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

THE GENERIC MANUFACTURERS' AND REPACKAGERS' RULE 12 MOTION TO DISMISS CONSOLIDATED CONSUMER AND THIRD-PARTY PAYOR CLASS ACTION COMPLAINTS ON THE GROUND OF FAILURE TO ALLEGE AN INJURY AND INCORPORATED MEMORANDUM OF LAW

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Pursuant to this Court's Pretrial Orders #30, 31, and 36, the Generic Manufacturer Defendants ("Generic Manufacturers") and the Repackager Defendants ("Repackagers") (as named in the Complaints), submit this Rule 12 motion to dismiss the Consolidated Consumer and Third-Party Payor Class Action Complaints for failure to allege a cognizable injury and memorandum of law in support.

I. INTRODUCTION

The "Consolidated Consumer Class Action Complaint" (Dkt. No. 889, the "Consumer Complaint") and the "Consolidated Third Party Payor Class Complaint" (Dkt. No. 888, the "TPP Complaint") (together, "Class Action Complaints") fail to allege a true injury-in-fact. To have a viable claim, a plaintiff must allege an injury that is distinct and palpable, as opposed to merely abstract, and the alleged harm must be actual or imminent, not conjectural or hypothetical. Yet, in both Class Complaints, Plaintiffs neither allege actual physical injury nor claim that the ranitidine-containing medications they allegedly purchased were ineffective. Indeed, the Class Complaints *affirm* the medication's efficacy. Because the ranitidine purchased or used by the Class Plaintiffs did exactly what it was supposed to do without physically injuring any Class Plaintiffs, Plaintiffs received the benefit of their bargain. They have alleged no injury-in-fact that meets the threshold for Article III standing, and their claims should be dismissed.

Plaintiffs try to slip this rule by asserting, without basis, that the medications were "worthless" due to the alleged presence of an impurity. The law does not support this expansive theory of liability. Federal appellate courts have repeatedly recognized that, absent any allegation of physical injury or inefficacy, Plaintiffs cannot assert that a lawfully purchased product was "worthless" due to the alleged presence of an impurity.

Beyond failing to allege a cognizable injury capable of satisfying Article III standing, the tort-based claims in the TPP Complaint must also be dismissed pursuant to the economic loss

doctrine. The TPP Plaintiffs seek to recover under negligence theories for purely economic loss relating to the product itself without alleging any personal injury or damage to "other property." The economic loss doctrine forecloses these claims.

Finally, the Court should dismiss the Consumer Class claims for injunctive relief because the medical monitoring requested here is not an injunctive remedy. Plaintiffs simply ask the Court to create "a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs as frequently and appropriately as necessary." Plaintiffs simply want the Court to create a fund to pay for any and all medical appointments loosely related to this litigation, a request that is simply monetary and lacks any principles of equity that a judicial injunction would rest upon. Courts repeatedly refuse to cast such monetary requests as "injunctive" relief.

Because Class Plaintiffs assert no bodily harm and do not claim that the ranitidine that they purchased was ineffective, they have alleged no injury at all. Moreover, because the TPP Plaintiffs are seeking purely economic losses, their tort-based claims must be dismissed under the economic loss doctrine. Finally, the Consumer Plaintiffs' injunctive claims for medical monitoring, which also seek only monetary damages, similarly fail. In short, Plaintiffs fail to assert any cognizable claim in the Class Complaints, and they must be dismissed.

II. FACTS ALLEGED IN THE COMPLAINTS

In this MDL, the Plaintiffs utilized consolidated and master pleadings as procedural devices to coordinate, categorize, and evaluate claims. The pleadings identified three categories of plaintiffs, each with claims that would be best addressed through separate pleadings: (1) individuals who allegedly suffered personal injury in the form of cancer from exposure to N-Nitrosodimethylamine ("NDMA"); (2) consumers who paid for a product that was "worthless"

because of the alleged presence of NDMA, and (3) third-party payors who reimbursed for the "worthless" product.[1]

Plaintiffs assert economic loss in the Consumer Complaint, brought on behalf of the individuals who used prescription or OTC ranitidine without incident, and the TPP Complaint, brought on behalf of the TPP Plaintiffs who reimbursed their individual members for ranitidine prescriptions. In the Master Personal Injury Complaint (Dkt. 887, the "PI Complaint"), Plaintiffs seek damages for personal injury. *See, e.g.*, PTO #36.

The Consumer and TPP Plaintiffs assert no viable injury. Instead of personal injury or product efficacy claims, they attempt to assert mere "economic losses" as their injury. The Class Action Complaints allege that Defendants' actions and omissions made Plaintiffs overpay for a "worthless" product. *See, e.g.,* Consumer Compl. ¶¶ 722, 743, 789, 1705(e); TPP Compl. ¶¶ 495, 617. They further allege that they never would have purchased or reimbursed for any ranitidine product if they had been aware of the potential presence of NDMA and the alleged risk associated with the use of ranitidine-containing products. *See, e.g.,* Consumer Compl. ¶¶ 13, 721, 1711; TPP Compl. ¶¶ 603, 617, 630.

The Consumer and TPP Plaintiffs seek to hold Defendants liable for failing to fix or disclose an alleged design defect and its attendant health risks, but the Plaintiffs in the Class Action Complaints do *not* allege any cognizable physical injury or bodily harm. Despite characterizing Defendants' ranitidine-containing products as worthless, Plaintiffs do not allege that the medication was ineffective—*i.e.*, that it failed to relieve their heartburn, duodenal or gastric ulcer, GERD, erosive esophagitis, or pathological hypersecretory condition.

[1] *See, e.g.*, PTO #31.

III. ARGUMENT

A. BECAUSE THE CLASS ACTION COMPLAINTS FAIL TO ALLEGE ANY COGNIZABLE INJURY, THEY MUST BE DISMISSED ENTIRELY.

Plaintiffs, in the two Class Action Complaints, attempt to establish an improper "no-injury" product liability class action against Defendants. "The striking feature of a typical no-injury class is that the plaintiffs have either not yet experienced a malfunction because of the alleged defect or have experienced a malfunction but not been harmed by it." *Coghlan v. Wellcraft Marine Corp.*, 240 F.3d 449, 455 n.4 (5th Cir. 2001). Such plaintiffs "have not suffered any physical harm or out-of-pocket economic loss." *Id.* But an injury is a necessary element of every cause of action, and courts generally forbid recovery without harm. *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990) (the "alleged harm must be actual or imminent, not conjectural or hypothetical.") Unsurprisingly, then, courts routinely dismiss these types of no-injury cases based either on a failure to state a claim under Rule 12(b)(6)[2] or a lack of Article III standing and under Rule

[2] *See, e.g., In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1017 (7th Cir. 2002) (holding that a party alleging a product defect claim cannot avoid the requirement of actual injury by "seek[ing] to move the suit out of the tort domain and into that of contract . . . and consumer fraud"); *Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 366 (D.N.J. 2004) (dismissing an action for "economic damages" purportedly caused by the inadequate warning on defendants' drugs for failure to state a claim because "the plaintiffs suffered no injury, [and] there is no theory under which they are entitled to recover"); *In re Air Bag Prod. Liab. Litig.*, 7 F. Supp. 2d 792, 803-04 (E.D. La. 1998) (dismissing no-injury tort and warranty claims where the plaintiffs alleged merely that the air bags in their vehicles might fail in the future); *Walus v. Pfizer, Inc.*, 812 F. Supp. 41, 44 (D.N.J. 1993) (dismissing a no-injury lawsuit after finding that the plaintiff could not assert a "cause of action based on a claim that a normally functioning [implanted heart valve] might fail at some unknown time"); *Porter v. Merck & Co.*, No. 04-CV-586, 2005 WL 3719630, at *3 (Kan. Dist. Ct. Aug. 19, 2005) (dismissing the plaintiff's claim under a consumer protection statute, seeking a refund for the pain medication Vioxx, because the plaintiff "suffered no physical injury and received a drug that provided relief for her pain[,] [and] [t]hus, she has no loss"); *see also Colville v. Pharmacia & Upjohn Co. LLC*, 565 F. Supp. 2d 1314, 1323 (N.D. Fla. 2008) (dismissing product liability claims because osteopenia was not an "injury," but rather was a "slow process in the bone that could lead to an injury"); *Eagle-Picher Indus., Inc. v. Cox*, 481 So. 2d 517, 521, 526 (Fla. 3d DCA 1985) (holding that "damages are not recoverable for the future risk of cancer" because

12(b)(1).[3] Accordingly, in this MDL, the Class Action Complaints must be dismissed because Plaintiffs cannot allege a personal injury and failed to allege an otherwise legally cognizable injury.

"sanctioning a damage award in the single action for the *risk* of cancer encourages the use of speculative testimony and leads, necessarily, to inequitable results" (emphasis in original)).

[3] The Third and Fifth Circuits, for example, consistently hold that a plaintiff who uses a product fully, safely, and effectively, and thus receives "the benefit of her bargain," lacks Article III standing to sue for a full refund based on nondisclosure of a defect that affected only others. *Rivera v. Wyeth-Ayerst Labs*., 283 F.3d 315, 320 (5th Cir. 2002) ("Notably, the wrongs Rivera and the class allege are those suffered by other, non-class member patients."); *see In re Schering Plough*, 678 F3d 235, 248 (3rd Cir. 2012) (holding that "pure conjecture" was required to conclude that the defendants' conduct ultimately caused the plaintiff injury, and therefore no standing existed); *Am. Fed'n of State Cty. & Mun. Employees, Dist. Council 47 Health & Welfare Fund v. Ortho-McNeil-Janssen Pharm., Inc*., 857 F. Supp. 2d 510, 516 (E.D. Pa. 2012) ("Plaintiffs cannot recover if they paid for an effective pain killer, and [their members] received just that—the benefit of [their] bargain.'" (citing *Rivera*, 283 F.3d at 320)); *Medley v. Johnson & Johnson Consumer Cos*., No. 2:10-cv-2291, 2011 WL 159674, at *2 (D.N.J. Jan. 18, 2011) (holding plaintiffs lacked an injury-in-fact from their purchase of baby shampoo containing a toxic ingredient because "the product worked as intended, meaning that the hair of Plaintiff's children was cleansed, and their eyes and skin were not irritated"); *Koronthaly v. L'Oreal USA, Inc.*, 374 F. App'x 257, 259 (3d Cir. 2010)(allegation that product failed to work as intended is necessary). Courts in other jurisdictions apply the same logic to dismiss no-injury actions for lack of standing. *See, e.g., Hughes v. Chattem, Inc.,* 818 F. Supp. 2d 1112, 1119 (S.D. Ind. 2011) (finding Plaintiffs had not established standing for purchase of supplements based on claims "that they may experience future harm from their limited exposure to hexavalent chromium [and] they now wish they had not purchased" the product and also dismissing as a matter of law, apart from standing, claims under Indiana's consumer protection act, and for breach of warranty and unjust enrichment); *In re Actimmune Mktg. Litig.,* No. C 08-02376 MHP, 2010 WL 3463491, at *9 n.2 (N.D. Cal. Sept. 1, 2010), *aff'd*, 464 F. App'x 651 (9th Cir. 2011) ("A consumer protection suit will not lie where a plaintiff actually receives the 'benefit of the bargain.'"). In *Debernardis v. IQ Formulations, LLC*, the Eleventh Circuit held that the plaintiffs had standing because they alleged to have experienced an economic loss when they purchased dietary supplements that the FDCA had already banned from sale because it was presumptively unsafe. 942 F.3d 1076, 1086 (11th Cir. 2019). This case is distinguishable to the case at hand not only because the court expressly refrained from opining on "a product that was lawfully sold at the time of purchase but whose sale later was prohibited" but also because it involved a different regulatory framework.

1. Class Action Plaintiffs allege no legally cognizable injury in the Class Action Complaints because they never allege that ranitidine they purchased or used was ineffective.

The Consumer Plaintiffs do not allege that ranitidine failed to relieve their heartburn, indigestion, duodenal or gastric ulcers, GERD, erosive esophagitis, or other pathological hypersecretory conditions, and the TPP Plaintiffs do not even suggest, let alone allege, that any of their members encountered ineffective Ranitidine-Containing Products. Ranitidine's efficacy is shown by the many named Plaintiffs who used the product for decades to relieve symptoms. *See, e.g.,* Consumer Compl. ¶ 63 ("Plaintiff Kristen Monger . . . used Ranitidine-containing Products . . . from approximately 1997 to 2020 to treat acid reflux . . . ."), *id.* ¶ 73 ("Plaintiff Ricardo Moron . . . used Ranitidine-containing Products . . . from approximately 1995 to 2020 to treat heartburn and acid reflux . . . ."), *id.* ¶ 81 ("Plaintiff Kathy Jeffries . . . used Ranitidine-containing Products . . . from approximately 1998 to 2020 to treat heartburn, stomach acid and esophagus acid . . . ."). Despite having not suffered a personal injury and having failed to allege that the ranitidine that they purchased was ineffective, the Class Action Complaints still attempt to claim damages.

Plaintiffs provide two bases for their claims of economic injury. First, Plaintiffs contend that Defendants' misconduct and omissions rendered the ranitidine they purchased "economically worthless." TPP Compl. ¶ 1 ("As a direct and proximate result of Defendants' unlawful conduct . . . , Plaintiffs and the Class . . . , suffered economic losses for the reimbursement and/or purchase of economically worthless Ranitidine-Containing Products."); *see also* Consumer Compl. ¶ 1705(e) (alleging that Defendants' conduct "resulted in a gross disparity between the true value of the Ranitidine-Containing Products and the price paid" by Plaintiffs). Second, Plaintiffs claim that, "[h]ad Defendants disclosed the true facts regarding the purported safety of Ranitidine-Containing Products, Plaintiffs and the Class members would not have purchased nor ingested Defendants' Ranitidine-Containing Products." Consumer Compl. ¶ 721; *see also id.*

¶ 837 ("As a result of Defendants' fraudulent conduct, Plaintiffs and members of the Class have been injured because they purchased a drug they otherwise would not have purchased and, thus, did not receive the benefit of the bargain and suffered out-of-pocket loss.").

The alleged economic injury claims presume that a purchaser who consumed the medication, received symptom relief, and suffered no apparent adverse effects attributable to the alleged defect is, nonetheless, entitled to damages.[4] But courts do not allow this. Courts consistently reject class actions against pharmaceutical manufacturers drawing on creative theories of economic loss when the drug at issue was effective for its approved indication and benefitted the class members.[5] The fact that ranitidine allegedly physically injured others (i.e., the PI Plaintiffs) is not relevant to Consumer and TPP Plaintiffs' claims. *See In re Johnson & Johnson*

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[4] The Consumer Class allegations stretch the theory further, by including as plaintiffs all individuals in the United States who purchased the product for family or household use, regardless of whether the purchasers ever used the medication. Consumer Compl. ¶ 734.

[5] *See, e.g., Ironworkers Local Union 68 v. AstraZeneca Pharms. LP*, 634 F.3d 1352, 1363 (11th Cir. 2011) (dismissing economic injury claims where the drug was not "ineffective or unsafe for the prescribed use"); *Rivera v. Wyeth-Ayerst Labs*., 283 F.3d 315, 319 (5th Cir. 2002) (holding plaintiffs lacked standing to seek reimbursement of value of drug found to have a risk of causing liver damage where only other patients may have experienced such harm and the class did not allege the drug caused them physical or emotional harm or that the drug was ineffective); *In re Vioxx Prods. Liab. Litig*., 874 F. Supp. 2d 599, 601 (E.D. La. 2012) ("There is no obvious, quantifiable pecuniary loss that Plaintiff incurred from purchasing a drug that worked for him and did not cause him any harm."); *Loreto v. Procter & Gamble Co*., 737 F. Supp. 2d 909, 922-23 (S.D. Ohio 2010) (dismissing economic injury claim where plaintiffs did not allege that medicine was ineffective based on "their own personal experience with the product" (internal quotation marks and citations omitted)); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 WL 2043604, at *15, *16 (D.N.J. July 10, 2009) (dismissing claims where plaintiffs "receive[d] the benefit of their bargain" and failed to allege that "any named plaintiff purchased one or more of the Subject Drugs that was prescribed and used for a condition for which it was ineffective"); *Williams v. Purdue Pharm. Co*., 297 F. Supp. 2d 171, 176-77 (D.D.C. 2003) (finding no injury in fact where class members suffered no ill effects or lack of efficacy from pain medication that was allegedly deceptively marketed); *In re Rezulin Prods. Liab. Litig*., 210 F.R.D. 61, 68-69 (S.D.N.Y. 2002) (denying class certification where it was undisputed that the drug was "enormously beneficial to many patients" who "presumably got their money's worth and suffered no economic injury").

Talcum Powder Prod. Mktg., Sales Practices & Liab. Litig., 903 F.3d 278, 289 (3d Cir. 2018) ("Although Estrada contends that Baby Powder is 'unsafe,' her own allegations require us to conclude that the powder she received was, in fact, safe as to her."); s*ee also Birmingham v. Walgreen Co.*, No. 12-60922-CIV, 2014 WL 12479929, at *4 (S.D. Fla. Jan. 3, 2014) ("Here, Plaintiff's claims of economic injury in fact are legally insufficient because Plaintiff already consumed the product, did not suffer 'distinct and palpable' adverse health consequences, and otherwise suffered no injuries from [the product]." (internal citations omitted)). Under this case law, Plaintiffs fail to assert a legally cognizable injury.

Likewise, in *James v. Johnson & Johnson Consumer Co., Inc.*, the New Jersey federal court rejected the plaintiffs' argument that they were economically harmed merely because they bought and used baby shampoo that was allegedly tainted with methyl chloride and thereafter "feared for the future safety of their children." No. 2:10-cv-03049, 2011 WL 198026, at *2 (D.N.J. Jan. 20, 2011). While the court acknowledged that the plaintiffs probably would not have purchased or used the baby shampoo if they had known about the alleged toxicity, "the conclusion that 'consequently, [p]laintiffs have been economically damaged' simply does not follow." *Id.* (citation omitted). The court explained:

> Once the product had been consumed, however, there was no economic injury for Plaintiffs to complain of, and the fear of future injury is legally insufficient to confer standing. Plaintiffs received the benefit of their bargain so long as there were no adverse health consequences, and the product worked as intended, meaning that the hair of Plaintiff's children was cleansed, and their eyes and skin were not irritated.

Id. This case is no different; the Class Action Complaints fail to allege non-conclusory facts to support a plausible claim against the Generic and Repackager Defendants.

A leading case on claims for economic injuries against pharmaceutical manufacturers, *Rivera v. Wyeth-Ayerst Laboratories*,[6] involved similar claims to those asserted by Plaintiffs in these consolidated cases. *Id.*, 283 F.3d at 317. *Rivera* was a class action alleging consumer deception under Texas law, breach of the implied warranty of merchantability, and unjust enrichment based on a pharmaceutical company's failure to warn of certain alleged health risks associated with its drug. *Id*. The plaintiffs in *Rivera* had taken a pain medication that was later withdrawn from the market due to reports of liver failure in some patients. *Id*. The class representatives sought to represent individuals who had used the drug but suffered no personal injury. *Id*. The class sought economic damages only on the theory that they were denied the benefit of the bargain and wanted their money back. *Id*. at 317, 320 (footnote omitted). The Fifth Circuit, however, held that "[s]uch wrongs cannot constitute an injury in fact." *Id*. at 320. "Consumer Plaintiff paid for an effective pain killer, and she received just that—the benefit of her bargain." *Id*. In holding that the plaintiffs failed to establish an injury-in-fact, the Fifth Circuit explained that the plaintiffs could not prevail by establishing that the defendants violated a legal duty owed to other consumers because the injury must be personal. *Id.* at 319-20.

The class in *Rivera* included consumers who purchased and used a pain medication—Duract—and did not manifest any liver damage or other physical injuries. Like the Consumer and TPP Plaintiffs here, the plaintiffs in *Rivera* claimed that the defendants did not list enough warnings on the Duract label and/or Duract was defective. Like the Plaintiffs in this action, the plaintiffs in *Rivera* sought, in part, reimbursement for their Duract purchases; those plaintiffs did not claim that Duract physically or emotionally injured them or was ineffective in providing pain

[6] Although a standing case, the Fifth Circuit's injury-in-fact analysis applies equally to the injury analysis involved in determining whether the plaintiff failed to state a claim.

relief. Like Plaintiffs here, the *Rivera* plaintiffs asserted that their spent cash was an "economic injury." *Id*. at 319. Therefore, the same result should follow: dismissal.

A court in this district has agreed with the Fifth Circuit's no-injury analysis, dismissing cases lacking allegations that the product did not work for its intended use. *See Papasan v. Dometic Corp*., No. 16-22482-CIV, 2019 WL 3317750, at *4 (S.D. Fla. July 24, 2019) (agreeing with the Fifth Circuit's analysis in *Rivera* that plaintiffs improperly oscillated between tort and contract law claims to obscure the fact that they asserted no concrete injury).

Courts examining the issue of injury allegations primarily in the context of proximate cause, likewise applied the reasoning in *Rivera*. For example, in *Ironworkers Local Union No. 68 v. AstraZeneca Pharmaceuticals LP*, the Middle District of Florida considered third-party payor plaintiffs' claims for economic damages where the plaintiffs sought to recover the excess payments they made for Seroquel prescriptions filled by their participating members. *Id*., 585 F. Supp. 2d 1339, 1342 (M.D. Fla. 2008). Since the plaintiffs failed to establish that alleged unlawful conduct caused the alleged injuries, citing serious concerns about the difficulties inherent in determining the cause of injury on a transaction-by-transaction basis, the court dismissed the complaint. *Id*. 1345. Approximately one year after its *Ironworkers* decision, the Middle District of Florida court re-applied the same reasoning to certain state-law claims brought by a health and welfare trust fund against the manufacturer of Seroquel. *See Pennsylvania Employees Ben. Tr. Fund v. Astrazeneca Pharm. LP*, No. 609-CV5003-ORL-22DAB, 2009 WL 2231686, at *1 (M.D. Fla. July 20, 2009). The plaintiff alleged that the defendant engaged in a wide spread fraudulent scheme to promote Seroquel that caused the plaintiff fund to unnecessarily pay the cost of Seroquel prescriptions where less expensive, safer, and more effective medication was available. *Id*. Applying the *Ironworkers* analysis, the court granted the defendants' motion to dismiss for failure

to state a claim, because the complaint lacked a sufficient connection between the conduct and the supposed injury. *Id.* at *6.

Here, Plaintiffs have alleged that they purchased ranitidine—an FDA-approved medication—and nothing more. They never allege that Plaintiffs who took the medication for heartburn relief continued to experience heartburn. The fact that several plaintiffs allegedly continued to purchase and use the product for *decades* suggests that the product effectively relieved the symptoms for which it was prescribed. Plaintiffs' allegations establish they received exactly what they paid for: an effective treatment for heartburn and indigestion without any demonstrable physical injury. Thus, the Consumer and TPP Plaintiffs suffered no injuries—economic, physical, or otherwise. Because there can be no recovery where there has been no cognizable harm, the Class Action Complaints must be dismissed in their entirety as to the Generic Manufacturer and Repackager Defendants.

2. Allegations of "cellular damage" do not qualify as personal injuries.

Plaintiffs do not allege a single supporting allegation of *actual* physical or emotional injury caused by ranitidine ingestion. The named plaintiffs do not allege that they (or any proposed absent class members) were diagnosed with cancer or any other disease in connection with their use or purchase of ranitidine. Instead, the Consumer Class Action Plaintiffs in the Consumer Complaint allege, without support, that ***all*** consumers "who ingested Defendants' Ranitidine-Containing Products have suffered physical damages in the form of cellular, sub-cellular, and/or genetic injuries that significantly increased their risk of developing various types of serious and potentially deadly cancers." *Id.* at ¶ 723.

Speculation is not enough to allege physical injury. As one federal court has explained, such "cellular damage does not rise to the level of physical injury as a matter of law because nothing in the record relates them to any objective symptoms of illness or disease." *Caputo v. Bos.*

Edison Co., No. CIV. A. 88-2126-Z, 1990 WL 98694, at *4 (D. Mass. July 9, 1990), *aff'd*, 924 F.2d 11 (1st Cir. 1991). An "increased risk of developing cancer or some other disease in the future does not by itself give rise to a claim for damages." *Id*. Most courts that have considered the issue have also found claims of sub-cellular or genetic "injuries" without physical manifestations are not injuries—and, thus, not compensable. *See, e.g., Ranier v. Union Carbide Corp.,* 402 F.3d. 608, 622 (6th Cir. 2005) (concluding that Kentucky case law does not equate sub-cellular damage with bodily injury in analyzing claim brought under the Price-Anderson Act); *In Re Berg Litig.,* 293 F.3d. 1127, 1131 (9th Cir. 2002) (reversing the District Court's decision to allow "those emotional distress claims of plaintiffs who were not ill, but who could demonstrate that their exposure more than doubled their risk of disease"); *see Dumontier v. Schlumberger Tech. Corp.,* 543 F.3d 567, 570 (9th Cir. 2008) ("But not every alteration of the body is an injury.").

Accordingly, the only injury that Plaintiffs in the Consumer Complaint *may allege* and the only *actual* losses alleged in the Consumer Complaint are economic in nature.[7]

[7] *See, e.g.,* Consumer Compl. ¶ 13 ("As a direct and proximate result of Defendants' violations of law, Plaintiffs and other members of the Class have suffered economic losses through their purchase of a product that should not have been available for sale in the U.S. and which they would not have purchased, but for Defendants' unlawful conduct."); *id.* ¶ 15 ("Plaintiffs, individually and on behalf of the Class, seek redress to compensate for their economic losses . . . ."); *id.* ¶ 1164 ("As a direct and proximate result of Defendants' actions and omissions, Plaintiffs and members of the Class have suffered physical injury, have a significantly increased risk of developing serious and potentially deadly cancers, and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring."); TPP Compl. ¶ 14 ("Plaintiffs . . . seek redress for their economic losses they suffered because they made payments or reimbursements for a product that was economically worthless . . . ."); *id*. ¶ 495 ("Plaintiffs and TPP Class members have been injured because they paid reimbursements for an economically worthless drug they otherwise would not have been obligated to pay, and suffered out-of-pocket loss.").

3. Even if Plaintiffs could allege a personal injury, they must confine all such claims to the Personal Injury Complaint.

The PI Complaint, filed "on behalf of all individually injured Plaintiffs . . . who have suffered personal injuries and/or death as a result of using Defendants' dangerously defective ranitidine-containing products," is the only one of the three Master Complaints in which Plaintiffs actually assert physical or emotional injury. PI Compl. ¶¶ 17-18; PTO #31, p. 2 ("By June 22, 2020, Plaintiffs shall file a Master Personal Injury Complaint on behalf of *all Plaintiffs asserting personal injury claims* in MDL No. 2924) (emphasis added)).[8] Any Plaintiffs seeking monetary damages for personal injury are to seek redress through the PI Complaint, not the Class Action Complaints. To allow otherwise would contradict existing Orders of this Court and add unnecessary confusion, duplication, and inefficiency to this MDL.

B. THE ECONOMIC-LOSS RULE BARS THIRD-PARTY PAYORS' TORT RECOVERY OF PURELY ECONOMIC LOSS IN A COMMERCIAL TRANSACTION.

In addition to being subject to dismissal for failure to allege a cognizable injury, the economic loss doctrine precludes the TPP Plaintiffs' tort claims sounding in fraud (Count 5), negligence (Counts 6 and 9), and violation of consumer protection laws (Count 7). The TPP Plaintiffs are commercial parties allegedly in privity with Defendants and asserting claims under both contract and tort law. *See* TPP Compl., Counts II-VI, IX. However, because they have limited their alleged damages to the product itself without alleging any personal injury or damage to "other property," the only claims they may assert are contractual—not tort—claims.

[8] Specifically, Plaintiffs in the PI Complaint are individuals who have developed various cancers allegedly caused by ranitidine. *See, e.g.*, PI Compl. ¶ 19. ("Plaintiffs were diagnosed with various cancers and their sequelae, which were directly and proximately caused by their use of ranitidine-containing products. These injuries include, but are not limited to, the following types of cancer: bladder, brain, breast, colorectal, esophageal or throat, intestinal, kidney, liver, lung, ovarian, pancreatic, prostate, stomach, testicular, thyroid, and uterine.").

The landmark case on the economic-loss doctrine in products liability is the Supreme Court's decision in *East River Steamship Corp. v. Transamerica Delaval*, 476 U.S. 858 (1986). Applying admiralty law, the *East River* Court had to "determine whether injury to a product itself is the kind of harm that should be protected by products liability or left entirely to the law of contracts." *Id.* at 859. The Court recognized and upheld the overwhelming "majority" approach of the States, which "held that preserving a proper role for the law of warranty precludes imposing tort liability if a defective product causes purely monetary harm." *Id.* at 868.

The Supreme Court's rule flows from the premise that when "a product injures only itself the reasons for imposing a tort duty are weak and those for leaving the party to its contractual remedies are strong." *Id.* at 871. The *East River* Court explained that damage "to a product itself is most naturally understood as a warranty claim" and "means simply that the product has not met the customer's expectations, or, in other words, that the customer has received insufficient product value." *Id.* at 872 (internal quotation marks omitted). The Court famously observed that, without proper limits on tort liability, "contract law would drown in a sea of tort." *Id.* at 866.

The liability-restricting rule not only operates to protect commercial parties whose transactions generally do "not involve large disparities in bargaining power," it also lowers prices for consumers. *See id.* at 872-73. The Court emphasized that, when "the parties may set the terms of their own agreements" and courts honor their "allocation of the risk" by precluding tort claims with no personal injury or other-property damage, "the purchaser pays less for the product." *See id.* Here, the TPP Plaintiffs are all commercial entities—self-identifying as "health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third party payors and any other health benefit provider"—and not the end-

user consumers who actually ingest the product. *See* TPP Compl. ¶¶ 506, 508. The economic-loss doctrine, thus, should be applied with full force.

After *East River* was issued, the economic-loss doctrine for product-liability cases[9], which the Supreme had recognized as "the majority approach," has remained well accepted by the clear majority of jurisdictions. *See* J.M. Zitter, Annotation, *Strict products liability: recovery for damage to product alone*, 72 A.L.R. 4th 12 (originally published in 1989).

Plaintiffs in the TPP Complaint are sophisticated commercial entities that paid negotiated prices for medications taken by their insureds. There is no cognizable claim that the third-party payors (or anyone else) were physically injured by paying for ranitidine medications. Therefore, the economic-loss doctrine bars the TPP Plaintiffs from asserting their tort claims of fraud, negligent misrepresentation and omission, violation of consumer protection laws and negligence. Thus, all the tort-based claims asserted against the Generic Manufacturers and Repackager Defendants are improper.

C. CONSUMER CLASS' CLAIMED MEDICAL-MONITORING "INJUNCTION" SHOULD BE DISMISSED AND AN INJUNCTION OF NON-EXISTENT SALES IS IMPROPER.

The Consumer Complaint contains a request for injunctive relief seeking the establishment of a trust fund to pay for medical monitoring, as well as "any and all appropriate preliminary and/or final injunctive" relief. Consumer Compl. ¶ 747. And putting to rest any doubt about what they seek, the Plaintiffs recent filings acknowledge ". . . this Court can fashion a simple remedy when

[9] Courts and commentators have noted that the singular term "economic-loss rule" is "something of a misnomer" as "there is not one economic loss rule broadly applicable throughout the field of torts, but rather several more limited rules that govern recovery of economic losses in selected areas of the law." *Sharyland Water Supply Corp. v. City of Alton*, 354 S.W.3d 407, 415 (Tex. 2011) (quoting Vincent R. Johnson, *The Boundary-Line Function of the Economic Loss Rule*, 66 Wash. & Lee L. Rev. 523, 534-35 (2009)). To be clear, only one version of the rule is being argued here: between commercial parties, claims for injury to the product itself without personal injury or other-property damage are contractual and not tort claims.

it finds liability: ordering Defendants to ***create a fund to pay*** for medical monitoring . . . ." (emphasis added) ECF No. 1980 at p. 11, § I(A); *Plaintiffs' Corrected Opposition To Defendants' Amended Motion to Dismiss And/Or Strike Consolidated Consumer and Third Party Payor Class Action Complaints on Grounds of Impermissible Shotgun Pleadings And Lack Of Article III Standing*. The Court should dismiss the claims for injunctive relief because (1) the medical monitoring requested here is not properly the subject of an injunction, and (2) the only other possible injunctive relief—precluding sales—is moot.[10]

First, Consumer Plaintiffs seek monetary damages for medical monitoring—not an injunction. Federal courts recognize that a "request for medical monitoring cannot be categorized as primarily equitable or injunctive *per se*." *Zinser v. Accufix Research Inst., Inc.*, 253 F.3d 1180, 1195 (9th Cir. 2001). Instead, the requested relief shapes whether their claims are injunctive/equitable or monetary/legal. *See*, *e.g.*, *Day v. NLO, Inc*., 144 F.R.D. 330, 335-36 (S.D. Ohio 1992), *vacated in part on other grounds*, *In re NLO. Inc*., 5 F.3d 154, 160 (6th Cir. 1993); *Donovan v. Philip Morris USA, Inc.*, 268 F.R.D. 1, 22 (D. Mass. 2010).[11] In fact, courts

[10] 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.

[11] In *Donovan* the plaintiffs sought court-supervised lung-cancer screenings, using technology that was "not generally available in Massachusetts" and "not available through most health insurance programs." *Donovan v. Philip Morris USA, Inc.*, 268 F.R.D. at 6, 26. Such relief required "the hiring of medical personnel, the purchase of equipment, and the development of outreach and record keeping procedures, among other things, which may make the program inaccessible to individual plaintiffs." *Id.* at 6. Such a unique program required court-supervised trustees, a registry, and group studies. *Id.* at 22-23. That relief fundamentally differs from the relief sought by the Plaintiffs here—the establishment of a trust fund. Indeed, despite its result, *Donovan*'s reasoning shows that courts are reluctant to categorize medical monitoring claims as injunctive relief. *Wal-Mart Stores, Inc. v. Dukes,* 564 U.S. 338 (2011). "[A] remedy requiring Defendants to do nothing more than writing a check" cannot be properly viewed as an injunction. *Barraza v. C. R. Bard Inc*., 322 F.R.D. 369, 389 (D. Ariz. 2017). The same principles apply in this circuit. *See, e.g., Jackson v. Purdue Pharma Co.,* No. 6:02-cv-1428-Orl-19KRS, 2003 U.S. Dist. LEXIS 6998, at *5 (M.D. Fla. Apr. 10, 2003).

must closely scrutinize plaintiffs' request for medical monitoring as injunctive relief or simply "a disguised request for compensatory damages." *Arch v. Am. Tobacco Co*., 175 F.R.D. 469, 483 (E.D. Pa. 1997). When plaintiffs, as they do here, seek an order to pay for medical monitoring, even if paid directly to care providers, they seek monetary damages and *not* injunctive relief. *See Day*, 144 F.R.D. at 335-36.

The court in *Barraza v. C. R. Bard Inc.* reviewed numerous cases to show the relevant factors for deciding whether medical monitoring relief is primarily compensatory or injunctive. *Id.*, 322 F.R.D. 369, 386 (D. Ariz. 2017). The *Barazza* court explained that where "a request for medical monitoring [is] coupled with a request for compensatory or punitive damages," the relief is properly considered primarily monetary. *Id.* Further—and particularly relevant here—"a request for transmission of money with little supervision from the court or further engagement by the defendants is likely to be considered primarily monetary." *Id.*

Although Plaintiffs allege that they have an inadequate remedy at law, the language they use to describe the medical monitoring relief exposes their claims as *only* monetary. The features of the program requested in the Consumer Complaint are nearly identical to those sought in the cases holding that the medical monitoring claim is one for compensatory damages. The Consumer Plaintiffs' medical-monitoring claims allege that ranitidine has increased their risk for various, unspecified forms of cancer. They want the Court to order Defendants to set up a trust fund to pay for regular cancer screenings with their own physicians. Plaintiffs claim that ranitidine somehow causes a multitude of common cancers, all with established diagnostic tests and treatment protocols. Payment for such cancer screenings and treatment is purely monetary damages; it is not injunctive relief. *See*, *e.g.*, *Zinser v. Accufix Research Inst., Inc.*, 253 F.3d 1180, 1196 (9th Cir. 2001); *Thomas v FAG Bearings Corp Inc,* 846 F Supp 1400 (W.D. Mo. 1994) (costs that are

nothing more than compensation for necessary medical expenses reasonably anticipated to be incurred in the future are not injunctive relief); *O'Connor v. Boeing N. Am., Inc.,* 180 F.R.D. 359, 379 (C.D. Cal. 1997) (finding relief primarily monetary where the plaintiffs sought establishment of a fund to pay for medical monitoring, including treatment, as well as other compensatory and punitive damages). Accordingly, their request a medical-monitoring injunction should be dismissed.

Second, the Consumer Plaintiffs repeatedly argue that the products present a "continuing risk" (*e.g.*, *id.* ¶ ¶943, 1042, 1138) and allege that Defendants have a duty to "cease marketing and discontinue" sales (¶ 851). Plaintiffs seek an injunction ordering the Defendants to remove ranitidine from the market. But, as Plaintiffs know, Defendants have already done that. This Court cannot enjoin something that is not happening. Therefore, there is no basis for any injunctive relief, and their demand for injunctive relief must be dismissed for this additional reason.

IV. CONCLUSION

Class Action Plaintiffs' claims in the Consumer Complaint and TPP Complaint fail to allege a cognizable injury. In addition, allegations that the TPP Plaintiffs suffered tort damages and the Consumer Plaintiffs are entitled to injunctive relief have no basis in law or fact. Accordingly, all claims asserted against the Generic Manufacturers and Repackagers in Plaintiffs' Class Complaints must be dismissed with prejudice.

Dated: October 8, 2020 Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 8, 2020, I electronically filed the foregoing **THE GENERIC MANUFACTURERS' AND REPACKAGERS' RULE 12 MOTION TO DISMISS CONSOLIDATED CONSUMER AND THIRD-PARTY PAYOR CLASS ACTION COMPLAINTS ON THE GROUND OF FAILURE TO ALLEGE AN INJURY AND INCORPORATED MEMORANDUM OF LAW** with the Clerk of Court using the CM/ECF system, which will provide automatic notification to all counsel of record.

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