IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

| | |
|---|---|
| IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION | MDL No. 2875 (RBK-JS) |
| *This Document Relates To All Actions*. | **MTD OPINION 3: Warranty Claims** |

KUGLER, United States District Judge:

Before the Court in this Multi-District Litigation ["MDL"] that concerns the sale in the U.S. of prescription generic drugs containing Valsartan ["VCDs"][1] and which were found to contain cancer-causing contaminants ["VCDs at issue"] are three Motions to Dismiss ["MTDs"] .

Since these MTDs seek dismissal of several claims for each set of plaintiffs, the Court is issuing a series of opinions to resolve the MTDs. Each opinion is numbered in the series, this opinion being the third in the series. This OPINION 3 resolves the arguments relating to claims for breach of express warranties, and for breach of implied warranties and for violation of the Magnuson-Moss Warranty Act.
.

An ORDER 3 of this date accompanies this OPINION 3.

Each MTD was brought by a different category of defendant, which is at a separate level in the drug supply chain. The defendant categories[2] are:

1) The manufacturers ["Mfrs"], which include the manufacturers of the Active Pharmaceutical Ingredient ["API"] ["API Mfrs"] and the manufacturers that make the finished Valsartan drug product ["Finished Mfrs"];

2) the business entities in the U.S. that obtain the finished drug product from the Mfrs ["Wholesalers"]; and distribute it to retail businesses in the U.S.; and

3) the retail businesses in the U.S. from which individuals can obtain the finished drug ["Pharmacies"].

Each MTD seeks dismissal of claims in all three Master Complaints. These include:

[1] Although this MDL consolidates cases that allege injury from the U.S. sales of contaminated valsartan, irbesartan and losartan, as of yet, there are no master complaints in this MDL that concern losartan and irbesartan. Therefore, defendants' motions here concern ONLY claims that allege injury relating to contaminated valsartan.

[2] Defendants also include repackagers and relabellers. These were categorized as peripheral defendants and dismissed without prejudice from the MDL and without waiving any of their rights. *See* ECF Doc. 248.

1) Economic Loss Master Complaint ["ELMC"] (ECF Doc. 121) filed 17 June 2019 by individual plaintiffs and plaintiff business entities that paid for and/or insured the VCDs at issue taken by individual plaintiffs and alleges economic damages;

2) Amended Personal Injury Master Complaint ["PIMC"] (ECF Doc. 122) filed 17 Jun 2019 by those individual plaintiffs who ingested the VCDs at issue and who were personally injured, including those who developed cancers or had cellular or bodily injury as a result; and

3) Medical Monitoring Master Complaint ["MMMC"] (ECF Doc. 123) filed 17 Jun 2019 by those individual plaintiffs who ingested the VCDs at issue and therefore bear an increased risk of developing cancer and consequently seek a fund to finance continued medical monitoring of that risk.

All three categories of defendants seek:

1) For lack of Standing: dismissal of the ELMC and the MMMC Complaints primarily because of a deficiency in pleading an injury in fact,

which issue has been resolved in the Opinion 2, ECF Doc. 728;

2) For Preemption by federal law and Primary Jurisdiction:

Under preemption by the Food Drug and Cosmetic Act: all 3 categories of defendant seek dismissal of any claim in the Master Complaints for negligence per se, strict liability design defect , breach of express warranty, fraudulent and negligent misstatement, and state consumer protection acts;

Under preemption by the Drug Supply Chain Security Act: Wholesales and Pharmacies seek dismissal of any claim in the Master Complaints

Under primary jurisdiction: defendants seek dismissal OR alternatively a stay of any claim for breach of implied warranty, strict liability, failure to warn, negligence and manufacturing defect until the U.S. Food & Drug Administration ["FDA"] completes its pending agency action relating to VCDs,

which issues have been resolved in Opinion 1, ECF Doc. 675 ;

3) For Subsumption: dismissal of all claims by New Jersey plaintiffs for common law and state law consumer protection violation as these claims are subsumed by the New Jersey Products Liability Act ["NJPLA"] AS WELL AS a dismissal of all similar claims by plaintiffs of other states having statutes similar to the NJPLA.

4) For Deficiencies In Specific Claims: a dismiss OR alternatively a stay of most of the enumerated claims in the Master Complaints, including fraud, unjust enrichment, negligence *per* se, punitive damages.

**The COURT HAVING REVIEWED** the parties' submissions (without a hearing in accordance with Rule 78.1 (b)) relating to Express Warranties, Implied Warranties, and Warranties under the Magnuson-Moss Warranty Act, and for the reasons stated below, and for good cause shown:

**As for Breach of Express Warranty Claims :**

Against Mfr defendants: the Court **DENIES** the Mfr defendants' motion to dismiss the breach of express warranty claims against them in all three Master Complaints **;**

Against the Wholesaler defendants and the Pharmacy defendants: the Court **GRANTS** the Wholesaler defendants' and the Pharmacy defendants' motions to dismiss the claims for breach of express warranty against them in all three Master Complaint**s** and **dismisses these claims WITHOUT PREJUDICE,**

Plaintiffs may file a motion for LEAVE TO AMEND all three Master Complaints as to the breach of express warranty claims against the Wholesaler defendants and the Pharmacies defendants, according to the deadlines set in the accompanying Order.

**As for Breach of Implied Warranty Claims:**

Against Mfr defendants and Wholesaler defendants as to the Personal Injury Master Complaint:

the Court **GRANTS** the Mfr defendants' and the Wholesaler defendants' motions to dismiss those claims in the Personal Injury Master Complaint for breach of implied warranty which arise under the law of Kentucky or Wisconsin and **dismisses these claims WITHOUT PREJUDICE**; and

the Court **DENIES** the Mfrs defendants' and the Wholesaler defendants' motions dismiss those claims in the Personal Injury Master Complaint for breach of implied warranty which arise under the law of any of the remaining states in the United States and including the District of Columbia and Puerto Rico.

Plaintiffs may file a motion for LEAVE TO AMEND these dismissed claims in the Personal Injury Master Complaint, according to the deadlines set in the accompanying Order.

Against the Mfr defendants as to the Economic Loss and the Medical Monitoring Master Complaints:

the Court **GRANTS** the Mfr defendants' motion to dismiss those claims in the Economic Loss Master Complaint and in the Medical Monitoring Master Complaint for breach of implied warranty which arise under the law of: Alabama, Arizona, Idaho, Iowa, Kansas, Kentucky, Michigan, North Carolina, Ohio, Oregon, Tennessee, Utah, or Wisconsin and **dismisses these claims WITHOUT PREJUDICE**; and.

the Court **DENIES** the Mfr defendants 'motion to dismiss those claims in the Economic Loss Master Complaint and in the Medical Monitoring Master Complaint for breach of implied warranty which arise

under the law of any of the remaining states in the United States and including the District of Columbia and Puerto Rico.

Plaintiffs may file a motion for LEAVE TO AMEND the these dismissed claims in the Economic Loss Master Complaint and the Medical Monitoring Master Complaint Master, according to the deadlines set in the accompanying Order.

Against the Wholesalers as to the Economic Loss and the Medical Monitoring Master Complaints

the Court **GRANTS** the Wholesaler defendants' motion to dismiss those claims in the Economic Loss Master Complaint and in the Medical Monitoring Master Complaint for breach of implied warranty which arise under the law of Arizona, Connecticut, Georgia, Idaho, Illinois, Iowa, Kansas, Kentucky, Michigan, New York, Oregon, Tennessee, Utah, Vermont, or Wisconsin and **dismisses these claims WITHOUT PREJUDICE**; and

the Court **DENIES** the Wholesaler defendants' motion to dismiss those claims in the Economic Loss Master Complaint and in the Medical Monitoring Master Complaint for breach of implied warranty which arise under the law of any of the remaining states of the United States and including the District of Columbia and Puerto Rico.

Plaintiffs may file a motion for LEAVE TO AMEND these dismissed claims in the Economic Loss Master Complaint and the Medical Monitoring Master Complaint against the Wholesaler defendants, according to the deadlines set in the accompanying Order.

Against the Pharmacy defendants in all three Master Complaints:

the Court **GRANTS** the Pharmacy defendants' motion to dismiss those claims in all three Master Complaints for breach of implied warranty which arise 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, or Wisconsin; and

the Court **DENIES** the Pharmacy defendants' motion to dismiss those claims in all three Master Complaints for a breach of implied warranty which arise under the law of Alaska, Colorado, Delaware, Idaho, Montana, Nevada, Oregon, Rhode Island, South Dakota, or Vermont.

Plaintiffs may file a motion for LEAVE TO AMEND all three Master Complaints as to the breach of implied warranty claims against the Pharmacy defendants, according to the deadlines set in the accompanying Order.

**As for Violation of the Magnuson Moss Warranty Act**

The Court **GRANTS** the motions to dismiss the claims in all three Master Complaints for violation of the Magnuson-Moss Warranty Act and **dismisses** plaintiffs' claims in all three Master Complaints **with prejudice**.

## 1.0 FACTS AND PROCEDURAL BACKGROUND

The Court having presented facts underlying this MDL in the previous two MTD opinions, this review is kept short. This MDL involves the generic active pharmaceutical ingredient, Valsartan, and the finished drugs produced with it, collectively termed here valsartan-containing drugs or VCDs. VCDs are universally prescribed drugs to lower blood pressure and/or treat heart failure.

In the summer of 2018, the U.S. Federal Drug Administration ["FDA"] and several of its counterparts in Europe and Canada discovered that certain batches of generic Valsartan[3] contained nitrosamines, known carcinogens, in amounts above what the FDA considered allowable, that is above 96 nanograms (ng) per day.. The first nitrosamine contaminant found was N-nitrosodimethylamine ["NDMA"]. Within a few months, other nitrosamines, which included N-Nitrosodimethylamine ["NDEA'], were also found in batches of VCDs.

In August 2018, these governmental health administrations began recalling VCDs made with the active pharmaceutical ingredient produced by certain API Mfrs located in China or India. These include Zhejiang Huahei Pharmaceuticals Ltd. and Aurobindo Pharmaceuticals. The contaminated API had gone into a finished pill made by Finished Mfrs located in India and Israel, which include Teva Pharmaceuticals, Mylan Pharmaceuticals, and Torrent. Many of these Mfrs also began issuing their own recalls of contaminated VCDs already in the drug supply chain. To be clear, almost all generic Valsartan sold in the U.S. had come from these API Mfrs and Finished Mfrs.

After the recalls began, FDA testing revealed the valsartan API manufactured by and for defendants had levels of NDMA of between 15,180 and 16,300 ng, much in excess of the FDA daily limit. Further, FDA testing revealed levels of NDEA was similarly well in excess of FDA limits.

VCDs were (and still remain) a drug of choice in lowering high blood pressure. Since they were widely prescribed worldwide and in the U.S., the recalls caused consternation during much of 2019 in the global medical community, including the American Medical Association, both as there developed a shortage of VCDs and as physicians moved their patients to some other drug perceived less effective in order to avoid potential contamination. Several months after the recalls, the FDA (and non-U.S. health administrations) posited the contaminants in the VCDs to be the result of changes the API Mfrs

[3] Valsartan is the generic name of a now off-patent drug Diovan® and is also used in a combination heart failure drug called Exforge®.

had adopted in their manufacturing processes, particularly in the solvents used. Some API Mfrs had adopted manufacturing changes as early as 2012, which means potentially contaminated API may have been present in much of the Valsartan drug supply sold in the U.S. for about 6 years.

By late August 2018, plaintiffs had begun filing personal injury individual complaints. By October 2018, individual plaintiffs and third-party payors who had paid for individual plaintiffs' prescriptions of the contaminated Valsartan, filed several class actions alleging economic losses. (Doc. No. 1). Consumers also filed a medical monitoring class action alleging "cellular damage, genetic harm, and/or an increased risk of developing cancer" as a result of exposure to the human carcinogens in the VCDs. Lastly, personal injury claims were filed on behalf of consumers who alleged they had developed cancer as a result of taking the contaminated VCDs.

On 14 February 2019, the Judicial Panel on Multi-District Litigation ["JPML"] consolidated all of the individual filings into this MDL, No. 2875. On 17 June 2019, three Master Complaints were filed with this Court: the Economic Loss Master Complaint ["ELMC"] at ECF Doc. 121., the Personal Injury Master Complaint ["PIMC"] at ECF Doc. 122; and the Medical Monitoring Master Complaint ["MMMC"] at ECF Doc. 123. Since then, this MDL has advanced significantly, both in terms of filings and in the management of the litigation through various discovery phases. Currently, with over 700 pending filings, the MDL is well into the discovery phase of intensive document production; and, depositions of individuals and under Rule 30(b)(6) are proceeding.

### 1.1 Economic Loss Master Complaint

Plaintiffs in this Master Complaint (ECF Doc. 121) include individual consumers who purchased the VCDs at issue as well as third party payors ["TPPs"] that paid or co-paid for the VCDs at issue that consumers ingested. TPPs are health care benefit providers, such as an employer's insurance company providing health care benefit to employees. Many of the TPPs providing such health care benefits have assigned their rights to recovery in this MDL to a select few entities, termed assignors, who now stand as plaintiffs here.

Since the VCDs at issue had been FDA-approved as a generic of an FDA-approved branded drug listed in the Orange Book, plaintiffs assert generally that defendants lied to the public when the VCDs at issue were sold and identified as an approved generic. That is, the contaminants made the VCDs at issue differ substantially from the FDA-approved generic.

Plaintiffs' claims include:

- Common Law Breach of express warranties by all defendants because inclusion of defendants' VCDs in the U.S. Orange Book serves as a warranty that the VCDs at issue constituted a generic drug that is bio-equivalent in every way to the patented drug.

- State Law Breach of implied warranties and of warranty for fitness of purpose by all, or all but the Pharmacy, defendants under the law of each state, the District of Columbia ["D.C."] , and Puerto Rico ["P.R."], which has adopted the Uniform Commercial Code covering such warranties.

- Breach of the Magnuson-Moss Warranty Act under 15 U.S.C. §2301 *et seq.* by all, or all but the Pharmacy, defendants.

- Fraud, intentional misrepresentation and/or negligent misrepresentation by all, or all but the Pharmacy, defendants by omitting to inform the public the VCDs at issue were not bio-equivalent to the branded, FDA-approved drug.

- Breach of State Consumer Statues for Unfair Competition or False Advertising in all fifty states and in D.C. and P.R.

- Unjust Enrichment against all, or all but Pharmacy, defendants.

- Common law negligence against all, or all but Pharmacy, defendants for breaching their duty to exercise reasonable care to oversee the safety of the VCDs at issue and prevent injury to plaintiffs and for failing to comply with current Good Manufacturing Practice ["cGMP"] federal regulations.

- Common law negligence *per se* against all, or all but Pharmacy, defendants for failing to ensure that VCDs sold in the U.S. were therapeutically equivalent to the Orange Book entry and failing to act as reasonably prudent actors throughout the U.S. drug supply chain.

### 1.2 Personal Injury Master Complaints

The plaintiffs in this Master Complaint include all those who pleaded in their individual actions that they had suffered personal injuries as a result of the use of the VCDs at issue as well as, where applicable, plaintiffs' spouses, children, parents, decedents, wards, and heirs as represented by plaintiffs' counsel. The plaintiffs plead many of the same claims as in the ELMC, but do NOT exclude the Pharmacy defendants.

The claims specific to the PIMC include:

- Strict liability / product liability -manufacturing defects for making a drug that was not bio-equivalent to the Orange Book entry or to the patented drug because of flawed, faulty, and non-compliant cGMPs, which created a foreseeable and unreasonable danger to those ingesting the VCDs at issue.

- Strict liability / product liability -failure to warn, to physicians that the VCDs at issue would cause harm.

- Strict liability / product liability -design defect, that the VCDs at issue failed to perform in a safe manner expected by an ordinary consumer and increased the risk of causing cancer.

- Wrongful Death, that certain plaintiffs died as a result of the injury causes by ingesting unreasonably harmful VCDs that defendants made and marketed throughout the U.S. drug supply.

- Survival Action, that decedent plaintiffs before death were caused injury, including loss of body function, disability, pain and suffering and loss of economy, as a result of ingesting unreasonably harmful VCDs that defendants made and marketed throughout the U.S. drug supply.

- Loss of Consortium

- Punitive Damages, because defendants' actions to make and market extremely dangerous drugs constitutes fraud and malice.

Claims similar to the ELMC include:

-Common Law Negligence, that defendants breached a duty to plaintiffs and physicians to exercise ordinary care in making the VCDs at issue and that such breach caused injury.

- Common Law Negligence *per se*, defendants' actions of making and selling a contaminated drug, while also violating federal and state law, also breached a common law duty by failing to act as reasonably prudent actors throughout the U.S. drug supply chain.

- Common Law Breach of Express Warranty, that defendants, through the drug labels and packaging of the VCDs at issue, made express representations to health care professionals about their quality and to consumers that ingestion of these was safe, which representations constituted an express warranty of drug safety and purity that was false.

- Common Law Breach of Implied Warranty and Fitness of Purpose, that defendants placed the VCDs at issue in the stream of commerce, implying that they were safe and fit for their purpose.

- Common Law Fraud and Intentional Misrepresentation, that defendants knew or should have known the VCDs at issue were unreasonably dangerous and intentionally concealed that fact to health care professionals and consumers.

- Common Law Negligent Misrepresentation, that defendants made untrue representations about the safety and quality of the VCDs at issue to health care professionals and to consumers.

- Breach of Consumer Protection Statutes, that defendants engaged in unfair competition by failing to warn plaintiffs of the unreasonable danger of the VCDs at issue, thereby violating the statutes of each state, D.C., and P.R.

### 1.3 Medical Monitoring Master Complaints

Plaintiffs in this Master Complaint include those consumers who ingested the VCDs at issue, thereby suffering cellular damage and genetic harm, and consequently are at an increased risk of developing cancer but have not yet been so diagnosed. The plaintiffs plead many of the same claims as

in the PIMC and some of the same claims as in the ELMC, but do NOT exclude the Pharmacy defendants.

The claims specific to the MMMC include:

- Medical Monitoring,

- Statutory Breach of Implied Warranty of Merchantability, that defendants placed the VCDs at issue in the stream of commerce, implying that they were safe and fit for their purpose in violation of laws in all 50 states, D.C., and P.R.

- Statutory Breach of Express Warranty of Merchantability, that defendants, through the drug labels and the packaging of the VCDs at issue, made express representations to health care professionals about their quality and to consumers that ingestion of these was safe, which representations constituted an express warranty of drug safety and purity that was false and which was a violation of laws in all 50 states, D.C., and P.R.

The claim similar to that in the ELMC includes:

- Breach of the Magnuson-Moss Warranty Act under 15 U.S.C. §2301 *et seq.* by all defendants.

The claims similar to those in the ELMC and PIMC include:

-Common Law Negligence, that defendants breached a duty to plaintiffs and physicians to exercise ordinary care in making the VCDs at issue and that such breach caused injury.

- Common Law Negligence *per se*, defendants' actions of making and selling a contaminated drug, while also violating federal and state law, also breached a common law duty by failing to act as reasonably prudent actors throughout the U.S. drug supply chain.

- Strict liability / product liability -manufacturing defects for making a drug that was not bio-equivalent to the Orange Book entry or to the patented drug because of flawed, faulty, and non-compliant cGMPs, which created a foreseeable and unreasonable danger to those ingesting the VCDs at issue.

- Strict liability / product liability -failure to warn, to physicians that the VCDs at issue would cause harm.

- Common Law Breach of Implied Warranty and Fitness of Purpose, that defendants placed the VCDs at issue in the stream of commerce, implying that they were safe and fit for their purpose.

- Common Law Breach of Express Warranty, that defendants, through the drug labels and packaging of the VCDs at issue, made express representations to health care professionals about their quality and to consumers that ingestion of these was safe, which representations constituted an express warranty of drug safety and purity that was false.

- Common Law Fraud and Fraudulent Concealment, that defendants knew or should have known the VCDs at issue were unreasonably dangerous and intentionally concealed that fact to health care professionals and consumers.

### 1.4 Defendants

Currently, there are about 40 defendants in this MDL, divided into 3 categories as described above:

Manufacturers ["Mfrs]", which include the Manufacturers of the Active Pharmaceutical Ingredient ["API Mfrs"], such as Zhejiang Huahei Pharmaceuticals Ltd., Hetero Laboratories, Aurobindo Pharma and Mylan Laboratories;[4] and the Finished Dose Manufacturers, such as Teva Pharmaceuticals and Torrent ["Finished Mfrs"]; Wholesalers, such as Amerisource Bergen, Cardinal Health and McKesson; and Pharmacies, such as Walgreens, Walmart, Kroger, CVS and others. Each category of defendant has filed its own motion to dismiss.

The Court recognizes that the Mfrs MTD has set forth the four arguments of Standing, Preemption and Primary Jurisdiction, Subsumption, and Deficiencies of Specific Claims, which the Wholesalers and the Pharmacies have incorporated by reference into their MTDs. In addition, the Wholesalers and the Pharmacies have each argued the facial deficiency of specific claims that are particularly pertinent to their status in the drug supply chain.

## 2.0 MOTION TO DISMISS STANDARD

Other than for standing, defendants' motions rely on *Fed.R.Civ.Proc.* ["FRCP" or "Rule"] *12(b)(6)*, which governs a court's dismissal of an action for failure to state a claim upon which relief can be granted. In evaluating a motion to dismiss, "courts accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler v. UPMC Shadyside,* 578 F.3d 203, 210 (3d Cir.2009) (*quoting Phillips v. Cnty. of Allegheny,* 515 F.3d 224, 233 (3d Cir.2008)). Put simply, a complaint must "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal,* 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009); *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).

The general inquiry in determining whether a claim is plausible on its face is not whether the moving party will succeed on the merits, but "whether they should be afforded an opportunity to offer evidence in support of their claims." *In re Rockefeller Ctr. Prop., Inc.,* 311 F.3d 198, 215 (3d Cir.2002). The

[4] This listing of defendants is not complete but exemplary.

specific inquiry involves a three-part analysis (*Santiago v. Warminster Twp.,* 629 F.3d 121, 130 (3d Cir.2010)) in which a court

1) states "the elements a plaintiff must plead to state a claim." *Id.* (*quoting Iqbal,* 556 U.S. at 675);

2) identifies the allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* at 131 (*quoting Iqbal,* 556 U.S. at 680); and

3) assuming the veracity of well-pleaded factual allegations, "determine[s] whether they plausibly give rise to an entitlement for relief." *Ibid.*

Practically speaking, this plausibility analysis is a "context-specific task requiring the reviewing court to draw on its judicial experience and common sense." *Iqbal,* 556 U.S. at 679. A claim fails when a court can infer only that it is merely possible rather than plausible. *Id.* Plausibility cannot lie upon legal conclusions or "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements". *Id.* at 678. The specific information a court reviews in deciding a motion to dismiss is limited to the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.,* 998 F.2d 1192, 1196 (3d Cir.1993).

**DISCUSSION OF WARRANTY CLAIMS**

For the specific warranty claims pleaded, see *supra* sections 1.1, 1.2, and 1.3.

**3.0 Pre-Suit Notice: Master Complaints for both express and implied warranty claims**

The Mfrs and Wholesalers argue plaintiffs fail to plead pre-suit notice in the Master Complaints for a number of states for both express and implied warranty claims. *See* ECF Doc. 520-3:49 citing ECF Doc. 520-5 (Exhibit 5): 43-48.

In their opposition, plaintiffs provide copies of pre-suit letters dated before the end of 2018—well before the dates of the Master Complaints— which they had sent to some or all defendant groups. *See* ECF Doc. 577,Exhibit 2. Plaintiffs argue both the sufficiency of the letters to as pre-suit notice and that their sufficiency is a fact question, which is therefore inappropriate for resolution on the pleadings. In examining these letters, the Court finds plaintiffs did provide pre-suit notice, even if the Master Complaints did not expressly plead it.[5]

Plaintiffs also assert that, in response to and in addition to the FDA recalls in the summer and fall of 2018 and in 2019, some Mfr defendants—both API and finished dose—issued their own voluntary recalls. According to plaintiffs, such recalls indicate Mfr defendants understood that their products,

[5] Typically, the Court would not consider these pre-suit letters in resolving a Motion to Dismiss. However, in the interests of judicial economy and with the firm belief the letters exist and were sent, the Court sees no reason to delay the inevitable by waiting for the issue to re-arise at a later time.

already on the market, were regarded as dangerous and non-compliant with FDA standards, and the FDA was researching how far-reaching in terms of root cause, spread, and duration the contamination extended. Further, Ps assert such voluntary recalls unmistakably show the Mfr and Wholesaler defendants alike recognized that lawsuits for injury owing to the contaminated API would likely ensue and indisputably represent a conscious business strategy to reduce injury and align with the FDA.

The Court agrees. To the extent necessary to comply with any formal pre-suit pleading requirements in those states demanding such, the Court hereby grants plaintiffs leave to amend the complaint to comply with those requirements.

## 4.0 BREACH OF EXPRESS WARRANTY CLAIMS

### 4.1 Manufacturers

In products liability law, express warranties are the seller's affirmative assertions made in connection to a sales transaction that the sold product has certain characteristics of quality, construction, performance capability, durability, or safety. An express warranty springs from a seller's words or other form of communication rather than from any inherent characteristic of the product itself.

Generally, the Uniform Commercial Code ["U.C.C."] §2-313 requires that, in claiming breach of express warranty in a products liability case, an injured plaintiff plead:

(1) a seller made an assertion about a product, which the product did not conform to;

(2) but which nonetheless became part of the basis of the bargain; and

(3) the buyer plaintiff bought the product from the seller or was a third-party beneficiary of the warranty.

Claims for breach of express warranty depend on neither deficiency in the product nor falsity of seller's asserted information, which relieves plaintiff from pleading product "defect" or seller's fault.[6]

#### 4.1.1 Basis for the Bargain, Specific Language, Labelling

Mfr defendants argue plaintiffs' claims neither identify specific language of an express warranty in terms of its time period, coverage, or source nor assert that plaintiffs saw or read such a warranty before filling a valsartan prescription. ECF Doc. 520-3:47. *See* ECF Doc. 520-5 (Exhibit 5:42). Further, Mfr defendants contend, absent specific assertions of express warranty language in the Master Complaints,

---

[6] .*See, e.g.*, *Forbes v. General Motors Corp.*, 935 So. 2d 869, 876 (Miss. 2006) ("An express warranty is any affirmation of fact or promise which concerns the product and becomes part of the basis for the purchase of such a product. Fault does not need to be shown to establish a breach. The plaintiff need only show that the product did not live up to its warranty."); *Bell Sports, Inc. v. Yarusso*, 759 A.2d 582, 594 (Del. 2000) (jury could find motorcycle helmet manufacturer made and breached express warranty while also finding that helmet was not defective and manufacturer was not negligent); *McCarty v. E. J. Korvette, Inc.*, 28 Md. App. 421, 347 A.2d 253, 264 (1975) ("no 'defect' other than a failure to conform to the warrantor's representations need be shown in order to establish a breach of an express warranty").

there can be no reliance by plaintiffs such that formed the basis for a bargain. They also assert that the FDA-required labelling of the risks and contraindications on the Valsartan drug packaging or insert does not create an express warranty as this labelling does not state the drug is free from all known side effects.

Plaintiffs argue Mfr defendants' express warranties arise not from statements in the product labeling, but from the very act of naming the product by the generic active ingredient, that is, by calling their generic drug "valsartan" or "valsartan HCT", etc., in patient information leaflets dispensed with each prescription, or on a third-party beneficiary basis. Plaintiffs further argue that, based on the prescription alone, plaintiffs could not have bought any other generic drug but valsartan (or VCDs), and that Mfr defendants' naming their API "valsartan" necessarily left plaintiffs no choice but to "rely" on Mfr defendants' name of the product, which stands as the basis for the bargain between Mfrs. and plaintiffs.

In their reply (ECF Doc. 598:29, n.22), Mfr defendants assert that the calling of a generic drug by its medically recognized generic name cannot ground an express warranty and refers to its arguments and cited case law in its Brief at ECF Doc. 520-3:48. However, defendants' arguments there relate to the requirement that the language of the warranty be specific. Thus, neither defendants' reply (nor their brief) squarely addresses whether calling a contaminated drug by its medically recognized generic name is a specific enough statement to induce reliance by purchasers that what they are buying is indeed the generic and not a contaminated substitute.

Ultimately, plaintiffs' argue that its claims properly plead a basis of the bargain under express warranty because of the way prescription drugs are sold in the U.S., namely, that:

- a drug is prescribed as a generic of an Orange Book pharmaceutical;

for the generic to get approval to be marketed, the generic has to be chemically and biochemically equivalent to the Orange Book drug; and

- regardless of whether the mfr's generic product deviates from the formulation of the Orange Book pharmaceutical, a plaintiff consumer as well as a third party payor have no option but to rely on a mfr's assertion that the generic drug sold is the chemical and biochemical equivalent of the Orange Book pharmaceutical .

In short, because of the economic reality of drug sales in the U.S., the mfr's identification of a generic drug as the chemical equivalent to the Orange Book brand name can do nothing else but constitute an express warranty. More specifically, plaintiffs argue that calling a drug by the generic name of "X" and marketing it as the generic of an Orange Book pharmaceutical is an express warranty that the product sold is that generic. Plaintiffs' argument concludes with: If the sold generic differs from the generic name, X, by virtue of its containing contaminants, then it differs from the Orange Book pharmaceutical and can NOT be called by the generic name. And if the generic mfr sells a contaminated drug using the generic name of an Orange Book equivalent, then a mfr can only have breached an express warranty.

The issue, then, as to pleading the basis of the bargain in this situation devolves to whether plaintiffs pleaded that either individual consumers or third party payors perceived an express warranty on the VCDs at issue, and then, based on that perceived warranty, chose to buy or fund them. The Court finds that, for prescription drugs, the mere identifying and marketing a drug as THE generic equivalent to a branded pharmaceutical listed in the Orange Book and then selling that generic equivalent when it contains a contaminant[7] not included in the Orange Book listing constitutes a breach of express warranty. A marketed generic containing a contaminant cannot be the equivalent to the chemical entity listed in the Orange Book.[8] Put simply, a seller cannot call its product "X" and sell it as "X" and then expect such identification not to create an express warranty that the product is "X".

The Mfrs' very naming of the drug as valsartan or valsartan-containing amounted to an express warranty on which plaintiffs had no choice but to "rely" when they were prescribed the drug and bought it as a medication for their high blood pressure. Plaintiffs did not have to "perceive" the package labelling or insert in order to create a benefit of the bargain. All they had to know was they were buying a generic drug that contained valsartan because the very name "valsartan" or "valsartan-containing" constituted itself an express warranty that what plaintiffs were purchasing was the chemical equivalent of the Orange Book pharmaceutical. *See, e.g.*, *Gremo v. Bayer Corporation*, 469 F.Supp.3d 240, 258 (D.N.J. 2020) *quoting* " 'A statement can amount to a warranty, even if unintended to be such by the seller, if it could fairly be understood … to constitute an affirmation or representation that the [product] possesse[s] a certain quality or capacity relating to future performance.' *Volin v. General Electric Company*, 189 F. Supp. 3d 411, 420 (D.N.J. 2016) (citations omitted)."

The Court finds that for both consumers and third party payors in those states where privity is not a required pleading element, plaintiffs have sufficiently pleaded this aspect of their express warranty claims. There was a benefit of the bargain, which arose from the Mfrs' identification of the drug as valsartan-containing, which informed plaintiffs the drug was approved as a generic of the Orange Book formulation, upon which plaintiffs relied and acted on in filling their prescriptions for VCDs.

#### 4.1.2 Privity

Defendants assert that eleven states[9] still require the element of privity between the product manufacturer and the consumer in order to plead properly a breach of express warranty. They argue

---

[7] The term contaminant as used herein does not refer to an unintended ingredient included in the generic drug in an amount so small as to be scientifically difficult to detect and/or to have no or *de minimis* effect on the generic's bioequivalence to the Orange Book listing.

[8] This finding does not at all address or implicate what remedies, damages, injunctive relief, etc. follow from a mfr's identifying and selling a generic drug that contains a contaminant, and because of that, is not chemically or biochemically equivalent to the Orange Book listing

[9] Connecticut, Florida, Georgia, Illinois, Indiana, Iowa, Kentucky, Maryland, Nevada, Virginia, and Wisconsin.

that, since plaintiffs did not buy VCDs directly from the Mfrs, there can be no showing of privity, and express warranty claims in those 11 states must therefore fail.

In response, plaintiffs have précised from each of the eleven states a case that heralds an exception exists in that state as to the required privity element. Plaintiffs have raised doubt as to the full breadth and complexity of the pleading standard for breach of express warranty in those 11 states. They argue, to fully flush out how exceptions to the privity requirement affect the pleading standard, discovery as to express warranty under certain fact scenarios is necessary.

The Court agrees that, at this stage, if the privity pleading requirements under a particular state's express warranty law vary depending on varying fact conditions, then ruling summarily that plaintiffs have not pleaded the required element of privity in these states is premature. At this point, the question as to what states require pleading the element of privity distills to a factual conclusion that the parties dispute, which motivates for prudence as to the dismissal of these claims. The claims of these eleven states depend not on the mere "suspicion [of] a legally cognizable right of action (*Atlantic Bell v. Twombly*, 50 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007) [citations omitted]) but on the uncertainty of what must or not be pleaded. The Court therefore denies defendants' motion to dismiss plaintiffs' express warranty claims in those eleven states (*See supra* fn. 9) against the Mfrs.

In addition, plaintiffs assert they alleged consumers and third party payors were third party beneficiaries because the Mfrs had expressly warranted the VCDs to Wholesalers and Pharmacies. As required by *Twombly*, 50 U.S. at 555, such allegations that the Mfrs expressed warranties to the Wholesalers and the Pharmacies must be accepted as true, which would mean plaintiff consumers and third party payors have been pleaded as third-party beneficiaries.

The Court finds, in all 3 Master Complaints, plaintiffs have met the requirements in most states to properly plead that Mfr defendants breached their express warranty and that in 11 states (*see* relevant footnote), plaintiffs have not failed to meet those pleading requirements against Mfr defendants. Accordingly, the Court **DENIES** the Mfr defendants' motion to dismiss the breach of express warranty claims against them in all three Master Complaints.

### 4.2 Wholesalers and Pharmacies

#### 4.2.1 Basis of the Bargain

In their MTD brief (ECF Doc. 522-1:19), the Wholesalers allege that plaintiffs' breach of express warranty claims in the three Master Complaints fail for not pleading privity in those states where it is a required element. Wholesalers allege plaintiffs cannot at all plead privity under any condition or fact scenario in any U.S. state because the Wholesalers made no statements about the VCDs or engaged in behavior that could imply an economic obligation or relationship between the Wholesalers and individual

consumer plaintiffs or third party payor plaintiffs. *Id*. at 20. Wholesalers' argument rests on the assertion that plaintiffs have not, and importantly cannot, allege any perceptible or inferable communication to plaintiffs that could form the "basis of the bargain" under U.C.C. §2-313. *Ibid.*

In their brief (ECF Doc. 523-1:17-18), the Pharmacies assert that, at most, pharmacies warrant they dispense properly the prescribed drug they received from an FDA-approved manufacturer. The Pharmacies' addition of a customer-specific label to the drug packaging, which together with the drug insert that may have already been provided to the Pharmacies, does not morph into a Pharmacies' warranty. To be clear, the Pharmacies state they made no representations about valsartan whatsoever but merely provided what the Mfrs were already required to by the FDA. They aver such conduct cannot form the basis of a bargain that either induced plaintiffs to fill their valsartan prescriptions or expressed that valsartan was superior to other available antihypertensive medications.

In their opposition (ECF Doc. 577:57-58), plaintiffs contend breach of express warranty claims are sustainable against both the Wholesalers and the Pharmacies primarily because the VCDs sold by them were contaminated, not defectively designed,[10] an allegation similar to that which plaintiffs asserted against the Mfrs. However, the Master Complaints neither plead an express statement made by Wholesalers or Pharmacies, which can implicate the basis of a bargain with consumer plaintiffs or third party payor plaintiffs, nor do plaintiffs point specifically to such a statement in their opposition.

What the Complaints do imply is that the very conduct of selling a contaminated product by Wholesalers and Pharmacies rises to an express warranty. This line of reasoning has some traction for the Mfrs' conduct because of the bridging argument that Mfrs have had to comply expressly with making their generic drug chemically and biologically equivalent to the Orange Book patented drug. However, 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.

In reviewing the Master Complaints, the Court finds a breach of express warranty claim is pleaded in the ELMC at ¶357, in the PIMC at ¶¶481 – 490, and in the MMMC at ¶323, but that plaintiffs' fact allegations specifically relate to Mfrs' statements and behavior, and not to 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.

[10] The Court agrees the cases defendants cite and which concern express warranty liability for defectively designed drugs are not particularly on point here.

### 4.2.2 Privity

Plaintiffs also did not plead privity with either the Wholesalers or Pharmacies in any of the Master Complaints. In Section **4.1.2** above, the Court has already reviewed the privity requirements for pleading express warranties and incorporates those findings here: to wit, that ruling summarily that plaintiffs have not pleaded this element in the eleven contested states is premature. Therefore, not pleading privity between the plaintiffs and the Wholesalers and Pharmacies does not ground dismissal of plaintiffs' express warranty claims against these defendant groups.

The Court finds that plaintiffs have not pleaded the required element of a basis of the bargain in their express warranty claims against the Wholesalers and the Pharmacies. Accordingly, the Court **GRANTS** the Wholesaler defendants' and the Pharmacy defendants' motions to dismiss the claims for breach of express warranty against them in all three Master Complaints and **dismisses these claims WITHOUT PREJUDICE.**

Plaintiffs may file a motion for LEAVE TO AMEND these claims in the Master Complaints according to the deadlines set in the accompanying Order.

### 5.0 Breach of Implied Warranty Claims

In the ELMC (ECF Doc.121), there are two counts of breach of implied warranty of merchantability and fitness: in one count (*Id.*¶¶ 446-55), the individual consumer plaintiffs plead against all defendants; and in the other (*Id.* ¶¶457–465), the third party payor plaintiffs plead against the Mfrs and Wholesalers. In each of the PIMC (ECF Doc. 122 ¶¶491-496) and of the MMMC (ECF Doc. 123 ¶¶ 457-467), the personal injury plaintiffs plead one count of this breach against all defendants.

The law of implied warranty aims to protect the buyer from bearing the burden of loss where merchandise, though not violating an expressly agreed promise, does not conform to normal commercial standards or meet the buyer's particular purpose. Most sales of a consumer product by a merchant carry at least the implied warranty of merchantability.

Practically speaking, there is little difference under the law of most states in the pleading elements of a breach of an implied warranty of merchantability and a strict liability in tort. Indeed, the elements of these two causes of action are almost identical, except implied warranty sounds in contract, which in some states requires pleading privity between buyer and seller, whereas strict liability sounds in tort, with no privity required. Consequently, pleading both an implied breach of warrantability and strict liability in tort may be a strategy to hedge against the subsumption of a strict liability count by a state's products liability law, thereby allowing at least one of these claims to move forward.

As the broadest and most important[11] warranty in the Uniform Commercial Code ["U.C.C"], the implied warranty of merchantability is liberally construed in favor of the buyer.[12] It is based on the buyer's reasonable expectation that goods bought from a merchant, when compared with other goods of that same kind, will be free of significant defects and perform in the way goods of that kind should perform. This warranty presupposes no special relationship of trust or reliance between the seller and buyer,[13] but is breached when the product is defective to a normal buyer making ordinary use of the product. To be clear, the Court takes the view that, if the parties refer to a warranty of fitness for a particular purpose, the better interpretation is that the reference is to merchantability, the broader, rather than narrower, implied warranty.[14]

To plead properly a breach of implied warranty of merchantability[15], a plaintiff must allege:

(1) that a merchant sold goods;

(2) which were not "merchantable" at the time of sale (i.e. they were defective);

(3) the plaintiff suffered injury and damages; and

(4) the defect (or other condition) proximately caused the injury.[16]

---

[11] *Omega Engineering, Inc. v. Eastman Kodak Co.*, 30 F. Supp. 2d 226 (D. Conn. 1998) (applying Connecticut law); *Keahole Point Fish LLC v. Skretting Canada Inc.*, 971 F. Supp. 2d 1017 (D. Haw. 2013) (applying Hawaii law); *Schneider Nat., Inc. v. Holland Hitch Co.*, 843 P.2d 561 (Wyo. 1992).

[12] *Haugland v. Winnebago Industries*, 327 F. Supp. 2d 1092 (D. Ariz. 2004) (applying Arizona law); *Rorick v. Hardi North America Inc.*, 88 U.C.C. Rep. Serv. 2d 1313 (N.D. Ind. 2016) (applying Indiana law); *Hyundai Motor America, Inc. v. Goodin*, 822 N.E.2d 947 (Ind. 2005); *Construction and effect of UCC Art 2*, dealing with sales, 17 A.L.R.3d 1010.

[13] *Guttmann v. La Tapatia Tortilleria, Inc.*, 2015 WL 7283024 (N.D. Cal. 2015) (applying California law); *Employers Mut. Cas. Co. v. Collins & Aikman Floor Coverings, Inc.*, 2004 WL 840561 (S.D. Iowa 2004), *supplemented*, 2004 WL 840258 (S.D. Iowa 2004) (applying Iowa law).

[14] It has been held in a pharmaceutical product case that a breach of implied warranty of merchantability has been shown to lie even if the product causes harm unrelated to the purpose for which the product was utilized. *See Oliver v. McNeil-PPC, Inc.*, 2013 WL 459630 (E.D. Cal. 2013), report and recommendation adopted, 2013 WL 1003484 (E.D. Cal. 2013 [plaintiffs' decedents allegedly ingested pain reliever, and were subsequently diagnosed with liver failure, which resulted in their death].

[15] In order to compare the pleading requirements of a breach of implied warranty of merchantability with those of a strict products liability claim, the elements of a strict liability claim are enumerated below:

In a jurisdiction following Restatement (Second) of Torts § 402A(1) (1965), a plaintiff must show:
(1) the seller was in the business of selling the product;
(2) and put a defective and unreasonably dangerous product on the market; and
(3) the condition of the product caused the consumer injury and damages.

In a jurisdiction following Restatement (Third) of Torts: Prods. Liab. § 2(b) (1998), a plaintiff must show:
(1) the product was designed with foreseeable risks of harm,
(2) which could have been reduced or avoided by utilizing an alternative design; and
(3) the failure to utilize the alternate design caused the product to fail to be reasonably safe.

Thus, the Restatement Second focuses on the unreasonable danger of the product, while the Restatement Third focuses on defective design of the product.

[16] *U.C.C. § 2-314 Implied Warranty: Merchantability; Usage of Trade*. Current through 2019 annual meetings of National Conference of Commissioner on Uniform State Laws and American Law Institute.

The individual consumer plaintiffs (and classes of these) in all three complaints specifically plead these required elements:

(1) that all 3 categories of defendants together put contaminated VCDs on the market,

(2) which were not "merchantable" at the time of sale because these VCDs contained carcinogens that, according to the Orange Book, were unexpected to be present,

(3) the individual plaintiffs suffered injury and damages because of ingesting these VCDs,

(4) which was the occurrence of cancer or the risk of a higher probability of it.

### 5.1 Mfrs and Wholesalers

#### 5.1.1 Benefit of the Bargain, Product's Functionality, and Present Injury

The Mfrs MTD (ECF Doc. 520-3:45-46) and the Wholesalers MTD (ECF Doc. 522-1:19, 21) assert that two additional required pleading elements are absent in plaintiffs' implied warranty claims: present injury and privity. These defendants contend that, in the MMMC and the ELMC, individual consumer plaintiffs and third party payor plaintiffs have alleged only future, not present, injury of the individual consumer plaintiffs. Defendants cite to several cases in this District for the proposition that, in a breach of implied warranty claim, plaintiffs must show how an alleged defect impaired the product's functionality and not merely that a defect or impurity was present in the VCDs. ECF Doc. 520-3:46 (Mfrs MTD, which argument Wholesalers MTD incorporates).

Plaintiffs argue that both individual consumers and the third party payors paid out of pocket for the VCDs at issue and are therefore economically injured. To plaintiffs' point, they rely on *Debernardis v. IQ Formulations, Inc.*, 942 F.3d 1076, 1084-85 (11th Cir. 2019) to aver that, when a product is rendered valueless as a result of its defect, there is no need to demonstrate how the alleged defect diminished the product's functionality. That is, plaintiffs contend a defective drug made dangerous because of carcinogenic contaminants is worthless, regardless whether it lowered consumers' blood pressure. Consequently, the purchase of a drug made worthless because of such danger incurs economic harm

---

(1) Unless excluded or modified (Section 2-316), a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. Under this section the serving for value of food or drink to be consumed either on the premises or elsewhere is a sale.
(2) Goods to be merchantable must at least be such as
(a) pass without objection in the trade under the contract description; and
(b) in the case of fungible goods, are of fair average quality within the description; and
(c) are fit for the ordinary purposes for which such goods are used; and
(d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and
(e) are adequately contained, packaged, and labeled as the agreement may require; and
(f) conform to the promises or affirmations of fact made on the container or label if any.
(3) Unless excluded or modified (Section 2-316) other implied warranties may arise from course of dealing or usage of trade.
*See* §20:6 AMERICAN LAW OF PRODUCTS LIABILITY 3D *Warranty Liability.*

The gravemen in *Debernardis* was whether plaintiffs had standing to sue, that is, whether they had pleaded an injury in fact. Finding guidance in a Seventh Circuit case and a Ninth Circuit case,[17] the *Debernardis* court determined that, at the motion to dismiss stage, an adulterated vitamin supplement was worthless and had no value because it should not have been sold in the first place. Since the issue of whether plaintiffs had standing by showing an injury in fact—namely, whether an adulterated product is worthless and therefore the cause of economic injury—a more stringent showing than finding "present injury" in an implied warranty liability claim, this Court is persuaded by *Debernardis* and the other Circuit cases it relied on.

This Court finds that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure. Put differently, contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for. Further, contaminated drugs do create a present injury because their sale should never have occurred. Accordingly, in both the MMMC and the ELMC, individual consumer plaintiffs and third party payor plaintiffs need not demonstrate a "benefit of the bargain" theory of economic damages to plead adequately a breach of implied warranty because they have alleged sufficient injury and the lack of the VCDs' functionality at the motion to dismiss stage.

#### 5.1.2 Privity: PIMC

The Mfr defendants contend that the PIMC fails to allege privity in its breach of implied warranty claim and that the following states--Florida, Georgia, Kentucky, and Wisconsin—still require privity for personal injury claims ECF Doc. 520-3:46, fn.45; *see* ECF Doc. 520-5 (Exhibit 5):35, fn. 6. Since none of the Master Complaints pleaded privity, Mfr defendants assert the PIMC implied warranty claims in these states must be dismissed.

Plaintiffs specifically contend, however, that Florida and Georgia do not require privity in an implied breach of warranty claim for individual consumers. ECF Doc 577:68. The Court agrees with plaintiffs.

Accordingly, the Court **GRANTS** the Mfr defendants' and the Wholesaler defendants' motions to dismiss those claims in the Personal Injury Master Complaint for breach of implied warranty which arise under the law of Kentucky or Wisconsin and **dismisses these claims WITHOUT PREJUDICE.** The Court **DENIES** the Mfrs defendants' and the Wholesaler defendants' motions dismiss those claims in the

[17] *In re Aqua Dots Products Liability Litig.*, 654 F.3d 748 (7th Cir. 2011); *Franz v. Beiersdorf, Inc.*, 745 F. App'x 47 (9th Cir. 2018) (unpublished).

Personal Injury Master Complaint for breach of implied warranty which arise under the law of any of the remaining states in the United States and including the District of Columbia and Puerto Rico.

Plaintiffs may file a motion for LEAVE TO AMEND these dismissed claims in the Personal Injury Master Complaint, according to the deadlines set in the accompanying Order.

### 5.1.3 Privity: ELMC and MMMC

The Mfrs and Wholesalers MTDs allege (ECF Doc. 520-3: 45-46) that neither the ELMC nor the MMMC explicitly pleads privity between plaintiffs and these defendants nor can these complaints imply privity because plaintiffs did not purchase the VCDs at issue directly from them. In ECF Doc. 520-5 (Exhibit 5):35-36, the Mfr Defendants allege privity is a required pleading element in 22 states: Alabama, Arizona, Connecticut, Florida, Georgia, Idaho, Illinois, Iowa, Kansas, Kentucky, Michigan, Nevada, New York, North Carolina, Ohio, Oregon, Tennessee, Utah, Vermont, Virginia, Washington, and Wisconsin. Interestingly, in ECF Doc. 522-2:17-18, the Wholesalers allege privity is required in 19 states: Alabama, Arizona, Connecticut, Florida, Georgia, Idaho, Illinois, Iowa, Kansas, Kentucky, Michigan, New York, North Carolina, Ohio, Oregon, Tennessee, Utah, Vermont, and Wisconsin. By their omission, Wholesalers appear to allege that privity for breach of implied warranty is not a required element in Nevada, Virginia and Washington. Even more interesting is that the Court's own research of the privity pleading requirements in each of the 22 states named above shows the Wholesalers' list is the more correct. Therefore, Nevada, Virginia, and Washington are excluded from the discussion in this section.

In their opposition (ECF Doc. 577: 68-71), plaintiffs raise the following points:

1) Case law in Florida, Georgia, Illinois, and Vermont imputes privity when the manufacturer has made express warranties to the ultimate consumer. Since the Court has found in a previous section the Mfr defendants made express warranties to the ultimate purchasers, which include plaintiffs in both the ELMC and the MMMC, Florida, Georgia, Illinois, and Vermont are excluded from defendants' list for the Mfr defendants, but not for the Wholesalers.

2) Case law in Alabama, Florida, Nevada, North Carolina, Ohio, and Washington relieves pleading privity based on a third party beneficiary theory when manufacturers have made warranties to a dealer or intermediate seller. Thus, these states are excluded from defendant's list for the Wholesalers, but not for Mfr defendants.

3) Case law in Connecticut and New York relieves pleading privity when the consumed products are food or drugs. Thus, these states are excluded from defendants' list for Mfr defendants, but not Wholesalers.

To summarize:

**for Mfr defendants**, case law in Alabama, Arizona, Idaho, Iowa, Kansas, Kentucky, Michigan, North Carolina, Ohio, Oregon, Tennessee, Utah, and Wisconsin requires the pleading of privity between a plaintiff and a manufacturer for a breach of implied warranty. The Court finds plaintiffs have not pleaded this required element in the ELMC and the MMMC for claims of breach of implied warranty arising in these states against the Mfr defendants.

Accordingly the Court **GRANTS** the Mfr defendants' motion to dismiss those claims in the Economic Loss Master Complaint and in the Medical Monitoring Master Complaint for breach of implied warranty which arise under the law of: Alabama, Arizona, Idaho, Iowa, Kansas, Kentucky, Michigan, North Carolina, Ohio, Oregon, Tennessee, Utah, or Wisconsin and **dismisses these claims WITHOUT PREJUDICE**. The Court **DENIES** the Mfr defendants 'motion to dismiss those claims in the Economic Loss Master Complaint and in the Medical Monitoring Master Complaint for breach of implied warranty which arise under the law of any of the remaining states in the United States and including the District of Columbia and Puerto Rico.

Plaintiffs may file a motion for LEAVE TO AMEND the these dismissed claims in the Economic Loss Master Complaint and the Medical Monitoring Master Complaint Master, according to the deadlines set in the accompanying Order.

**For Wholesaler defendants**, 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 beneficiary 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.

Accordingly, the Court **GRANTS** the Wholesaler defendants' motion to dismiss those claims in the Economic Loss Master Complaint and in the Medical Monitoring Master Complaint for breach of implied warranty which arise under the law of Arizona, Connecticut, Georgia, Idaho, Illinois, Iowa, Kansas, Kentucky, Michigan, New York, Oregon, Tennessee, Utah, Vermont, or Wisconsin and **dismisses these claims WITHOUT PREJUDICE.** The Court **DENIES** the Wholesaler defendants' motion to dismiss those claims in the Economic Loss Master Complaint and in the Medical Monitoring Master Complaint for breach of implied warranty which arise under the law of any of the remaining states of the United States and including the District of Columbia and Puerto Rico.

Plaintiffs may file a motion for LEAVE TO AMEND these dismissed claims in the Economic Loss Master Complaint and the Medical Monitoring Master Complaint against the Wholesaler defendants, according to the deadlines set in the accompanying Order.

Accordingly, the Court **GRANTS** the Wholesalers' motion to dismiss plaintiffs' claims in the ELMC and the MMMC of breach of implied warranty arising under the law of: Arizona, Connecticut, Georgia, Idaho, Illinois, Iowa, Kansas, Kentucky, Michigan, New York, Oregon, Tennessee, Utah, Vermont, and Wisconsin and **dismisses these claims WITHOUT PREJUDICE.**

To be clear, the Court **DENIES** the Wholesalers motion to dismiss plaintiffs' claims in the ELMC and the MMMC of breach of implied warranty arising under the law of any of the remaining states, of the District of Columbia, or of Puerto Rico.

Plaintiffs may file a motion for LEAVE TO AMEND the ELMC and the MMMC according to the deadlines set in the accompanying Order.

**5.2 Pharmacies for all three Master Complaints**

In their MTD (ECF Doc. 523-1: 11-12), the Pharmacies assert that pharmacies generally are not subject to strict liability for latent defects in the drugs they dispense. This is largely because pharmacies provide a service not a product. Pharmacies imply that since a claim for a breach of implied warranty is but a kind of strict liability claim, pharmacies are not subject to these warranty claims and provide an exhibit listing state law cases dismissing such claims. ECF Doc. 523-3 (Exhibit B).

Plaintiffs argue that the legal theory of implied warranty here is not at all the same as a strict liability-design defect (to wit, that the Pharmacies sold VCDs that were defectively designed). Rather, plaintiffs' legal theory in these claims is that the drugs were adulterated and the pharmacies failed to warn, to wit, a strict liability-failure to warn theory, not a defective design theory. Thus, plaintiffs distinguish the strict liability basis that underlies their breach of implied warranty claims. This distinction is relevant because at least one state, Nevada, allows pharmacies to be sued for a breach of implied warranty under a strict liability theory of failure to warn.

Plaintiffs do not dispute the accuracy of the cited case law in Pharmacies' Exhibit B (Doc. 523-3). In an effort to apply the recommended liberality towards breach of implied warranty claims, the Court examined in detail the cases cited in Pharmacies' Exhibit B for any case that either relied on a strict liability–failure to warn theory or for any state that lacked case law with specific applicability to pharmacies. In essence, the Court was looking for any jurisdictions where the Pharmacies' assertions likely did not apply or where the law was as yet unclear.

Accordingly, the Court **GRANTS** the Pharmacy defendants' motion to dismiss those claims in all three Master Complaints for breach of implied warranty which arise 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, or Wisconsin. The Court **DENIES** the Pharmacy defendants' motion to dismiss those claims in all three Master Complaints for a breach of implied warranty which arise under the law of Alaska, Colorado, Delaware, Idaho, Montana, Nevada, Oregon, Rhode Island, South Dakota, or Vermont.

Plaintiffs may file a motion for LEAVE TO AMEND all three Master Complaints as to the breach of implied warranty claims against the Pharmacy defendants, according to the deadlines set in the accompanying Order.

### 6.0 Magnuson-Moss Warranty Act

The Magnuson-Moss Warranty Act (MMWA), 15 U.S.C. 2301-2312, is the federal law governing warranties for consumer products, which was enacted around forty-five years ago in order to make warranties more understandable and limit the use of disclaimers. In a nutshell, if a seller of consumer products opts to include a warranty (which the law does not require), it has to follow federal guidelines calling for conspicuous warranties in readily understood language. The Act requires manufacturers and sellers of consumer products to provide consumers with detailed information about warranty coverage before and after the sale of a warranted product. When consumers believe they are the victim of an MMWA violation, the statute allows them to proceed through a warrantor's informal dispute resolution process or sue in court.

To plead a violation under the MMWA, a plaintiff must assert there is a valid warranty, the product was presented for repair during the warranty period, and the manufacturer failed to conform the product to the provisions of the warranty within a reasonable amount of time or number of repair attempts. The measure of damages for breach of warranty under Magnuson-Moss is the difference in the value of the goods at the time and place the party accepted the goods and the value they would have had if they had been as warranted. Magnuson-Moss defines "implied warranty" as a creature of state law

Defendants argue 15 U.S.C. §2311(d)[18] prohibits the MMWA from applying to any express or implied warranty claims that involve the labelling of valsartan products because federal law governs the content of a generic drug's label.[19] This argument is a relatively recent one.

---

[18] ..." (d) Other Federal warranty laws :

This chapter (other than section 2302(c) of this title) shall be inapplicable to any written warranty the making or content of which is otherwise governed by Federal law. If only a portion of a written warranty is so governed by Federal law, the remaining portion shall be subject to this chapter.

[19] It hasn't been until recently that this provision has been cited in a matter concerning drugs as FDA-regulated products for dismissing MMWA claims.

Through the Food Drug and Cosmetic Act, the FDA extensively regulates the labeling, marketing, and sale of all over-the-counter medications. . . . As such, the MMWA is inapplicable to any alleged express or implied warranty claims on [such products]. See a most recent promulgation of that in this Court at *Hernandez v. Johnson & Johnson Consumer, Inc.*, 2020 WL 2537633, at *5 (D.N.J. May 19, 2020) (citations omitted). Further, *Hernandez* cited several cases involving other types of

One reason why this argument has been unused is that the MMWA does not allow recovery of personal injury damages (See 15 USC §2311(b)(2)[20]) and therefore will not advance personal injury claims of those who ingested drugs. Another is that drugs have not been considered typical "consumer" products within the scope of the MMWA. *See Kanter v. Warner-Lambert Co.*, 122 Cal. Rptr.2d 72, 86 (Cal. App. 2002); *Bates v. Monarch Dental Services*, 2019 WL 5067904, at *4 (N.D. Tex. 9 Oct. 2019); *Bhatia v. 3M Co.*, 323 F. Supp.3d 1082, 1102-03 (D. Minn. 2018); *MHA, LLC v. Siemens Healthcare Diagnostics, Inc.*, 2017 WL 838797, at *2 (D.N.J. 2 March 2017); *In re Minnesota Breast Implant Litigation*, 36 F. Supp.2d 863, 876 (D. Minn. 1998); *Goldsmith v. Mentor Corp.*, 913 F. Supp. 56, 63 (D.N.H. 1995); *Kemp v. Pfizer, Inc.*, 835 F. Supp. 1015, 1024 (E.D. Mich. 1993); *see also In re DePuy Orthopaedics, Inc. ASR Hip Implant Products Liability Litigation*, 953 F.3d 890, 896 (6th Cir. 2020) [raising, but not deciding issue].

This Court has recently endorsed the argument that the MMWA prohibits warranty claims involving FDA-regulated items. *See Hernandez v. Johnson & Johnson Consumer, Inc.*, 2020 WL 2537633, at *5 (D.N.J. 19 May 2020) (citations omitted) [involving over-the-counter medications]. In dismissing the MMWA claim at issue, *Hernandez* cited several cases involving other types of FDA-regulated products. *Ibid.* [*citing Dopico v. IMS Trading Corp.*, 2018 WL 4489677 (D.N.J. 18 Sept. 2018) (pet food), *Reid v. GMC Skin Care USA Inc.*, 2016 WL 403497, at *13 (N.D.N.Y. 15 Jan. 2016) (skin cream), and *Jasper v. MusclePharm Corp.*, No. 14–02881, 2015 WL 2375945, at *5–6 (D. Colo. 9 April 2015) (dietary supplement)).

Plaintiffs assert that all three Master Complaints plead a violation of the MMWA. In their opposition, they contend that the viability of the MMWA claims depends on applicable state law, and argue that, because the state warranty claims are viable, so also are the MMWA claims. ECF Doc. 577: 54, n. 12.

Although this Court has found here that the Mfr defendants did make an express warranty to plaintiffs because of their naming the product "valsartan" and that the Mfr defendants and Wholesalers as well as the Pharmacies are liable for breaching an implied warranty in select states, the Court also finds that plaintiffs have not and cannot have pleaded their Magnuson Moss claims properly for two reasons:

1) based on *Hernandez*, consumer items regulated by the FDA are not the proper subject of a MMWA claim; and

---

FDA-regulated products in dismissing the MMWA claim at issue. *Ibid*. [*citing Dopico v. IMS Trading Cor*p., 2018 WL 4489677 (D.N.J. Sept. 18, 2018) (pet food), *Reid v. GMC Skin Care USA Inc*., 2016 WL 403497, at *13 (N.D.N.Y. Jan. 15, 2016) (skin cream), and *Jasper v. MusclePharm Corp*., No. 14–02881, 2015 WL 2375945, at *5–6 (D. Colo. April 9, 2015) (dietary supplement)).

[20] "Nothing in this chapter . . . shall [] affect the liability of, or impose liability on, any person for personal injury. .. ."

2) plaintiffs cannot meet the pleading requirements of the MMWA because plaintiffs failed to present to any defendant that the drug was contaminated and sought a "repair".

Accordingly, The Court **GRANTS** the motions to dismiss the claims in all three Master Complaints for violation of the Magnuson-Moss Warranty Act and **dismisses** plaintiffs' claims in all three Master Complaints **WITH PREJUDICE**.

## 5.0 Conclusion

For the reasons discussed above, the Court rules as follows on defendants' motion to dismiss in the Master Complaints the claims of breach of express warranty, of breach of implied warranty, and of violation of the Magnuson Moss Warranty Act:

**As For Breach of Express Warranty Claims**

Against Mfr defendants: the Court **DENIES** the Mfr defendants' motion to dismiss the breach of express warranty claims against them in all three Master Complaints **;**

Against the Wholesaler defendants and the Pharmacy defendants: the Court **GRANTS** the Wholesaler defendants' and the Pharmacy defendants' motions to dismiss the claims for breach of express warranty against them in all three Master Complaint**s** and **dismisses these claims WITHOUT PREJUDICE,**

Plaintiffs may file a motion for LEAVE TO AMEND all three Master Complaints as to the breach of express warranty claims against the Wholesaler defendants and the Pharmacies defendants, according to the deadlines set in the accompanying Order.

**As For Breach of Implied Warranty Claims**

Against Mfr defendants and Wholesaler defendants as to the Personal Injury Master Complaint:

the Court **GRANTS** the Mfr defendants' and the Wholesaler defendants' motions to dismiss those claims in the Personal Injury Master Complaint for breach of implied warranty which arise under the law of Kentucky or Wisconsin and **dismisses these claims WITHOUT PREJUDICE**; and

the Court **DENIES** the Mfrs defendants' and the Wholesaler defendants' motions dismiss those claims in the Personal Injury Master Complaint for breach of implied warranty which arise under the law of any of the remaining states in the United States and including the District of Columbia and Puerto Rico.

Plaintiffs may file a motion for LEAVE TO AMEND these dismissed claims in the Personal Injury Master Complaint, according to the deadlines set in the accompanying Order.

Against the Mfr defendants as to the Economic Loss and the Medical Monitoring Master Complaints:

the Court **GRANTS** the Mfr defendants' motion to dismiss those claims in the Economic Loss Master Complaint and in the Medical Monitoring Master Complaint for breach of implied warranty which arise under the law of: Alabama, Arizona, Idaho, Iowa, Kansas, Kentucky, Michigan, North Carolina, Ohio, Oregon, Tennessee, Utah, or Wisconsin and **dismisses these claims WITHOUT PREJUDICE**; and.

the Court **DENIES** the Mfr defendants 'motion to dismiss those claims in the Economic Loss Master Complaint and in the Medical Monitoring Master Complaint for breach of implied warranty which arise under the law of any of the remaining states in the United States and including the District of Columbia and Puerto Rico.

Plaintiffs may file a motion for LEAVE TO AMEND the these dismissed claims in the Economic Loss Master Complaint and the Medical Monitoring Master Complaint Master, according to the deadlines set in the accompanying Order.

Against the Wholesalers as to the Economic Loss and the Medical Monitoring Master Complaints

the Court **GRANTS** the Wholesaler defendants' motion to dismiss those claims in the Economic Loss Master Complaint and in the Medical Monitoring Master Complaint for breach of implied warranty which arise under the law of Arizona, Connecticut, Georgia, Idaho, Illinois, Iowa, Kansas, Kentucky, Michigan, New York, Oregon, Tennessee, Utah, Vermont, or Wisconsin and **dismisses these claims WITHOUT PREJUDICE**; and

the Court **DENIES** the Wholesaler defendants' motion to dismiss those claims in the Economic Loss Master Complaint and in the Medical Monitoring Master Complaint for breach of implied warranty which arise under the law of any of the remaining states of the United States and including the District of Columbia and Puerto Rico.

Plaintiffs may file a motion for LEAVE TO AMEND these dismissed claims in the Economic Loss Master Complaint and the Medical Monitoring Master Complaint against the Wholesaler defendants, according to the deadlines set in the accompanying Order.

Against the Pharmacy defendants in all three Master Complaints:

the Court **GRANTS** the Pharmacy defendants' motion to dismiss those claims in all three Master Complaints for breach of implied warranty which arise 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, or Wisconsin; and

the Court **DENIES** the Pharmacy defendants' motion to dismiss those claims in all three Master Complaints for a breach of implied warranty which arise under the law of Alaska, Colorado, Delaware, Idaho, Montana, Nevada, Oregon, Rhode Island, South Dakota, or Vermont.

Plaintiffs may file a motion for LEAVE TO AMEND all three Master Complaints as to the breach of implied warranty claims against the Pharmacy defendants, according to the deadlines set in the accompanying Order.

**As for Violation of Magnuson Moss Warranty Claims**

The Court **GRANTS** the motions to dismiss the claims in all three Master Complaints for violation of the Magnuson-Moss Warranty Act and **dismisses** plaintiffs' claims in all three Master Complaints **with prejudice**.

Dated: 22 January 2021

/s Robert B. Kugler
ROBERT B. KUGLER
United States District Judge