs. The Plaintiffs' allegations are sufficient to plead "significantly increased risk" at this time.

For the foregoing reasons, it is **ORDERED AND ADJUDGED** that the Defendants' Motion to Dismiss Amended Consolidated Medical Monitoring Class Action Complaint [DE 4106] is **DENIED**. The Defendants shall file their Answers to the Amended Consolidated Medical Monitoring Class Action Complaint within 20 days of the date of this Order.

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 6th day of October, 2021.

ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

Copies furnished to Counsel of Record