UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

MDL NO 2924
20-MD-2924

JUDGE ROBIN L. ROSENBERG
MAGISTRATE JUDGE BRUCE E. REINHART

_____/

THIS DOCUMENT RELATES TO: ALL CASES

PLAINTIFFS' OPPOSITION TO GENERIC MANUFACTURER AND REPACKAGER DEFENDANTS' RULE 12 MOTION TO DISMISS CLASS COMPLAINTS ON THE GROUND OF FAILURE TO ALLEGE AN INJURY

DATED: November 9, 2020

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Rules

OTHER AUTHORITIES

Plaintiffs submit the following memorandum of law in opposition to the Generic Manufacturer and Repackager Defendants' Rule 12 Motion to Dismiss Class Complaints on the Ground of Failure to Allege an Injury. D.E. 2037 (Injury Mot.).

INTRODUCTION

Consumers and third-party payors (TPPs) spent billions on ranitidine, a product we now know produces high levels of NDMA, a potent carcinogen. Consumer Class Action Complaint (CCAC), D.E. 889 ¶¶ 1–2, 427, 499, 756–57; Third Party Payor Class Complaint (TPPCAC), D.E. 888, ¶¶ 495, 522, 562, 577, 586, 618, 675. The Consumers are at an increased risk of developing cancer, and will reasonably need costly medical monitoring to diagnose adverse health developments in time to treat them. The CCAC and TPPCAC alleged hundreds of counts under federal law and the law of every state, the District of Columbia, and Puerto Rico. Defendants seek to dismiss every last count on a single theory: neither complaint alleges an injury.

Defendants' gambit fails. Binding Eleventh Circuit case law holds that products that are so unsafe that they are illegal to buy or sell are also economically worthless and give rise to constitutional injury in fact when plaintiffs purchase them. The complaints carefully allege that ranitidine is just such a product. Even leaving aside any regulatory bar on sales, a reasonable consumer would not have purchased

ranitidine at all (much less for the same price), and TPPs would not have covered it, if Defendants had disclosed that it contains a carcinogen. The consumers allege the additional injuries of unwittingly ingesting a carcinogen without their consent and requiring periodic, costly medical surveillance necessary to detect physical harm due to Plaintiffs' increased risk of developing cancer. Plaintiffs suffered multiple forms of injury that suffice to show standing.

Unable to sustain their Article III challenge, Defendants repackage their argument under the "economic-loss rule," which, they insist, bars the TPPs' claims. But Defendants fail entirely to explain which states apply this rule, and under what circumstances. Incanting the words "economic loss rule" and nothing more cannot provide a ground to dismiss a claim. Only applicable law can do that.

The final request in Defendants' motion to dismiss does not actually seek to dismiss anything. In yet another effort to smuggle Rule 23 arguments into a 12(b)(6) motion, *cf.* Opp'n on Shotgun Pleadings and Article III Standing, D.E. 1980 at 14–16, Defendants argue that any medical monitoring *remedy* be deemed "*not* injunctive relief." Injury Mot. at 17. The type of relief sought may well impact the sort of class the Court may eventually certify. *Compare* Fed. R. Civ. P. 23(b)(2) *with* 23(b)(3). But it has absolutely no bearing on whether Plaintiffs *state a claim* upon which relief can be granted, which is the sole inquiry on a Rule 12(b)(6) motion to dismiss. No doubt that is why *all* of Defendants' cited cases turn on questions of class

certification, which they can brief at the appropriate time. *See* Pre-Trial Order 36, D.E. 1346 (limiting briefing to Rule 12 motions for these rounds). What they cannot do is treat a "motion to dismiss" as an open-ended wish list for all manner of judicial relief that is unmoored from the text, purpose, and structure of Rule 12(b)(6). Defendants' motion should be denied.

ARGUMENT

I. Legal Overview

A complaint will survive a motion to dismiss if it "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' 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) (citations omitted). Whether well-pleaded *facts* amount to a *claim* turns on that claim's elements under substantive law, which is why "[i]n *Twombly*, the Court found it necessary first to discuss the antitrust principles implicated," and did the same for supervisory liability in *Iqbal*. *Id.* at 675. Analogously, whether the pleaded facts demonstrate *standing* turns on the elements of standing under federal constitutional doctrine. *See Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) ("the plaintiff must 'clearly . . . allege facts demonstrating' each element [of standing]").

The "irreducible constitutional minimum of standing" has three elements:

> [1] an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical[;]
> [2] a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court[; and]
> [3] it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Lujan v. Defs. of Wildlife, 504 U.S. 555, 560–61 (1992) (quotations, citations, and alterations removed).

The claims alleged in the class complaints turn on elements supplied by state law.[1] When sitting in diversity, federal courts are required to apply the substantive law of the states. *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). On questions of state law, this Court is bound by the rulings of state supreme courts. Where a state's highest court has not addressed a question, "federal courts are bound by decisions of a state's intermediate appellate courts unless there is persuasive evidence that the highest state court would rule otherwise." *Bravo v. United States*, 577 F.3d 1324, 1325 (11th Cir. 2009) (per curiam) (internal quotation marks omitted). When there is no state decision on point, a federal court must act as a state court would, predicting as best it can how the state's highest court would rule. *Id.* at 1325–26.

[1] The charts in Plaintiffs' Class Standing and Shotgun Pleading Opposition, D.E. 1980, set out the universe of claims in a concise, visual form. *See id.* at 4, Figure 1 (summarizing the CCAC claims); *id.* at 5, Figure 2 (summarizing the TPPCAC claims).

For a Rule 12 motion to succeed on a particular state law claim under *Iqbal*, it would be "necessary first to discuss the [substantive legal] principles implicated" to identify the claim's elements—which would require an *Erie* prediction—and next to identify an essential element of the claim that was not pleaded in the complaint. 556 U.S. at 675.

II. Plaintiffs' Injuries Are Cognizable

Defendants do not explain whether their Rule 12 Motion is brought under Rule 12(b)(1) ("lack of subject-matter jurisdiction") or Rule 12(b)(6) ("failure to state a claim"). *See* Injury Mot. at 4–5 (arguing courts dismiss similar actions "under Rule 12(b)(1)" or "Rule 12(b)(6)"). The distinction is crucial. If the former, dismissal must be *without* prejudice, *but see id.* at 18 ("all claims . . . must be dismissed with prejudice"), and the Court could *not* address state law merits questions. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998) ("Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause." (citation omitted)). If the latter, the analysis depends on the elements of substantive *state* law, and would need to be decided under the framework of an *Erie* prediction, not the constitutional standing inquiry for redressable economic injury.[2] Defendants blur the line between

[2] Whatever Justice Story's reservations, the Supreme Court long ago recognized state judicial decisions as "law" that supply the relevant rule of decision in diversity

jurisdiction and the merits in hopes of obtaining the best of both worlds: dismissal with prejudice (to prevent refiling in state court), but under federal law at one stroke (to avoid the hard work of actually explaining varied state law).

This Court should not allow that legerdemain. The ruse depends on treating the separate legal definitions of the word "injury" as interchangeable. For constitutional purposes, injury *in fact* refers to a wide category of harms that can form the basis of an Article III "case" or "controversy." By contrast, injury *at law* turns on whether state statutory or common law authorizes a recovery. Injury in fact concerns jurisdiction, which must be transsubstantive and focused on the nature of judicial power to resolve disputes. Injury at law turns on the merits, which can be either quite general (anyone aggrieved has a claim) or can require as an element very particular kinds of injury (invasion of privacy; injury to competition; physical injury; reputational injury; out-of-pocket losses, and so on).

If, as Defendants intimate, the laws of some states do not allow claims based on the sorts of injuries Plaintiffs allege, Defendants should have stated clearly which state laws are at issue and provided citations and legal argument. Plaintiffs are confident the Complaints plausibly alleged injury at law, but cannot be expected to

---

cases. *Cf. Erie,* 304 U.S. 64, *overruling Swift v. Tyson*, 41 U.S. 1 (1842) (Story, J.). By definition, federal constitutional law articulating the limits of Article III's case or controversy requirement is *not* state substantive law on the sorts of injuries that support claims or remedies.

canvas all relevant states to shadowbox a camouflagued 12(b)(6) Motion. In the absence of any particular 12(b)(6) argument to refute, Plaintiffs will focus on standing.

Defendants do not appear to challenge the traceability or redressability elements of standing. Instead, Defendants argue that both Class Complaints "*Must Be Dismissed Entirely*" because they allege no injury in fact. Injury Mot. at 4. This is a startling contention. It amounts to saying that even though TPPs and consumers paid for ranitidine that was "adulterated, misbranded, and therefore illegal to sell and economically worthless," TPPCAC ¶ 9, and even though consumers "face an increased risk of developing cancer and will be forced to pay for and endure lifelong medical monitoring, treatments, and/or medications, and to live with the fear and risk of developing additional health consequences," CCAC ¶ 13, nevertheless, they are *constitutionally forbidden* from even having a federal court adjudicate whether state law permits a recovery. That is not so.

Plaintiffs' allegations demonstrate standing in at least two ways. Both the Consumer and TPP Class Complaints allege "a type of economic injury, which is the epitome of 'concrete'" injury in fact under Article III. *MSPA Claims 1, LLC v. Tenet Fla., Inc.*, 918 F.3d 1312, 1318 (11th Cir. 2019). The CCAC also alleges physical injury, since it pleads that consumers ingested a carcinogen that presents a substantial risk of future health consequences.

A. TPP and Consumer Plaintiffs Have Alleged a Pocketbook Injury

1. Eleventh Circuit case law supports standing

In *DeBernardis v. IQ Formulations, LLC*, plaintiffs alleged that a dietary supplement was adulterated and misbranded under the Food, Drug, and Cosmetic Act (FDCA), and demanded damages under state law. No. 17-CV-21562, 2018 WL 1536608, at *2 (S.D. Fla. Mar. 29, 2018). Relying on the same authorities Defendants cite here, the district court dismissed the case on standing grounds, because "plaintiffs alleged neither adverse health consequences nor that the supplements failed to perform as advertised." *Id.* The Eleventh Circuit vacated and remanded on appeal. *See Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1080 (11th Cir. 2019).

The Eleventh Circuit started with first principles: "Certainly, an economic injury qualifies as a concrete injury." *Id.* at 1084. Though "[o]rdinarily, when a plaintiff purchases a product with a defect, the product retains some value," there is a "notable exception" when a "product is rendered valueless as a result of a defect." *Id.* In that case, "damages will be equal to the entire purchase price of the product." *Id.* The Court narrowed its inquiry to "two questions: (1) does a purchaser acquire a worthless product when he purchases an adulterated supplement? And, if so, (2) did the plaintiffs adequately allege that the supplements they purchased were adulterated?" *Id.* at 1085. As to the first question, the court "accept[ed], at least at

the motion to dismiss stage" that one "who purchased an adulterated dietary supplement . . . received a product that Congress judged insufficiently safe for human ingestion," and consequently of "no value." *Id.* The court further accepted the plaintiffs' allegations that the supplement was adulterated. *Id.* The same reasoning applies here.

First, if an adulterated *supplement* is worthless, surely an adulterated or misbranded *drug* is too. That is sufficient here, since ranitidine is governed by the FDCA, the very same statute at issue in *Debernardis*. Still, it bears mention that the logic of the Eleventh Circuit opinion is not limited to a product deemed unsafe under federal law. The case itself starts from the premise that some serious defects render a product valueless, then concludes that an adulterated supplement fits within that category. Any sufficiently serious defect—including that a product is valueless by operation of *state* law—could produce the same result.[3] The TPPs allege that their

[3] In the criminal law context, courts consistently find that consumers suffer a loss when they purchase a drug of unknown safety or efficacy. *See United States v. Bhutani*, 266 F.3d 661, 670 (7th Cir. 2001) ("[M]edical effectiveness of the drug or its dangerousness after adulteration ought not be the core of the inquiry; . . . there was indeed loss to consumers because consumers bought drugs under the false belief that they were in full compliance with the law."); *United States v. Marcus*, 82 F.3d 606, 610 & n.3 (4th Cir. 1996) (because "consumers would not purchase a drug of unknown safety and efficacy at any price," a drug company's gross sales "were the appropriate measure of the actual loss suffered by consumers"; irrespective of whether the drug "was actually safe and effective, customers suffered a loss by not receiving a drug of known safety and efficacy"); *United States v. Milstein*, 401 F.3d 53, 74 (2d Cir. 2005) ("contaminated medicine" may be found to be "worthless to the consumer").

economic losses stem "from making payments or reimbursements for purchases of a product that should not have been available for sale in the U.S., for which they would not have made payments or reimbursements, but for Defendants' unlawful conduct." TPPCAC ¶ 12; *see also id.* ¶¶ 493, 495 522, 559, 615, 638–40, 643–44, 649, 651, 659, 675. The Consumer Plaintiffs similarly allege that Defendants engaged in acts "with the common purpose of obtaining significant monies and revenues from Plaintiffs and Class members based on the concealment of the truth, while providing Zantac drugs that were worth significantly less than the purchase price paid." CCAC ¶ 789.

Second, both the TPP Complaint and the Consumer Complaint allege that ranitidine is, and has long been, misbranded and adulterated. *E.g.*, TPPCAC ¶¶ 335–41 (Section IX entitled, "Defendants' Ranitidine-Containing Products Are Misbranded and Adulterated Because They Contain Biologically Relevant Levels of NDMA"); CCAC ¶¶ 595–604 (detailing Section III D, same). These allegations are detailed and plausible. It is telling that although the Class Complaints use the terms "adulterate" or "misbrand" more than one hundred times, no form of those words appear in Defendants' Motion even once.

Even worse for Defendants than *Debernardis*'s holding is the theory it expressly rejected: theirs. Defendants' legal theory is that a class action for "economic loss" is unavailable "when the drug at issue was effective for its approved

indication and benefitted the class members." Injury Mot. at 7. The Eleventh Circuit summarized defendants' argument similarly: they argued no standing existed "because the complaint included no allegation that the supplements *failed to perform as advertised* or were purchased at a premium due to a misrepresentation about the product." 942 F.3d at 1085–86 (emphasis added). While "these allegations [a]re *sufficient* to establish standing," they are not "*necessary* to establish standing." *Id.* at 1086 (emphasis in original).[4] Judge Sutton, concurring, stated the issue even more simply:

> All Debernardis and Damore say is that they would not have bought the supplements had they known that IQ Formulations failed to comply with federal law. Debernardis and Damore nonetheless plausibly allege an injury in fact—that they paid more for IQ Formulations' dietary supplements than they would have paid had they known the company did not follow the law. This

[4] *See also* 942 F.3d at 1087 ("[A]t least one other circuit has recognized that . . . an economic injury occurs when the purchaser acquires a worthless product, even if there is no indication that she was physically harmed by the product, the product failed to work as intended, or she paid a premium for the product.") (citing *In re Aqua Dots Prods. Liab. Litig.*, 654 F.3d 748, 751 (7th Cir. 2011) ("none of the plaintiffs (or their children) was injured by swallowing the [toxic] beads. This means that members of the class did not suffer physical injury, but it does not mean that they were uninjured. The plaintiffs' loss is financial: they paid more for the toys than they would have, had they known of the risks the beads posed to children. A financial injury creates standing.")); *Franz v. Beiersforf, Inc.*, 745 F. App'x 47, 49 (9th Cir. 2018) (plaintiff had standing where she claimed injury from purchasing a skin lotion that qualified as a "drug" under the Food Drug and Cosmetic Act, but had not been approved by the FDA); *Blue Cross Blue Shield Ass'n v. Glaxosmithkline LLC*, 417 F. Supp. 3d 531 (E.D. Pa. 2019) (denying summary judgment and finding that the TPP plaintiffs had alleged injury in fact to support standing where they paid for drugs non-compliant with CGMPs).

> difference in price states a concrete economic harm that satisfies Article III standing's injury in fact element, no matter the label we give it.

Id. at 1090 (Sutton, J., concurring). The en banc Eleventh Circuit recently reaffirmed *Debernardis*: "Although the plaintiffs suffered no physical harm from the supplement, we concluded that they were sold a worthless product 'that Congress judged insufficiently safe for human ingestion.' *Id.* at 1085. That deprived the plaintiffs of the benefit of their bargain and amounted to a direct economic loss that supported standing." *Muransky v. Godiva Chocolatier, Inc.*, No. 16-16486, 2020 WL 6305084, at *6 (11th Cir. Oct. 28, 2020).

Defendants' sole mention of this controlling precedent is buried at the tail end of a half-page-long string cite contained in a single-spaced footnote. Injury Mot. at 5, n.3; *but see Mazzeo v. Nature's Bounty, Inc.*, No. 14-60580, 2014 WL 5846735, n.1 (S.D. Fla. Nov. 12, 2014) ("Defendant also raises a standing argument in a footnote, 'which [is] the wrong place for substantive arguments on the merits of a motion.' The Court accordingly will not consider this argument." (citations omitted)). In two dismissive sentences, Defendants claim *Debernardis* is "distinguishable" because ranitidine was "lawfully sold at the time of purchase" and also "involved a different regulatory framework." Injury Mot. at 5, n.3 (internal quotations and citations omitted). Defendants' conclusory distinctions do not withstand scrutiny. By repeatedly alleging that ranitidine was misbranded and

adulterated, the Class Complaints pleaded that the drug was *not* "lawfully sold at the time of purchase." Defendants imply that some proceeding declared the supplement at issue in *Debernardis* adulterated, but that is not true. The defendants in *Debernardis*—like Defendants here—vigoriously disputed that their product was adulterated, but the court adhered to the allegations in the complaint. 942 F.3d at 1085, n.5.

Though *Debernardis* left open the situation of "a product that was lawfully sold at the time of purchase but whose sale later was prohibited," *id.* at 1088, n.8 (citing *O'Neil v. Simplicity, Inc.*, 574 F.3d 501, 504 (8th Cir. 2009)), that is no help to Defendants. Ranitidine was not lawfully sold, at least as soon as Defendants knew or should have known that the molecule breaks down into NDMA. 21 U.S.C. §§ 351–52. That the FDA recognized this at a point in time (and requested a recall), does not mean that the FDCA's provisions did not apply before that. To put the same point a different way, if the FDA had—after the relevant sales—ordered the defendant in *Debernardis* to recall its product, that would not have cast standing into doubt for sales that occurred before the recall.

2. Defendants' other arguments are unavailing because each plaintiff purchased a defective product

Defendants' primary argument boils down to the idea that a plaintiff cannot sue merely because a product bought by someone else was defective. That principle

is incorrect, since defects can affect the value of the product.[5] Even if it were correct, that principle has no application here, because Plaintiffs allege that all ranitidine breaks down into NDMA and can cause cancer. To illustrate this, consider that the ranitidine plaintiffs who now have cancer took was no different—as far as the pleaded allegations go—from the ranitidine that others ingested. That only some plaintiffs have developed cancer by now does not prove the ranitidine others took was any different, or less defective. Purchasing a defective drug is an injury.

Similar principles distinguish Defendants' primary, out-of-circuit case, *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315 (5th Cir. 2002). There, Wyeth sold Duract with a warning that it could cause liver failure, and so should be used "only for the short term (10 days)." *Id.* at 317. Many patients used it longer anyway, and some of them were injured, leading Wyeth to recall the drug. Plaintiffs brought a

[5] *See, e.g.*, *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig.*, 754 F. Supp. 2d 1145, 1162 (C.D. Cal. 2010) ("According to Plaintiffs' allegations, Toyota vehicles with [electronic throttle control systems] dropped in value owing to the alleged SUA [sudden unintended acceleration] defect. If a defect causes SUA to manifest itself in a small percentage of Toyota vehicles, it makes sense that people would be less willing to buy or use those vehicles on the off-chance that they might experience the SUA defect. . . . Hence, the alleged economic loss."); *Cole v. Gen. Motors Corp.*, 484 F.3d 717, 722–23 (5th Cir. 2007) (rejecting defendants' argument that plaintiffs lacked standing "[b]ecause plaintiffs' air bags never deployed inadvertently" on the reasoning that "each plaintiff suffered economic injury at the moment she purchased a DeVille because each DeVille was defective. . . . Whether recovery for such a claim is permitted under governing law is a separate question; it is sufficient for standing purposes that the plaintiffs seek recovery for an economic harm that they allege they have suffered.").

class-action suit, but the Fifth Circuit dismissed the suit on standing grounds. The problem was that "[t]he plaintiffs do not claim Duract caused them physical or emotional injury . . . or has any future health consequences to users . . . . The plaintiffs claim that Wyeth . . . [sold] a defective drug, but then aver that *the drug was not defective as to them*," and plaintiffs "concede[d] they were not among the injured." *Id.* at 319–20 (emphasis added). In other words, unlike in this case, plaintiffs pleaded themselves out of court, as the class was full of people who used Duract as intended—for short periods—and alleged neither any ill effects nor any risk of latent injuries. Ranitidine is nothing like this, since Consumer Plaintiffs alleged that they "face an increased risk of developing cancer and will be forced to pay for and endure lifelong medical monitoring, treatments, and/or medications, and to live with the fear and risk of developing additional health consequences." CCAC ¶ 13.[6]

[6] Contrary to Defendants' suggestion, the Middle District of Florida did not even cite *Rivera* in *Ironworkers Local Union No. 68 v. AstraZeneca Pharmaceuticals LP*, 585 F. Supp. 2d 1339 (M.D. Fla. 2008). *Compare* Injury Mot. at 10 (suggesting *Ironworkers* as an "example" of courts that "applied the reasoning in *Rivera*). Perhaps Defendants meant the Eleventh Circuit case, which cited *Rivera* for the unrelated proposition that the plaintiff needed to allege that a prescription was one "the physician should not have prescribed because the drug was unsafe or ineffective for its prescribed use." *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1363 (11th Cir. 2011). If Defendants meant to imply that *Rivera* has been accepted in this Circuit, that is dubious. The only other case to cite it distinguishes it tersely as arising under different state law. *See London v. Wal-Mart Stores, Inc.*, 340 F.3d 1246, 1252 (11th Cir. 2003).

B. Consumer Plaintiffs Have Alleged Other Forms of Economic Injury and Physical Injuries

Beyond the economic harms noted above, which themselves establish standing, the consumer class plaintiffs allege that they "have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring." CCAC ¶ 1602. Defendants do not engage with this injury. They do not explain if a particular feature of Plaintiffs' medical monitoring allegations are supposedly insufficient or if their argument is simply that medical monitoring classes *never* have standing. The leading case in this District on this question comes from Judge Rosenbaum, who carefully examined nationwide precedent and concluded that "courts that have considered the issue specifically in the context of medical monitoring have held that an alleged increased risk of future harm satisfies Article III's injury-in-fact requirement." *Bouldry v. C.R. Bard, Inc.*, 909 F. Supp. 2d 1371, 1375 (S.D. Fla. 2012) (collecting cases).[7] Defendants make no attempt to explain why *Bouldry* and other cases are not persuasive here.

[7] *See also Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568 (6th Cir. 2005); *In re Agent Orange Product Liab. Litig.*, 996 F.2d 1425, 1434 (2d Cir. 1993) (rejecting argument that injury in fact means injury that is manifest, diagnosable or compensable; "some types of injury to the body occur prior to the appearance of any symptoms; thus, the manifestation of the injury may well occur after the injury itself"), *overruled on other grounds by Syngenta Crop Prot., Inc. v. Henson*, 537 U.S. 28 (2002); *Brown v. C.R. Bard, Inc.*, 942 F. Supp. 2d 549 (E.D. Pa. 2013) (plaintiffs who had defective medical devices implanted have alleged an injury in fact); *In re Welding Fume Prods. Liab. Litig.*, 245 F.R.D. 279, 287 n.37 (N.D. Ohio 2007) ("plaintiffs clearly

The consumer plaintiffs also allege they have "been subjected to the accumulation of NDMA in their bodies, including the resulting cellular damage, subcellular damage, and related symptoms; and . . . sustained a significantly increased risk of developing various types of serious and potentially deadly cancers." CCAC ¶ 1601. Defendants baldly deny that such changes count as physical or personal injury, but rely entirely upon cases that, amazingly, address *neither* standing *nor* state law on medical monitoring. *See* Injury Mot. at 11–12 (*first citing Caputo v. Bos. Edison Co.*, No. CIV. A. 88-2126-Z, 1990 WL 98694, at *4 (D. Mass. July 9, 1990) (rejecting "cellular damage" on the merits applying Massachusetts law not involving medical monitoring),[8] *then citing Ranier v. Union Carbide Corp.*, 402 F.3d 608, 621–22 (6th Cir. 2005) (construing the federal Price Anderson Act, finding no "bodily injury" for a damages claim under Kentucky law, in part due to difficulty

have standing under Article III to assert their claims for medical monitoring"); *Carlough v. Amchem Prods., Inc.*, 834 F. Supp. 1437, 1454 (E.D. Pa. 1993) ("exposure to a toxic substance constitutes sufficient injury in fact to give a plaintiff standing to sue in federal court"); *cf. Petito v. A.H. Robins Co., Inc.*, 750 So. 2d 103, 106–07 (Fla. Ct. App. 1999) (recognizing a cause of action for medical monitoring under Florida law when a consumer has yet to develop any identifiable physical injuries or symptoms).

[8] *But see Donovan v. Philip Morris USA, Inc.*, 914 N.E.2d 891, 902 (Mass. 2009) (requiring plaintiffs to show "at least, **subcellular changes** that substantially increase[] the risk of serious disease" for a medical monitoring claim) (emphasis added).

determining "how damages could presently be calculated"),[9] *then citing In re Berg Litig.*, 293 F.3d 1127, 1133 (9th Cir. 2002) (in light of the "purposes behind the [federal] enactment of the Price Anderson Act," the statutory term "bodily injury" did not include "a future risk of disease")).

C. The PTO Does Not Require Class Allegations to Be Repleaded in the MPIC

Defendants urge that the "Orders of this Court" require that the putative Class Representative Plaintiffs replead the Class Complaints to include them within the MPIC. Injury Mot. at 13. To the extent this is merely a housekeeping request, Plaintiffs respectfully disagree with Defendants' interpretation of this Court's orders. The MPIC is not a class complaint, and adding these claims there would not streamline this MDL. To the extent Defendants hope to whittle down Plaintiffs' claims substantively, Plaintiffs would simply point out that this Court's Orders were never meant to exclude any type of claim, but to coordinate them. The three master complaints do this job serviceably.

[9] The distinction between medical monitoring and other claims is crucial. *See In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 861 (3d Cir. 1990) ("Because the district court appears to have applied the standards for enhanced risk claims in an action for medical monitoring, we find error, and we will therefore reverse the grant of summary judgment on this point.").

III. Defendants Cannot Urge Dismissal on "Economic-Loss Rule" Grounds Without Identifying a Positive Source of Law

Defendants argue "only one version of the [economic-loss] rule," namely, that "between commercial parties, claims for injury to the product itself without personal injury or other-property damage are contractual and not tort claims." Injury Mot. at 15, n.9. Defendants cite a sum total of two authorities: an A.L.R. article from 1989, and *East River Steamship Corp. v. Transamerica Delaval*, 476 U.S. 858 (1986). *See* Injury Mot. at 13–15. As Defendants themselves recognize, *East River* was "[a]pplying admiralty law." Injury Mot. at 14. None of the TPP claims accuse Defendants of misconduct on the high seas.

At minimum, to warrant dismissing any claims Defendants would need to identify law incorporating their proposed rule that *applies in this case*. Defendants do not even attempt to meet this standard. At most, Defendants' argument is that dicta from a 1980s admiralty case recognized a "majority approach" that they claim helps them. Even if true, that does not provide this Court grounds to dismiss any claims, since Defendants do not even identify which jurisdictions apply this purported "majority" rule. General averments that "'nearly all' of plaintiffs' state-law claims" fail cannot suffice, since such generalities provide no "helpful or specific analysis to assist [a court] in drawing those lines." *In Re: Juul Labs, Inc., Mktg., Sales Practices, & Prods. Liab. Litig.*, No. 19-MD-02913-WHO, 2020 WL 6271173, at *12 (N.D. Cal. Oct. 23, 2020) (deferring resolution to "the bellwether

stage or a different, later date."). Plaintiffs should not be required to repulse a phantom.[10]

Defendants' argument is forfeited and erroneous. It should be rejected.

IV. Plaintiffs Properly Pleaded Available Remedies

A. Plaintiffs' Medical Monitoring Request Should not Be Dismissed

Defendants' arguments are, yet again, procedurally improper. For almost 100 years, the Federal Rules have applied to both actions at law and cases in equity—regardless of the label affixed to the remedy, plaintiffs bring one form of "civil action." *See* Fed. R. Civ. P. 1, Advisory Note 3. Rule 12 instructs that a defendant may assert by motion a "defense to a *claim*." Fed. R. Civ. P. 12(b) (emphasis added). Defendants do not present a "defense to a claim," and one can be perfectly sure of that because they say it expressly: "Defendants are moving as to the request for an injunction and *reserve the arguments* that the Consumer Plaintiffs *failed to state claims* for medical monitoring under applicable states' laws." Injury Mot. at 16 n.10 (emphasis added). Defendants are not claiming that the pleaded independent cause of action or relief for a recognized tort claim is unavailable—only that, whether

[10] Plaintiffs have responses on the merits and stand ready to brief the issue at a later stage. Other MDL courts have rejected similar arguments after careful briefing. *See, e.g.*, *In re Nat'l Prescription Opiate Litig.*, 440 F. Supp. 3d 773, 814 (N.D. Ohio 2020) (upholding third-party-payor negligence claims, and citing cases); *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, 336 F. Supp. 3d 1256, 1326, (2018) (rejecting economic loss argument).

available or not, this Court should label it as "*not* injunctive relief." Injury Mot. at 17. In the 19th Century, Defendants may have had a point: whether a chancellor or a law judge should adjudicate a dispute was jurisdictionally relevant. Today, Defendants' desire to recategorize the form of relief is both irrelevant and improper at this procedural posture—Defendants' sole reason for raising it is to preview their class certification argument. As Professor Rubenstein has noted,

> Medical monitoring has proved confusing to the courts . . . [including] whether it represents injunctive . . . or monetary relief . . . . [That] question is obviously key for class certification purposes—if medical monitoring represents only injunctive relief ordering a defendant to provide a service, medical monitoring classes may be maintainable under Rule 23(b)(2); however, if medical monitoring is monetary relief, (b)(2) certification will likely be unavailable [requiring certification through (b)(3)].

2 *Newberg on Class Actions* § 4:45 (5th ed.).

The distinction between dismissing a claim under Rule 12 and deciding class certification under Rule 23 matters. None of the cases Defendants cite involved a Rule 12 motion—all involved a motion for class certification. *See* Injury Mot. at 15–18 (citing cases). That is no doubt because Rule 12 does not allow Defendants to recharacterize the remedies Plaintiffs seek. Rule 8's pleading standard requires only that a plaintiff plead "a demand for the relief sought, which may include relief in the alternative or different types of relief." Fed. R. Civ. P. 8(a)(3). There is no question that the CCAC satisfies this standard. Plaintiffs are still engaged in

discovery, have not yet moved for class certification, and have not yet detailed the contours of the medical monitoring relief they will seek. No rule requires Plaintiffs to do so, and PTO 30 does not contemplate class certification motion practice until December 20, 2021. *See* D.E. 875. Defendants' Rule 12 motion should be denied.[11]

B. Because Defendants May Seek to Market Ranitidine in the Future, Plaintiffs' Request for Injunctive Relief Is not Moot

The Supreme Court's test "for determining whether a case has been mooted by the defendant's voluntary conduct is stringent: . . . if subsequent events ma[k]e it absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000) (internal quotation marks omitted). Defendants argue that "This Court cannot enjoin something that is not happening," but this is not the standard for mootness. Injury Mot. at 18. The FDA sought voluntary consent for a recall "to protect the public health from products that present a risk of injury." D.E. 889 ¶ 711. The FDA's order is not a permanent order, and it is not "absolutely clear" that Defendants will never again sell ranitidine.

[11] Plaintiffs used the shorthand of "create a fund to pay for medical monitoring" as part of a redressability argument, but that does not limit the relief Plaintiffs can seek or that the Court can award. *See* Fed. R. Civ. P. 54(c) (the Court may grant any relief to which a prevailing party is entitled, "even if the party has not demanded that relief in its pleadings."); *see also* TPPCAC, Prayer for Relief ("Award such further and additional relief as is necessary to redress the harm caused by Defendants' unlawful conduct and as the Court may deem just and proper under the circumstances"); CCAC, Prayer for Relief (same).

The Eleventh Circuit has elaborated three factors for mootness in this context:

> (1) whether the challenged conduct was isolated or unintentional, as opposed to a continuing and deliberate practice; (2) whether the defendant's cessation of the offending conduct was motivated by a genuine change of heart or timed to anticipate suit; and (3) whether, in ceasing the conduct, the defendant has acknowledged liability.

Sheely v. MRI Radiology Network, P.A., 505 F.3d 1173, 1184 (11th Cir. 2007). All three factors favor Plaintiffs here.

First, Defendants sold ranitidine for decades and made billions of dollars by deceiving millions of consumers into purchasing and ingesting a defective, misbranded, adulterated, and harmful drug. CCAC ¶¶ 1–2. Plaintiffs allege Defendants engaged in a conspiracy, making their conduct even more deliberate. *See, e.g.*, *id.* ¶¶ 754–70; *see also United States v. W.T. Grant Co.*, 345 U.S. 629, 632 n.5 (1953) ("When defendants are shown to have settled into a continuing practice or entered into a conspiracy . . . courts will not assume that it has been abandoned without clear proof.") (citation omitted).

Second, given the timing of the voluntary withdrawal, the only reasonable inference—and certainly a plausible one when construed in Plaintiffs' favor—is that Defendants were motivated by anticipated litigation, not a change of heart. Indeed, the Brand-Name Manufacturer Defendants have asserted to this Court that there is no "real-world evidence that Zantac use increases the risk of cancer." D.E. 1580 at

1; *see also* D.E. 1582 at 31 (Generic and Repackager Defendants' Motion, adopting some "arguments [in D.E. 1582 that] apply equally to" them).

Third, and most obviously, no Defendant has acknowledged liability. *See United States v. Endotec, Inc.*, No. 606-cv-1281, 2009 WL 3111815, at *3 (M.D. Fla. Sept. 28, 2009) (no mootness where defendants "have continually failed to concede any wrongdoing and are still urging the validity of their actions"). Accordingly, Plaintiffs' request for injunctive relief is not moot.

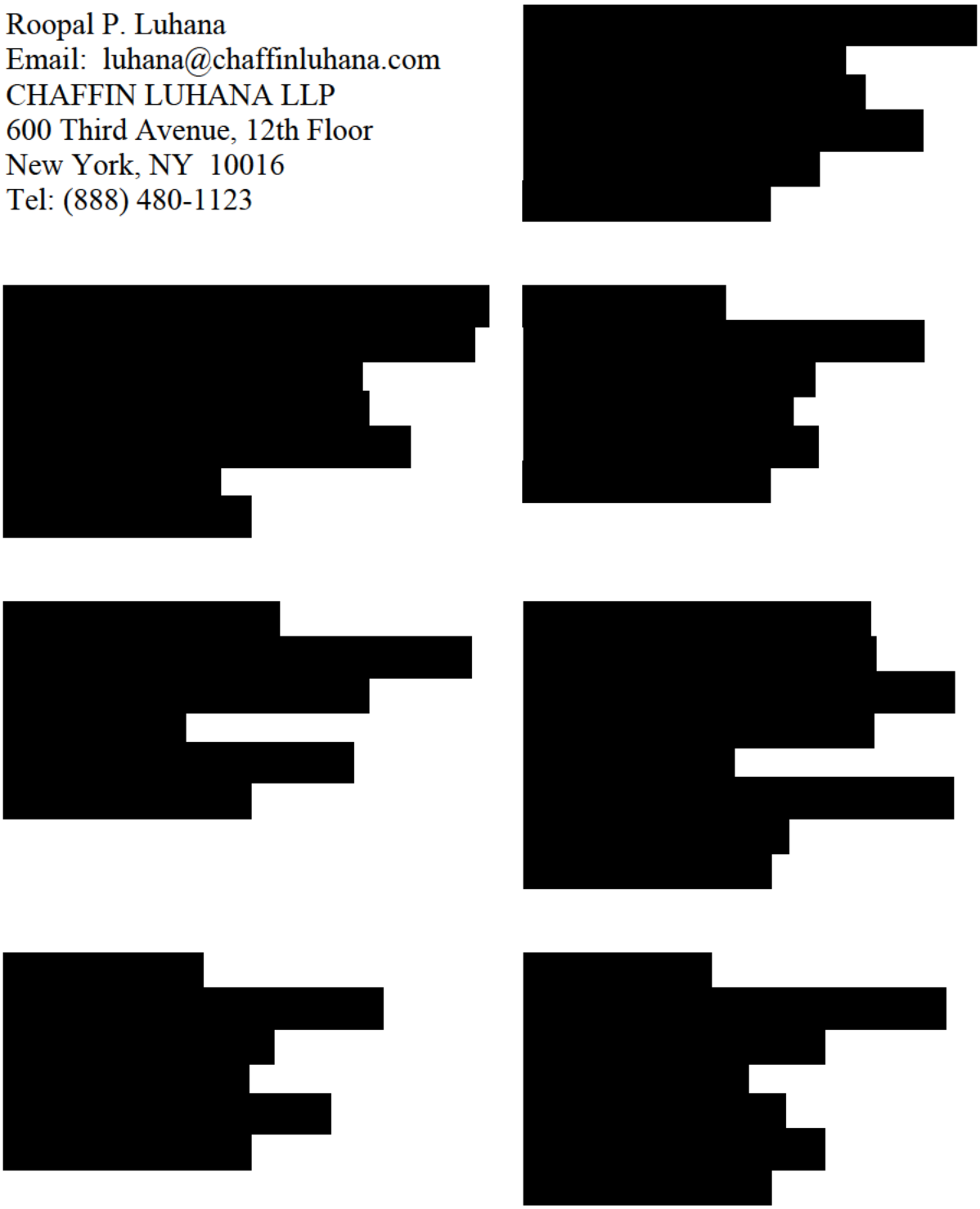
CONCLUSION

For the foregoing reasons, Generic Manufacturer and Repackager Defendants' Motion to Dismiss on the Ground of Failure to Allege an Injury should be denied.

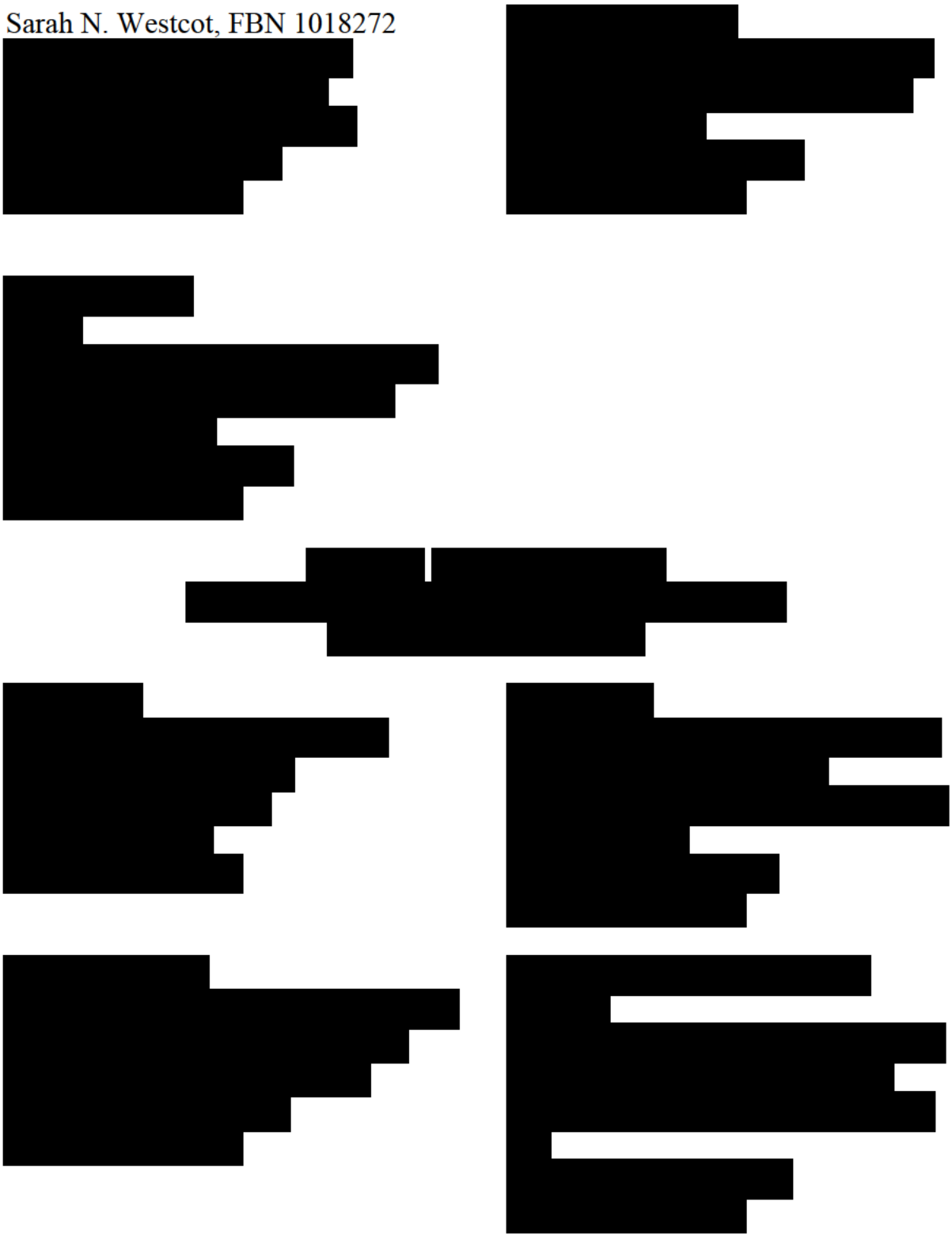
/s/ Michael L. McGlamry

Plaintiffs' Co-Lead Counsel

Roopal P. Luhana
Email: luhana@chaffinluhana.com
CHAFFIN LUHANA LLP
600 Third Avenue, 12th Floor
New York, NY 10016
Tel: (888) 480-1123



Sarah N. Westcot, FBN 1018272



Plaintiffs' Leadership Development Committee

CERTIFICATE OF SERVICE

I hereby certify that on November 9, 2020, 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.

[redacted]