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 1**

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 will be numbered in the series, this opinion being the first in the series. This OPINION 1 resolves the arguments relating to Preemption by two Federal Laws of plaintiffs' state law claims and the Primary Jurisdiction of the FDA over these claims. An ORDER 1 of this date accompanies this OPINION 1.

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

[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.

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 Complaint in its entirety primarily because of a deficiency in pleading an injury in fact;
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: 3 defendants of defendant 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;
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 Preemption by two Federal Laws of plaintiffs' state law claims and the Primary Jurisdiction of the FDA over these claims, and for the reasons stated below, and for good cause shown:

As for preemption by the Food, Drug, and Cosmetic Act by federal law, the Court DENIES defendants' Motions to Dismiss the claims in any Master Complaint;

As for preemption by the Drug Supply Chain Security Act, the Court DENIES Wholesalers'

and Pharmacies' Motions to Dismiss the claims in any Master Complaint;

As for the primary jurisdiction of the FDA over claim for breach of implied warranty, strict liability, failure to warn, negligence and manufacturing defect, the Court DENIES defendants' Motions to Dismiss.

1.0 FACTS AND PROCEDURAL BACKGROUND

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], a quite universally prescribed drug to lower blood pressure, contained nitrosamines, known carcinogens. 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. As used herein, "VCDs at issue" refer to VCDs that were contaminated by these nitrosamines and sold in the U.S.

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.

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 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, third-party payors who had paid for individual plaintiffs' prescriptions of the contaminated Valsartan, had filed several complaints. On 14 February 2019, the Judicial Panel on Multi-District Litigation ["JPML"] consolidated all of the individual filings into this MDL, No. 2875. Since

[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®.

then, this MDL has advanced significantly, both in terms of filings and in the management of the litigation through various discovery phases. Currently, with almost 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) will commence shortly.

2.0 CONTENTIONS

2.1 Plaintiffs

Generally, the three Master Complaints as a unit allege approximately three dozen claims on behalf of hundreds of individual plaintiffs and of putative statewide and nationwide classes of consumers against over 40 separate defendants. The claims cite violations of federal and state statutory law, common law and theories of equity, which the Complaints assert equally apply across all 50 states and in the District of Columbia and Puerto Rico. Specifically, plaintiffs belong to one or more of the groups named in each of the three Master Complaints below.

2.1.1 Economic Loss Master Complaints

Plaintiffs in this Master Complaint 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.

2.1.2 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.

2.1.3 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.

2.2 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.

3.0 MOTION TO DISMISS STANDARD

Defendants' motions rely on *Fed.R.Civ.P.* ["FRCP" or "Rule"] *12(b)(1)* and *(6).* Against the PIMC, these motions are brought under Rule *12(b)(6)*. Against the ELMC plaintiffs and the MMMC plaintiffs, these motions assert a facial challenge under Rule *12(b)(1)* for lack of standing, which is reviewed under the same standard as a Rule *12(b)(6)* motion. ECF Doc. 520-3:7 (Mfrs Brief). In a footnote, MFR's Brief identifies the PIMC as an administrative master complaint, while the ELMC and the MMMC complaints are termed operative. Defendants state the difference is that an administrative complaint summarizes the claims of individuals but nonetheless retains the claims for the duration of the MDL, while an operative complaint not only summarizes the claims of the individual plaintiffs but supersedes them during the MDL. They rely on an uncited footnote, note 3, in *Gelboim v. Bank of Am. Corp.*, 574 U.S. 405, 135 S.Ct. 897,190 L.Ed.2d 789 (2015).[5] However, the Court finds *In re Refrigerant Compressors*

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

[5] "Cases consolidated for MDL pretrial proceedings ordinarily retain their separate identities,[3] so an order disposing of one of the discrete cases in its entirety should qualify under § 1291 as an appealable final decision. Section 1407 refers to individual "actions" which may be transferred to a single district court, not to any monolithic multidistrict "action" created by transfer. See *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach,* 523 U.S. 26, 37, 118 S.Ct. 956, 140 L.Ed.2d 62 (1998) (§ 1407 does not "imbu[e] transferred actions with some new and distinctive ... character"). [footnote omitted]. And Congress anticipated that, during the pendency of pretrial proceedings, final decisions might be rendered in one or more of the actions consolidated pursuant to § 1407. It specified that "at or before the conclusion of ... pretrial proceedings," each of the transferred actions must be remanded to the originating district "*unless [the action] shall have been previously terminated.*" § 1407(a) (emphasis added).

[3] Parties may elect to file a "master complaint" and a corresponding "consolidated answer," which supersede prior individual pleadings. In such a case, the transferee court may treat the master pleadings as merging the discrete actions for the duration of the MDL pretrial proceedings. *In re Refrigerant Compressors Antitrust Litigation,* 731 F.3d 586, 590–592 (C.A.6 2013). No merger occurs, however, when "the master complaint is not meant to be a pleading with legal effect but only an administrative summary of the claims brought by all the plaintiffs." *Id.*, at 590. "

Antitrust Litigation, 731 F.3d 586, 590 (6th Cir. 2013) presents better definitions of these two kinds of complaints.[6]

FRCP 12(b)(6) 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 specific inquiry involves a three-part analysis (*Santiago v. Warminster Twp.,* 629 F.3d 121, 130 (3d Cir.2010)) in which ta 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." *Id.*

Practically speaking, this plausibility determination is a "context-specific task that requires 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 and "[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).

Gelboim, 574 U.S. at 413.

[6] "Because each transferred case comes with its own pleadings, a multidistrict transfer threatens to submerge the transferee district court in paper. A common solution to this difficulty, one adopted in this case, is for the plaintiffs to assemble a "master complaint" that reflects all of their allegations. In many cases, the master complaint is not meant to be a pleading with legal effect but only an administrative summary of the claims brought by all the plaintiffs. When plaintiffs file a master complaint of this variety, each individual complaint retains its separate legal existence. [citation omitted]... But, in other cases, the court and the parties go further. They treat the master complaint as an operative pleading that supersedes the individual complaints. The master complaint, not the individual complaints, is served on defendants. The master complaint is used to calculate deadlines for defendants to file their answers. And the master complaint is examined for its sufficiency when the defendants file a motion to dismiss. [citation omitted].

4.0 PREEMPTION

4.1 Preemption by the Federal Food, Drug and Cosmetic Act ["FDCA"]

The Mfrs contend in their MTD that the following claims—negligence *per se*, strict liability-defective design, breach of express warranty, fraud misstatement and negligent misstatement and state consumer-protection laws— in the Master Complaints are improper attempts to enforce the FDCA through state law and are preempted because the FDCA gives no right of action for private litigants. The Mfrs do not cite the latest, single-most, on-point Supreme Court case for preemption of the FDCA in a pharmaceutical context, *Wyeth v. Levine*, 555 U.S. 555, 129 S.Ct. 118 7173 L.Ed.2d 51 (2009). Instead, they cite **pre**-*Wyeth* cases—a Supreme Court case, *Buckman Co. v Plaintiffs' Legal Comm*,[7] and a Third Circuit case—*Horn v. Thoratec*[8] and They also cite a post-Wyeth Third Circuit case[9] that involves preemption of the Federal Communication Commission ["FCC"] (primarily because it cites generally to *Buckman)* but which has nothing to do with preemption of the FDCA.

To the point, *Wyeth* concerns the state law claim of failure of a drug label to warn of the danger to injecting the anti-nausea drug Phenergan intravenously. The Court held that the FDCA did NOT preempt plaintiff's state law claim and rejected both of Wyeth's arguments. First, Wyeth argued "impossibility", that it could not comply with both state and federal law because the drug label, once FDA approved, could only be changed by the FDA; second, Wyeth argued recognition of plaintiff's state law action would create an unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *Wyeth*, 555 U.S. at 564.

The Court stated two guiding principles to determining preemption of federal law: 1) "the purpose of Congress is the ultimate touchstone in every preemption case." [citations omitted]; and 2), "[i]n all preemption cases, and particularly in those in which Congress has 'legislated ... in a field which the States have traditionally occupied,' ... we 'start with the assumption that the historic police powers of the States **were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress**.' " [citations omitted]. *Id*. at 565. [emphasis added].

As for the "impossibility defense", the Court found it nearly impossible for a drug manufacturer to succeed there, because a drug manufacturer never relinquishes its responsibility to present accurate labelling. *Id.* at 570-573.

As for the "unacceptable obstacle" defense, the Court stated that Congress had not intended to pre-empt state law claims in pharmaceutical cases.[10] Despite Wyeth's argument that the FDA had

---

[7] 531 U.S. 341, 353, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001).
[8] 376 F.3d 163, 170-71 (3d Cir. 2004)
[9] *Farina v. Nokia, Inc.*, 625 F.3d 97, 124 (3d Cir. 2010).
[10] The Wyeth Court stated:

> "If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's 70–year history. But despite its 1976 enactment of an express preemption provision for medical devices, see § 2, 90 Stat. 574 (codified at 21 U.S.C. § 360k(a)), Congress

stated in the preamble of its 2006 regulations that FDA label approval preempts conflicting or contrary State law, the Court nevertheless retained the authority to perform "its own conflict determination, relying on the substance of state and federal law and not on agency proclamations of preemption." *Id*. at 575-576. The Court declared the weight accorded to an agency's explanation of a state law's impact on the federal scheme depends on the thoroughness, consistency, and persuasiveness of that explanation. *Id*. at 577. The Court found the FDA's "throwaway" statement regarding preemption in the preamble of its 2006 regulations could not be accorded deference. As a single, simple statement, the Court found it an outlier to the FDA's time-honored and traditional position that "[i]n keeping with Congress' decision not to pre-empt common-law tort suits" . . . the FDA traditionally regarded state law as a complementary form of drug regulation**."** *Id*. at 578**.** The Court therefore found the "state law as obstacle" argument meritless.[11]

As for the Mfrs' reliance on *Buckman*, in *Tigert v. Ranbaxy Pharmaceuticals, Inc*., Civ. No. 12–00154, 2012 WL 6595806 (D.N.J. 18 December 2012) (Kugler, J.), this Court had the opportunity to review the breadth and significance of the *Buckman* holding. In *Tigert,* defendant pharmaceutical manufacturer moved for judgment on the pleadings under Rule 12(c) and argued the immunity exception (under Texas law) that plaintiff had invoked was pre-empted by federal law. Injured by using defendant's acne medication, plaintiff sued defendant under state law for strict products liability or a

---

> has not enacted such a provision for prescription drugs. See *Riegel [v. Medtronic],* 552 U.S. [312], at 327, 128 S.Ct., at 1009 ("Congress could have applied the preemption clause to the entire FDCA. It did not do so, but instead wrote a preemption clause that applies only to medical devices"). [footnote omitted]. Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness. As Justice O'Connor explained in her opinion for a unanimous Court: "The case for federal preemption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.,* 489 U.S. 141, 166–167, 109 S.Ct. 971, 103 L.Ed.2d 118 (1989) (internal quotation marks omitted); see also *supra,* at 1194 [564] (discussing the presumption against preemption)."

[11] Moreover, not only Supreme Court jurisprudence, but also the Corpus Juris Secundum informs the Court's decision and makes clear that preemption does not generally apply to state law claims for pharmaceuticals. To wit:

"The provision of the Federal Food, Drug, and Cosmetic Act
> [footnote 11:[11] which prevents states from establishing any requirements for medical "devices" different from, or in addition to, federal requirements],

is not applicable to prescription drugs,
> [footnote 12: *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024 (D.N.J. 1988); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 8 U.C.C. Rep. Serv. 2d 983 (D. Or. 1989)]

and does **not preempt state tort law**. [emphasis added]
> [footnote 13: *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662 (D. Md. 1989); *Simpson v. The Kroger Corp.*, 219 Cal. App. 4th 1352, 162 Cal. Rptr. 3d 652 (2d Dist. 2013)].

For example, **the approval by the Food and Drug Administration of a prescription drug as a safe and effective product does not preempt a state products liability suit against the drug's manufacturer**. [emphasis added]
> [footnote 14: *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 6 U.C.C. Rep. Serv. 2d 143 (D. Minn. 1988); *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312 (S.D. N.Y. 2017); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 8 U.C.C. Rep. Serv. 2d 983 (D. Or. 1989); *McCormick v. Medtronic, Inc.*, 219 Md. App. 485, 101 A.3d 467, 84 U.C.C. Rep. Serv. 2d 981 (2014).]"

John Bourdeau et. al., 28 C.J.S. DRUGS AND NARCOTICS § 137, *Governing law—Preemption under Federal Food, Drug, and Cosmetic Act*, Corpus Juris Secundum, September 2020 Update.

negligence theory of liability and for failure to warn and urged this Court to find no preemption of these claims. Defendant invited this Court to apply the Fifth Circuit's interpretation of *Buckman*, whereas plaintiff argued for the Second Circuit's interpretation[12]. This Court adopted the latter because of the Second Circuit's rationale--that *Buckman* held only that a claim of Fraud-on-the FDA, not the product liability claims, was pre-empted. *Tigert*, 20120 WL 6595806, at *3 and at footnote 3. In particular, this Court found in *Tigert* that the Supreme Court in *Buckman* "reached concerns of interference [with the FDA's regime] only after first finding that fraud on the agency claims presented a unique circumstance in which the traditional presumption against preemption of state law did not apply." *Id*. at 5. Thus, this Court ruled in *Tigert* that "the Supreme Court's narrow ruling in *Buckman* is unstable ground on which to rest a finding of preemption." *Ibid*.

Our rationale in *Tigert* as well as that of the Second Circuit's also applies here especially since defendants arguments for preemption rest chiefly on their re-formulation of these tort claims at issue as somehow fraud-on-the-FDA claims in disguise. "Because of its important role in state regulation of matters of health and safety, common law liability cannot be easily displaced in our federal system." *Desiano,* 467 F.3d at 98.

Plaintiffs' claims depend on traditional tort and contract law sources and not on a "fraud-on-the-FDA" claim, it follows from a full and accurate interpretation of *Wyeth* and *Buckman* taken together that federal law does not preempt such state law and common law claims.

Accordingly, the Court **DENIES all three defendants' motions to dismiss the Master Complaint claims of negligence *per se*, strict liability-defective design, breach of express warranty, fraud misstatement and negligent misstatement and state consumer-protection laws because of preemption by the FDCA.**

4.2 Preemption by the Drug Supply Chain Security Act ["DSCSA"]

The Wholesalers and the Pharmacies argue that plaintiffs' claims are expressly preempted by the Drug Supply Chain Security Act ("DSCSA"). ECF Doc.523-1:5; ECF Doc. 522-1:10). As the Supreme Court has held, a federal enactment can expressly preempt state law by so stating in express terms. *Hillsborough Cty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713, (1985). Express preemption applies where "Congress, through a statute's express language, declares its intent to displace state law." *Farina v.* Nokia Inc., 625 F.3d 97, 115 (3d Cir. 2010) (internal citation omitted).

In identifying whether a common law action is expressly preempted by a statute, the Court is guided by two principles. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484, 116 S.Ct. 2240,135 L.Ed.2d 700 (1996). First, the Court considers Congress' intent in passing the statute and in drafting the preemption

[12] *Desiano v. Warner-Lambert & Co.,* 467 F.3d 85 (2d Cir. 2006).

clause. *Ibid.* As the Supreme Court has noted, the intent of Congress is the "ultimate touchstone of preemption analysis." *Ibid.* Congress' intent is "discerned from the language of the pre[]emption statute and the 'statutory framework' surrounding it." *Id.* at 486 (internal citation omitted). Also relevant is the "structure and purpose of the statute as a whole." *Ibid.* (internal citation omitted).

Second, the Court should operate under the assumption that the "historic police powers of the States are not to be superseded by the federal enactment" unless that is the "clear and manifest purpose of Congress." *Id.* at 485. Accordingly, "when the text of a pre[]emption clause is susceptible of more than one plausible reading, courts ordinarily accept the reading that disfavors pre[]emption." *Farina*, 625 F.3d at 118 (internal quotations and citations omitted).

With these principles in mind, the Court now examines the DSCSA. In 2013, Congress enacted the Drug Supply Chain Security Act, 21 U.S.C. §360eee–360eee-4, in an effort to "protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful."[13] The DSCSA seeks to regulate the drug supply chain by implementing a uniform, interoperable system to trace and verify the identity of a drug as it passes through a manufacturer, wholesaler distributor, dispenser, or re-packager in the supply chain. *Ibid.* The DSCSA imposes certain obligations on the entities in the distribution process. The DSCSA at 21 U.S.C.§ 360eee-1(b)(2) requires manufacturers to affix machine-readable product identifiers on drug packages and at 21 U.S.C. § 360eee-1(d)(1)(A)(i) prohibits pharmacies from accepting ownership of a prescription drug unless the previous owner provides specific information about that drug. Additionally, the Act requires pharmacies at 21 U.S.C. § 360eee-1(d)(1)(A)(iii) to capture various information as necessary to investigate a suspect product and at 21 U.S.C. § 360eee-1(d)(4) to implement a system for quarantining suspect products to determine whether they are unfit for distribution.

The DSCSA preemption clause is as follows:

> [N]o State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are *inconsistent* **with, less stringent than, directly related to, or covered by** the standards and requirements applicable under section 353(e) of this title, in the case of a wholesale distributor, or section 360eee-3 of this title, in the case of a third-party logistics provider.
>
> 21 U.S.C. § 360eee-4(b)(1) [emphasis added].

The clause also states that "[n]othing in this section shall be construed to preempt State requirements related to the distribution of prescription drugs if such requirements **are not related to product tracing**". 21 U.S.C. §360eee-4(e) [emphasis added].

---

[13] *Drug Supply Chain Security Act*, U.S. Food & Drug Admin., (https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa) (last visited Dec. 11, 2020).

The Pharmacies and Wholesalers contend that they complied with the requirements of the DSCSA. ECF at 8. They assert that plaintiffs' claims impose tracking requirements on defendants that are more stringent than those required by the DSCSA. ECF Doc.523-1::8; ECF Doc. 522-1:11.) Therefore, the Pharmacies and Wholesalers argue that plaintiffs cannot impose such requirements because the DSCSAs preemption clause plainly bars state requirements that are more stringent than, or in addition to, those imposed by the Act. In response, plaintiffs' argue that, by its plain language, the preemption clause only applies to state requirements *related to product tracing*. ECF Doc. 577:47–48. Plaintiffs argue that none of their claims implicates product tracing or whether the defendants properly traced the products. (*Id.* at 48.) Accordingly, plaintiffs contend that the DSCSA's preemption clause is not implicated in this case. (*Ibid.*)

The Court notes that neither the Third Circuit nor any other court in this Circuit has opined on the scope of the DSCSA's preemption clause. This issue is a matter of first impression. In evaluating the preemption issue, the Court looks first to Congress' intent. As this Court recently noted, "Congress enacted the DSCSA to create a '[u]niform national policy' for drug supply chain regulation . . . and to fix the supply chain's vulnerability to counterfeit drugs[.]" *Matrix Distributors, Inc., et al. v. Nat'l Assoc. of Bds. of Pharmacy, et al.*, No. 18-17462, 2020 WL 7090688 (D.N.J. 4 December 2020) (*citing* 21 U.S.C. §360eee-4)). This vulnerability exists, according to Congress, "in large part, due to a patchwork of inconsistent State regulations." *Id.* (*citing* H.R. rep. 113-83, at 24 (2013)). Although the preemption clause seeks to eliminate inconsistent State regulations related to tracing of pharmaceuticals, Congress did not enact the DSCSA in an effort to displace all state law regarding defective pharmaceutical drugs.

Under defendants' view of the Act, Congress would have barred most, if not all relief, for persons injured by defective pharmaceuticals. Defendants' view would therefore "have the perverse effect of granting complete immunity from" products liability claims to an entire industry, so long as the actors complied with basic tracing requirements. *Medtronic*, 518 U.S at 487. Such a reading would ultimately preclude courts from affording state consumers any protection from defective drugs. The Court therefore finds this reading to be incorrect.

Moreover, while the preemption clause appears broad in scope on its face, Congress intentionally included important limiting language in the clause. "The plain wording of a preemption provision is of paramount importance in interpreting the scope of an express preemption provision". *Roth v. Norfalco* LLC, 651 F.3d 367, 375 (3d Cir. 2011) (internal citation omitted). The plain wording of the preemption provision indicates that the DSCSA was not intended to preempt State requirements "related to the distribution of prescription drugs if such requirements *are not related to product tracing*[.]" 21 U.S.C. §360eee-4(e) (emphasis added). This limiting language is decisive—it again reinforces the notion that the Act is only meant to displace state law regarding product tracing. Plaintiffs' claims here allege that the VCDs were contaminated before they entered the supply chain.

Accordingly, plaintiffs' claims do not arise out of any defective tracing. Therefore, the plain language of the preemption clause again negates defendants' interpretation.

Finally, the Court is guided by the presumption against preemption in this case. Although the preemption clause arguably could be subject to more than one interpretation—and could potentially be read more broadly, as defendants urge—the Court chooses to read the clause in a way that disfavors preemption. *See Farina*, 625 F.3d at 118.

The Court finds the DSCSA preempts none of plaintiffs' claims. Accordingly, the Court **DENIES Wholesalers' and Pharmacies' MTDs of any claim in the three Master Complaints for preemption by the Drug Supply Chain Security Act.**

5.0 PRIMARY JURISDICTION

The Mfrs admit plaintiffs' claims of breach of implied warranty, strict liability-failure to warn, negligence, and manufacturing defect do not expressly depend on establishing a violation of the FDCA (ECF Doc 520-3:27) but nonetheless seek a dismissal or a stay of these. They assert that, since these claims are inextricably linked to pending FDA investigations and regulatory action, the FDA has primary jurisdiction over them which compels this Court's abstention from resolving these claims until after the completion of the FDA proceedings.

Although the Mfrs cite correct authority, they misapply it. Citing proper precedents,[14] the Third Circuit in *Baykeeper v. NL Industries, Inc.*, 660 F.3d 686 (3d Cir. 2011), recognized that the inquiry into whether a claim requires the decision-making within the special competence of an administrative body lacks a fixed formula, but that courts have resolved the inquiry by using these four factors:

"(1) Whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise;

(2) Whether the question at issue is particularly within the agency's discretion;

(3) Whether there exists a substantial danger of inconsistent rulings; and

(4) Whether a prior application to the agency has been made.

Global Naps, Inc. v. Bell Atl.–N.J., 287 F.Supp.2d 532, 549 (D.N.J.2003)." *Id.* at 691.

This Court's review of these factors weighs against abstention.

[14] *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 64 (1956); *MCI Telecomms. Corp. v. Teleconcepts, Inc.*, 71 F.3d 1086, 1103 (3d Cir. 1995)

(1) Whether the Issues Are Within the Conventional Experience of Judges

Defendants argue the Complaints frame the breach of implied warranty, strict liability-failure to warn, negligence, and manufacturing defect claims in terms of "technical drug manufacturing and safety issues", which "require investigation into whether Defendants' VCDs are bioequivalent in their pharmacokinetic profiles to the brand or reference listed drugs" in the Orange Book or were manufactured using cGMPs. ECF Doc. 520-3: 28-29. They assert these matters are outside the Court's conventional expertise and require the FDA to make the initial determination.

The Court finds the FDA has already made an initial determination as to the general bioequivalence when it recalled the VCDs at issue. That is, the recall serves to point out that the VCDs at issue contained contaminants not listed in the Orange Book and makes the Court's starting point as to the VCDs' lack of general chemical bioequivalence plain and simple. Further the FDA has already issued an initial determination that API MFRs likely did not follow cGMPs when they changed the solvent(s) in the API manufacturing process. Following from these initial FDA determinations and as in any traditional products liability litigation that the Court has overseen, there will be provided experts' reports as to how the VCDs at issue demonstrate or not the claims of breach of implied warranty, strict liability-failure to warn, negligence, and manufacturing defect. Thus, the Court's review of the relevant scientific and technical data is NOT outside the Court's normal range of competence or purview in products liability actions.

(2) Whether the Question at Issue Is Particularly Within the Agency's Discretion

The question at issue focuses on whether the API MFRs practiced cGMPs, current good manufacturing practices, throughout the relevant time period before the FDAs recall. In reporting its gathering a cadre of external scientists to help figure out how API Mfrs could avoid the NDMA and NDEA contaminants from entering their drug product, the FDA was implicitly clarifying it had not known about the presence of them before the Valsartan recalls.[15] The FDA's report[16] does not and cannot attest to its particular, that is, special or unique, discretion over the presence of these contaminants and the promotion of cGMPs that prevent their formation in the U.S. drug supply. Rather, it indicates the scientific community, which, as experts would alert and educate this Court about the details of these contaminants, would be the better source of understanding the question at issue, and not the FDA.

---

[15] Scott Gottlieb *et al.*, Commissioner of the FDA, 4 April 2019 Press Release: FDA Statement on the agency's list of known nitrosamine-free valsartan and ARB class medicines, as part of agency's ongoing efforts to resolve ongoing safety issue, available at https://www.fda.gov/news-events/press-announcements/fda-statement-agencys-list-known-nitrosamine-free-valsartan-and-arb-class-medicines-part-agencys, last accessed 4 December 2020.

[16] Although FDA reports and press releases are not in the complaint, this Court may consider these because they are a matter of public record.

(3) Whether There Exists a Substantial Danger of Inconsistent Rulings and

(4) Whether There's a Prior Application to the Agency

Since there has been no prior application to the FDA to resolve these legal claims, element 4 is moot. As for element (3), by August 2019, the FDA had already researched the cause of the NDEA and NDMA contamination sufficiently to report that it:

> "is working to incorporate what we have learned about the process risks that caused these impurities into our oversight of drug manufacturing, which includes how we assess applications and changes to applications, as well as enhancing our inspection coverage to evaluate the controls in place to prevent unacceptable levels of nitrosamine" …

and that:

> "We have known that certain drug manufacturing processes pose a risk for forming genotoxic impurities, and this is an issue the FDA and other regulators have been working on for a number of years – well before the nitrosamine impurities were discovered in ARBs last summer. In fact, we issued guidance in early 2018 to provide [original link to: https://www.fda.gov/media/85885/download] information to manufacturers regarding their responsibilities to assess the risks and implement appropriate controls for their manufacturing process. Now that **we know some of the root causes** [original link to: https://www.fda.gov/media/122643/download] of the nitrosamine impurity problem, we're using these findings to inform our evaluation of medicines other than ARBs."[17] [emphasis added]

That is, the FDA now knows enough to better review applications from non-U.S. generic drug manufacturers as well as do a better job of inspecting their manufacturing sites to ferret out the formation of possible contaminants. And this knowledge arises only from the FDA's sufficient, even if not entirely complete, understanding of what chemical processes caused the NDEA and NDMA contamination.

This Court's purview does not involve the Court's separate research or decision-making about the cause of the "nitrosamine impurity problem", but rather the legal ramifications of that cause already understood by the FDA. There is no opportunity for inconsistent rulings about the tort claims as the FDA is not researching those.

Accordingly, the Court **DENIES all three defendants' Motions to Dismiss or stay the Master Complaint claims of breach of implied warranty, strict liability-failure to warn, negligence, and manufacturing defect because of the primary jurisdiction of the FDA.**

---

[17] Janet Woodcock, FDA Director for the Center for Drug Evaluation and Research, 28 August 2019 Press Release: FDA Statement on the Agency's Ongoing Efforts to Resolve Safety Issue with ARB Medications, available at https://www.fda.gov/news-events/press-announcements/statement-agencys-ongoing-efforts-resolve-safety-issue-arb-medications, last accessed 4 December 2020.

6.0 CONCLUSION

For the reasons stated herein, the Court**, the Court DENIES defendants' Motions to Dismiss the claims in any Master Complaint for preemption by the Food, Drug, and Cosmetic Act by federal law;**

the Court DENIES Wholesalers and Pharmacies Motions to Dismiss the claims in any Master Complaint for preemption by the Drug Supply Chain Security Act;

the Court DENIES defendants' Motions to Dismiss for the primary jurisdiction of the FDA over claims for breach of implied warranty, strict liability, failure to warn, negligence and manufacturing defect.

Dated: 17 December 2020

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