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July 31, 2019

VIA ECF

The Honorable Robert B. Kugler
United States District Court - District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
1 John F. Gerry Plaza
Camden, NJ 08101

Re: ***In re: Valsartan Products Liability Litigation*, MDL No. 19-2875 - Request to Brief Motions to Dismiss to Narrow the Scope of the Case and Discovery**

Dear Judge Kugler:

The crux of this case is straightforward: Plaintiffs allege that a change to the valsartan active pharmaceutical ingredient ("API") manufacturing process caused the valsartan drugs at issue to contain an impurity at levels Plaintiffs contend cause cancer. This litigation will determine when, how, and why the alleged impurity occurred, and whether it harmed Plaintiffs. Yet the Master Complaints—each well over 400 paragraphs—go far afield of these core questions, positing theories that are not and never will be viable as a matter of law. Addressing these incurable legal deficiencies now will narrow the scope of the case by pruning unworkable claims, while establishing Plaintiffs' evidentiary burden and streamlining discovery with respect to the remaining claims. Motions to dismiss will, in short, serve the purpose envisioned by Rule 12: conserving judicial and party resources and expediting the efficient resolution of this litigation. Defendants therefore ask leave to brief motions to dismiss.[1]

I. All of the Economic Loss Plaintiffs lack Article III standing.

As a threshold matter, this Court has an "independent obligation" to decide whether Plaintiffs have standing, "as that is a jurisdictional requirement." *Manuel v. NRA Grp. LLC*, 722

[1] Per the Court's directive, this letter addresses only those issues that would significantly decrease the resources that the parties expend on discovery. Defendants understand that the Court will set a separate schedule for filing other Rule 12 motions at a later date. Accordingly, this letter does not raise issues like the irrelevant, sensationalist accusations that rely on *Bottle of Lies* by Katherine Eban. *See, e.g.*, Economic Loss Master Complaint ("ELMC") ¶¶ 258–87.

Fed. App'x 141, 145 (3d Cir. 2018). Deciding the question of standing now will fulfill the Court's independent obligation and will substantially narrow the scope of the case and discovery.

The consumer Plaintiffs have not alleged an injury-in-fact. The consumer Plaintiffs cannot satisfy Article III by alleging they would not have purchased a valsartan product had they known that it might cause cancer. *See In re Johnson & Johnson Talcum Powder Prods. Marketing, Sales Practices, and Liab. Litig.*, 903 F.3d 278, 281–82 (3d Cir. 2018) ("A plaintiff…must do more than simply characterize [a] purchasing decision as an economic injury."). Yet that is the entirety of their economic loss theory. *See* ELMC ¶¶ 11–34, 306–25, 363. Notably, Plaintiffs do ***not*** allege that their valsartan drugs actually increased their risk of cancer or failed to provide the same therapeutic effect as unaffected lots. They allege only that they purchased valsartan drugs containing nitrosamines, which have the ***potential*** to cause cancer. *See* ELMC ¶¶ 306–25, 363. That is not a concrete injury satisfying Article III. *Johnson & Johnson*, 903 F.3d at 289–90.[2]

Plaintiffs attempt to plead around their lack of standing by insisting that the nitrosamines rendered their valsartan drugs "worthless" and "non-therapeutically interchangeable with" the brand-name drugs. ELMC ¶¶ 357, 362. That assertion is implausible. Plaintiffs do not even allege that the valsartan drugs failed to provide them with the desired therapeutic effect, much less that they caused physical harm. *See, e.g., Bowman v. RAM Med., Inc.*, No. 10-4403, 2012 WL 1964452, at *1, *3 (D.N.J. May 31, 2012) (rejecting conclusory contention that counterfeit surgical mesh "had zero value" when plaintiffs did not allege that mesh performed defectively as to them).[3]

The Third-Party Payor ("TPP") Plaintiffs have not pled an injury or causation. The TPP Plaintiffs also lack standing for four reasons: (1) their injury rises and falls on the consumer Plaintiffs' injury, *see, e.g.*, ELMC ¶¶ 439, 445, 462–65, 479, 497–507, 523–25, 554–56, 570–71, 588 (relying on therapeutic value consumers received); (2) they cannot rely on a benefit-of-the-bargain theory of injury because they do not allege that a difference in therapeutic value affects reimbursement rates; (3) they assume the risk of overpayment as part of their regular course of business, *see, e.g., Ironworkers Local Union 68 v. AstraZeneca Pharms*, 634 F.3d 1352, 1364 (11th Cir. 2011); and (4) they cannot show that Defendants' conduct caused them to reimburse for prescriptions, *see, e.g., In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 484 F. Supp. 2d 973, 983 (D. Minn. 2007).[4]

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[2] *See also Koronthaly v. L'Oreal USA, Inc.*, 374 F. App'x 257, 259 (3d Cir. 2010); *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319–20 (5th Cir. 2002); *Medley v. Johnson & Johnson Consumer Cos., Inc.*, No. 10-02291, 2011 WL 159674, at *2 (D.N.J. Jan. 18, 2011).

[3] Plaintiffs make no attempt to plead (1) the alternative product theory, or (2) the premium price theory. *See Johnson & Johnson*, 903 F.3d at 282–83. If granted permission to file a brief in support of a motion to dismiss the ELMC, Defendants will brief the futility of any attempt by Plaintiffs to amend the ELMC to include either theory.

[4] Plaintiff MSP Recovery Claims, Series LLC ("MSP") lacks standing for two more reasons: (1) MSP does not identify any assignments in its favor rather than in favor of its underlying series, *see* ELMC ¶¶ 38–42 and *MSP Recovery Claims, Series LLC v. USAA Gen. Indem. Co.*, No. 18-21626, 2018 WL 5112998, at *7, *12 (S.D. Fla. Oct. 19, 2018); and (2) the Medicare Advantage Organizations that purportedly assigned claims to MSP ***themselves lack standing*** because they exercise no discretion, *see Humana Med. Plan, Inc. v. W. Heritage Ins. Co.*, 832 F.3d 1229, 1235–38 (11th Cir. 2016).

Addressing standing will significantly impact the scope of the case and discovery. Aside from being a jurisdictional requirement, dismissal for lack of standing would eliminate the ELMC entirely, which would streamline the MDL by eliminating all discovery specific to these claims. For example, the following questions would no longer be at issue: (1) the therapeutic value of valsartan drugs containing nitrosamines that exceeded FDA-approved levels; (2) the therapeutic value's effect on economic value; (3) the contracting and reimbursement regime of TPPs and how the alleged difference in economic value would carry through to this reimbursement, if at all; and (4) Plaintiffs' expectations of valsartan drugs' economic and therapeutic value. There would also be no need to conduct discovery with respect to peripheral defendants' sales, revenues, profits, and pricing. And even if Plaintiffs could somehow amend the ELMC to allege an injury-in-fact, that would dramatically affect Plaintiffs' evidentiary burden: Plaintiffs would need to prove that the valsartan drugs ***actually caused*** an increased risk of cancer to the class. This claim-narrowing and discovery-altering effect would reverberate across the scope of the Plaintiff and Defendant Fact Sheets and the merits, including which experts are necessary given the precise evidentiary burden. All parties would benefit by knowing sooner than later whether the ELMC claims will survive and, if so, the proofs that will be required for Plaintiffs to establish their claims.

II. The Master Complaints seek to pursue preempted claims based on Defendants' representations, and claims that the valsartan drugs at issue are "new drugs."

All claims based on Defendants' alleged representations are preempted. Plaintiffs predicate numerous claims in the ELMC, Personal Injury Master Complaint ("PIMC"), and Medical Monitoring Master Complaint ("MMMC") on the premise that Defendants failed to provide representations that their drugs contained nitrosamines. Each of these claims arises out of a putative obligation to provide labeling disclosures that would breach the federal "duty of sameness," and, consequently, each of these claims is preempted. A state law claim is preempted and "without effect" when federal law prohibits an action that state law requires. *Mutual Pharm. Co., Inc. v. Bartlett,* 570 U.S. 472, 480 (2013). Generic drugs are subject to a "duty of sameness" under federal law, meaning the generic drugs' warning labels must always be the same as those of the brand-name or reference-listed drug. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011). This "duty of sameness" encompasses not only the labels affixed to the drugs, but all other warning information and communications distributed by the generic manufacturer. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 751 F.3d 150, 160–61 (3d Cir. 2014). The duty of sameness thus prevents generic drug companies from disseminating additional information or directly corresponding with healthcare providers concerning enhanced warnings. *Moore v. Zydus Pharm. (USA), Inc*., 277 F. Supp. 3d 873, 878 (E.D. Ky. 2017).

Many of the claims in all three Master Complaints would require Defendants to violate their federal duty of sameness by giving new, different, or additional warnings prohibited by federal law. *See*, *e.g.,* ELMC at Cause of Action One and Two (breach of express warranties); *id.* at Cause of Action Three and Four (breach of implied warranties); PIMC ¶¶ 448–49 (failure to warn); ELMC at Cause of Action Seven and Eight (fraud); *id.* at Cause of Action Nine and Ten (negligent misrepresentation); *id.* at Cause of Action Eleven and Twelve (consumer protection for "fraudulent and deceptive acts, omissions, or concealment"); PIMC ¶¶ 481–90 (breach of express warranty); *id.* ¶¶ 491–96 (breach of implied warranty); *id.* ¶¶ 497–509 (fraud); *id.* ¶¶ 510-19 (negligent misrepresentation); *id.* ¶¶ 520–79 (state consumer protection for "false and misleading

representations and omissions of material facts regarding the safety and potential risks" of valsartan drugs); MMMC ¶¶ 437-42 (failure to warn); *id.* ¶¶ 468-76 (breach of express warranties).

The Master Complaints contain improper legal conclusions that call upon the Court and/or juries to make determinations that are properly left to the FDA. The Master Complaints base several theories of liability on a number of improper legal conclusions on subjects left exclusively to the FDA to decide.[5] Most glaringly, the Master Complaints assert that valsartan drugs containing impurities constitute new drugs. *See* ELMC ¶¶ 159-167; PIMC ¶¶ 213-223; MMMC ¶¶ 121-29. This "new drug" theory fails as a matter of law, because determinations governing the "newness" of drugs are preempted by the primary jurisdiction doctrine. *See Reiter v. Cooper*, 507 U.S. 258, 268 (1993); *Coyle v. Hornell Brewing Co.*, No. 08-02797, 2010 WL 2539386, at *3 (D.N.J. June 15, 2010). The "FDA has jurisdiction to decide . . . the 'new drug' status of individual drugs or classes of drugs." *Weinberger v. Bentex Pharms, Inc*., 412 U.S. 645, 652 (1973) (concluding that the District Court's referral of "new drug" determination to FDA was appropriate in action to determine whether drugs in question were exempt from "new drug" requirements under the FDCA). Because the question of whether a product constitutes a "new drug" involves "complex chemical and pharmacological considerations," those questions are reserved for the FDA, which has unique experience in this field. *Id.* at 655.[6] The prospect of juries imposing liability based upon their own inexpert assessment of whether a drug is "new" is directly counter to the regulatory regime established by Congress under the FDCA. *See Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672–73 (2019).[7]

Addressing preemption will materially narrow the scope of the case and discovery. Plaintiffs make more than 150 allegations directed to Defendants at various levels of the supply chain regarding Defendants' purported misrepresentations. *See* ELMC ¶¶ 351–404; PLMC ¶¶ 346–390; MMMC ¶¶ 317–380. If this Court agrees that some or all of these claims are preempted, discovery into these 150+ allegations will not be necessary. This will avoid the need to take discovery of areas including, but not limited to: (1) Defendants' product labeling decision making; (2) Defendants' communications with various actors, including TPPs, MAOs, pharmacy benefit managers, healthcare providers, patients known to be taking valsartan drugs, and the public at large; and (3) Defendants' marketing efforts and related issues. Similarly, if this Court determines that only the FDA can determine whether the valsartan drugs at issue are "new drugs," a number of issues will no longer be relevant, including, but not limited to: (1) the nature, content, and intent of Defendants' representations regarding valsartan drugs; (2) the chemical composition of

[5] *See* PIMC ¶¶ 202-206 and MMMC ¶¶ 110-114 (arguing that generic drugs are required to be "chemically the same" as related brand drugs); PIMC ¶ 212 and MMMC ¶ 120 (alleging that "Defendants' unapproved drug was adulterated and/or misbranded"); ELMC ¶¶ 224-302 (alleging that several manufacturer Defendants' products were "adulterated, misbranded, and/or unapproved" drugs).

[6] In an effort to minimize the FDA's role in this determination, Plaintiffs rely on a characterization of the word "drug" from the agency's website. ELMC ¶ 17. "New drug" is defined by the FDCA and applicable regulations, not a website. *See* 21 U.S.C. § 321(p); 21 CFR § 310.3(h).

[7] Plaintiffs' assertions that the valsartan drugs were adulterated are similarly defective, as they impermissibly attempt to enforce the FDCA. Enforcement is limited to the FDA. *See* 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 788–89 (3d Cir. 1999).

valsartan drugs, including their inactive ingredients; and (3) the bioequivalence of generic valsartan drugs to Diovan (brand drug valsartan).

III. Plaintiffs lack standing to pursue claims against repackager, distributer, and wholesaler Defendants.

Standing must be demonstrated against each defendant. *See 6803 Boulevard East, LLC v. DirecTV, LLC*, 17 F. Supp. 3d 427, 431–32 (D.N.J. 2014) (citation omitted). Here, Plaintiffs have not alleged an injury that has a "causal connection between the injury and the conduct complained of," as required by Article III's traceability requirement. *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 359 (3d Cir. 2015). The Master Complaints do not make any allegations regarding conduct of the repackager, distributer, or wholesaler Defendants that caused the valsartan drugs to contain the alleged impurities. Plaintiffs therefore lack standing and the claims against these Defendants should be dismissed. Dismissing these Defendants would greatly streamline discovery and related discovery disputes. Even if Plaintiffs were able to amend to establish standing, any discovery from these Defendants must be narrowly tailored according to their alleged role.

IV. Defendants that qualify as "innocent sellers" are entitled to dismissal.

Many states exempt sellers from liability if they did not manufacture the product, were unaware of the defect, could not have reasonably discovered the defect, and merely passed on the product in the chain of commerce. For example, New Jersey entitles "a product seller" to dismissal if the seller "file[s] an affidavit certifying the correct identity of the manufacturer of the product which allegedly caused the injury, death or damage." N.J. Stat. § 2A:58C-9(a). *See also, e.g.,* Colo. Rev. Stat. § 13-21-402(1); Del. Code tit. 18, § 7001; 735 ILCS 5/2-621; Kan. Stat. § 60-3306; Ky. Rev. Stat. § 411.340; Md. Cod. § 5-405; Minn. Stat. § 544.41.

V. Conclusion

In summary, early resolution of dispositive issues on legally impossible claims will allow all parties to focus on the straightforward question in this case—whether Plaintiffs suffered any legally cognizable harm from the valsartan drugs at issue as a result of the manufacturing process change for valsartan API. Resolving these issues before merits discovery will save the parties the effort and expense of dozens, if not hundreds, of depositions, and the review and exchange of millions of pages of documents and electronically stored information of the 40 or more defendants.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg