IN THE UNITED STATES DISTRICT COURTFOR THE DISTRICT OF NEW JERSEY CAMDEN DIVISION

IN RE: VALSARTAN LOSARTAN, and IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	**MDL No. 19-2875 (RBK/KW)**
This Order Relates to all Cases	:	**ORDER**

SPECIAL MASTER REPORT ON PLAINTIFFS' MOTION FOR LEAVE TO AMEND MASTER COMPLAINTS

I. INTRODUCTION

Pending in this multi-district litigation arising from the production and sale of certain generic blood pressure medication (referred to in this decision as Valsartan or VCDs ("Valsartan Containing Drugs")), is Plaintiffs' Motion for Leave to Amend Master Complaints.[1] (ECF No. 1148). Plaintiffs seek leave to file Amended Master Complaints in the wake of a series of six Court decisions that resolved a multitude of issues presented on motions to dismiss filed on behalf of the Defendants.[2] The first

[1] There are three Master Complaints: a Personal Injury Master Complaint ("PIMC"); an Economic Loss Master Complaint ("ELMC"); and a Medical Monitoring Master Complaint ("MMMC"). Each Master Complaint has its own set of Plaintiffs. Likewise, there are three proposed Amended Master Complaints: a proposed Amended Personal Injury Master Complaint ("PPIMC"); a proposed Amended Economic Loss Master Complaint ("PELMC"); and a proposed Amended Medical Monitoring Master Complaint ("PMMMC").

[2] There are three groups of Defendants for each Master Complaint: (1) the Manufacturer Defendants, *i.e.*, the companies that produced the "Active Pharmaceutical Ingredient" ("API") in the finished drug as well as the companies that made the finished drug; (2) the "Wholesaler Defendants," *i.e.*, the entities that obtained the finished product and sold it to retailers; and (3) the retailer entities who

decision was issued on December 18, 2020 ("MTD Opinion 1" (ECF No. 675)), and denied Defendants' motions to dismiss the Master Complaints on preemption and primary jurisdiction grounds.[3] The final decision in the series, "MTD Opinion 6" (ECF No. 1019), was issued on March 12, 2021. Orders accompanying MTD Opinions 2 through 6 granted the motions to dismiss in part, but gave Plaintiffs the opportunity to attempt to cure certain pleading defects. Plaintiffs' Motion for Leave to Amend the Master Complaint, filed on April 12, 2021, represents that attempt to cure pleading defects.

Plaintiffs assert that their proposed Amended Master Complaints satisfy the concerns raised in the various decisions of the Court; Defendants vigorously contest this assertion. The motion has been fully briefed, with each group of Defendants having filed Surreply briefs on August 2, 2021. (*See* ECF No. 1451 (Manufacturer Defendants' Surreply Brief); ECF No. 1452 (Pharmacy Defendants' Surreply Brief); and ECF No. 1454 (Wholesaler Defendants' Surreply Brief)). This decision will address the issues presented in the proposed Amended Master Complaints in the same order in which they were considered by Opinions 2 through 6 of the Court, with the first issue being Article III standing.

II. THE THRESHOLD PROCEDURAL ISSUE

Before discussing the substantive issues presented by the parties, however,

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sold the finished medication to consumers (the "Pharmacy Defendants").

[3] By Order entered on January 11, 2021 (ECF No. 725), Defendants' Motion to Reconsider MTD Opinion 1 (ECF No. 709) was denied.

there is a threshold procedural objection raised by Defendants that must be resolved. Plaintiffs submitted newly-revised proposed Amended Master Complaints along with their Reply Memorandum of Law in Further Support of their Motion for Leave to Amend Master Complaints, ECF No. 1382. (*See* Exhibits A-1, A-2, B-1, B-2, C-1 and C-2, ECF Nos. 1382-1, 1382-2 and 1382-4 through 1382-7.) Defendants argue that Plaintiffs could not present newly revised proposed Amended Master Complaints without first obtaining leave of court, citing Local Civil Rule 15.1, CMO 22 (ECF No. 726), and *Capers v. FedEx Ground Package System, Inc.*, CIV. 2:02-05352 WJM, 2012 WL 5818137 (D.N.J. Nov. 15, 2012). The authority cited by Defendants deals with the improper filing of an amended complaint without leave of court. Here, by way of contrast, Plaintiffs have merely submitted revised proposed Amended Master Complaints. The proposed Amended Master Complaints accompanying Plaintiffs' reply brief are submitted in redline format in relation to the already-filed Master Complaints, enabling the Court to ascertain the changes being proposed. Local Civil Rule 15.1(a)(2) requires a party to submit "a form of the amended pleading that shall indicate in what respect(s) it differs from the pleading which it proposes to amend…." Plaintiffs' newly revised proposed Amended Master Complaints comply with that requirement. The fact that the revised proposed Amended Master Complaints differ in certain respects from the initially-submitted proposed amended complaints that accompanied the Motion for Leave to Amend (ECF Nos. 1148-1 through 1148-6) is immaterial. Plaintiffs' revised proposed Amended Master Complaints address some of the objections to the initially-proposed Amended Master Complaints interposed by

Defendants and are intended to avoid further motion practice. Furthermore, Defendants were granted leave to file Surreply briefs so they have had an opportunity to address the newly proposed amended master complaints. Under these circumstances, it is the sufficiency of the revised proposed Amended Master Complaints, (ECF Nos. 1382-1, 1382-2, and 1382-4 through 1384-7), that will be considered. Defendants' request to strike the revised proposed Amended Master Complaints will be denied.

III. SUFFICIENCY OF THE PROPOSED AMENDED MASTER COMPLAINTS

A. Article III Standing (MTD Opinion #2)

MTD Opinion #2 (ECF No. 728) addressed the question of whether Plaintiffs had alleged facts sufficient to support a conclusion that they had standing to pursue the claims for economic loss and medical monitoring asserted in the corresponding Master Complaints.[4] The Court held that the ELMC and the MMMC alleged the requisite

[4] Standing with respect to the claims presented in the PIMC was not at issue. (MTD Op. 2, ECF No. 728, at 3.)

injury-in-fact to allow the economic loss[5] and medical monitoring[6] claims to proceed.

1. Traceability

After rejecting Defendants' broad-based challenges to standing, the Court proceeded to consider whether Plaintiffs had satisfied the standing requirement of "traceability," *i.e.* whether the alleged injury was allegedly caused by a named defendant. The Court explained that "in order to establish standing in the class action context, for each named defendant, at least one named plaintiff must be able to allege an injury traceable to that defendant." (MTD Op. 2 (ECF No. 728) at 17.) Because the ELMC and MMMC contained "conclusory allegations that lump Defendants together," (*id.*), precluding a determination that a particular Defendant caused a specific named plaintiff harm, Plaintiffs had not satisfied the "traceability" requirement. The Court, however, gave Plaintiffs the opportunity to submit an amended pleading that linked a

[5] The Court found that ELMC presented at least three theories of economic injury: (1) receipt of a worthless product due to the failure to receive the benefit of the bargain; (2) receipt of a less valuable product because of the failure to receive the benefit of the bargain; and (3) loss from having to buy replacement medication due to voluntary recalls. The Court held that the first and third theories were viable because a fact-finder would not have to resort to conjecture to value Plaintiffs' injury. (*Id.* at 13.) The second theory, however, could not be pursued because Plaintiffs failed to provide a basis for the factfinder to determine the diminished value of the contaminated medication. (*Id.*) Plaintiffs have made clear that they are not proceeding on a "less valuable" product theory, (Reply Brief (ECF No. 1382) at 6), thus obviating consideration of Defendants' argument that Plaintiffs were persisting in their "less valuable" product theory. (*See, e.g.*, Mfr. Def. Brief (ECF No. 1277) at 13-15.)

[6] The Court concluded that Plaintiffs' allegation that they consumed medication contaminated with carcinogens, resulting in genetic and cellular damage, "easily" satisfied the Article III standing requirement of an injury-in-fact. (*Id.* at 15.)

particular defendant to a specific named plaintiff, observing that "Plaintiffs should be able to amend their Complaints with relative ease to satisfy this requirement." (*Id.* at 18.)

Each group of Defendants contends that the proposed Amended Master Complaints remain deficient on the traceability issue in a number of respects. While acknowledging that "the PELMC and PMMMC now purport to trace each [named] Plaintiff's purchases to one or more named Defendants," (Mfr. Defendants' Surreply Br. (ECF No. 1451) at 7), the Manufacturer Defendants assert that there are still five "untraced" Defendants in the PELMC and eleven "untraced" Defendants in the PMMMC.[7] (*Id.*) Five of these Defendants, however, are subject to conditional orders of dismissal without prejudice, (*see* ECF No. 248, conditional order of dismissal as to AvKARE, Inc., Harvard Drug Group, LLC, Major Pharmaceuticals, Inc., Preferred Pharmaceuticals, and Remedy Repack, Inc.), and three of them have in fact been dismissed (Harvard Drug Group, LLC, and Major Pharmaceuticals, Inc. (ECF No. 498), and Preferred Pharmaceuticals, Inc. (ECF No. 543)). Inclusion of these peripheral defendants in the PELMC and PMMMC does not warrant denying leave to amend.

[7] The Manufacturer Defendants identify AvKARE, Inc., Humana Pharmacy, Inc., Major Pharmaceuticals, Inc., Preferred Pharmaceuticals, and Remedy Repack, Inc. as "untraced" Defendants in the PELMC. None of these entities is a Manufacturer Defendant. The allegedly "untraced" Defendants in the PMMMC are Arrow Pharm Malta, Ltd., Albertson's LLC, AvKARE, Inc., the Harvard Drug Group, LLC, Humana Pharmacy, Inc., the Kroger Co., Major Pharmaceuticals, Inc., OptumRx, Remedy Repack, Inc., Torrent Pharma, Inc., and Torrent Pharmaceuticals, Inc. Only Arrow, Torrent Pharma, and Torrent Pharmaceuticals are classified as Manufacturer Defendants.

Three of the "untraced" Defendants in the PMMMC and PELMC are subsidiaries of "traced" Defendants: Arrow Pharma Malta Ltd. is alleged to be a subsidiary of Defendant Teva, (*see* PELMC, ECF No. 1382-4, ¶ 101; PMMMC, ECF No. 1382-6, ¶ 442); and Torrent Pharma, Inc. and Torrent Pharmaceuticals, Ltd. are alleged to be subsidiaries of Torrent (*see* PELMC, ECF No. 1382-4, ¶¶ 104-06; PMMMC, ECF No. 1382-6, ¶¶ 445-46). The corporate relationship of the parties, however, is not, in and of itself, sufficient to trace an injury caused by a parent to its subsidiary for purposes of standing. *See Akaosugi v. Benihana Nat. Corp.*, C 11-01272 WHA, 2011 WL 5444265, at *3 (N.D. Cal. Nov. 9, 2011). And it appears that there remain untraced in the PELMC Defendant Humana Pharmacy, Inc. and, in the PMMMC, Defendants Albertson's LLC, Humana Pharmacy, Inc., the Kroger Co., and OptumRx. Plaintiffs will be given an opportunity to show cause why the claims asserted against Humana Pharmacy, Inc., Arrow Pharma Malta, Torrent Pharmaceuticals and Torrent Pharma in the PELMC and the claims asserted against Albertson's, LLC, Humana Pharmacy, Inc., the Kroger Co., OptumRx, Arrow Pharma Malta, Torrent Pharmaceuticals and Torrent Pharma in the PMMMC should not be dismissed with prejudice.

The Wholesaler Defendants argue that there are named Plaintiffs in the PELMC and the PMMMC that do not trace their purchases of VCDs to each Wholesaler Defendant. But the standard is not whether each named Plaintiff has traced her injuries to each Defendant. Instead, the test is whether *a* named Plaintiff has traced her injury to *a* particular Defendant. The PELMC and the PMMMC satisfy this standard for the Wholesaler Defendants. (*See* PELMC, ECF No. 1382-4, ¶¶ 153, 156, and 159;

PMMMC, ECF No. 1382-6, ¶¶ 501, 503, 505.)

Similarly, except as noted above with respect to Albertson's, LLC, Humana Pharmacy, Inc., the Kroger Co., and OptumRx, the PMMMC adequately alleges facts sufficient to show that a named Plaintiff purchased VCDs from a named Pharmacy Defendant, (*see* PMMMC, ECF No. 1382-6, ¶¶ 456, 465, 469, 472, 477), and, with the exception of Humana, the PELMC adequately alleges facts sufficient to show that a named Plaintiff purchased VCDs from a named Pharmacy Defendant. (*See* ECF No. 1382-4, ¶¶ 115, 124, 128, 131, 134, 137.) In summary, with the exception of a few of the Pharmacy Defendants, the PELMC and the PMMMC satisfy the traceability requirement for standing.

2. Consumer Plaintiffs Standing to Pursue Economic Loss and Medical Monitoring Claims Based upon State Law

MTD Opinion #2 (ECF No. 728) identified another standing defect in the ELMC and the MMMC: named Plaintiffs were asserting claims under the laws of all fifty states, the District of Columbia, and Puerto Rico, but there was not a named Plaintiff from each of these jurisdictions. The Court dismissed, without prejudice, the claims based upon the laws of the jurisdictions where a named Plaintiff neither resided nor was injured.[8] The PELMC and PMMMC added a named Plaintiff for only one state,

[8] The PELMC does not have a named Plaintiff from the following states: Alaska, Arizona, Colorado, Delaware, District of Columbia, Hawaii, Idaho, Iowa, Maryland, Michigan, Missouri, Montana, Nebraska, Nevada, New Hampshire, North Dakota, Oklahoma, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Washington, West Virginia, Wisconsin, and Wyoming. The PMMMC does not have a named Plaintiff from the following states: Alabama,

Arkansas, and Plaintiffs will be granted leave to amend those Master Complaints to that extent.

Named Plaintiffs persist in their pursuit of claims on behalf of putative class members under the laws of states where the named Plaintiffs do not reside and were not injured. While "accept[ing] the Court's MTD Order No. 2 insofar as it held that a named plaintiff from State X, asserting claims under State X's law for injuries sustained in State X, cannot assert claims under State Y's laws," (Plaintiffs' Reply Brief, ECF No. 1382, at 15-16), Plaintiffs argue that "a named plaintiff of State X may represent persons from State X, as well as persons in states whose laws do not conflict with the laws of State X." (*Id.* at 16.) They contend that the issue is not one of standing, but of predominance under Fed. R. Civ. P. 23, (*id*. at 15, citing a host of cases, including *Langan v. Johnson & Johnson Consumer Cos., Inc.*, 897 F.3d 88, 96 (2d Cir. 2018)), and that the determination of whether a "false conflict" exists should be determined at the class certification stage. (Plaintiffs' Reply Brief (ECF No. 1382) at 16-18.)

To be sure, there is an apparent conflict in the cases on the question of whether named class representatives can assert claims under the laws of states where they do not reside and were not injured. *Compare Ponzio v. Mercedes-Benz USA, LLC*, 447 F. Supp. 3d 194, 222-23 (D.N.J. 2020) (concluding that plaintiffs "lack standing to assert

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Alaska, Arizona, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Indiana, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, Wisconsin, and Wyoming.

claims on behalf of unnamed plaintiffs in jurisdictions where Plaintiffs have suffered no alleged injury"), *with Rickman v. BMW of N. Am.*, CV 18-4363(KM) (JBC), 2020 WL 3468250, at *11 (D.N.J. June 25, 2020) (question of standing to pursue claims under the laws of states where no named plaintiff lived deferred to class certification stage); *Gress v. Freedom Mortg. Corp.*, 386 F. Supp. 3d 455, 461–62 (M.D. Pa. 2019) (concluding that whether claims under state laws where no named plaintiff resided could be pursued in the class action context presented a question of predominance, not standing). This conflict in the law had been presented to the Court on the original motions to dismiss, and MTD Opinion #2 opted to follow *Ponzio* and the line of authority on which it is premised. But the Court's decision did not take into account the fact that "unnamed, putative class members need not establish Article III standing. Instead, the 'cases or controversies' requirement is satisfied so long as *a* class representative has standing…." *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 362 (3d Cir. 2015) (emphasis supplied). MTD Opinion #2 also did not consider the Supreme Court's recognition that in a multistate class action, like this one, a particular state's law may be applied where it does not conflict with the law of the state where members of the class resided. *See Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 816 (1985) ("There can be no injury in applying Kansas law if it is not in conflict with that of any other jurisdiction connected to this suit.") There thus appears to be no reason why a named plaintiff from state X could not serve as a class representative for unnamed plaintiffs from state Y where the laws of both states are not in conflict. The "key" is that "a class action is a *representative* action brought by a named plaintiff or

plaintiffs. Named plaintiffs are the individuals who seek to invoke the court's jurisdiction and they are held accountable for satisfying jurisdiction." *Neale*, 794 F.3d at 364. "Requiring individual standing of all class members would eviscerate the representative nature of the class action. It would also fail to recognize that the certified class is treated as a legally distinct entity even though the outcome of such an action is binding on the class." *Id.* As explained in *Gress*:

> [T]here is a distinction between the named plaintiff vis-à-vis the defendant and the named plaintiff's role as a potential class representative. The named plaintiff, as a threshold matter, must "demonstrate individual standing vis-à-vis the defendant; he cannot acquire such standing merely by virtue of bringing a class action." *Fallick*, 162 F.3d at 423 (citing *Brown v. Sibley*, 650 F.2d 760, 770 (5th Cir. 1981)). "[H]owever, 'once an individual has alleged a distinct and palpable injury to himself he has standing to challenge a practice even if the injury is of a sort shared by a large class of possible litigants.'" *Id*. (quoting *Senter v. Gen. Motors Corp*., 532 F.2d 511, 517 (6th Cir. 1976)) (emphasis added). "Once his standing has been established, whether a plaintiff will be able to represent the putative class, including absent class members, depends solely on whether he is able to meet the additional criteria encompassed in Rule 23 of the Federal Rules of Civil Procedure." *Id*. (citing *Cooper v. Univ. of Tex. at Dallas*, 482 F. Supp. 187 (N.D. Tex. 1979)).

386 F. Supp. 3d at 462. The Court in *Gress* concluded that "Plaintiffs' capacity to state claims under the laws of other states on behalf of putative class members, who themselves likely would have standing to raise those claims, is a matter to be decided under the rubric of Rule 23, not constitutional standing under Article III." *Id.* A similar result is appropriate here. Accordingly, Plaintiffs will be granted leave to file their PELMC and PMMMC asserting claims under the laws of states where the named Plaintiffs do not reside and have not been injured, but will need to establish the absence

of a conflict between the laws where they live and the laws of states that do not have named class representatives.[9]

3. Standing of Third Party Payor Plaintiffs

Finally, there remains the challenges to the standing of the Third Party Payor ("TPP") class representatives in the PELMC – MSP Recovery Claims, Series LLC ("MSPRC"), and Maine Automobile Dealers Association, Inc. Insurance Trust ("MADA"). The PELMC adds an averment that MSPRC reimbursed consumers in the following states and territories: Alabama, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Indiana, Louisiana, Massachusetts, Maryland, Maine, Michigan, Missouri, Mississippi, North Carolina, New Jersey, Nevada, New York,

[9] The Wholesaler and Pharmacy Defendants each request dismissal of individual Wholesaler Defendants and individual Pharmacy Defendants who are not identified as sellers of VCDs by a particular class representative. For example, with respect to the State of Georgia, the PELMC alleges that Lubertha Powell purchased VCDs from a Walgreens Pharmacy that had been distributed by Wholesaler Defendant AmerisourceBergen, and Lawrence Edwards purchased VCDs from CVS and Rite Aid without any indication as to the wholesaler who had distributed the VCDs to the retail outlets. The Pharmacy Defendants request that claims under Georgia law should be dismissed with prejudice as to Walmart, Express Scripts, Kroger, OptumRx, Albertson's, and Humana because no named Plaintiff alleges the purchase of VCDs in Georgia from one of these Pharmacy Defendants. Similarly, the Wholesaler Defendants request that claims under Georgia law should be dismissed as to Cardinal Health, Inc. and McKesson because no named Plaintiff has alleged a purchase of VCDs distributed in Georgia by one of these wholesalers. Plaintiffs persuasively respond that they have alleged the unique National Drug Code ("NDC") numbers for VCDs that they purchased, that the VCD numbers will enable identification of the wholesalers and retailers, and that discovery on this aspect of the case is continuing. Under these circumstances, dismissal of claims under certain state laws for which there is a named Plaintiff simply because there is not a named Plaintiff who alleges buying VCDs from each Pharmacy or Wholesaler Defendant in that state would be premature.

Ohio, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Tennessee, Texas, Virginia, Wisconsin, and West Virginia. (PELMC, ECF No. 1382-4, ¶ 68.) As to MADA, the PELMC adds the following allegation: "MADA's payments include payments made on behalf of members in Maine, Florida and New Jersey." (*Id.*, ¶ 72.) These averments are sufficient to support an inference that the named TPPs were injured in those states. The PELMC also alleges NDC numbers for prescriptions reimbursed by the TPPs and identifies the Manufacturer Defendant for each transaction.

"To establish Article III standing in a class action, it is not required that each named plaintiff must have a claim against each named defendant. Rather, for every named defendant there must be at least one named plaintiff who can assert a claim directly against that defendant. . . ." *Cent. States Se. & Sw. Area Health & Welfare Fund v. Merck-Medco Managed Care, LLC*, 504 F.3d 229, 241 (2d Cir. 2015) (quoting 1 Newberg on Class Actions § 2:6 n.3 (4th ed. 2002)). Plaintiffs have satisfied this standard as to the Manufacturer Defendants. Thus, MSPRC and MADA at least have standing to assert claims for economic losses on behalf of other TPPs operating or injured in the listed states and territories against the Manufacturer Defendants.[10] For

[10] The Manufacturer Defendants argue that the stipulation entered into by MSPRC to limit its claims to three specific assignees operating in Connecticut, Ohio and New York (ECF No. 650) necessarily precludes MSPRC from asserting economic losses outside of those states. (ECF No. 1277 at 15-16.) The stipulation, however, provides that it "does not impair and is without prejudice to MSPRC's or any other proposed TPP class representatives' ability to move for class certification as to the class definition set forth above." (ECF No. 650, ¶4.) The defined class includes "[a]ll TPPs in the United States and its territories." Thus, the stipulation itself does not seem to limit MSPRC from serving as a class representative for other TPPs besides

the reasons set forth above, the TPPs also have standing to assert claims against the Manufacturer Defendants and the Wholesaler Defendants under the laws of states where the TPPs are not located and were not injured.[11] At the class certification stage, however, the TPPs will need to establish the absence of a conflict between the laws of the states where they are located or where injured and the laws of states for which there is no named class representative.[12]

B. Warranty Claims (MTD Opinion #3)

1. Express Warranty Claims[13]

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those in New York, Connecticut, and Ohio.

[11] In rejecting the argument that indirect purchaser plaintiffs lacked standing to bring state law claims under the laws of a state in which a named plaintiff did not reside, the court in *In re Liquid Aluminum Sulfate Antitrust Litig*., CV 16-MD-2687 (JLL), 2017 WL 3131977, at *19 (D.N.J. July 20, 2017), explained:

> [T]he United States Supreme Court has made it clear that District Courts should defer addressing standing questions concerning putative class members who are not named until after class certification when certification of the class is "logically antecedent" to the issue of standing. *See Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 612 (1997). It is true that class certification here is "logically antecedent" to the issue of standing. This is because class discovery will unveil the various members of the currently unknown class. . . . Upon such revelation, the Court will be able to ascertain whether each of the 33 state-based claims has a proper representative who resides in the subject states and if those claims may proceed….

[12] It does not appear that the TPP Plaintiffs have asserted any claims against the Pharmacy Defendants.

[13] The Manufacturer Defendants do not challenge Plaintiffs' motion for leave to amend the Master Complaints with respect to express warranty claims.

MTD Opinion #3 (ECF No. 775) concluded that the Master Complaints did not allege "*specific* statements, conduct, or communications made by Wholesalers and Pharmacies, which could reasonably imply these defendants made an express warranty to plaintiffs that formed the basis of a bargain," the *sine qua non* of an express warranty claim.[14] (*Id.* at 16.) The Court explained that "the mere act of selling a contaminated product by a downstream entity lacking an obligation to comply with the Orange Book formulation cannot create a bridging argument that translates the sale into an express warranty made by Wholesalers and Pharmacies."[15] (*Id.*)

a. The Pharmacy Defendants

The proposed Amended Master Complaints seek to cure the deficiency of the

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[14] Section 313 of Article 2 of the Uniform Commercial Code provides:

> (1) Express warranties by the seller are created as follows:
> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

[15] The "Orange Book" is the shorthand reference for the publication titled, "Approved Drug Products with Therapeutic Equivalence Evaluations." The Orange Book "identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information." *Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book*, U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book (last visited October 6, 2021).

original Master Complaints vis a vis the Pharmacy Defendants by relying upon the general allegation in the original complaints that "each Retail Pharmacy Defendant warrants that the generic drugs for which they receive payments . . . are the same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics. More generally, Retail Pharmacy Defendants warrant that prescription drugs they sell are of a standard quality." (PELMC (ECF No. 1382-5) ¶ 463.) This averment, found insufficient to support an express warranty claim against the Pharmacy Defendants, is not made sufficient by allegations pertaining to individual Pharmacy Defendants, such as Defendant "CVS has represented and warranted that it sells drugs manufactured in accordance with quality standards" (*id.* ¶ 557); Defendant "Walgreens claims it aims to do 'business fairly and with integrity' which has led Walgreens to 'drive responsible sourcing practices throughout our supply chain, protecting human rights and engaging with suppliers around ethical and environmental issues'" (*id.* ¶ 568); or Ride-Aid states that "its mission is to 'improve the health and wellness of our communities through engaging in experiences that provide our customers with the best products, services and advice to meet their unique needs.'" (*Id.* ¶ 578.) These allegations do not constitute the requisite "*specific* statements, conduct, or communications . . . which could reasonably imply these defendants made an express warranty to plaintiffs that formed the basis of a bargain." (ECF No. 775 at 16.) Accordingly, Plaintiffs' Motion for Leave to Amend the Master Complaints to assert breach of express warranty claims against the Pharmacy Defendants (PELMC Count 1; PMMMC Count 7; and PPIMC Count 6)

will be denied.

b. The Wholesaler Defendants

Similarly, the proposed Amended Master Complaints do not allege a viable basis for an express warranty claim against the Wholesaler Defendants. Plaintiffs baldly assert that they are third-party beneficiaries of certain agreements between Wholesaler Defendants that "provide warranties pertaining to the VCDs' non-adulterated and FDCA-compliant status," (ECF No. 1382 at 24), but nowhere do they explain how that supposed third party beneficiary status translates into an express warranty being made to the Plaintiffs or became the basis of the bargain for the purchase of VCDs. Nor have Plaintiffs cited any authority in support of this claim.

Plaintiffs also contend that "electronic records or manifests" that accompany "totes" in which VCDs are shipped from Wholesalers constitute express warranties that the "totes" contain a certain product. Once again, however, no authority is cited to support a claim that the Wholesaler Defendants made an express warranty to any plaintiff, and the Court has already ruled that the mere sale of a VCD does not support an express warranty claim. There must be something more to support an inference that a defendant made a warranty that became part of the basis of the bargain. That something more is lacking here with respect to the express warranty claims against the Wholesaler Defendants. Accordingly, leave to amend the Master Complaints to assert express warranty claims against the Wholesaler Defendants will be denied.

2. Implied Warranty Claims

a. The Manufacturer Defendants, the Wholesaler Defendants,

and the PPIMC

MTD Opinion #3 (ECF No. 775) and its accompanying Order dismissed, without prejudice, Plaintiffs' implied warranty claims against the Manufacturer Defendants and the Wholesaler Defendants in the PIMC asserted under the laws of Wisconsin and Kentucky, finding that Plaintiffs had failed to allege privity as required by the law of those jurisdictions. Plaintiffs have withdrawn their implied warranty claims under Wisconsin law in the PIMC, but assert that the law in Kentucky on the privity requirement is too unsettled to permit dismissal of their implied warranty claims under Kentucky law at this time. In support of this argument, Plaintiffs rely upon the fact that a 1998 Kentucky Supreme Court opinion stated that "privity is not a prerequisite to the maintenance of an action for breach of an implied warranty in products liability actions." *Griffin Indus., Inc. v. Jones*, 975 S.W.2d 100, 102 (Ky. 1998). As Plaintiffs acknowledge, however, the Kentucky Supreme Court later held that this pronouncement was based upon an erroneous reading of earlier Kentucky Supreme Court precedent, and that there is "*no doubt* that privity remains a prerequisite for products liability claims based on warranty" under Kentucky law. *Compex Int'l. Co., Ltd. v. Taylor*, 209 S.W.3d 462, 464 (Ky. 2006), as modified on denial of rehearing (January 25, 2007). Given the definitiveness of this assertion, Plaintiffs' argument that "the common law on this issue in Kentucky is still ambiguous," (Plaintiffs' Reply Brief (ECF No. 1382) at 28), is without merit. *See Simpson v. Champion Petfoods USA, Inc.*, 397 F. Supp. 3d 952, 969 (E.D. Ky. 2019) ("*Compex* is the last word from the Kentucky Supreme Court on the issue of privity in implied warranty claims. In *Compex*, the

Kentucky Supreme Court was clear that privity is a strict requirement for implied warranty claims."); *Hurst v. Dixie Truss, Inc.*, 2020-CA-0816-MR, 2021 WL 1826881, at *4 (Ky. App. May 7, 2021) (same). Accordingly, Plaintiffs' motion for leave to amend the PIMC to assert a claim for breach of implied warranty against the Manufacturer and Wholesaler Defendants under Kentucky law will be denied.

b. The Manufacturer Defendants and the PELMC and PMMMC

MTD Opinion #3 (ECF No. 775) concluded that privity was a required element for economic loss and medical monitoring claims under the laws of Alabama, Arizona, Idaho, Iowa, Kansas, Kentucky, Michigan, North Carolina, Ohio, Oregon, Tennessee, Utah, and Wisconsin,[16] and that the ELMC and MMMC failed to allege the existence of privity between Plaintiffs and the Manufacturing Defendants. In seeking leave to amend the ELMC and MMMC to assert implied warranty claims against the Manufacturer Defendants, Plaintiffs argue that "privity is viewed as a question of fact that is ill-suited for resolution at the motion to dismiss or motion for leave to amend stage." (Plaintiffs' Reply Brief (ECF No. 1382) at 27.) That privity is a question of fact, however, does not relieve Plaintiffs of the obligation to allege a plausible basis for concluding that privity between a Manufacturer Defendant and Plaintiffs exists. *See, e.g., Cummings v. FCA US LLC*, 401 F. Supp. 3d 288, 313 (N.D.N.Y. 2019); *Glauberzon v. Pella Corp.*, CIV.A. 10-5929 JLL, 2011 WL 1337509, at *7 (D.N.J. Apr.

[16] As noted above, Plaintiffs have removed from the proposed Amended Master Complaints any claim for breach of implied warranty under Wisconsin law.

7, 2011) ("Plaintiffs have failed to nudge their implied warranty claims, and in particular, their theory of privity, 'across the line from conceivable to plausible.'") (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 547 (2007)).

Plaintiffs also argue that third-party beneficiary status suffices to dispense with privity under the laws of Alabama, Idaho, North Carolina, and Ohio. Accepting that to be the case, Plaintiffs have failed to allege facts plausibly suggesting that they are third-party beneficiaries of any agreements between the Manufacturer Defendants and any other party with respect to the sale of VCDs. Conclusory averments that Plaintiffs are "intended third-party beneficiaries," such as appear at ¶¶ 149, 237, 655-56, and 672 of the PELMC; ¶¶ 95 and 653 of the PPIMC; and ¶¶ 190 and 647-8 of the PMMMC, are not sufficient to present a plausible claim of such status. *See Atlas Commun. Tech., Inc. v. DXC Tech. Servs., LLC,* 319CV19033BRMDEA, 2020 WL 5105197, at *3 (D.N.J. Aug. 31, 2020) ("Atlas alleges they are a third-party beneficiary of a written contract between Citibank and DXC. . . . Citibank, however, contends this conclusory statement is insufficient to state a claim for a third-party beneficiary breach of contract claim. The Court agrees."); *Dixon v. Ford Motor Co.*, 14-CV-6135 JMA ARL, 2015 WL 6437612, at *4-5 (E.D.N.Y. Sept. 30, 2015) (plaintiff failed to present a plausible third-party beneficiary status where no contractual provisions between the manufacturer and the seller indicating third-party beneficiary status was alleged). Accordingly, Plaintiffs will be denied leave to amend to assert claims for breach of implied warranties against the Manufacturer Defendants under the laws of Alabama, Idaho, North Carolina, and Ohio.

Plaintiffs contend that Arizona, Kansas, Tennessee, and Utah do not require privity to present the non-personal injury claims presented in the PELMC and PMMMC. As to Kansas, Plaintiffs rely upon the statement that privity is required only where the allegedly defective product is inherently dangerous to assert that Kansas law would allow pursuit of claims for "only economic loss suffered by a buyer who is not in contractual privity with the remote seller or manufacturer." *Prof'l Lens Plan, Inc. v. Polaris Leasing Corp.*, 675 P.2d 887, 898–99 (Kan. 1984). Plaintiffs contend that the contaminated VCDs are inherently dangerous so that they should be able to maintain their claims in the PELMC and PMMMC under Kansas law. The Manufacturer Defendants have not responded to this argument, and so Plaintiffs will be granted leave to assert implied warranty claims under the law of Kansas in their PELMC and PMMMC.

The Manufacturer Defendants also do not address the question of whether Iowa requires privity to present an implied warranty claim. In this regard, it appears that Iowa has "abolishe[d] privity as a defense when a defective product causes 'personal injury or property damage'—as opposed to merely causing 'economic loss'…." *Klingenberg v. Vulcan Ladder USA, LLC*, 15-CV-4012-KEM, 2018 WL 1248007, at *12 (N.D. Iowa Mar. 9, 2018), *aff'd*, 936 F.3d 824 (8th Cir. 2019). Plaintiffs will thus be granted leave to amend the ELMC and MMMC to assert implied warranty claims under Iowa law.

In *Pack v. Damon Corp.*, 434 F.3d 810, 820 (6th Cir. 2006), the Sixth Circuit declared that "Michigan has abandoned the privity requirement for implied-warranty

claims...." The Manufacturer Defendants do not address the issue of whether Michigan law requires privity for an implied warranty claim. Accordingly, Plaintiffs will be granted leave to amend the ELMC and MMMC to assert implied warranty claims under Michigan law.

Citing *Turnage v. Oldham*, 346 F. Supp. 3d 1141, 1157 (W.D. Tenn. 2018), Plaintiffs contend that privity is not required "[i]n all causes of action for personal injury or property damage brought on account of negligence, strict liability or breach of warranty, including actions brought under the provisions of the Uniform Commercial Code...." But *Turnage* also recognized that privity is required when the plaintiff seeks recovery for "purely economic harm." *Id.* The PELMC and PMMMC appear to seek recovery for "purely economic harm." Plaintiffs have also failed to show that Arizona does not require privity to assert breach of implied warranty claims to recover for economic harm. Accordingly, Plaintiffs will be denied leave to amend those Master Complaints to assert claims under Arizona and Tennessee law for breach of implied warranty against the Manufacturer Defendants.

Finally, Plaintiffs contend that the law of Utah does not mandate privity to assert breach of implied warranty claims. *See Stembridge v. Nat'l Feeds Inc.*, 1:11CV49DAK, 2013 WL 5347455, at *6 (D. Utah Sept. 23, 2013). The Manufacturer Defendants have not refuted this contention. Accordingly, Plaintiffs will be granted leave to amend the PELMC and PMMMC to assert claims under Utah law for breach of implied warranty against the Manufacturer Defendants.

In summary, Plaintiffs will be denied leave to amend the PELMC and PMMMC

to assert claims for breach of implied warranties against the Manufacturer Defendants under the laws of Alabama, Arizona, Idaho, Kentucky, North Carolina, Ohio, Oregon, and Tennessee. Plaintiffs will be granted leave to amend the PELMC and PMMMC to assert claims for breach of implied warranties against the Manufacturer Defendants under the laws of the remaining states, including Iowa, Kansas, Michigan, and Utah, as well as the District of Columbia and Puerto Rico.

c. The Wholesaler Defendants and the PELMC and PMMMC

As to the Wholesaler Defendants, MTD Opinion #3 concluded:

> case law in Arizona, Connecticut, Georgia, Idaho, Illinois, Iowa, Kansas, Kentucky, Michigan, New York, Oregon, Tennessee, Utah, Vermont, and Wisconsin requires pleading privity based on a third party benefici theory between the manufacturer and a downstream dealer or intermediary. The Court finds plaintiffs have not pleaded this required element in the ELMC and the MMMC for claims of breach of implied warranty in these states against the Wholesalers.

(ECF No. 775 at 22.) In seeking leave to amend the ELMC and MMMC to assert implied warranty claims against the Wholesaler Defendants under the laws of the states listed above, Plaintiffs assert that "[t]he same reasoning applies as to why Plaintiffs have properly alleged breach of implied warranty claims against the Manufacturer Defendants as to the Wholesaler Defendants." (ECF No. 1382 at 31-32.) Plaintiffs have been granted leave to amend the ELMC and MMMC to assert claims for breach of implied warranties against the Manufacturer Defendants under the laws of Iowa, Kansas, Michigan, and Utah, and by similar reasoning will be granted leave to amend the ELMC and MMMC to assert claims for breach of implied warranties against the Wholesaler Defendants under the laws of those four states. As

to Arizona, Connecticut, Georgia, Idaho, Illinois, Kentucky, New York, Oregon, Tennessee, Vermont, and Wisconsin, however, Plaintiffs have failed to show that the original determination that Plaintiffs are unable to maintain breach of implied warranty claims against Wholesaler Defendants under the laws of those states was erroneous. Indeed, cases cited by Plaintiffs, such as *Kahn v. Volkswagen of Am., Inc.*, 2008 WL 590469, at *8 (Conn. Super. Ct. Feb. 13, 2008), confirm the conclusion that Plaintiffs have not pleaded viable breach of implied warranty claims for economic loss and medical monitoring against the Wholesaler Defendants in those states.[17] Accordingly, Plaintiffs will be denied leave to amend the ELMC and MMMC to assert breach of implied warranty claims against the Wholesaler Defendants under the laws of Arizona, Connecticut, Georgia, Idaho, Illinois, Kentucky, New York, Oregon, Tennessee, Vermont, and Wisconsin.

d. Implied Warranty Claims against the Pharmacy Defendants in All Three Master Complaints[18]

[17] It bears noting that this determination is based upon the fact that the economic loss and medical monitoring claims do not involve recovery of personal injury damages. Some of the states listed above do dispense of the privity requirement in personal injury actions. *See, e.g., Bristol Vill., Inc. v. Louisiana-Pac. Corp.*, 916 F. Supp. 2d 357, 363 (W.D.N.Y. 2013) ("under New York law, [a] claim based upon a breach of an implied warranty requires a showing of privity between the manufacturer and the plaintiff when there is no claim for personal injuries") (internal quotation marks and citations omitted); *Wheeler v. Sunbelt Tool Co.*, 537 N.E.2d 1332, 1340 (Ill. App. Ct. 4th Dist. 1989) (under Illinois law, "privity was not required when a buyer who has sustained personal injuries predicates recovery against a remote manufacturer for a breach of implied warranty").

[18] MTD Opinion #3 did not address separately the viability of breach of implied warranty claims against the Pharmacy Defendants for personal injury, economic loss, and medical monitoring, and this decision also will not attempt to determine whether

After surveying the case law, MTD Opinion #3 (ECF No. 775) granted the Pharmacy Defendants' motion to dismiss the breach of implied warranty claims asserted against them under the laws of Alabama, Arizona, Arkansas, California, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Pennsylvania, Puerto Rico, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin. Undaunted, Plaintiffs have asserted breach of implied warranty claims against the Pharmacy Defendants in each of the proposed Amended Master Complaints. Plaintiffs argue that privity is inapplicable with respect to the claims against the Pharmacy Defendants because the VCDs were sold by the Pharmacy Defendants to consumer plaintiffs. The dismissal of the implied warranty claims, however, was not based on privity concerns. Instead, dismissal was based on an analysis of the cases cited in Exhibit 2 to the Pharmacy Defendants' Brief in Support of their Motion to Dismiss the Master Complaints (ECF No. 523-3) and Plaintiffs' failure to refute the accuracy of the case law cited therein. (ECF No. 775 at 23.) Plaintiffs have not pointed to any averments in the proposed Amended Master Complaints that affect the Court's original conclusion with respect to the implied

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an implied warranty claim against the Pharmacy Defendants may be viable for personal injury claims but not for economic claims, and so on.

warranty claims against the Pharmacy Defendants under the laws of the 35 listed states, the District of Columbia and Puerto Rico.

The Pharmacy Defendants observe that MTD Opinion #3 did not issue a ruling as to the viability of breach of implied warranty claims against the Pharmacy Defendants under the laws of Connecticut, Indiana, Nebraska, Oklahoma, Utah and Wyoming. (ECF No. 1280 at 45.) The Pharmacy Defendants assert that Plaintiffs cannot maintain a breach of implied warranty claim against the Pharmacy Defendants under Connecticut law, and Plaintiffs do not dispute that assertion. Plaintiffs do contest the Pharmacy Defendants' contention that breach of implied warranty claims cannot be maintained against them under the laws of Oklahoma and Utah. The Pharmacy Defendants have not cited any controlling authority that rejected pharmacy liability in the context presented here. Accordingly, Plaintiffs will be granted leave to assert implied warranty claims against the Pharmacy Defendants under the laws of Oklahoma and Utah. The Pharmacy Defendants note that Plaintiffs could state a claim for breach of implied warranty under the laws of Indiana, Nebraska, and Wyoming, so Plaintiffs will be granted leave to file Amended Master Complaints for breach of implied warranty against the Pharmacy Defendants under the laws of those jurisdictions.

In summary, Plaintiffs will be denied leave to amend the Master Complaints to assert breach of implied warranty claims against the Pharmacy Defendants under the laws of Alabama, Arizona, Arkansas, California, Connecticut, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Iowa, Kansas, Kentucky, Louisiana,

Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Pennsylvania, Puerto Rico, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin. Plaintiffs will be granted leave to assert implied warranty claims against the Pharmacy Defendants under the laws of Alaska, Colorado, Delaware, Idaho, Indiana, Montana, Nebraska, Nevada, Oklahoma, Oregon, Rhode Island, South Dakota, Utah, and Wyoming.

C. Fraud-Based Claims (MTD Opinion #4)

MTD Opinion #4 (ECF No. 818) and its accompanying order (ECF No. 819) addressed challenges to Plaintiffs' fraud-based claims (fraudulent misrepresentation; fraudulent concealment; fraud by omission; state consumer protection statutes sounding in fraud; and negligent misrepresentation).[19] As to the Manufacturer Defendants, MTD Opinion #4 concluded that the Master Complaints adequately alleged the fraud-based claims and denied the request of the Manufacturer Defendants to dismiss those claims against them. As to the Pharmacy and Wholesaler Defendants, however, MTD Opinion #4 concluded that (1) the master complaints failed to satisfy the particularity requirement of Fed. R. Civ. P. 9(b) in that "the allegations lump all of the defendants together"; (2) Plaintiffs failed to specify the

[19] MTD Opinion #4 also addressed challenges to strict liability claims asserted in the PIMC and MMMC. (ECF No. 818 at 22-28.) (The ELMC did not include any strict liability claims.) The accompanying MTD Order #4 either granted with prejudice some aspects of the motions to dismiss the strict liability claims or denied the motions as to the strict liability claims against the master complaints.

time, place, and content of the purportedly fraudulent statements; and (3) the conclusory allegations of knowledge of falsity were "insufficient to satisfy the strictures of Rule 8." (ECF No. 818 at 20.) MTD Opinion #4 also found that the fraud-based claims against the Wholesaler Defendants in the MMMC were insufficient because Plaintiffs had not alleged reliance with the requisite particularity. As a result, the fraud-based claims against the Wholesaler and Pharmacy Defendants were dismissed, but without prejudice, and Plaintiffs were granted leave to amend those claims.

In seeking leave to amend the Master Complaints to present fraud-based claims, Plaintiffs rely upon the following averment:

> Defendants affirmatively misrepresented material facts . . . that their VCDs were therapeutically equivalent to their RLDs and/or complied with cGMPs and/or were not adulterated and/or misbranded, contaminated, adulterated and/or misbranded. These misrepresentations were present on, among other things, the patient package inserts, medication guides, instructions for use, and the transaction data produced by the Wholesaler Defendants and the API and Finished Dose Manufacturer Defendants. . . . Defendants further misrepresented material facts by lauding their safety and risk mitigation approaches on their websites, brochures, and other marketing or informational materials.

(PMMMC ¶599; PELMC ¶682; PPIMC ¶755.)

This averment is sufficient to give notice to the individual Pharmacy and Wholesaler Defendants of the "who, what, where, and when" of the purportedly actionable fraudulent statements. The "who" is each Defendant. The "what" is the representations that the VCDs were manufactured in compliance with cGMPs and

were therapeutically equivalent to their reference listed drugs ("RLDs").[20] The "where" and "when" are the materials that accompanied the sales of the VCDs. Although the proposed Amended Master Complaints continue to "lump" all Defendants together, Plaintiffs do adequately describe each Defendant's role so as to give fair notice to each Wholesaler and Pharmacy Defendant of the fraud-based claims being asserted.

Plaintiffs point out that some of their state consumer protection statutory claims asserted in the PPIMC and PELMC may not require allegations of fraudulent conduct or reliance, but may only require deceptive or unfair conduct and resultant damages. As Plaintiffs have pled the who, what, when, and where of the allegedly actionable conduct and Defendants have not challenged the viability of Plaintiffs' claims under particular consumer protection statutes, Plaintiffs will be granted leave to amend the PPIMC and PELMC to assert claims under those statutes. (PPIMC, Count X; PELMC, Ninth and Tenth Causes of Action.)

The proposed amended complaints, however, have not cured the original complaints' failings with respect to the Wholesaler and Pharmacy Defendants' asserted knowledge of the falsity of their representations concerning cGMP compliance, etc. In dismissing the fraud-based claims against the Wholesaler and Pharmacy Defendants, the Court observed, the "conclusory allegation that the

[20] A reference listed drug is an FDA "approved drug product to which new generic versions are compared to show bioequivalence." *Reference Listed Drug*, THE FREE DICTIONARY BY FARLEX, https://medical-dictionary.thefreedictionary.com/RLD (last visited October 6, 2021)

Wholesaler and Pharmacy Defendants 'knew or should have known based on information provided or available from each manufacturer or Wholesaler defendant, of the actual or potential adulteration, misbranding, or contamination of VCDs they purchased from Manufacturing Defendants' is insufficient to satisfy the strictures of Rule 8." The PPIMC, PELMC, AND PMMMC continue to rely upon such a conclusory averment. *See, e.g.*, PPIMC ¶394; PELMC ¶715; PMMMC ¶471. In particular, there are no allegations from which knowledge of falsity may be inferred as at least plausible. *See DeFrank v. Samsung Elecs. Am., Inc.*, CV1921401KMJBC, 2020 WL 6269277, at *6 (D.N.J. Oct. 26, 2020) ("For allegations regarding mental state, . . . a plaintiff need only plead mental state allegations with sufficient factual content to render them plausible.") (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 686-87 (2009)). Accordingly, Plaintiffs will be denied leave to amend the Master Complaints to present their fraud-based claims against the Pharmacy and Wholesaler Defendants in the Fifth through Eighth Causes of Action in the PELMC; the Third and Eighth Claims for Relief in the PMMMC; and Counts VIII and IX in the PPIMC.

D. Claims Subsumed by State Products Liability Acts (MTD Opinion #5.)

1. Common law claims in general

Among the issues addressed in MTD Opinion #5 (ECF No. 838) was whether certain claims, such as negligence claims, were subsumed by the Products Liability Acts (PLAs) of states that have enacted such legislation. The Opinion addressed the

issue for each of the three Master Complaints and for each of the three categories of Defendants under the laws of the states that had in place a PLA. Plaintiffs' proposed Amended Master Complaints have once again prompted disputes concerning whether certain claims against certain Defendants remain viable.

The Manufacturer Defendants argue that, although subsumed claims have been omitted from the PPIMC, the PELMC "simply adds alternative Louisiana PLA allegations to each count," and the PMMMC "seeks to add a new shotgun count . . . purporting to assert claims under nine states' PLAs '[t]o the extent any claims above are subsumed[.]'" (ECF No. 1451 at 14.) The Wholesaler Defendants similarly assert that the PMMMC and PELMC fail to omit the subsumed claims, but "simply add new claims on top of futile, subsumed claims." (ECF No. 1454 at 17-18.)

MTD Opinion #5 went to great pains to identify the subsumed claims in the ELMC and MMMC, dismissing the subsumed claims with prejudice. For example, as to claims asserted under the law of Connecticut in the MMMC, the Court ruled that "all claims are subsumed by the Connecticut Products Liability Act," (ECF No. 839 at 2), and dismissed the subsumed claims with prejudice. Plaintiffs cannot re-assert such dismissed claims and will be required to submit amended ELMC and MMMC that omit the claims that have been dismissed with prejudice.[21]

2. Medical Monitoring Claims

[21] It should be noted that the Court generally found that state PLAs did not subsume claims presented in the ELMC, but did subsume those claims asserted in the MMMC.

MTD Opinion #5 concluded that some states, while not recognizing an independent cause of action for medical monitoring, did "allow a plaintiff under certain circumstances to recover damages for medical monitoring premised on another tort." (ECF No. 838 at 33.) Accordingly, the Court granted, without prejudice, Defendants' motions to dismiss the independent claims for medical monitoring under the laws of states that disallowed a separate medical monitoring cause of action but granted Plaintiffs leave to seek "recovery for medical monitoring in concert with any other claim in accordance with the law of those jurisdictions." (*Id.*)

Defendants argue that the PLAs of nine states either exclude medical monitoring claims or require physical harm as a condition for medical monitoring claims.[22] Of those states, only Mississippi categorically rejects medical monitoring claims in the absence of an "injury [that] is medically cognizable and treatable." *Paz v. Brush Engineered Materials, Inc.*, 949 So. 2d 1, 4 (Miss. 2007). Some of the other states appear to recognize claims for medical monitoring based upon something as nebulous as a "lump in the throat" following radiation exposure. *See, e.g., Spring v. Shell Oil Co.*, CV 17-1754-JWD-RLB, 2018 WL 1914293, at *6-7 (M.D. La. April 23, 2018). And as to other states, Defendants' argument is based upon broad definitions of cognizable claims in the PLAs that do not explicitly include medical monitoring claims. *See, e.g.* Kan. Stat. Ann. § 60-3302(d) ("'Harm' includes: (1)

[22] The nine states are Connecticut, Indiana, Kansas, Louisiana, Mississippi, New Jersey, Ohio, Tennessee, and Washington.

Damage to property; (2) personal physical injuries, illness and death; (3) mental anguish or emotional harm attendant to such personal physical injuries, illness or death.") But such broad definitions of harm do not exclude cellular or even subcellular injury, and it would not be prudent to bar medical monitoring claims at this juncture of the case in the absence of definitive controlling authority from a particular state. Accordingly, Plaintiffs will be granted leave to amend the MMMC with respect to the Manufacturer and Wholesaler Defendants as they have proposed with the exception of their proposed claim under Mississippi law.

The Pharmacy Defendants assert that, except as to Illinois law, Plaintiffs cannot assert independent medical monitoring claims against them. Plaintiffs, however, insist that they can pursue medical monitoring relief from the Pharmacy Defendants under the laws of California, Florida, Kansas, Maryland and Texas, as well as Illinois.

Florida evidently recognizes an independent cause of action for medical monitoring based upon a defendant's negligence. *See Petito v. A.H. Robins Co., Inc.*, 750 So. 2d 103, 106 (Fla. 3d Dist. App. 1999). The Pharmacy Defendants argue that Plaintiffs have not presented a viable claim for negligence against them, but that decision is better suited for a summary judgment determination.

As to Kansas law, the Pharmacy Defendants do not contest the existence of a cause of action for medical monitoring, arguing instead that Plaintiffs failed to initially plead a medical monitoring claim under the Kansas PLA and are thus foreclosed from pursuing one now. The failure to plead a medical monitoring claim under the Kansas PLA has nothing to do with whether such a claim is futile. The

Pharmacy Defendants do not claim prejudice as a result of the failure to include this claim in the original MMMC. Accordingly, Plaintiffs will be granted leave to include a medical monitoring claim under the Kansas PLA.

As to claims for medical monitoring-type "relief" (as opposed to a separate cause of action), there appears to be no dispute that Plaintiffs may seek medical monitoring as a remedy under the laws of California, Maryland and Texas. Accordingly, Plaintiffs will be granted leave to amend to seek such relief from the Pharmacy Defendants under the law of those states in concert with any other viable claim.

E. Negligence Claims against the Wholesaler and Pharmacy Defendants (MTD Opinion #5)

MTD Opinion #5 found that the Master Complaints failed to present viable negligence claims against both the Wholesaler as well as the Pharmacy Defendants because Plaintiffs had "fail[ed] to separate the alleged negligent conduct of the Wholesaler Defendants from that of the Pharmacy Defendants," and had "fail[ed] to precisely articulate the duty that the Pharmacy Defendants and the Wholesaler Defendants owed to Plaintiffs and the specific breach that occurred." (ECF No. 838 at 32.) Plaintiffs were given leave to amend to cure the pleading deficiencies.

The Wholesaler and Pharmacy Defendants insist that Plaintiffs proposed Amended Master Complaints still fail to present plausible negligence claims against them. A careful review of the proposed Amended Master Complaints confirms the defense assertions. As to each Wholesaler Defendant, Plaintiffs alleged that they had

a duty to comply with Good Distribution Practices ("GDPs") that included periodic risk assessments concerning the quality and integrity of pharmaceutical products, (*e.g.*, PELMC ¶ 498), but Plaintiffs cite no authority for the proposition that distributors of pharmaceuticals owe a duty to verify the integrity of a drug manufacturer's product. The proposed Amended Master Complaints state that each Wholesaler Defendant "knew or should have known that Manufacturer Defendants utilized different manufacturing and quality practices or controls than those used by the brand-reference drug manufacturer, on account of the public availability of the regulatory submissions on file with the FDA, the information available . . . upon request to each Defendant Manufacturer pursuant to the contracts, the information available . . . upon request to manufacturers of Diovan or other valsartan, and the price differential between Manufacturer Defendants' VCDs and other properly made, non-adulterated, or non-misbranded valsartan." (PELMC ¶ 535.) Allegations such as these, however, are insufficient to give each Wholesaler Defendant fair notice of a non-conclusory and plausible claim of negligence. Notably absent from the proposed Amended Master Complaints is an allegation that any Wholesaler Defendant knew of the nitrosamine contamination and failed to take reasonable steps in response to such knowledge. And notably absent from Plaintiffs' briefs is the citation to any authority holding that a wholesaler's duty of care extends to testing the integrity of the manufacturer's products.

These deficiencies are even more pronounced with respect to the negligence claims asserted against the Pharmacy Defendants. Citing *Arrington v. Walgreen Co.*,

664 F. Supp. 2d 1230, 1233 (M.D. Fla. 2009), Plaintiffs argue that pharmacies "have a duty to use due and proper care in filling prescriptions and selling products to the public."[23] (ECF No. 1382 at 39.) But Plaintiffs fail to cite any case for the proposition that the duty to use due care in filling prescriptions extends to assuring the integrity of the manufacturer's product. As observed in *Walton v. Bayer Corp*., 643 F.3d 994, 1000 (7th Cir. 2011), "[i]t would be senseless, especially given drug regulation by the Food and Drug Administration and the extensive tort liability of drug manufacturers, to make pharmacies liable in tort for the consequences of failing to investigate the safety of thousands of drugs." In *In re Zantac (Ranitidine) Products Liab. Litig.*, 20-MD-2924, 2021 WL 2685605, at *10 (S.D. Fla. June 30, 2021), the court dismissed, with prejudice, negligence claims arising from NDMA contamination of prescription and over-the-counter Zantac against wholesaler and retailer defendants based upon a general allegation that adulteration of the drug occurred due to increased heat during shipment of the drug by common carrier. The court's analysis is instructive here:

> The Plaintiffs have elected not to base their negligence claim on any concrete act of negligence, such as an overheated warehouse in South Florida or, as was discussed at the prior motion to dismiss hearing, a "hot [delivery] truck in the Arizona desert." Instead, the Plaintiffs' negligence claim rests upon the decision of the Defendants to, from

[23] *Arrington* involved an allegation that the pharmacy "knew that [the patient] was allergic to sulfa-based drugs and filled her prescription for such a drug without warning her or double-checking with her physician . . . ." *Id.* By way of contrast, there is no allegation here that any Pharmacy Defendant filled a prescription for valsartan knowing of the nitrosamine contamination, and Plaintiffs' conclusory assertion that Pharmacy Defendants should have known of the likelihood of such contamination is devoid of any allegation of supporting fact.

> time to time, utilize the services of common carriers to deliver room-temperature drugs. It would be no small act for this Court to conclude that the decision to utilize common carriers to ship room-temperature drugs—and nothing else—plausibly stated a claim for negligence.

Id. at *9 (internal citations omitted). *Accord Winters v. Alza Corp*., 690 F. Supp. 2d 350, 356 (S.D.N.Y. 2010) ("The plaintiff here does not allege that the pharmacist failed to follow the doctor's prescription or the manufacturer's prescribing information, and he concedes that the drug dispensed to the decedent was FDA-approved. Under these circumstances, we see no valid reason for finding that the [pharmacy] could be negligent for inadequately second-guessing the FDA."). In this matter, Plaintiffs have not provided a single allegation of fact that any Pharmacy Defendant had knowledge of nitrosamine contamination so as to trigger an obligation on its part that extended beyond filling a physician's prescription in a competent manner.[24] Accordingly, Plaintiffs' motion for leave to file Amended Master Complaints asserting negligence claims against the Pharmacy and Wholesaler Defendants will be denied.[25]

F. Unjust enrichment claims in the PELMC against all Defendants (MTD Opinion #6)

[24] The fact that one retailer, Valisure, apparently tests drugs it receives from pharmaceutical manufacturers, *see* PPIMC, ECF No. 1382-1, ¶526, is not sufficient to establish a standard of care, let alone a duty of care. *See Morello v. Kenco Toyota Lift*, 142 F. Supp. 3d 378, 383 (E.D. Pa. 2015) (industry standards have no bearing on whether a duty of due care is owed).

[25] Although the initial iterations of the amended master complaints included negligence per se claims, Plaintiffs conceded that negligence per se claims under the laws of Arkansas, Arizona, California, Maine, Massachusetts, Nebraska, Rhode Island, and Texas were not viable and omitted such claims from the PPIMC, PELMC, and the PMMMC.

Following a comprehensive review of the laws of the individual States, MTD Opinion #6 dismissed, without prejudice, Plaintiffs' unjust enrichment claims under the laws of Florida, Iowa, Kansas, and Louisiana on the basis that these states require pleading the absence of an adequate remedy at law, and the ELMC failed to do so. (ECF No. 1019 at 41.) MTD Opinion #6 also dismissed, without prejudice, the unjust enrichment claims under the laws of Alabama, Hawaii, Idaho, Illinois, Massachusetts, Mississippi, Oklahoma, South Carolina, and West Virginia, as well as under the laws of Florida and Louisiana, on the ground that these states affirmatively preclude an unjust enrichment claim when an adequate remedy at law exists. (*Id.*)

Plaintiffs proposed Eleventh and Twelfth Causes of Action in the PELMC purport to cure this pleading deficiency by summarily alleging that the unjust enrichment claim is presented in the alternative "in the event it is subsequently determined that no adequate remedy at law exists," PELMC (ECF No. 1382-4) ¶786, and by averring that "Plaintiffs an [sic] other Class Members do not have adequate remedy at law." (*Id.* ¶787.) Defendants argue that the conclusory averments are insufficient and request that leave to amend to assert unjust enrichment claims under the laws of these eleven states be denied.

The sufficiency of an allegation that no adequate remedy at law exists was considered in a similar context in *In re Processed Egg Products Antitrust Litig.*, 851 F. Supp. 2d 867 (E.D. Pa. 2012). Specifically, in that case Judge Pratter considered the sufficiency of the following allegation:

> The enrichment of Defendants that occurred because of Defendants' illegal activities was without legally cognizable justification. *To the extent legal remedies do not sufficiently accomplish disgorgement* of Defendants' illegal profits from their sales to indirect purchasers in Arizona, Defendants should be ordered to make restitution for the benefit of Arizona indirect purchasers because it would be unjust to allow Defendants to retain the benefits of their sales of eggs at illegally inflated prices.

Id. at 918 (emphasis in original). Judge Pratter concluded that this allegation was sufficient, stating:

> In light of Rule 8(d)(2)'s permissiveness of alternative pleading, given the [amended complaint's] italicized language above, and allowing for all inferences to be drawn in favor of Plaintiffs, the Court cannot rule as a matter of law that Plaintiffs have failed to plausibly suggest that there is an absence of an adequate remedy at law.

Id.

Whether an adequate remedy at law exists would seem to be a question of law, not dependent upon specific averments of fact. Thus, as in *Processed Egg Products*, a conclusory averment to that effect should suffice, especially given the prerogative of alternative pleading authorized by Fed. R. Civ. P. 8(d)(2).[26] Accordingly, Plaintiffs will be granted leave to amend the ELMC to assert the proposed Eleventh and Twelfth Causes of Action.

G. Other Claims at Issue on Plaintiffs' Motion

[26] Citing *Soule v. Hilton Worldwide, Inc.*, 1 F. Supp. 3d 1084, 1103 (D. Haw. 2014), the Manufacturer Defendants argue that pleading an unjust enrichment claim in all states is not allowed. (ECF No. 1451 at 13.) *Soule* was based upon a definitive finding that an unjust enrichment claim could not be pursued because "an express contract or agreement concerning the same subject matter existed between the parties," *id.* (citations omitted), a scenario that does not exist here.

1. PLA Claims against Pharmacy Defendants

The Pharmacy Defendants argue that the product liability acts of Kansas, Washington, Tennessee, Connecticut, Mississippi, Ohio and New Jersey effectively insulate them from product liability claims. The law of each of these states will be considered in turn.

a. Kansas

The Pharmacy Defendants contend that they are exempt from the reach of the Kansas PLA because the statutory definition of "product seller" found at Kan. Stat. Ann. § 60-3302 excludes a "health care provider" as defined in Kan. Stat. Ann. § 40-3401. Although the Kansas medical malpractice reform statute does define health care provider broadly, and specifically includes licensed pharmacists, it does not explicitly cover nationwide pharmacies like Rite Aid and Walgreens. Defendants have not cited any authority holding that these retailers are outside the reach of the Kansas PLA. The case on which the Pharmacy Defendants place principal reliance, *Luttrell v. Brannon*, No. 17-2137-JWL, 2018 WL 3032993 (D. Kan. June 19, 2018), did not involve a retail pharmacy. Absent a directly controlling authority, it would not be prudent to preclude claims against the Pharmacy Defendants under the Kansas PLA at this juncture of the litigation. Accordingly, Plaintiffs will be granted leave to present a claim against the Pharmacy Defendants under the Kansas PLA.

b. Washington

The Pharmacy Defendants also rely upon inapposite authority to claim that the Washington PLA, Wash. Rev. Code Ann. § 7.72.010, *et seq*., does not apply to them.

While the Washington law does expressly exempt licensed pharmacists, it says nothing about retail pharmacies. The case upon which the Pharmacy Defendants rely to urge denial of leave to amend to assert a claim against them under the Washington PLA, *Long v. Rite Aid H.Q. Corp.*, 8 Wash. App. 2d 1013, *review denied sub nom. Long v. Rite Aid Corp.*, 445 P.3d 560 (Wash. 2019), concerned application of the "learned intermediary" doctrine and did not involve a claim under the Washington PLA. Accordingly, Plaintiffs will be granted leave to assert claims against the Pharmacy Defendants under the Washington PLA.

c. The Ohio and New Jersey PLA

The Pharmacy Defendants contend that leave to amend to assert claims under the Ohio and New Jersey PLAs should be denied because they exclude "service providers." The Ohio statute concerns the liability of a product "supplier," which is defined to exclude "[a] provider of professional services who, incidental to a professional transaction the essence of which is the furnishing of judgment, skill, or services, sells or uses a product." Ohio Rev. Code Ann. § 2307.71. The New Jersey statute concerns the potential liability of a "product seller," which excludes "[a] provider of professional services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill or services." N.J. Stat. Ann. § 2A:58C-8. Plaintiffs argue that no exercise of professional judgment or skill is involved in filling Valsartan prescriptions. A determination of whether professional skill or judgment was exercised by any of the Pharmacy Defendants cannot be made at this stage of the

case. Accordingly, leave to amend to assert claims against the Pharmacy Defendants under the New Jersey and Ohio PLAs will be granted.

d. Tennessee

The Pharmacy Defendants argue that "claims against pharmacies may not be brought under the Tennessee PLA, because claims against pharmacies are governed by the Tennessee Health Care Provider Act." (ECF No. 1280 at 42.) In support of this argument, the Pharmacy Defendants cite Tenn. Code Ann. § 29-26-101; *Heaton v. Mathes*, No. E2019-00493-COA-R9-CV, 2020 WL 1652571, at *7-8 (Tenn. Ct. App. Apr. 3, 2020); and *In re New England Compounding Pharmacy, Inc. Prods. Liab. Litig.*, MDL No. 13-02419, 2016 WL 11045600, at *2 (D. Mass. Feb. 29, 2016). Neither the statute nor the case law, however, exempt retail pharmacies from the reach of the Tennessee PLA. The Tennessee Health Care Liability Act cited by the Pharmacy Defendants does include "pharmacy technicians" within the definition of "health care provider," Tenn. Code Ann. § 29-26-101, but does not explicitly cover retail pharmacies. *Heaton* did not address the question of whether the Tennessee PLA applied to retail pharmacies. The issue before the court in *New England Compounding Pharmacy* involved the question of whether the Tennessee PLA or the Tennessee Health Care Provide Act applied in the context of the injection of contaminated methylprednisolone acetate ("MPA"). Judge Zobel, while recognizing that either law could apply, concluded that the more specifically-applicable statute in the context presented there was the Tennessee Health Care Liability Act. 2016 WL 11045600, at *2. Judge Zobel' decision was made on summary judgment motions, a

procedural avenue that provides an appropriate factual context to make a determination as to which law should be applied in this case. Accordingly, Plaintiffs will be granted leave to amend to assert claims against the Pharmacy Defendants under the Tennessee PLA.

e. Mississippi

In arguing that Plaintiffs should be denied leave to amend to assert claims under the Mississippi PLA, Miss. Code. Ann. § 11-1-63, the Pharmacy Defendants rely upon *In re Rezulin Products Liab. Litig*., 133 F. Supp. 2d 272 (S.D.N.Y. 2001). That case held that Mississippi's learned intermediary doctrine precluded claims against pharmacies for failure to warn of the dangers of certain prescription drugs. *Id.* at 289-90. It did not address potential liability under the Mississippi PLA, and thus does not afford a basis for denying leave to amend to assert claims against the Pharmacy Defendants under the Mississippi PLA.[27]

2. Strict Liability Claims against Pharmacy Defendants (MTD Opinion No. 5)

MTD Opinion No. 5 dismissed, without prejudice, the strict liability claims in any of the Master Complaints asserted against the Pharmacy Defendants under the laws of all but Alaska; Colorado; Idaho; Kentucky; Minnesota; Missouri; Montana; Nebraska; Nevada; Oregon; Puerto Rico; Rhode Island; South Carolina; South Dakota; Texas; Vermont; Wisconsin; and Wyoming. (ECF No. 838 at 35.) MTD

[27] Plaintiffs have withdrawn their proposed claims against the Pharmacy Defendants under the Connecticut and Louisiana PLAs. (ECF No. 1382 at 66.)

Opinion No. 5 was silent as to North Dakota and was inconsistent as to Iowa, both granting and denying the Pharmacy Defendants' motion to dismiss the strict liability claims. (*Id.*) Plaintiffs contend that they can pursue strict liability failure to warn and design defect claims against the Pharmacy Defendants under the laws of those two jurisdictions, and the Pharmacy Defendants contest this assertion.

As to the strict liability claims against them under Iowa law, the Pharmacy Defendants rely upon *Merfeld v. Domestic Corp.*, 306 F. Supp. 3d 1070 (N.D. Iowa 2018). And as to North Dakota law, the Pharmacy Defendants rely upon *Bornsen v. Pragotrade, LLC*, 804 N.W.2d 55, 61 (N.D. 2011). Both cases involve application of innocent seller statutes. In MTD Opinion No. 5, the Court ruled that innocent seller defenses were not amenable to a ruling absent the development of a factual record. (ECF No. 818 at 27-28.) This ruling applies with equal force to the Iowa and North Dakota innocent seller defenses. Accordingly, Plaintiffs will be granted leave to amend the PIMC to assert strict liability design defect and failure to warn claims against the Pharmacy Defendants under Iowa and North Dakota law.

Plaintiffs' Reply Brief stated that strict liability failure to warn and design defect claims were asserted against the Pharmacy Defendants under the laws of Connecticut, Mississippi, Missouri, South Carolina, and Texas. The PPIMC, however, lists Mississippi, Missouri, South Carolina, and Texas as jurisdictions excepted from the strict liability failure to warn and design defect claims against the Pharmacy Defendants. Accordingly, Plaintiffs will be denied leave to amend the PIMC to assert strict liability claims against the Pharmacy Defendants under the laws

of Mississippi, Missouri, South Carolina, and Texas. Because the Court dismissed *with prejudice* as subsumed by the Connecticut PLA all claims asserted in the PIMC against the Pharmacy Defendants, Plaintiffs also will be denied leave to amend the PIMC to present strict liability claims against the Pharmacy Defendants under Connecticut law.

H. "Official Compendia" Averments

The Manufacturer Defendants argue at great length that the proposed Amended Master Complaints impermissibly introduce an "unauthorized" liability theory, to wit, that the Defendants' VCDs did not "conform to the 'official compendium' standards or requirements for valsartan drugs of the same name." (ECF No. 1277 at 31-32.)[28] Plaintiffs, however, disavow any intent to introduce a new liability theory. They point out that the original Master Complaints contained allegations pertaining to the Orange Book and the USP, and that the Court had referenced those allegations in denying motions to dismiss on preemption grounds. *See* MTD Opinion No. 1, ECF No. 675, at 16. Plaintiffs argue that the new averments simply provide "some additional facts and clarifications." Because Plaintiffs are not pursuing a new liability

[28] Because the proposed amended master complaints do not add a new cause of action or separate claim based upon provisions of the Orange Book or United States Pharmacopeia ("USP"), the relief Defendants seek is more in the nature of a request to strike immaterial or impertinent matter. *See* Fed. R. Civ. P. 12(f). "'Immaterial' matter is that which 'has no essential or important relationship to [any] claim[s] for relief.' 'Impertinent' matter consists of 'statements that do not pertain, and are not necessary, to the issues in question.'" *Roamingwood Sewer & Water Assn. v. Natl. Diversified Sales, Inc.*, 509 F. Supp. 3d 198, 204 (M.D. Pa. 2020) (citations omitted). Defendants have not shown that the averments pertaining to the Orange Book and the USP have no bearing on this matter or do not pertain to this case.

theory, Defendants' resurrected preemption argument rings hollow. Nor does Defendants' assertion of prejudice resonate. Accordingly, the "official compendia" allegations of the proposed Amended Master Complaints will not be stricken.

IV. CONCLUSION

Many of Plaintiffs' proposed amendments remedy the pleadings defects found to exist in the six comprehensive decisions resolving Defendants' motions to dismiss. There are, however, claims that are foreclosed as a matter of law and there are other deficiencies in the Master Complaints that are not remedied by the Proposed Amended Master Complaints. For example, the negligence claims asserted against the Wholesaler and Pharmacy Defendants have been found to be without any merit. The Order accompanying this Report identifies with some precision the claims for which leave to amend has been denied.[29] Because leave to amend has been denied in

[29] Consistent with this Report, the accompanying Special Master Order No. 46 denies Plaintiffs leave to amend the Master Complaints to assert breach of express warranty claims against the Pharmacy Defendants and the Wholesaler Defendants; denies leave to amend the Personal Injury Master Complaint to assert a claim for breach of implied warranty against the Manufacturer and Wholesaler Defendants under the law of Kentucky; denies leave to amend the Master Complaints to assert claims for breach of implied warranties against the Manufacturer Defendants under the laws of Alabama, Arizona, Idaho, North Carolina, Ohio, and Tennessee; denies leave to amend the Economic Loss and Medical Monitoring Master Complaints to assert breach of implied warranty claims against the Wholesaler Defendants under the laws of Arizona, Connecticut, Georgia, Idaho, Illinois, Kentucky, New York, Oregon, Tennessee, Vermont, and Wisconsin; denies leave to amend the Master Complaints to assert breach of implied warranty claims against the Pharmacy Defendants under the laws of Alabama, Arizona, Arkansas, California, Connecticut, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North

some respects, Plaintiffs will be required to submit new Amended Master Complaints that conform to the holdings expressed in this Report and embodied in the accompanying Order.[30] In accordance with Fed. R. Civ. P. 53(f)(2), objections to or requests for modification of this Report must be submitted within twenty-one days of today.[31]

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master

October 7, 2021
Date

Dakota, Ohio, Pennsylvania, Puerto Rico, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin; denies leave to amend the Master Complaints to present fraud-based claims against the Pharmacy and Wholesaler Defendants; denies leave to amend the Medical Monitoring Master Complaint to assert a claim for medical monitoring under Mississippi law; denies leave to amend the Master Complaints to assert negligence claims against the Pharmacy and Wholesaler Defendants; and denies leave to amend the Personal Injury Master Complaint to assert strict liability claims against the Pharmacy Defendants under the laws of Connecticut, Mississippi, Missouri, South Carolina, and Texas. The Order also directs Plaintiffs to show cause why the claims asserted against Humana Pharmacy, Inc., Arrow Pharma Malta, Torrent Pharmaceuticals, and Torrent Pharma in the economic lass master complaint and the claims asserted against Albertson's, LLC, Humana Pharmacy, Inc., the Kroger Co., OptumRx, Arrow Pharma Malta, Torrent Pharmaceuticals, and Torrent Pharma in the medial monitoring master complaint should not be dismissed with prejudice. Finally, Plaintiffs are given until November 1, 2021 to file amended master complaints that comply with this Report and the accompanying Order.

[30] Defendants, of course, may seek dismissal with prejudice of the claims for which leave to amend has been denied.

[31] The parties' filings on the Plaintiffs' motion raised a plethora of complex issues, and it may be that this Report and accompanying Order did not resolve all issues (or perhaps raised other issues). Any questions or concerns with respect to this Report and accompanying Order may also be raised in the parties' agenda letters for the regularly scheduled conferences.