UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875**
	Honorable Renée Marie Bumb, Chief District Judge
This Documents Relates to All Actions	

JOINT STATUS REPORT

Defendants' Executive Committee[1] and Plaintiffs' Co-Lead Counsel[2] jointly submit the following joint status report in advance of the July 23, 2024 status conference. The Court has requested that the parties provide "an update on: (1) all pending matters; (2) any matters that the parties have settled; and (3) any other

[1] Defendants' Executive Committee includes Jessica Davidson of Skadden, Arps, Slate, Meagher and Flom LLP, Lori Cohen of Greenberg Traurig LLP, Clem Trischler of Pietragallo Gordon Alfano Bosick & Raspanti, LLP, Jeffrey Geoppinger of UB Greensfelder, and Sarah E. Johnston of Barnes & Thornburg LLP. Ms. Davidson is Defendants' Liaison Counsel. (*See* [ECF 96] Case Management Order No. 6; [ECF 313] Case Management Order No. 18; [ECF 2102] Case Management Order No. 27.)

[2] Plaintiffs' Co-Lead Counsel includes Ruben Honik of Honik LLC, Daniel Nigh of Nigh Goldenberg Raso & Vaughn PLLC, Adam Slater of Mazie Slater Katz & Freeman, LLC, and Conlee Whiteley of Kanner & Whiteley, LLC. Adam Slater is Plaintiffs' Liaison Counsel to the Court and the Defendants, and David J. Stanoch of Kanner & Whiteley, LLC is Plaintiffs' Liaison Counsel to other plaintiffs. (*See* [ECF 96] Case Management Order No. 6; [ECF 2457] Case Management Order No. 34.)

matter requiring the Court's attention."[3] This joint report summarizes the status of the various matters pending in the MDL proceeding and in related state court proceedings, as well as the status of settlements agreed to by certain parties. In addition, each side has provided its own respective submission regarding outstanding matters in the litigation that require the Court's attention.

I. DEFENDANTS' STATUS UPDATE ON ALL PENDING MDL MATTERS.[4]

a. The Parties And Claims

[3] [ECF 2701.]

[4] The Court requested that the parties' joint status report provide an update on "all pending matters." The parties disagree regarding what that entails and have submitted separate sections on all pending matters. It is Defendants' position that an update on "all pending matters" contemplates a discussion of the relevant history of the different aspects of this large multi-year MDL. Defendants have sought to provide the Court with a complete and accurate description of all pending matters in this MDL, including the relevant history. It is Plaintiffs' position that an update on "all pending matters" should provide the Court with a concise description of pending matters without an accompanying discussion of the history and underlying facts of the litigation and the Court's Orders and decisions to date. If the Court had intended that the parties would provide extensive background and history, and competing positions and interpretations, that would have been stated in the Order. Plaintiffs also object to Defendants' rendition and characterization of the substantive issues discussed, which Plaintiffs believe is not even-handed, accurate, or complete in material respects, and Plaintiffs did not believe that it would be fruitful or reasonable to engage in a lengthy meet and confer to try to resolve the many issues presented by Defendants' rendition. After meeting and conferring, the parties were unable to resolve their disagreements, and agreed instead to submit separate descriptions of all pending matters, with certain points of disagreement noted but without lengthy rebuttal or counter-argument.

The cases in this litigation arise out of certain voluntary recalls of generic medications containing the active pharmaceutical ingredients ("API") valsartan, losartan, and irbesartan, following the identification of nitrosamine impurities in these medications. To date, the litigation has primarily focused on claims and discovery relating to valsartan.

Defendants are entities at various levels of the U.S. supply chain for generic valsartan, losartan and irbesartan medications to the U.S. market. With respect to claims pertaining to valsartan, Defendants fall into six distinct groups:

- **Valsartan API manufacturers** (Zhejiang Huahai Pharmaceutical Co., Ltd.; Huahai U.S., Inc.; Hetero Labs, Ltd.; Hetero Drugs, Limited; Hetero USA Inc.; Mylan Laboratories, Ltd.; Aurobindo Pharma, Ltd.);
- **Finished dose valsartan manufacturers** (Mylan Pharmaceuticals, Inc.; Teva Pharmaceuticals USA, Inc.; Actavis LLC; Actavis Pharma, Inc.; Torrent Pharmaceuticals Ltd.; Aurobindo Pharma, Ltd.; Aurolife Pharma, LLC; Prinston Pharmaceutical Inc.);
- **Finished dose distributors** (Aurobindo Pharma USA, Inc.; Solco Healthcare U.S., LLC; Torrent Pharma, Inc.; Camber Pharmaceuticals, Inc.);
- **Wholesalers** (AmerisourceBergen Corporation (n/k/a Cencora, Inc.); Cardinal Health, Inc.; McKesson Corporation, collectively "Wholesalers");[5]

[5] With respect to the sartan-containing drugs ("SCDs") at issue, Wholesalers are pass-through entities in the pharmaceutical supply chain whose business model involves purchases of drugs from drug manufacturers and sales of drugs to pharmacies, not individuals or insurance plans. The Pharmacies bought many of the SCDs in issue directly from the Manufacturers and non-party wholesalers—with no Wholesaler involvement whatsoever. It is also undisputed that Wholesalers did not *(cont'd)*

- **Now-dismissed repackagers** (AvKARE, Inc.; Major Pharmaceuticals, Inc.);[6] and

- **Pharmacies** that allegedly dispensed valsartan (Albertson's LLC; CVS Pharmacy Inc.; Express Scripts, Inc.'s affiliated pharmacy entities; Humana Pharmacy, Inc., The Kroger Co.; OptumRx; Rite Aid Corporation;[7] Walgreen Co.; Walmart, Inc.).[8]

There are three categories of plaintiffs asserting claims in the litigation:

- **Personal injury plaintiffs** who allegedly ingested valsartan and claim that it contained nitrosamines that caused them to develop cancer;

- **Medical monitoring plaintiffs** who allegedly ingested valsartan and claim to require lifetime diagnostic monitoring due to an increased risk of cancer; and

- **Economic loss plaintiffs**, including both consumers and TPPs who allegedly paid for valsartan prescriptions (in whole or in part) and claim it was "worthless" due to the impurity.

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formulate, manufacture, test or label any of the SCDs, and did not sell or dispense them to consumers or third-party payors ("TPPs"). Moreover, Wholesalers did not have any relationship or contact with the Pharmacies' customers who consumed the SCDs or with the TPPs that reimbursed or "covered" all, or a portion of, the consumer costs of those SCDs. Given these realities, and the contractual provisions between Manufacturers and Wholesalers, Wholesalers have asserted indemnity rights as to Manufacturers in this litigation.

[6] Pursuant to CMO 15, these Defendants were dismissed without prejudice by stipulation of the parties. *See* ECF Nos. 247, 495, and 1762.

[7] Rite Aid Corporation is a pharmacy defendant but has declared bankruptcy and therefore all claims against Rite Aid are subject to an automatic stay.

[8] Defendants Hetero USA, Inc., and Prinston Pharmaceutical, Inc., serve only as FDA liaisons for other entities that fall into the five groups enumerated here. Notably, some of the Defendants fall into more than one group.

None of the plaintiff groups alleges that the valsartan they purchased and/or ingested did not work or failed to provide the intended therapeutic benefit of treating hypertension.

Plaintiffs consolidated their valsartan claims into three Valsartan Master Complaints: two putative nationwide class action complaints asserting medical monitoring and economic loss claims and one personal injury complaint asserting product liability claims sounding in negligence, strict liability, breach of warranty, fraud, and consumer protection.[9]

Initially, Defendants moved to dismiss all claims against them in the Valsartan Master Complaints. With respect to the Manufacturers, the Court dismissed all federal claims under the Magnuson-Moss Warranty Act and state-specific claims for Plaintiffs from jurisdictions that do not recognize certain causes of action or require those causes of action to be asserted under the applicable state's Product Liability Act. With respect to Wholesalers, the Court dismissed the main conduct-based claims, including fraud, breach of express warranty, and negligence. The remaining claims against Wholesalers (such as unjust enrichment and strict liability) are premised on Wholesalers' role as an intermediary in the supply chain.

[9] (*See* [ECF 123] Am. Medical Monitoring Master Compl.; [ECF 398] Second Am. Economic Loss Master Compl.; [ECF 122] Personal Injury Master Compl.)

With respect to the Pharmacy Defendants, given their role in merely dispensing an FDA-approved medication pursuant to valid prescriptions, the Court dismissed the negligence and fraud claims, as well as numerous other claims on a state-specific basis, leaving only the class unjust enrichment and medical monitoring claims and, under some but not all states' laws, implied warranty, non-fraud-based consumer protection, or strict liability claims. Following briefing on Plaintiffs' motion to amend their complaint, the Court again concluded that Plaintiffs could not assert a negligence claim, noting that Plaintiffs had not alleged that any Pharmacy "knew of the nitrosamine contamination and failed to take reasonable steps in response to such knowledge" and finding "no facts—neither behavior nor an atypical economic reality between Mfrs and the Wholesalers and Pharmacies—that support the existence of a duty borne by downstream defendants to investigate MFRs' GMPs to confirm the purity of the sold, generic valsartan drugs." (ECF 1994 at 12-13.)

Pursuant to the Court's order, the majority of Defendants have not yet filed answers to the Valsartan Master Complaints or asserted affirmative defenses.[10] The Court ordered that: (1) all other Answer deadlines are stayed; (2) any objections to venue and personal jurisdiction would be decided at the conclusion of pretrial proceedings; and (3) all Defendants' other objections and affirmative defenses of

[10] The three Manufacturer Defendants involved in the TPP Class Trial, *see* Sections I.Aa, III *infra*, submitted Answers to the Valsartan Master Complaints that pertained to the claims of the class plaintiffs at issue in that proposed trial.

improper venue and lack of personal jurisdiction would be preserved. (CMO2, ECF 72; CMO 3, ECF 76; CMO 19, ECF 376).

Plaintiffs similarly consolidated their claims into Irbesartan and Losartan Master Complaints.[11] Personal injury plaintiffs, including those asserting claims related to valsartan, losartan and irbesartan, are required to file individual Short Form Complaints.[12]

Plaintiffs' Master Complaints assert a wide variety of common law and statutory product liability causes of action, as well as requests for punitive damages. Currently, this MDL proceeding involves approximately 1100+ active valsartan cases, 90+ active losartan cases, less than 10 active irbesartan cases, and 75 cases with a combination of drug usage alleged. These numbers include the class actions alleged under each of the Master Complaints related to each medication (which

[11] (*See* [ECF 751] Master Losartan Economic Loss Class Action Compl.; [ECF 680] Master Irbesartan Economic Loss Class Action Compl.; [ECF 681] Master Losartan Med. Monitoring Class Action Compl.; [ECF 682] Master Losartan Personal Injury Compl.; [ECF 683] Master Irbesartan Personal Injury Compl.; [ECF 752] First Am. Consolidated Irbesartan Economic Loss Compl.)

[12] (*See* [ECF 187] Case Mgmt. Order No. 13; [ECF 376] Case Mgmt. Order No. 19.) Plaintiffs with currently-filed personal injury cases were also ordered to file a Short Form Complaint, the form of which was approved in Case Management Order No. 13. (*See* [ECF 187] Case Mgmt. Order No. 13.) Personal injury direct filed cases in the MDL were ordered to use the Short Form Complaint. (*See* [ECF 187] Case Mgmt. Order No. 13; *see also* [ECF 234] Case Mgmt. Order No. 13(a) (attaching amended version of operative Short Form Complaint).)

include medical monitoring, consumer economic loss and TPP class actions as discussed further below).

b. The Products At Issue

The valsartan-containing drugs ("VCDs") at issue are the generic versions of certain branded angiotensin II receptor blocker ("ARB") drugs approved primarily for the treatment of hypertension and heart failure. In July 2018, certain Defendants, with guidance from the FDA, began announcing voluntary recalls of certain VCDs after trace amounts of a nitrosamine class impurity, N-nitrosodimethylamine ("NDMA"), were detected in some, but not all, lots of valsartan.[13] As the FDA has noted, NDMA is common "in water and foods, including cured and grilled meats, dairy products and vegetables."[14] In November 2018, additional lots of valsartan were recalled by companies due to the presence of trace amounts of a different nitrosamine class impurity, N-nitrosodiethylamine ("NDEA").

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[13] *See* FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity | FDA (2018), https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity (last visited Apr. 27, 2024).

[14] *See* Information about Nitrosamine Impurities In Medications | FDA, https://www.fda.gov/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications (last visited Apr. 27, 2024) (also stating that "[e]veryone is exposed to some level of nitrosamines" and "[n]itrosamine impurities may increase the risk of cancer if people are exposed to them above acceptable levels and over long periods of time, but a person taking a drug that contains nitrosamines at-or-below the acceptable daily intake limits every day for 70 years is not expected to have an increased risk of cancer").

In October 2018, companies also began recalling specific batches of two other types of ARBs, losartan and irbesartan, for possible trace amounts of NDEA. In addition, a small number of batches of losartan were recalled for potentially containing a third impurity, N-Nitroso-N-Methyl-4-aminobutyric acid ("NMBA"). Although losartan and irbesartan are in the same class of medication as valsartan, these two drugs contain different APIs, are created using different manufacturing processes, and have different chemical structures than valsartan. The scope of recalls for losartan and irbesartan was also narrower than for valsartan. For example, in the United States, 624 lots of valsartan-containing drugs were recalled, while approximately 500 lots of losartan-containing drugs and 122 lots of irbesartan-containing drugs were recalled.

The valsartan recalls resulted in an investigation by the FDA and the identification of the presence of NDMA and/or NDEA in valsartan API. The FDA issued its first official guidance with regard to the acceptable amount of nitrosamines that may be present in VCDs in September 2020, more than two years after the initial recalls.[15] With regard to NDMA, the FDA estimated the theoretical increased risk posed by ingesting recalled valsartan medications at one additional case of cancer

[15] *See* Control of Nitrosamine Impurities in Human Drugs – Guidance for Industry | FDA (2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/control-nitrosamine-impurities-human-drugs (last visited Apr. 27, 2024).

for every 8,000 persons who consumed the recalled medications at the highest potential dose daily for four years.[16] Per the FDA, the estimated theoretical increased risk related to ingesting recalled medications containing NDEA was 1 in 18,000.[17] The FDA also issued statements in connection with the recalls, noting that the "risk to patients taking affected products is extremely low" and recommending that patients continue taking their current medication, even if recalled, until their healthcare provider prescribed a replacement due to the low risk posed and the seriousness of the conditions the medications treat.[18]

c. General Causation and Rule 702

A key question in this litigation is whether exposure to nitrosamines at the trace levels contained in at-issue valsartan, and for the duration those products were on the market, can cause individuals to develop cancer.

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16 *See* Statement on the agency's ongoing efforts to resolve safety issue with ARB medications | FDA (2019), https://www.fda.gov/news-events/press-announcements/statement-agencys-ongoing-efforts-resolve-safety-issue-arb-medications (last visited Apr. 27, 2024).

17 *See* Laboratory Analysis of Valsartan Products | FDA (2019), https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products#:~:text=FDA%20scientists%20estimate%20that%20if,lifetime%20of%20these%2018%2C000%20people. (last visited June 19, 2024).

18 *See* 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 | FDA (2019), https://www.fda.gov/news-events/press-announcements/fda-statement-agencys-list-known-nitrosamine-free-valsartan-and-arb-class-medicines-part-agencys (last visited Apr. 27, 2024).

Plaintiffs initially identified 13 categories of cancer that they believed could be linked with exposure to affected valsartan.[19] They subsequently disclosed five general-causation experts: Dipak Panigrahy, Mahyar Etminan, David Madigan, Stephen Hecht, and Stephen Lagana. Plaintiffs' experts collectively offer opinions in support of 10 of the 13 designated cancers: liver, bladder, blood, gastric, colorectal, pancreatic, esophageal, prostate, lung, and kidney.[20]

Each of Plaintiffs' experts performed a literature review in connection with formulating their opinions, but the breadth and scope of their reports varied considerably. Dr. Panigrahy, a pathologist, purported to have reviewed all relevant literature—including animal studies, dietary studies, cohort studies, epidemiological studies, and in vitro/mechanistic studies—to offer opinions regarding the potential association between NDMA and different types of cancer.[21] Dr. Etminan,[22] an ophthalmology professor who offers epidemiologic opinions, described his methodology as "a systematic search of the scientific evidence" to determine

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19 (ECF 706.)

20 (*See, e.g.*, Panigrahy Rep. at 96-147; Etminan Rep. at 16-24; Madigan Rep. at 9.)

21 (Panigrahy Rep. at 91-146.)

22 **Plaintiffs' Position**: This excerpt discussing Dr. Etminan illustrates Plaintiffs' basis to object to Defendants' extensive rendition of history, with an overlay of spin and argument that the Court did not request in its Order. The *Daubert* decisions are easily accessed and presumably the Court will review and draw its own conclusions, and request further input from the parties only if required.

whether nitrosamine impurities in valsartan "increase the risk of different types of cancer."[23] In contrast, Dr. Lagana and Dr. Hecht discussed a more generalized association between NDMA/NDEA and "cancer." Dr. Lagana did not conduct a separate analysis of NDEA, but suggested that his discussion of NDMA would apply equally to both compounds.[24] Finally, Dr. Madigan did not opine on causation, but performed a statistical analysis in support of Dr. Etminan's literature review.[25]

In response, Defendants disclosed rebuttal experts across multiple scientific disciplines to opine on general causation. Those experts included Michael Bottorff (pharmacology), Herman Gibb (epidemiology), Jon Fryzek (epidemiology), Lee-Jen Wei (statistics), John Flack (cardiology), George Johnson (toxicology), and Janice Britt (toxicology). Defendants' experts each concluded that there was no causal link between NDMA or NDEA and cancer based on the route, dose, and duration of exposures potentially at issue here.

The parties filed Rule 702 motions on November 1, 2021. In March 2022, the Court held a limited hearing[26] on those motions, at the conclusion of which oral

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[23] (Etminan Rep. at 3.)

[24] (*See, e.g.*, Lagana Rep. at 5 ("Therefore, to the extent NDMA is discussed herein, the conclusions as to NDMA apply to NDEA as well, unless otherwise indicated.").)

[25] (Madigan Rep. ¶ 3.)

[26] The Court declined to conduct a "science day" at that time. The Court also declined Defendants' request for a full Rule 702 hearing. Defendants would *(cont'd)*

rulings were issued from the bench.[27] Omnibus written rulings followed.[28] The Court generally denied the parties' motions to exclude experts, with a few limited exceptions.

First, the Court granted Defendants' motions to preclude the testimony of Dr. Panigrahy and Dr. Etminan concerning NDEA and causation of all cancers other than pancreatic, as well as Defendants' motion to preclude Dr. Madigan's testimony concerning NDEA and all cancer causation.[29] These rulings acknowledged the lack of support in the scientific literature regarding NDEA and cancer causation.[30] As a result, Plaintiffs are precluded from offering expert testimony at trial that exposure to NDEA in VCDs can cause any cancer other than pancreatic cancer.[31]

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welcome the opportunity to make a live presentation regarding the state of the science regarding NDMA/NDEA and cancer causation. **Plaintiffs' Position**: This is another example of the Defendants providing unsolicited commentary and argument on matters not the subject of the Court's Order.

27 (*See* March 2, 2022 Hr'g Tr., ECF 1959)

28 (*See Daubert* Order 1, ECF 1958; *Daubert* Order 2, ECF 1974.)

29 Dr. Hecht and Dr. Lagana did not purport to offer expert opinions regarding NDEA and causation of specific types of cancer. **Plaintiffs' Position**: This characterization is misleading, and fails to inform the Court that the Court did not limit the opinions of Dr. Hecht or Dr. Lagana on this issue, which is the subject of one of the motions that will require the Court's attention when appropriate.

30 (*See* March 2, 2022 Hr'g Tr. 152:22-153:4, ECF 1959.)

31 **Plaintiffs' Position**: This ruling is the subject of the cross-motion Plaintiffs intend to file per the Court's direction, as discussed below.

Second, the Court precluded the opinions offered by Defendants' expert, Janice Britt. The Court found that Dr. Britt's toxicology opinions were not predicated on a reliable methodology. The Court also partially limited the testimony that may be offered by Dr. Wei and Dr. Flack. In all other respects, Defendants' general causation experts will be permitted to testify to their opinions at trial.

To date, no jury has been asked to decide general causation (i.e., whether exposure to NDMA or NDEA in VCDs can cause any particular type of cancer) or specific causation (i.e., whether any particular plaintiff's cancer was caused by use of VCDs).

d. **Personal Injury Claims**

Currently, there are roughly 1200+ personal injury claims pending in the MDL in which Plaintiffs allege that they developed cancer after using valsartan, losartan, irbesartan or a combination of these medications. Plaintiffs filed their Disclosure of Cancer Types at Issue on December 31, 2020, identifying the following cancers: bladder, blood, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, pharyngeal, prostate and uterine. (*See* [ECF 706] Plaintiffs' Disclosure of Cancer Types).

A direct-file order is in place (*see* [ECF 76] Case Mgmt. Order No. 3; [ECF 376] Case Mgmt. Order No. 19), allowing cases to be filed directly into the MDL without JPML transfer pursuant to 28 U.S.C. §1407(a), with all jurisdiction and

venue objections reserved. Defendants specifically reserved and have not waived any *Lexecon* rights. As discussed above, Plaintiffs are required to file individual short form complaints. (*See* [ECF 187] Case Mgmt. Order No. 13.)

The Court approved the form of the personal injury Plaintiff Fact Sheet for valsartan on October 3, 2019 (*see* [ECF 249] Case Mgmt. Order No. 16) and an updated consolidated personal injury Fact Sheet for both valsartan and losartan/irbesartan on February 13, 2024. (*See* [ECF 2636] Special Master Order No. 92.) Since then, the Court and the parties have followed a show-cause process to address deficiencies, which requires a meet-and-confer process, two consecutive listings on the monthly Case Management Conference ("CMC") agenda, followed by Court-ordered dismissal if not satisfactorily resolved. (*See* [ECF 249] Case Mgmt. Order No. 16.) This meet-and-confer process has continued uninterrupted, and the parties anticipate continuing the show-cause listings and hearings when the CMCs resume. Additionally, some individual plaintiffs and individual defendants have negotiated voluntary dismissals for lack of product identification in specific cases. A formal process to dismiss cases for lack of product identification has not yet been put in place for those that cannot be resolved voluntarily, and Defendants anticipate seeking the initiation of such a process.

The parties followed an agreed procedure for selecting a pool of 28 valsartan personal injury plaintiff bellwether cases to be worked up for trial before submitting

a list of 28 such names to the Court. (*See* [ECF 969-3] Proposed Order Establishing Trial Pool Cases.) The cases are all valsartan cases involving an array of cancer type allegations and a mix of defendants. The parties began initial discovery in those 28 cases, which included the depositions of the named Plaintiffs and two treating physicians (typically the prescribing physician and one treating physician) per case. The parties have disclosed and deposed their valsartan general causation experts, which were subject to Rule 702 briefing and orders as discussed above. The parties have not yet disclosed their specific causation and damages experts for these bellwether cases or identified the trial order of these cases, but are ready to initiate a schedule for doing so.

e. Class Certification

Briefing on class certification commenced in November 2021, when Plaintiffs moved for certification of nationwide and multistate valsartan classes asserting claims for: (1) consumer economic loss; (2) TPP economic loss; and (3) medical monitoring.

The consumer economic loss plaintiffs are individuals who were prescribed and purchased VCDs, and claim that the medications were worthless due to the presence of NDMA or NDEA.[32] These plaintiffs proposed a three-phase class trial

[32] With respect to Wholesalers, Plaintiffs sought certification as to only one claim: unjust enrichment. (See ECF 1747-1 at 60-63; ECF 1747-2 at 3-4.)

involving 93 proposed subclasses of individuals.[33] The TPP economic loss plaintiffs are insurers and other companies who paid for a portion (or all) of the cost of consumer prescriptions under prescription drug insurance plans. The TPP economic loss plaintiffs assert that all TPPs are entitled to full refunds for all VCD payments between 2012 and 2019 because the medications were rendered worthless by the presence of NDMA or NDEA.[34] The Court ordered the parties to begin working up for a bellwether MDL trial the claims of one of the two proposed representatives of the TPP economic loss class—MSP Recovery Claims, Series LLC ("MSP")—for a single-plaintiff trial of its claims against three of the manufacturer defendants in the litigation, ZHP, Teva and Torrent.[35]

Plaintiffs also moved to certify two medical-monitoring classes. The first—a 28-jurisdiction class—sought to assert substantive medical-monitoring causes of action.[36] The second—a 49-jurisdiction class—sought to recover medical monitoring as a form of relief under nine distinct product liability theories.[37]

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33 (*See* [ECF 1748] Pls.' Mem. of Law in Supp. of Their Mot. for Class Certification of Consumer Economic Loss Claims.)

34 (*See* [ECF 1749] Third-Party Payors' Br. in Supp. of Mot. to Certify Class.)

35 (*See* [ECF 2151] Transcript of Case Mgmt. Proceedings held on Aug. 24, 2022, before Judge Robert B. Kugler and the Honorable Thomas I. Vanaskie.)

36 (*See* [ECF 1750] Mem. of Law in Supp. of the Med. Monitoring Pls.' Mot. for Class Certification.)

37 (*See id.*)

Plaintiffs defined both classes to include individuals "who consumed a sufficiently high Lifetime Cumulative Threshold [LCT] of NDMA, NDEA, or other nitrosamine, in generic valsartan-containing drugs manufactured by or for Defendants . . . since January 1, 2012."[38]

On February 8, 2023, the Court issued an order certifying nearly all of Plaintiffs' proposed classes.[39] Specifically, the Court certified a consumer economic loss class including 93 subclasses under Rule 23(b)(3).[40] The Court also certified a 49-jurisdiction class of consumers seeking medical monitoring as a "remedy" under Rule 23(b)(2), as well as a 28-jurisdiction class asserting medical monitoring claims as an independent cause of action class under Rule 23(b)(3).[41] In addition, the Court certified a class of TPPs composed of 18 subclasses asserting four causes of action under the laws of 43 states, with MSP (and, initially, the Maine Automobile Dealers Association ("MADA")) as class representatives.[42] Defendants sought interlocutory review pursuant to Fed. R. Civ. P. 23(f), but the Third Circuit denied the petition.

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38 (*See id.* at 6.)

39 (*See* [ECF 2262] Order on Certification of Proposed Classes under FRCP *Rule 23* and on Class Certification Expert Reports under *FRE* 702.)

40 (*See* [ECF 2261] Opinion on Certification of Proposed Classes under FRCP *Rule 23* and on Class Certification Expert Reports under *FRE* 702 at 28.)

41 (*See id.* at 70.)

42 (*See id.* at 42.) Plaintiffs submitted an initial Class Notice Plan, to which Defendants objected. [ECF 2375, ECF 2412]. The parties thereafter negotiated an agreed form and manner of class notice, with Defendants reserving their objections *(cont'd)*

In a subsequent ruling, the Court ordered that the single-plaintiff trial of MSP's claims against manufacturers ZHP, Teva and Torrent would instead become a class trial of four multi-state subclasses asserting causes of action for breach of express warranty, breach of implied warranty, fraud, and violation of statutory consumer protection laws, with each subclass encompassing different combinations of states.[43] After the Court issued the class certification order and set the TPP class trial, Plaintiffs conceded that summary judgment should be entered against the implied warranty TPP subclass. As a result, the parties prepared for a class trial on three causes of action—breach of express warranty, fraud and violation of statutory consumer protection laws—alleged on behalf of TPPs from 42 different jurisdictions. That trial was set by the Court to begin on March 18, 2024.[44]

In preparation for a class trial, the TPP Trial Defendants[45] filed a motion for decertification of the TPP class and both parties filed cross-motions for summary

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to the underlying class certification order, and the Court approved it on November 15, 2024. [ECF 2532]. Plaintiffs' counsel have advised Defendants' counsel that class notice has been completed in accordance with the approved class notice plan and have provided opt-out reports at the request of Defendants' counsel. The Class Administrator has not yet filed a report with the Court confirming the execution of the class notice plan or informing the Court of opt-outs.

43 (*See* [ECF 2343] Case Mgmt. Order No. 23.)

44 (*See* [ECF 2529] Tr. of Case Mgmt. Conference held on Nov. 1, 2023, before Judge Robert B. Kugler.)

45 The "TPP Trial Defendants" comprise Zhejiang Huahai Pharmaceutical Co., Ltd.; Huahai U.S., Inc.; Prinston Pharmaceutical Inc.; Solco Healthcare U.S., LLC; *(cont'd)*

judgment, motions to preclude expert testimony under Federal Rule of Evidence 702, motions regarding the proper scope of deposition designations, and extensive motions in limine. The Court denied the decertification motion without holding oral argument and before Plaintiffs had filed an opposition.[46]

Following the Court's class certification ruling—and the denials of the TPP Trial Defendants' motion for a stay by Judge Kugler and for decertification—the parties focused on TPP-class-specific expert discovery for the bellwether TPP class trial,[47] which involved, *inter alia*, the submission of expert reports with respect to chemistry, manufacturing, and regulatory issues, including what was known in the

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Teva Pharmaceuticals USA, Inc.; Actavis LLC; Actavis Pharma, Inc.; Torrent Pharmaceuticals Ltd.; and Torrent Pharma, Inc.

[46] (*See generally* [ECF 2657] Order & Mem. on Defs.' Mot. to Decertify the TPP Trial Classes.)

[47] The Court had previously permitted depositions of named consumer and TPP class representatives on liability issues. After directing the work-up of the bellwether MSP trial, the Court and Special Master authorized additional fact and expert discovery relating to damages for the bellwether trial, including the production of additional documents relating to MSP's damages, the disclosure of initial and supplementary damages expert reports, and the depositions of damages experts. Following class certification (described below), the Court and Special Master expanded bellwether-specific damages discovery to the certified subclasses for the first TPP class bellwether trial (described below), and authorized additional expert discovery on defendant-specific liability issues for the bellwether trial. To date, full liability and damages discovery has only taken place with respect to the TPP bellwether trial for ZHP, Teva, and Torrent. There have been initial discussions of additional damages discovery with respect to initial class representative Maine Automobile Dealers Association ("MADA"), but no additional documents have yet been produced, no damages expert opinions have been disclosed, and no fact or expert disclosure deadlines have been set.

scientific community about the risks of nitrosamine formation during the relevant period, FDA and other regulatory requirements applicable to the manufacture and sale of API and VCDs, and the TPP class's alleged damages, which are based on a theory that all recalled VCDs are worthless due to the presence of trace amounts of nitrosamines despite providing effective therapeutic relief to patients.[48] On January 5, 2024, the Court ruled on the parties' various motions to exclude each side's liability experts.[49] On January 17, 2024, the ZHP Defendants filed a motion to amend or correct the Court's opinion on the parties' liability experts, noting several inconsistent rulings that precluded certain of Defendants' experts from offering opinions—including on grounds that they constitute improper legal opinions—while allowing other, similarly qualified Plaintiffs' experts to offer essentially the same testimony.[50] That motion remains pending.

On March 26, 2024, shortly before announcing his retirement and canceling the planned TPP class trial, the Court issued an order addressing the parties' various

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[48] **Plaintiffs' Position**: Defendants' reference to "trace" amounts is another example of misleading argument by the Defendants. The nitrosamines at issue are highly toxic, thus relatively small quantities pose significant danger.

[49] (*See* [ECF 2582] Order on Liability Expert Reports under *FRE* 702.)

[50] (*See* [ECF 2591-1] Defendants Zhejiang Huahai Pharmaceutical Co., Ltd.; Huahai U.S., Inc.; Prinston Pharmaceutical Inc.; and Solco Healthcare U.S., LLC's Mem. of Law in Supp. of Mot. to Amend or Correct the Court's Opinion on the Parties' Liability Experts.)

motions for summary judgment.[51] The Court denied the majority of the parties' motions as raising questions of fact that should be resolved by the jury. There were, however, a few exceptions. The Court granted summary judgment in favor of Plaintiffs on the following issues:

- Whether the TPP Trial Defendants' "affirmations, statements, labelling of their VCDs constitute express warranties that their VCDs were the equivalent to the Orange Book formulation"[52];
- "[W]hether plaintiffs gave defendants pre-suit notice of the breach of express warranty claim"[53];
- Whether the "statute of limitations limits the filing of breach of express warranty claims in some jurisdictions in" the express warranty subclass.[54]

The Court also granted summary judgment in favor of the TPP Trial Defendants on Plaintiffs' consumer protection claims under the law of Missouri, as well as Plaintiffs' claims for punitive damages based on breach of warranty and consumer protection allegations under the laws of New Hampshire and Nebraska.[55]

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51 (*See* [ECF 2695] Order on TPP Trial Summ. J. Motions.)

52 (*See* [ECF 2695] Order on TPP Trial Summ. J. Motions at 2.)

53 (*See id.* at 3.)

54 (*See id.*)

55 (*See id.* at 4–5.)

The parties submitted exhibit lists (with objections), witness lists (with objections), trial briefs,[56] proposed jury instructions, and proposed verdict forms as scheduled ahead of the planned TPP class trial. The Court did not provide rulings on the parties' motions in limine or the parties' Rule 702 motions with respect to damages experts; nor did he address the variety of legal issues and objections raised in the parties' trial briefs and pretrial submissions, prior to removing the planned TPP class trial from the Court's calendar. The Court did not resolve any exhibit objections, witness objections, jury instructions, or verdict forms.

f. Status Of Losartan And Irbesartan Cases

As explained above, this MDL proceeding also includes individual personal injury and proposed class cases arising out of the voluntary recall of losartan and irbesartan medications. Those losartan-containing drugs ("LCDs") and irbesartan-containing drugs ("ICDs") are generic versions of certain branded ARB drugs approved by the FDA primarily for treatment of hypertension and heart failure.

[56] Defendants also submitted responses to certain issues raised in Plaintiffs' Trial Brief, which sought specific relief that had not previously been briefed. The Court struck Defendants' responses to Plaintiffs' motion, stating that: "1) NO responsive trial brief relating to the TPP Trial shall be filed by any party; 2) there was and is NO need for responsive trial briefs for the TPP Trial; 3) there shall be no further briefing by the parties for the TPP Trial." ECF No. 2691. Defendants respectfully submit that their responses should not have been stricken and request leave to resubmit them. Defendants also seek clarification as to whether the Court order that there shall be no further briefing with respect to the previously-scheduled TPP trial remains in effect.

Notably, several defendants named in the losartan and irbesartan cases were not named in any of the valsartan cases and, as such, those defendants have not participated in the discovery and briefing undertaken to date with respect to the valsartan cases.

The Defendants named in the Master Irbesartan Personal Injury Complaint are API and finished dose manufacturers, re-packagers, wholesalers, and pharmacy defendants.

- **API and Finished Dose Manufacturers**: Aurobindo Pharma, Ltd.; Huahai U.S., Inc.; Prinston Pharmaceuticals Inc.; ScieGen Pharmaceuticals, Inc.; Solco Healthcare US, LLC; and Zhejiang Huahai Pharmaceutical Co., Ltd.

- **Re-packagers**: Golden State Medical Supply; and Westminster Pharmaceuticals.

- **Wholesalers**: AmerisourceBergen Corporation (n/k/a Cencora, Inc.); Cardinal Health, Inc.; and McKesson Corporation.

- **Pharmacies:** Albertsons Companies, LLC; Cigna Corporation; CVS Pharmacy, Inc.; Express Scripts Holding Company; Express Scripts, Inc.; Humana, Inc; Humana Pharmacy, Inc.; OptumRx,; Optum, Inc.; Rite Aid Corporation; The Kroger Company; UnitedHealth Group; Walgreens Boots Alliance, Inc.; Walgreen Co.; and Walmart, Inc.

Defendants in the Master Losartan Personal Injury Complaint also are API and finished dose manufacturers, re-packagers, wholesalers, and pharmacy defendants.

- **API and Finished Dose Manufacturers:** Camber Pharmaceuticals, Inc.; Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals Inc., Hetero

Drugs, Ltd.; Hetero Labs, Ltd.; Hetero USA, Inc.; Huahai U.S., Inc.; Macleods Pharmaceutical Limited; Macleods Pharma USA, Inc.; Major Pharmaceuticals; Prinston Pharmaceuticals Inc.; Sandoz, Inc.; Solco Healthcare US, LLC; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Torrent Pharmaceuticals, Ltd.; Torrent Pharma, Inc.[57]; Vivimed Life Sciences Pvt Ltd.; and Zhejiang Huahai Pharmaceutical Co, Ltd.

- **Re-packagers**: Golden State Medical Supply; and H J Harkins, Co. Inc.

- **Wholesalers:** AmerisourceBergen Corporation (n/k/a Cencora, Inc.); Cardinal Health, Inc.; and McKesson Corporation.

- **Pharmacies:** Albertsons Companies, LLC; Cigna Corporation; CVS Pharmacy, Inc.; Express Scripts, Inc.; Express Scripts Holding Company; Humana, Inc.; Humana Pharmacy, Inc.; OptumRx; Optum, Inc.; Rite Aid Corporation; The Kroger Company; UnitedHealth Group; Walgreens Boots Alliance, Inc.; Walgreen Co.; and Walmart, Inc.

1. Losartan/Irbesartan Motion Practice

Pursuant to the Court's direction, defendants in the losartan and irbesartan cases have not filed motions to dismiss. Instead, in the interest of conserving the Court's and the parties' resources, the parties have negotiated a proposed stipulation and order on dismissal of certain losartan and irbesartan claims. If approved by the Court, that stipulation and order would effectively apply the Court's prior rulings regarding dismissal of valsartan claims to those plaintiffs' losartan and irbesartan claims, while reserving all rights to challenge the claims at other stages of the

[57] Torrent Pharma, Inc. is a distributor associated with manufacturer Torrent Pharmaceuticals, Ltd.

litigation and on appeal. The parties are prepared to file a motion for entry of the proposed stipulation and order at the Court's convenience.

2. Discovery to Date in the Losartan and Irbesartan Cases

Given the differences among VCDs, LCDs and ICDs in terms of, among other things, chemical compositions, manufacturing processes, and recall histories, the Court determined early in the litigation to first focus on valsartan. As such, the Court directed the parties to complete production of valsartan-related documents first, with losartan/irbesartan discovery beginning almost three years later.[58] The parties negotiated search terms, custodian lists, and other aspects related to the scope of custodial and non-custodial document production related to losartan and irbesartan in July and August of 2023, and the manufacturer defendants began rolling productions of losartan and irbesartan documents in the fall of 2023.[59] The manufacturing defendants recently substantially completed those productions, just weeks before the Court announced the cancellation of the TPP class trial.

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[58] (*See, e.g.,* [ECF 88] MDL Order Regarding Core Discovery ("At this time, the production of core discovery is limited to Valsartan and not Losartan or Irbesartan"); [ECF 2132] Core Discovery Order for Losartan and Irbesartan (setting forth requirements for "core discovery for losartan and irbesartan"); [ECF 2343] (CMO allowing initial discovery requests regarding losartan and irbesartan focused on discovery supporting plaintiffs' class-certification allegations for economic loss claims).)

[59] (*See* [ECF 2538] Case Mgmt. Order governing production of losartan and irbesartan noncustodial and custodial documents by manufacturing defendants.)

This Court has entered orders approving a Plaintiff Fact Sheet for losartan and irbesartan personal injury plaintiffs and third-party payor economic-loss plaintiffs.[60] The parties are in the process of negotiating a Plaintiff Fact Sheet for losartan and irbesartan consumer economic loss plaintiffs and medical monitoring plaintiffs. The parties have begun the meet-and-confer process to discuss corporate depositions, including topics and witnesses, and are working together on a proposed schedule for completing those depositions. No expert discovery has been conducted yet in the losartan and irbesartan cases, but the parties anticipate a schedule for expert discovery to follow corporate depositions.

At the May 31, 2024 conference regarding Plaintiffs' settlement discussions with Hetero, this Court instructed Plaintiffs to ask Special Master Vanaskie to set a discovery conference regarding the status of Plaintiffs' requests for depositions of corporate witnesses related to claims involving losartan and irbesartan. A discovery conference on these issue was held on June 25, 2024. Judge Vanaskie indicated he will order (1) Plaintiffs to identify their desired Manufacturer Defendant fact witnesses by July 15, 2024; (2) Manufacturer Defendants to identify their 30(b)(6) witnesses, topics, and proposed dates by July 31, 2024; and (3) Depositions of Manufacturer Defendants to be completed by October 31, 2024.

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[60] (*See* [ECF 2247] Order on personal injury PFS; [ECF 2636] Order on third-party payor PFS.)

g. State Cases And Coordination

There are 20 personal injury cases pending in New Jersey state court against various defendants that mirror the personal injury allegations related to cancer that are asserted in the MDL proceeding. The cases were filed in Middlesex County, but Plaintiffs have not served all Defendants in these cases. These cancer-related cases are presently stayed.

There is one active case, brought by plaintiffs Danny and Marysol Colon, that is pending in Middlesex County in which the plaintiffs allege that Mr. Colon developed Amyotrophic Lateral Sclerosis as a result of taking valsartan. The Court dismissed the *Colon* case from the MDL proceeding for lack of subject matter jurisdiction on July 13, 2022, and the case was refiled in state court in Middlesex County. *Colon* is the only personal injury case filed to date involving such non-cancer allegations.

One additional case filed by LHC Group, Inc. as administrator of the LHC Group Benefit Plan, is pending in the Superior Court of the State of Delaware. The plaintiff alleges claims for medical expenses paid on behalf of its plan members. The LHC Group case is presently stayed.

IA. PLAINTIFFS' STATUS UPDATE ON ALL PENDING MDL MATTERS

As set forth above in footnote 4, Plaintiffs did not understand the Court's Order to request a historical accounting of the litigation and detailed arguments over

the meaning and import of the prior rulings in this litigation. Plaintiffs do not agree with the Defendants' rendition in many respects, for example characterization of the strengths and weaknesses of claims in the litigation, the outcomes of the many motions decided by the Court to date, and repeated description of the contamination as trace impurities when in fact the amount of nitrosamines found in the drugs was sufficient to require a recall of the pills sold by the Defendants.[61]

Plaintiffs agree with Defendants' identification of the pending matters, including the certified economic loss and medical monitoring class actions, and the personal injury claims, including the small number of personal injury claims pending (and stayed) in state court.

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[61] Defendants' reliance on an FDA press release is telling because after the initial recall, the FDA had to defend its failure to uncover the contamination earlier. As a result, the FDA's press releases are generic and self-serving attempts to minimize the fallout of the recalls for itself. However, when the FDA addressed Defendants individually in formal communications, the FDA made it clear that the contamination was unacceptable, that Defendants should and could have prevented it, and that Defendants had to change their operations to prevent such a contamination in the future. *See, e.g.*, FDA, Warning Letter to ZHP (Nov. 29, 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/zhejiang-huahai-pharmaceutical-566685-11292018. In fact, ZHP was banned from importing any drugs from its valsartan manufacturing facilities in China for over three years. *Id.* The Court should consequently disregard Defendants' reliance on the FDA's self-serving press releases. As the Court will see in addressing the motions in limine, the press releases are far from exculpatory for Defendants.

The following sections present the information that Plaintiffs understood the Court to have requested with regard to the matters that are actively pending at present:

a. Trial of TPP Class Claims Against ZHP, Teva, and Torrent.

The Court previously scheduled the trial of segments of the certified TPP economic loss class claims pending against Defendants ZHP, Teva, and Torrent (and their affiliates). That trial was scheduled to begin on March 18, 2024, and the Court adjourned the trial without a new date based on Judge Kugler's retirement, thus the trial needs to be rescheduled, presumably in the fall, 2024.

Judge Kugler addressed a number of issues related to the trial, including determination of the parties' dispositive motions. The following remains to be addressed:

The parties briefed motions in limine, many of which are critical to the parties' trial preparation. For example, the Court's decision on the scope of the issues to be determined at trial will have a significant impact on the parties' efforts to resolve objections to the deposition designations, including discussion of exhibits, to be submitted at trial. Plaintiffs also filed a separate motion to preclude Defendants from playing (1) affirmative deposition designations for available witnesses and (2) counter designations in Plaintiffs' case, unless required for "completeness." Once those motions are decided it is expected that this will resolve a large number of the

designation objections and allow the parties to narrow the issues that remain in dispute. This will also allow the parties to plan ahead as to which experts and witnesses will need to testify.

The parties submitted a joint proposed Pre-Trial Order, which they did not have the opportunity to discuss with the Court. It is expected that the rulings on the motions in limine will provide helpful guidance to the parties as to the issues to be addressed at trial, allowing them to streamline the exhibits, as well as witnesses.

Deposition designations were exchanged, and the parties were actively meeting and conferring on the proposed testimony and objections when the trial was adjourned. A great deal of progress was made in those discussions, but those discussions ceased at that time. Due to the locations of the Defendants, and other factors, many of the witnesses will be presented at trial via video, thus the determination of the objections to the designations will to a large extent determine the testimony and evidence to be heard and seen by the jury at trial. As stated above, the Plaintiffs are hopeful that the determination of the motions in limine will streamline the issues in dispute and drastically reduce the number of additional disputes that will need to be submitted to the Court for decision.

Prior to trial, Plaintiffs served requests for punitive damages financial discovery on Defendants. Defendants refused to respond. As argued during the June 25, 2024 conference with the Special Master, Plaintiffs request production of the

requested discovery, or at the very least Defendants' confirmation of their corporate net worth, and gross revenues, for use at trial, and then to be updated in advance of any future trials.[62]

The parties served supplemental economic loss expert reports regarding the damages at issue at the trial, deposed the experts, and filed Daubert motions. Those motions are pending.

b. Defendants' Joint Motion for Clarification Regarding Daubert Hearing Order 1 and Plaintiffs' Cross Motion.

On March 18, 2022, Defendants filed a motion for clarification regarding the permissible scope of Plaintiffs' experts Dr. Hecht's and Dr. Lagana's general causation opinions for n-nitrosodiethylamine (NDEA). (ECF 1976). In their March

[62] **Defendants' Position**: Plaintiffs served Defendants with punitive damages discovery for the first time on February 23, 2024, just 23 days before the originally scheduled trial date and years after the close of fact discovery in June 2021, in the form of a "Notice to Produce Evidence of Financial Condition at Trial." That request was untimely by years, as the Court has reaffirmed multiple times in denying "clearly untimely" discovery requests made after the close of discovery. *See* ECF 2469 at 7-8; *see also* ECF No. 2476; ECF No. 2554; ECF No. 2701. Plaintiffs have not shown good cause to modify the discovery schedule to accommodate their untimely requests, as required by Fed. R. Civ. P. 16(b)(4). Nor have they shown why they could not have propounded such discovery during the time prescribed by the Court to complete discovery, or why their overbroad and highly burdensome requests, including tax returns, bank statements, asset documentation, income documentation, liabilities, and trusts and other entities, are relevant to punitive damages or proportionate to the needs of the case, where Plaintiffs themselves acknowledge that at most they need only net worth and gross revenues. Special Master Vanaskie reserved this issue for the Court upon being informed at the June 25, 2024 conference that it was briefed before the Court in the parties' Pretrial Briefs.

29, 2022 agenda letter, Plaintiffs informed the Court and Defendants that they were preparing their opposition as well as a cross motion for clarification of the Court's ruling on another Plaintiffs' expert, Dr. Panigrahy, which Plaintiffs believe mistakenly limited his testimony on NDEA causation to pancreatic cancer. (ECF 1983). At the related case management conference on March 30, 2022, the Court suggested "the two sides just talk to each other" before proceeding further with the motions, and the motions were tabled. (3/30/2022 Hearing Tr. 19:1-2, ECF 1993).

During the subsequent meet and confer, Plaintiffs proposed including the motions as part of the first set of relevant trial motions. Defendants explained that they intend to file omnibus Rule 56 motions for summary judgment on personal injury claims related to NDEA and cancers other than pancreatic, and thus want to have the clarification motions decided before any Rule 56 motions on the personal injury cases based on the underlying *Daubert* decisions. Plaintiffs agreed that if the Court is inclined to allow the filing of such a motion (Plaintiffs would object to the filing of Rule 56 motions directed to specific personal injury cases at this phase), the Plaintiffs would agree to hold these motions, to be heard prior to the filing of dispositive motions. (ECF 2026). The Court agreed with the Parties, and the motions have been held in abeyance ever since. (4/29/2022 Hearing Tr. 13:16-14:8, ECF 2030).

c. ZHP's Motion to Amend or Correct the Court's Opinion on the Parties' Liability Experts and Plaintiffs' Cross Motion to Exclude Dr. Afnan's Opinions that Rely on Dr. Xue's Excluded Opinions.

On January 17, 2024, ZHP filed a motion for the Court to amend or correct its opinion regarding the Parties' liability experts in order to either permit all of its cGMP expert Dr. Afnan's opinions or exclude certain opinions of Plaintiffs' experts Dr. Plunkett and Dr. Najafi. (ECF 2591). On February 6, 2024, Plaintiffs opposed the motions and cross moved to exclude Dr. Afnan's opinions that were based on the excluded chemistry related opinions of another ZHP expert, Dr. Xue. (ECF 2626). Two weeks later, ZHP replied and opposed the cross motion. (ECF 2651). These motions are pending.

d. Plaintiffs' Motion to Amend/Correct the Court's Daubert Ruling on Timothy Anderson.

Plaintiffs filed a limited motion to amend/correct the Court's Daubert ruling as to one of Teva's liability expert witnesses, Timothy Anderson. The motion remains pending.

II. STATUS OF SETTLEMENT

Plaintiffs and the Hetero Defendants have resolved all valsartan-based claims—including economic loss class actions, the medical monitoring class action, and personal injury claims—as well as the losartan-based medical monitoring class action and personal injury claims. The only remaining unsettled claims against the Hetero Defendants are the losartan-based economic loss class actions. Plaintiffs and

the Hetero Defendants appeared in Court for a status conference on May 31, 2024, and the Court issued an Order directing that the settlement documentation for all settlements be finalized by June 30, 2024, and directed the parties to actively continue their mediation efforts with the Honorable Joel Schneider, U.S.M.J. (ret.). The Parties are moving forward as directed, and have requested an extension of the June 30, 2024 deadlines. The Court also indicated that no motion for preliminary approval of the class settlements will be granted prior to resolution of the Losartan economic loss claims, unless Judge Schneider attests to the Court of an irresolvable impasse, so that the economic loss class claims can be addressed on one motion.

Plaintiffs and Aurobindo have resolved all irbesartan-based claims in the litigation, through mediation with the Honorable Joel Schneider, U.S.M.J. (ret.). A term sheet was signed on April 12, 2023. As of the writing of this agenda letter, the Parties are working to complete the settlement documentation.

On January 4, 2021, the Court appointed the Honorable Gregory M. Sleet and the Honorable Lawrence F. Stengel to serve as Special Masters for Settlement in this litigation. *See* [ECF 708.] The Court thereafter formally appointed settlement counsel for each party, with separate settlement counsel to represent Plaintiffs, individual Manufacturer Defendants, individual Wholesaler Defendants, and Pharmacy Defendants, respectively, in settlement negotiations overseen by the Settlement Special Masters. *See* [ECF 1957.]

It is Plaintiffs' position that in practice, the settlement discussions with the Special Masters have unfortunately not advanced, and appointed settlement counsel has not been involved in the settlement discussions that have advanced (with the exception of Hetero), and litigation counsel has handled or led the settlement negotiations that have advanced, including for Plaintiffs where co-lead counsel has been leading the settlement negotiations.

It is Defendants' position that discussions with the Special Masters have made limited progress, but Defendants do not agree that they have not advanced. Defendants agree that co-lead litigation counsel for Plaintiffs has handled or led settlement negotiations for Plaintiffs, but disagree that appointed settlement counsel for Defendants has not been involved in the settlement discussions that have advanced, as most Defendants' appointed settlement counsel continue to take the lead in settlement discussions with Plaintiffs' counsel.

Plaintiffs have had direct settlement discussions with Teva and Torrent, and Plaintiffs and Teva and Torrent appeared for an in-person mediation on January 26, 2024, with the Special Masters, which was unsuccessful. Those discussions did not continue as the Parties approached the March 18, 2024 trial date. Plaintiffs are prepared to resume settlement discussions with Teva and Torrent.

Plaintiffs have had discussions, and continue discussions, with other manufacturer defendants on a confidential basis, and can provide more detail to the Court on a confidential basis.

Plaintiffs have had settlement discussions with certain Pharmacy Defendants. Plaintiffs look forward to resuming those discussions. The details can be shared with the Court on a confidential basis.

It is Plaintiffs' position that Plaintiffs are and have been ready to enter serious settlement discussions with the ZHP Defendants, and have communicated recently with ZHP in this connection. It is Plaintiffs' understanding that ZHP has no interest in entering into serious discussions as to any of the contaminated products at issue.

It is the ZHP Defendants' position that Plaintiffs have not made a formal demand to the ZHP Defendants, and based on the ZHP Defendants' general understanding of the amount Plaintiffs are seeking to resolve the claims at issue, it appears that there is too wide a gulf between the parties' views regarding the value of any potential settlement for further negotiations to be fruitful.

Mylan's settlement counsel has engaged in discussions with the Settlement Special Masters, Judge Stengel and Judge Sleet, but Mylan has not had direct discussions with Plaintiffs' counsel. Plaintiffs' counsel made efforts to initiate discussions with Mylan prior to the appointment of Settlement Counsel, but those discussions did not progress.

Wholesalers' settlement counsel has also engaged in discussions with Settlement Special Masters. Wholesalers' settlement counsel has not engaged in any other settlement discussions with Plaintiffs' counsel.

III. PARTIES' ASSESSMENT OF ISSUES TO ADDRESS IN THE LITIGATION MOVING FORWARD

In addition to providing an update as to the status of the litigation thus far, the Court asked the parties to identify issues that will require the Court's attention moving forward.

a. Defendants' Submission

In connection with announcing his retirement, the Court made clear that there is "no obligation on the new judge" assigned to oversee this MDL proceeding to follow the Court's prior approach.[63] As the Court recognized, the "new judge . . . may decide to proceed in a different manner" with respect to "when and even whether" to proceed with the previously-envisioned TPP class trial.[64] Defendants submit that the question of causation should be addressed first so as to provide the parties with crucial information necessary to assess the value of the claims at issue in this proceeding. Defendants respectfully request that this Court redirect the focus of this MDL to causation, which must occur before any case in this MDL can proceed

63 (*See* [ECF 2698] Tr. of Status Conference/Mot. Hr'g held on Mar. 27, 2024, before the Court and Special Master Vanaskie 4:16-20.)

64 (*Id.*)

to trial. (The Torrent Defendants believe that the Court should proceed with the TPP class trial at this time and write separately from the Defendants regarding this issue, *see infra* at III. B.)

A change in direction is both appropriate and necessary at this point because the proceedings thus far have demonstrated that: (i) the proposed TPP trial is an imperfect vehicle to address the central issue in this MDL, which relates to causation and is better addressed through specific causation work-up, specific causation Rule 702/*Daubert* motions, and potential bellwether trials of personal injury cases; and (ii) the proposed TPP class trial is inherently inefficient and inconsistent with Rule 23 and therefore any class verdict will likely be reversed on appeal.

In short, the significant time and resources that would be expended by the Court and the parties by proceeding with an unmanageable TPP class trial would be better focused on causation. An inventory of more than 1,200 personal injury cases—which comprise approximately 98% of the coordinated cases in this MDL proceeding—have languished for years. Notably, these cases involve individuals who claim that ingestion of VCDs caused them to develop cancer. Yet Plaintiffs' counsel have largely ignored these cases while focusing exclusively on economic loss claims that will not provide any insight as to whether the VCDs at issue posed a health risk to patients at the trace levels at issue in this litigation.

This approach is contrary to that taken in the vast majority of mass tort MDL proceedings. *See, e.g.*, *In re Vioxx Prods. Liab. Litig*., No. 2:05-md-1657, [ECF 5865]; *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig.*, 8:10-ml-2151, [ECF 806]; *In re Zantac (Ranitidine) Prods. Liab. Litig.* MDL No. 2924, [ECF 767]. As countless MDL courts have recognized, issues related to causation—both general and specific—are central to the merit of large-scale product liability litigation. Defendants respectfully request that this Court redirect the focus of this MDL to causation by moving forward with personal injury bellwether cases, including work-up of specific causation experts, Rule 702 motions directed to specific causation, summary judgment practice focused on specific causation and other dispositive questions that may focus the direction of the MDL and efforts to bring it to resolution, and potential bellwether trials for personal injury cases. And even if the Court is inclined to proceed with the TPP class trial, the Court's prior general causation decision should still be revisited through new hearings under amended Rule 702 before any case in this MDL can proceed to trial. Additionally, Defendants request that the Court enter a comprehensive Rule 16 scheduling order setting forth clear deadlines in the losartan and irbesartan cases, moving forward.[65]

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[65] **Plaintiffs' Position**: Defendants' request for a losartan/irbesartan scheduling order beyond that already entered by the Special Master should be denied. As the *(cont'd)*

i. The Proposed TPP Class Trial Is Unworkable.

The process of working up the TPP "bellwether" case for trial was valuable in only one respect: it demonstrated, beyond a shadow of a doubt, that Plaintiffs' class claims are unmanageable and cannot be fairly tried consistent with Rule 23. (*See generally* [ECF 2633], TPP Trial Defendants' Mot. For Decertification of the TPP Trial Subclasses.) Should the TPP "bellwether" case proceed to trial, it will be a tremendously expensive and inefficient exercise, occupying the Court's and the jurors' time for months, and the likelihood of reversal on appeal is overwhelming for three specific reasons, among many others that apply more generally to all of the class action claims.

First, the TPP trial subclasses are riddled with choice-of-law issues and errors that demonstrate why these cases are unsuitable for class treatment. The Court initially ruled that each TPP's claims are governed by the laws of its home state. (*See* [ECF 818, at 9-12].) The TPP subclasses set for trial, however, are defined based on the state in which a TPP ***paid for*** the medications at issues. The problem is that in most instances, TPPs are not a party to the transaction in the state where a consumer pays for a prescription. Rather, the TPP reimburses a Pharmacy Benefits Manager after the fact, in a different state. As such, the "point of sale" (state where PBM pays

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ordered discovery proceeds the parties can discuss next steps and potential deadlines, and bring those discussions to the Court when the parties reach agreement or an impasse.

the pharmacy) and the "point of transaction" (state where the TPP reimburses the PBM) can be in two different states. This creates issues with respect to the determination of both liability and damages. The Court acknowledged this "mismatch" in its ruling on the parties' motions for summary judgment with respect to the TPP class claims. (*See* [ECF 2694], Op. on TPP Trial Mot. for Summary Judgment, at 60.) But instead of addressing it, the Court declared, with no explanation, that a yet-to-be-defined "translating mechanism" could be used to "convert the TPPs Point of Sale [POS] data" to "the TPPs Point of Payment [POP] locations." (*Id.*) Defendants are not aware of any "translation mechanism" that can somehow be applied to correct the predominance and ascertainability problems that permeate the certified TPP subclasses, and Plaintiffs have provided no explanation as to what the "translation mechanism" might be in the several years this litigation has been pending. Further, even if such a mechanism theoretically existed, it would have to be applied before trial, requiring additional discovery and briefing.

Relatedly, Plaintiffs have failed to satisfy Rule 23's ascertainability requirement. Indeed, both the Third Circuit and a court in this District have recently excluded Plaintiffs' expert, Laura Craft, because her core methodology—using PBM data to identify TPP class members—is unreliable. *See In re Niaspan Antitrust Litig.*, 67 F.4th 118, 135-40 (3d Cir. 2023) ("Given the record before the Court, it was not an error, let alone a clear error, to conclude that Ms. Craft's data matching technique

could not adequately determine class membership); *In re Lipitor Antitrust Litig.*, No. 3:12-CV-2389, 2024 WL 2865074, at *16 (D.N.J. June 6, 2024) ("Based upon the Court's review of the evidence, there is no methodology proposed that is specific to the case. Stating that data has been produced and can be analyzed by a computer to determine where it complies with the conditions of the class definition is insufficient."). Ms. Craft's methodology here is similarly flawed and does nothing to resolve the "mismatch" identified by both Defendants and the Court.

Second, the previously contemplated TPP class trial would be completely unmanageable, confirming that individual trials are a superior remedy. Because the subclasses that were assigned to be tried involve the laws of 42 different states, the Court would be forced to spend multiple days charging the jury. (*See* [ECF 2680], Defendants' Proposed Jury Instructions (totaling more than 400 pages).) No reasonable juror, after sitting through a month or more of trial involving complex scientific and economic issues, will be able to absorb the minute details and distinctions between each of the state laws at issue. This would render any subsequent verdict subject to attack on appeal. Likewise, if the Court were to oversimplify the jury instructions in the interest of expediency, any verdict rendered would be tainted by the error of merging the distinct laws of disparate jurisdictions into omnibus instructions accurately summarizing the law of no jurisdictions.

Third, because TPP class members would be included in trial for some causes of action and some prescriptions, but excluded for others, the trial structure would very likely require multiple juries to reexamine the same issues. That is because each of the three claims that are set to be tried involves different subclass state groupings. For example, a Texas plaintiff may have its express warranty claim resolved at trial, but not its fraud or consumer protection law claims. (*See* [ECF 2343], CMO 32 (selecting subclasses for TPP class trial).) That would necessitate a later trial on the same facts, which implicates the reexamination clause of the Seventh Amendment. U.S. Const. amend. VII ("no fact tried by a jury[] shall be otherwise re-examined in any [c]ourt of the United States, [other] than according to the rules of the common law."). For this reason, too, any verdict in the TPP class case would likely be overturned.

ii. All Claims In This MDL Proceeding Revolve Around Causation

This MDL proceeding was established more than five years ago. Rather than expend further time and resources on a lengthy and complicated trial that is all but certain to end in reversible error, the Court should follow the precedents of numerous MDL courts that have focused on causation and personal injury bellwether cases rather than unwieldy class actions. That approach has proven to be the most effective means to bring cases to resolution, whether by dismissal, verdict, or settlement. Alternatively, to the extent the Court is nonetheless inclined to proceed with the TPP

class trial, once that trial (and any subsequent appeal) is completed, the Court should turn its attention to addressing the large inventory of personal injury cases. Specifically, the Court should direct work-up of specific causation experts in bellwether personal injury cases, followed by Rule 702/*Daubert* motions and summary judgment practice directed to specific causation and other potential case-dispositive issues, followed by potential bellwether trials of personal injury cases.

Defendants disagree at the outset with Plaintiffs' position that the question of general causation would not be a factor in a TPP subclass trial. That issue is subject to a pending and contested motion in limine [ECF 2648-1 at 15; ECF 2667 at 12]. Judge Kugler explicitly stated that a jury would decide the question of general causation in a TPP case. *See* ECF 1946, 41:6-12 (Kugler, J.) ("[T]he first and most important questions here, which is general causation. So we'll pick a case if we have to, ***probably a third-party payor case*** because the damages are relatively easy to calculate in those cases, ***and just to get a jury to say yes or no on the question of general causation and get that done***") (emphasis added); *see also* ECF 77, 5:12-16 (Kugler, J.) ("causation carries over" into the economic loss class actions, because "if the contamination is not dangerous, then maybe [Plaintiffs] don't have such a great argument that [they] should get [their] money back for paying for it."). Indeed, in creating this MDL, the Judicial Panel on Multidistrict Litigation found in its Transfer Order that "whether the amount of NDMA and NDEA in the medication

presented a risk of cancer or other injuries" is one of the "common questions of fact" in all cases—both class actions and personal injury actions—warranting consolidation and creation of the MDL. ECF 1 at 3. A TPP subclass trial that does not address general causation would thus fall outside the scope of the Transfer Order.

Although causation has a significant bearing on the resolution of all claims in the MDL, the TPP class trial is an imperfect vehicle to obtain guidance from a jury on all aspects of the causation question. By contrast, work-up of a series of personal injury bellwether cases would allow the parties to further develop the record, including with regard to specific causation, which has never been addressed in this proceeding. Plaintiffs have never articulated why they are prioritizing economic loss claims over the more individually impactful personal injury claims of Plaintiffs that allegedly developed cancer from ingesting VCDs. Redirecting attention to the important causation issues at the heart of these claims will move this entire MDL towards its conclusion.

Re-focusing on causation would also allow the Court to revisit general causation in the context of amended Rule 702 of the Federal Rules of Evidence, which was revised in December 2023 to underscore the heightened level of judicial scrutiny required before expert testimony is admitted. This is something that is required here before any case can proceed to trial.

In ruling on the admissibility of expert causation opinions, the Court found that most of the opinions offered by the parties' causation experts were admissible because the witnesses "followed" a "methodology"—typically, a literature review—and "explain[ed] how they [came] to their opinions."[66] According to the Court, nothing more was required based on what he perceived to be his "very, very limited role" under Rule 702.[67] Further, the Court determined that any criticisms as to how an expert ***applied*** his or her methodology to the underlying data were to be addressed through cross-examination and, ultimately, would be left to the jury to sort out at trial.[68] As a result, the Court did not conduct the thorough analysis regarding the

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66 (March 2, 2022 Hr'g Tr. 149:4-14, ECF 1959.)

67 (*Id.* 93:1-2; *see also* Feb. 28, 2022 Hrg. Tr. 33:15-36:25, ECF 1946 (the Court describing what it understood to be its "extremely limited role" and its "very circumscribed" gatekeeper function under Rule 702, pursuant to which only "science which no reasonable scientist could ever support" is to be excluded, and finding that a "deep dive" by the Court into the data underlying an expert's opinions is not permitted).)

68 (*Id.* 154:23-155:5 ("And remember *Daubert*. The opinion expressed does not have to be generally accepted in the scientific community. What has to be accepted is the way you go about doing your research. The methodology he uses is the same as everyone else, he examines all the studies that are available, he explains why he thought some were not terribly helpful or relevant and why some were. The jury will have to straighten this out."); *see also id.* at 142:12-16 ("[T]he jury's going to have to hear all this argument and, you know, you're going to -- defense is going to cross-examine vigorously the plaintiffs' experts, and they're doing a great job so far of doing it, and the jury's going to have to determine."); 151:4-7 ("The jury is going to have to determine which of these studies they think are important and which are not for the reasons that you're going to illustrate to them."); 153:1-3 ("Again, he provides an explanation as to why some [studies] are noteworthy and some aren't. *(cont'd)*

reliability of the opinions being offered that is now clearly required under the Federal Rules. *See* FED. R. EVID. 702, Committee Notes on Rules – 2023 Amendment ("But many courts have held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a)."); *Kuhar v. Petzl Co.*, 2022 WL 1101580, at *7 (3d Cir. Apr. 13, 2022) ("[T]he expert must have 'good grounds' for his or her belief.") (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994)); *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291 (3d Cir. 2012) ("[T]he reliability analysis . . . applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, [and] the link between the facts and the conclusion.") (citation omitted); *In re Acetaminophen – ASD-ADHD Prods. Liab. Litig.*, No. 22-md-3043, 2023 WL 8711617, at *16 n.27 (S.D.N.Y. Dec. 18, 2023) (emphasizing the importance of "judicial gatekeeping" under Rule 702).

By contrast, in the *Zantac* MDL proceeding, the court examined general causation opinions that are largely indistinguishable from those presented here and reached the opposite result. *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F.

Again, this is a jury question."); 155:9-12 ("These weaknesses in all these experts are certainly going to be fertile ground for counsel in examining and cross-examining these experts."); 158:8-10 ("Again, how and why experts rely on certain studies and not on other studies is a jury question.").)

Supp. 3d 1075 (S.D. Fla. 2022). The general causation experts in *Zantac*, which similarly involved allegations that medication users were exposed to nitrosamines such as NDMA as a result of the use of a medication, analyzed much of the same scientific literature and applied the same methodology as the *Valsartan* experts. Unlike here, the *Zantac* court took a deep dive into the underlying science, conducting a multi-day hearing and authoring an extensive opinion, which ultimately held that the plaintiffs' experts did not pass muster under Rule 702.[69]

In addition, in the years since the Court issued Rule 702 rulings in March 2022, the epidemiological literature has continued to evolve in Defendants' favor. For example, a peer-reviewed human epidemiological study—the largest cohort study conducted to date—published after the Court's ruling, found no overall increased cancer risk in patients who took valsartan during the relevant time period. *See* Imène Mansouri, et al., *N-nitrosodimethylamine-Contaminated Valsartan and Risk of Cancer: A Nationwide Study of 1.4 Million Valsartan Users*, Journal of the

[69] In a single-page order, the Court declined to reconsider his general causation rulings in light of the *Zantac* litigation, stating that "in this MDL, unlike in the Ranitidine MDL, there is no scientific doubt about the presence of nitrosamines in the human body upon the ingestion of the 'valsartan-containing drugs containing NDMA or NDEA', because the VCDs contained nitrosamines before ingestion." *See* [ECF 2210]. But the FDA's testing of ranitidine detected NDMA in ***every single lot tested***. *See* Laboratory Tests - Ranitidine, https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine (accessed June 17, 2024). It is therefore unclear why or how the Court concluded that NDMA might not have been present in ranitidine at the time it was ingested by patients.

Am. Heart Assoc. (2022). This lends significant additional support to prior human epidemiological studies conducted regarding valsartan, as well as the overwhelming weight of the studies that have examined other NDMA exposure through medications such as ranitidine.

Accordingly, both a change in the relevant facts and an important clarification with respect to the law require that the Court revisit the Court's prior general causation rulings through further briefing and a full Rule 702 hearing, which was not previously held. There is recent precedent within the District of New Jersey for this approach. *See In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Liab. Litig.*, MDL No. 2738, 2024 WL 1914881, at *1 (D.N.J. Apr. 30, 2024) (quoting March 27, 2024 Text Order, stating "[t]he Court is persuaded that the recent changes to Federal Rule of Evidence 702, the emergence of new relevant science, and the language of Chief Judge Wolfson's previous *Daubert* Opinion make a full refiling of *Daubert* motions appropriate"). In the *Talc* MDL, the plaintiffs moved for reconsideration of the court's order reopening Rule 702 issues after reassignment of the MDL, arguing that the recent amendments to Rule 702 merely clarified the prior rule, but did not change it. The *Talc* MDL court, however, found that "[t]he fact that Rule 702 is not a change in the law but a clarification is precisely why it would be inappropriate for this Court to preclude Defendants from challenging this Court's previous Rule 702 holdings." *Id.* at *3. Other courts have

similarly found that the amendments to Rule 702 justify a re-examination of prior Rule 702 rulings. *See, e.g.*, *West v. Home Depot U.S.A., Inc.*, No. 1:21-cv-1145, 2024 WL 1834112, at *4 (N.D. Ill. Apr. 26, 2024), *modified on reconsideration*, No. 1:21-cv-1145, 2024 WL 2845988 (N.D. Ill. June 5, 2024) (excluding expert who relied on inaccurate data and rejecting older decisions that said such testimony was fodder for cross-examination, stating "this is the precise type of weight vs. admissibility distinction the recent amendment to Rule 702 aimed to correct"); *State Automobile Mut. Ins. Co. v. Freehold Management, Inc.*, No. 3:16-CV-2255, 2023 WL 8606773, at *10 (N.D. Tex. Dec. 12, 2023) ("issues pertaining to the sufficiency of facts or data relied upon by an expert and the sufficiency of an expert's bases do not always concern questions of weight that should be left to the jury").

In addition to the causation issues affecting all Defendants, there are also unique causation and traceability issues with respect to Wholesalers, based on their role in the supply chain. *See supra* n. 5. Wholesalers maintain that Plaintiffs cannot establish standing as to Wholesalers, and similarly cannot establish certain essential elements of their remaining causes of action, because they cannot reliably or systematically trace any particular SCD transaction to any particular Wholesaler. The Court in its class certification opinion acknowledged that "it may be difficult and even impossible to link which Wholesaler's [SCDs] were ingested by which consumer." ECF 2261 at 26, 69. Whether addressed in terms of standing or

causation, this issue is fatal to all of Plaintiffs' claims as to Wholesalers across the individual Plaintiffs' personal injury cases and the TPP and consumer Plaintiffs' class cases.

This Court now has the opportunity to refocus this MDL proceeding, consistent with established practice in MDL proceedings across the country, on the cases and issues that are most likely to bring about final resolution of the litigation. The first step in that process is to allow the parties to conduct expert discovery regarding specific causation and to evaluate both general and specific causation through Rule 702/*Daubert* motions, summary judgment motions, and potential bellwether trials in the context of specific personal injury cases. This will provide the parties with guidance on the core issue in this litigation and will avoid further waste of time and resources on the hopelessly flawed class cases.

iii. A Losartan/Irbesartan Scheduling Order Is Necessary.

As explained above, the Court has several significant issues to resolve related to the valsartan litigation, including the utility of proceeding with the previously contemplated TPP class trial. As the Court and parties navigate those issues, Defendants request that the Court enter a comprehensive Rule 16 scheduling order to govern further discovery (including fact and expert discovery) and motion practice (including class certification motions, Rule 702 motions, and dispositive motions) in the losartan and irbesartan cases. Such an order would provide needed

guidance to the parties, lessen future arguments on the timeliness of filings and other submissions (of which there have been many so far), and allow the parties to more effectively prepare the cases for remand and/or trial. Once the parties have more clarity on how the Court will proceed with the valsartan cases, Defendants propose that the parties meet and confer and submit a proposed scheduling order (or competing scheduling orders should an agreement not be reached) addressing these issues.

b. Torrent's Submission

Although Torrent agrees that the TPP class is inconsistent with Rule 23 and should be de-certified or that the certification of that class should be overturned on appeal and that there is justification to re-examine the Court's prior general causation rulings, Torrent's position is that the TPP class trial should go to trial first. Proceeding with the TPP class trial first is the most efficient path because the case is trial ready. All involved parties have spent months preparing for the TPP class trial, including preparing witnesses, negotiating deposition designations and exhibit lists (each containing over 500 exhibits), briefing evidentiary issues (including over 70 motions in limine) and submitting a detailed pre-trial order (over 200 pages). Additionally, the TPP class trial will resolve the claims of an entire class of Plaintiffs and will clarify certain issues for all parties, such as whether the parties manufactured VCDs in compliance with cGMPs, whether VCDs were effective at

treating hypertension, whether and when the parties knew about the presence of nitrosamines in VCDs, and whether the steps taken in response were reasonable, all of which will provide guidance for future cases and/or settlement.

c. **Plaintiffs' Submission.**

Plaintiffs look forward to lining up the major steps in the litigation in addition to the TPP economic loss class trial. The following aspects of the litigation will need to be scheduled and managed:

Consumer economic loss certified class claims related to Valsartan. The logical next step with regard to valsartan economic loss claims, following the TPP trial, would be a trial of the consumer economic loss class claims, or some part thereof. Inasmuch as the parties will have most completely worked up the cases against ZHP, Teva, and Torrent, it would be most efficient to use that groundwork to try the consumer claims against those Defendants.

Plaintiffs also look forward to working up the valsartan economic loss class claims pending against the other manufacturers and parties, as well as the retailer defendants and the wholesaler defendants.

Hetero Losartan supply chain economic loss claims. The vast majority of the contaminated losartan sold in the United States contained contaminated losartan API manufactured by Hetero, in India. This includes contaminated losartan finished dose pills distributed and sold by Hetero via its wholly owned subsidiary Camber,

as well as contaminated losartan finished dose pills containing Hetero's contaminated losartan API sold by Hetero's downstream customers including finished dose manufacturers Torrent, Teva, Stride's/Vivimed, and MacLeod's. In light of the Court's recent rulings on the Losartan and Irbesartan discovery, Plaintiffs submit that the logical progression would be to complete that discovery and move to class certification of the Hetero losartan economic loss class claims, to be followed by the scheduling of a trial or trials against one or more of Hetero and its customers. Plaintiffs believe that the current scheduling order for the completion of fact discovery is sufficient at present, and that the parties should meet and confer regarding the following deadlines.

Personal Injury Claims. The personal injury claims progressed through depositions of bellwether plaintiffs, and the Daubert rulings on the general causation experts (subject to the motions for clarification described above). ZHP faces the largest number of personal injury cases (based both on pills sold directly by ZHP, and pills sold by Teva and Torrent containing ZHP's contaminated valsartan API), and it would be most efficient to proceed to work up those personal injury cases for trial at the appropriate time inasmuch as the case against ZHP has been developed for the TPP economic loss class trial and much of that work will translate to the personal injury claims.

The remaining aspects of the litigation include:

- Economic loss class claims pending against the remaining Defendants, including ZHP, Teva, Torrent, Mylan, Aurobindo, and the downstream members of the supply chain.

- Personal injury claims pending against the remaining Defendants, including ZHP, Teva, Torrent, Mylan, Aurobindo, and the downstream members of the supply chain.

- Medical monitoring certified class claims.

In terms of priority,[70] it is submitted that it would be most efficient for the Court to proceed with the TPP economic loss subclass trial that was on the cusp of being tried in March 2024. The parties' efforts since mid-2022 have been principally focused on preparation for this TPP subclass trial.[71] These efforts include:

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[70] **Defendants' Position**: The remainder of this joint status report contains Plaintiffs' arguments in opposition to Defendants' submission on issues to be addressed in this litigation going forward. Defendants disagree with Plaintiffs' views on each point but will not further extend the length of this submission with a point-by-point rebuttal. Defendants would welcome the opportunity to brief these issues fully for the Court in a separate filing.

[71] Over two years ago, as Defendants acknowledged at the time, Judge Kugler told the parties "to concentrate 'the third-party payor economic loss cases[.]'" *See* Defs.' 7/26/22 Ltr. (ECF 2139) (quoting 6/1/22 Tr. at 14:1-6). After the June 1, 2022 conference, on July 18, 2022, Judge Kugler entered CMO No. 28, which established a schedule for TPP economic loss liability expert reports, *Daubert* motions, and summary judgment briefing. *See* ECF 2131. Defendants then propounded supplemental discovery requests to the named TPP class plaintiffs. *See* Defs.' 7/26/22 Ltr. (ECF 2139) at 8 n.2. Following class certification in February 2023 and the parties' input, Judge Kugler identified the four discrete TPP subclasses for trial. *See* CMO No. 32, ECF 2343.

- Named TPP Plaintiffs responding to Defendants' supplemental, pre-trial written discovery, including heavily-negotiated supplemental document and data productions;
- Dissemination of class notice, the final form of which was agreed-upon by all parties following lengthy negotiations;
- Exchange of liability and damages expert reports;
- Depositions of liability and damages experts;
- Completion of *Daubert* briefing and the issuance of *Daubert* rulings
- Completion of summary judgment briefing (and on which Judge Kugler already issued rulings, *see* ECF 2694-95)
- Filing of over 70 motions *in limine*
- Submission of deposition designations for at least 47 witnesses
- Submission of exhibit lists (over 10,800 exhibits, some of which are duplicative across lists)
- Submission of a detailed pre-trial order (over 200 pages)
- Proposed jury instructions and verdict sheets

And prior to all of the above, the parties had focused on extensive class certification briefing including with regard to Defendants' Rule 23(f) motion that was denied by the Third Circuit, discovery and depositions of dozens of named class representatives, and class expert reports, depositions, and *Daubert* briefing.

Plaintiffs agree with Torrent, one of the three TPP subclass trial defendants (along with ZHP and Teva), that the TPP subclass trial should be tried first because of the extensive efforts committed to trial preparation and the trial-ready posture. Other Defendants' suggestion that this Court cast aside the parties' countless hours

of work in the last 3-4 years and pivot to trying personal injury cases *seriatim* is inefficient and illogical.

Defendants' assorted arguments for why this Court should abandon the parties' and Judge Kugler's years of effort to get a TPP subclass case to the doorstep of trial are implausible, legally unsupportable, or both. More fundamentally, Defendants' insinuations that the long-planned TPP subclass trial *could* implicate *eventual* issues that *might* be subject to appeal ring hollow. Such hypothetical possibilities exist for every claim in every case at nearly every stage of a litigation.

First, Judge Kugler's selection of four discrete TPP subclasses for a bellwether trial is not unusual. Other MDL courts have held bellwether class trials. *See, e.g.*, *In re JUUL Labs, Inc.*, *Mktg., Sales Pracs., & Prods. Liab. Litig.*, 19-md-02913 (N.D. Cal. Sept. 19, 2023) (noting the court had "granted the contested motion to certify bellwether classes asserting federal and California law claims, certifying four classes of purchasers of JUUL products"); *In re Syngenta AG MIR 162 Corn Litig.*, 357 F. Supp. 3d 1094, 1100 (D. Kan. 2018) (noting the "Kansas class claims proceeded to trial" before other claims); *In re Copley Pharm., Inc.*, *Albuterol Prods. Liab. Litig.*, 50 F. Supp. 22d 1141 (D. Wyo. 1999) (previously certifying multi-state class claims in MDL involving contaminated drug, which then proceeded to trial).

The court in one of Defendants' own cases prioritized a bellwether class trial.[72] These Courts' and Judge Kugler's informed decisions to prioritize bellwether class trials were entirely consistent with MDL and class action management in other litigations.[73]

Second, Defendants' fox-guarding-the-henhouse suggestion that the personal injury cases in this MDL have "languished for years" is simply untrue. Plaintiffs have prepared multiple iterations of a Master Personal Injury Complaint (alongside the Master Economic Loss and Medical Monitoring Complaints), and fended off multiple motions to dismiss. Every single individual plaintiff must complete a lengthy 94-page plaintiff fact sheet, provide up to seven different authorizations, and respond to nearly two-dozen document requests. Depositions of bellwether plaintiffs and some of their treating physicians were conducted. The parties also engaged in

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[72] *See In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Pracs. & Prods. Liab. Litig.*, 838 F. Supp. 2d 967, 972 (C.D. Cal. 2012) ("A bellwether class action trial is currently set for July 31, 2013."). Defendants' other two cases involved very different allegations than those here, and involved a great many more personal injury cases than the ~1,300 here. *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, 20-md-2924, 2021 WL 5415027, at *1 (S.D. Fla. Nov. 19, 2021) (noting "in excess of 150,000 [personal injury] Claimants"); *In re Vioxx Prods. Liab. Litig.*, 760 F. Supp. 2d 640, 656 (E.D. La. 2010) (noting approximately 50,000 claims were resolved through global settlement).

[73] *See, e.g.*, *In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124, 141 (2d Cir. 2001) (Sotomayor, J.) (Rule 23 expressly empowers district courts "to devise imaginative solutions created by the presence in a class action litigation" of certain issues, and district courts have a "number of management tools available" to manage class actions.).

exhaustive *Daubert* briefing on general causation, which is discussed further below. The suggestion that the Plaintiffs have ignored the cancer cases is obviously untrue.

Both Plaintiffs and Judge Kugler quite rightly recognized that a class trial is the most efficient way to get at the underlying liability questions that pervade all three case tracks (economic loss, personal injury, and medical monitoring) such as: how did Defendants' valsartan become contaminated with NDMA? When? What cGMP failures might have led to this contamination? What is the economic value of an adulterated, contaminated valsartan pill that, in the words of ZHP in connection with the recall, posed, "an unacceptable carcinogenic risk to the intended patient population?" All of these common questions and more can be answered most easily in the TPP subclass trial, without the need to deal with the specific causation inquiry of whether valsartan was a substantial cause of a given individual's cancer since the economic loss claims are not predicated on physical injury, thus the question of general causation is not a factor in those cases.[74]

Third, the bellwether TPP subclass trial is not "unworkable." Judge Kugler already rejected these defense arguments three times—at class certification (ECF 2261), at summary judgment (ECF 2695), and in denying Defendants' motion to

[74] Defendants' suggestion that "98% of the consolidated cases in this MDL" are personal injury cases is obviously misleading. The certified economic loss and medical monitoring subclasses are comprised of tens if not hundreds of thousands of individuals and TPPs.

decertify (ECF 2657). The fourth time now is not the charm for Defendants. Defendants' thrice-rejected arguments amount to nothing more than untimely and procedurally-improper requests for reconsideration.

That aside, Defendants' recycled arguments all lack merit. Judge Kugler already found at class certification that Plaintiffs established all class members, consumers and TPPs alike, were ascertainable. *See* ECF 2261. Notably, unlike in Defendants' pair of antitrust cases (*Niaspan* and *Lipitor*), Defendants here never filed a *Daubert* motion challenging Ms. Craft's opinions at class certification. *See* ECF 2261 at 67-68 (noting defendant "did not oppose" her opinions). Judge Kugler nonetheless thoroughly analyzed the ascertainability-related issues addressed by Ms. Craft and Plaintiffs' other record evidence, and found Plaintiffs satisfied this implied Rule 23 requirement. *Id.* at 66-70. Further, Defendants already had the lower court decisions in *Niaspan* from June 2020 and August 2021 in hand when they deposed Ms. Craft, filed their opposition briefs to the class certification motion, and chose not to file a *Daubert* motion as to her opinions. Defendants also had all the *Niaspan* opinions when the Third Circuit denied Defendants' Rule 23(f) appeal of Judge Kugler's class certification opinion in 2023, and when Defendants filed their since-denied motion to decertify earlier this year. Simply put, there nothing 'new' about the fact-specific circumstances of the *Niaspan* litigation.

Defendants' choice-of-law nitpicks fare no better. As noted above, Judge Kugler already ruled the certified subclasses are ascertainable. There is no "mismatch" between the certified class definitions and Plaintiffs' damages modeling. Plaintiffs need not "prove" a "translating mechanism" now or during trial because that is not an element of any of Plaintiffs' claims. Rather, consistent with Judge Kugler's class certification opinion and Third Circuit law, verifying TPP claimants' eligibility for any jury award of damages is a matter of post-trial claims administration and will be based on claimants' own records. *See, e.g.*, *Kelly v. RealPage Inc.*, 47 F.4th 202, 222-23 (3d Cir. 2022) (ascertainability satisfiable by matching records in separate databases); *Krakauer v. Dish Network, L.L.C.*, 925 F.3d 643, 663 (4th Cir. 2019) (affirming class certification and jury verdict for class plaintiffs, as well as post-trial claims administration process to match and verify eligible class members' claims). To the extent deemed necessary, this process can be modeled in advance of trial.

Defendants' recurring boogeyman of a days-long charge is similarly of no moment, since no such monstrosity exists. At class certification, Plaintiffs rolled up their sleeves and presented comprehensive analyses to demonstrate – successfully – that the applicable states' laws can be grouped and charged to the jury relative to the groupings. Plaintiffs' proposed jury charge and verdict form (*see* ECF 2683 & 2684) follow Judge Kugler's own analysis of the state law groupings. The proposed charge,

including preliminary and general instructions, is no longer than those in many individual cases (*see id.*), and the verdict form is straight-forward and user-friendly (*id.*).

Finally, Defendants' recycled Seventh Amendment concerns are of no moment. There is no claim-splitting here. The JPML already has consolidated all nationwide actions. The issue here relates to the Court's ability to try distinct claims or issues, consistent with the Federal Rules (*see* Fed. R. Civ. P. 21 & 42(b)), MDL guidance (*see* MANAGING RELATED PROPOSED CLASS ACTIONS IN MULTIDISTRICT LITIGATION (Fed. Jud. Ctr. 2018); MANUAL FOR COMPLEX LITIG. (FOURTH), § 21.23), and Defendants' own prior representations (*see* DEC 3/9/2020 Ltr. to Ct. (ECF 393) ("Any Defendant-specific issues related to certification could still be addressed in this context…[S]hould certification be granted, Plaintiffs could still seek to sever a specific subclass or issue class for a discrete trial.")).

General Causation. Defendants grossly overstate and misrepresent the importance of general causation in this litigation, and for the economic loss class claims in particular. **General Causation is not an element of any of the economic loss class claims.** Defendants' quote of a comment by the Court regarding the interplay of general causation and the potential trials in this case, prior to the full work up of the TPP trial is misleading. In fact, in denying Defendants' motion to

decertify, the Court stated in part: "The Class Cert. Op. for the TPP Eco Loss subclasses focused on and reviewed arguments about the economic loss claims, which turned not on personal injury causation elements but on the variability of evidence to demonstrate TPPs reimbursements for contaminated VCDs, whether the VCDs were improperly or properly merchantable, and what was the bargained-for exchange between the parties." (ECF 2657, at 5). At the TPP subclass trial, Plaintiffs do not need to prove that NDMA "causes" cancer or caused cancer to any person. The question there is "unacceptable risk" from a regulatory perspective, and the FDA already answered that question in requiring the recalls. As stated above, ZHP accurately framed the issue in its press releases announcing the recall due to the "unacceptable carcinogenic risk to the intended patient population."

The at-issue valsartan was admittedly recalled, and the FDA declared the API in the valsartan to be adulterated because of cGMP violations. Defendants' own records corroborate that NDMA was present in their valsartan at unacceptable levels. The only real question, which Judge Kugler identified early on, is the value of an adulterated, contaminated valsartan pill that could not be legally sold (i.e., damages). That is the driving fact question the jury will decide at the TPP subclass trial, which will provide an assessment of Defendants' exposure in all facets of this MDL.

Plaintiffs also disagree with the request of Defendants, besides Torrent, to ignore over two years of progress in this case and relitigate general causation anew.

Preliminarily, Defendants never raised the need to reevaluate the Court's general causation opinions for the TPP trial, and Plaintiffs and Defendants agree that general causation is not at issue in the TPP trial that was postponed shortly before jury selection was scheduled to commence. Defendants' request is simply an attempt to distract the Court from moving forward with the TPP trial and to inject delay into the process.

Defendants contend that Judge Kugler did not follow Rule 702 when he issued his general causation opinions in this case. In support of their argument, Defendants rely heavily on the 2023 amendment to Rule 702, which did not change the substance of the Rule, only clarifying that (1) the proponent of an expert must show the requirements are met by a preponderance of the evidence and (2) changing Subsection (d) as follows: "the ~~expert has reliably applied~~ **expert's opinion reflects a reliable application of** the principles and methods to the facts of the case." Compare F.R.E. 702 (effective Dec. 1, 2023), *with* F.R.E. 702 (effective Dec. 1, 2011). A plain reading of these amendments shows that there is no significant change, and Defendants certainly have not shown that the application of the amended language would change the outcome of Judge Kugler's general causation decisions. See Advisory Committee Note to the 2023 Amendment to Rule 702 (stating, "Nothing in the amendment imposes any new, specific procedures.").

Defendants attack Judge Kugler's explanation of the *Daubert*/Rule 702 standard, all of which was based on current Third Circuit precedent, and some of which is even quoted in the comments to the 2023 amendment itself. After fully briefing their motions to exclude Plaintiffs' general causation experts, Defendants insisted that the Court should hold a full hearing with testimony from all general causation experts. (2/28/2022 Tr. 22:1-17). Judge Kugler disagreed and analyzed the Third Circuit cases rejecting Defendants' position. (*Id.* at 22:18-24:6). When Defendants nevertheless continued to argue for their understanding of a full hearing, Judge Kugler explained why their request was based on a misunderstanding of *Daubert*/Rule 702:

> There seems to be this theory that if they put on this theatrical production with these witnesses, somehow I'm going to come to like one side's witnesses over the other. That's not my job. That's not what the Supreme Court or Third Circuit have told me to do.
>
> * * *
>
> But let's talk about Daubert. I've talked about this a little bit before. I want to talk about it and tell you a little bit more where we're going with this. I don't want there to be any surprises where we're going with this.
>
> Now, I'm old enough to have practiced law under the old Frye, F-R-Y-E, standard in which the proponent had to show that the opinion was generally accepted in the relevant scientific community.
>
> And that didn't work out so well, because, you know -- I don't want to go into the history of this, but you had all

these cancer cluster cases around landfills and Superfund sites and industrial sites. And there were no studies whatsoever that would make the linkage. So the people who claimed to be injured as a result of those exposures had no ability to seek compensation.

So they changed the rules. The Supreme Court came out with Daubert, which would permit novel scientific testimony on three conditions. One was qualifications. Well, that's really never an issue. It's not an issue in this case.

Another one was what the former Chief Judge and the late Ed Becker used to call fit or relevance. Don't see much of those anymore.

But there's this intense focus on methodology now, to make sure that these opinions being generated, given by these so-called experts are arrived at the same way good scientists would arrive at their opinions.

But you got to understand that Daubert is not -- Daubert is not a dress rehearsal for trial. And the Court, as I've said previously, has an extremely limited role. And my role is not to pick which side has the better witnesses.

* * *

The gatekeeper function that I have and district courts have is very circumscribed by the Supreme Court and the Third Circuit. It's not to weed out weak science, **it's to weed out what some people have called junk science, that is, science which no reasonable scientist could ever support.**

And I'll remind you what the Supreme Court wrote in Daubert. This is at page 152.

Vigorous cross-examination, presentation of contrary evidence and careful instruction in the burden of proof are

the traditional and appropriate means of attacking shaky but admissible evidence.

Notice the use of the word "shaky."

What Judge McKee wrote in the Oddi, O-D-D-I, v. Ford Motor case: That the analysis of the conclusions themselves is for the trier of fact where the expert is subject to cross-examination. **And the evidentiary requirement of reliability is lower than the merits standard of correctness.**

The standard for determining scientific reliability of a proffered expert is not that high. The test is not whether the expert might have done a better job. **That's at 234 F.3d 155.**

Now, look, I get it. Here almost all the experts on both sides have some weaknesses. **The fact remains that pretty much all of them use the same general methodology, which is review of the relevant literature.** They went over it in the beginning of their reports. It's all there. And you questioned them extensively about it.

All of them agree that human clinical trials are not possible. It's unethical. But they all looked at animal studies and observational studies, statistical analyses and all that kind of stuff. And this is what scientists do. Then they chose which of the data they felt is most important and which is less so, which everyone on both sides refers to as cherry-picking, you know. And the defendants rely on the Pottegard, P-O-T-T-E-G-A-R-D; and Goom, G-O-O-M; Yoon, Y-O-O-N; and other studies. The plaintiffs place a lot of stock in Hidajat, H-I-D-A-J-A-T.

But the point is they all use the same methodology. They just gave different emphasis to different things. And this is a methodology that is clearly accepted by all the scientists in the field.

Now, look, I know, and you've cited the cases where there are some judges around the country who have done a deep dive and drilled down into all these studies to look at the underlying data. And then they pick which size and which studies they think are the more reliable and the consequences that has for an expert's opinion. That is not my job, folks, and I'm not doing that. That's not what the Supreme Court and the Third Circuit have told me that I have to do.

All these expert reports have weaknesses which you, all of you, have done a great job pointing out.

But again, as the Supreme Court and the Third Circuit have said, my concern is not weak opinions or opinions that might be better. I'm not going to make any determination.

This is not a dress rehearsal, which side has the better witnesses. I'm not going to make any determination as to the relative strengths of the witnesses or the underlying data.

Take, for example, that these animal studies that everybody talks about. No question they're fraught with danger when you're trying to extrapolate into humans. Everybody knows that.

But those scientists I'm aware of who completely disregard an animal study, that's not what they do. They all look at them and draw whatever conclusions they think are appropriate for the reasons that they give.

And the Hidajat study we just talked about, defendants are right. There are some problems with that study. It's inhalation, it's not ingestion. It doesn't control for other factors that can cause cancer, like smoking. Pointing out their strengths, it's a lot of people over a

> **long time, 47 years or something. It's not up to me to determine whether or not these studies are appropriately considered, because I'm focusing on the way they came to their opinions. And scientists come to their opinions by looking at studies.**
>
> So I'm not going to be focusing on that. I'll be focusing on the methodology. I don't care what the conclusions are. I don't care whose side it benefits. I just want to know -- and it's laid out in the depositions. It's laid out in the reports. It's laid out, I think, for the most part in these declarations as to how they got where they got.
>
> So on Wednesday, that's all we're going to talk about.

(*Id.* at 31:14-36:25 (emphasis added)).

Defendants specifically focus on Judge Kugler's reliance on the, "no reasonable scientist" standard, but that is the governing standard in the Third Circuit. In *In re Paoli R.R. Yard PCB Litigation*, from which the 2023 Amendment approvingly quotes, the Third Circuit affirmed the district court's exclusion of an expert because "**no reasonable scientist** in the field of exposure assessment would perform such a calculation." 35 F.3d 717, 773 (3d Cir. 1994) (emphasis added). The Third Circuit also stated, "If the underlying data are so lacking in probative force and reliability that **no reasonable expert** could base an opinion on them, an opinion which rests entirely upon them must be excluded." *Id.* at 748 (emphasis added). Other Third Circuit cases have applied the same standard. *See In re TMI Litig.*, 193 F.3d 613, 697 (3d Cir. 1999), *amended*, 199 F.3d 158 (3d Cir. 2000); *Montgomery Cnty. v. Microvote Corp.*, 320 F.3d 440, 448 (3d Cir. 2003); *Stecyk v. Bell Helicopter*

Textron, Inc., 295 F.3d 408, 417 (3d Cir. 2002). In fact, this Court has quoted and applied this standard. *Horan v. Dilbet, Inc.*, No. CIV.A. 12-2273, 2015 WL 5054856, at *14, 16 (D.N.J. Aug. 26, 2015) (J., Bumb) (also noting, **"Because researchers cannot simply inject people to determine the infective dosage levels, they must resort to animal studies."** (emphasis added)).

It is also important to note what type of "facts" or "data" violate this standard. In *In re TMI Litig.*, the expert was excluded because he relied on "incomplete" "medical summaries prepared from interviews conducted by nonprofessionals … aligned with counsel for one of the litigants." 193 F.3d at 697-98. In *Microvote Corp.*, the Third Circuit affirmed the exclusion of a defense expert's videotaped deposition, which did not include any cross examination from the plaintiffs, because the expert "did not base his determination on primary data," and although he, "relied on audit trail tapes, these were a sampling of tapes that were selected by an attorney." 320 F.3d at 448-49. As Judge Kugler explained, all the Parties' experts relied on essentially the same set of peer-reviewed literature, with Plaintiffs' experts emphasizing certain animal studies and epidemiological studies and Defendants' experts emphasizing others. As a result, these experts were relying on the same facts and data.

Defendants also cherry pick words and phrases from Judge Kugler's analysis of Dr. Lagana's opinions, which is provided with more context below:

Let's start with Dr. Lagana, who, by the way, said something very interesting during his testimony today, which may be obvious, but it needed to be said. And that **when these experts are determining which studies they want to rely on and which studies they don't want to rely on, there is an element of human judgment involved in this**.

And I think that's true of every expert on both sides of this case. I don't think that's objectionable at all.

* * *

Defendants also raised the issue of, again, which studies he relied on, which studies he didn't rely on, why didn't he give certain weight to some studies, why did he give so much weight to other studies. And this is a complaint that both sides have as to every single expert in this case. And this is about the cherry-picking of the data. **But really that's what experts do. They look at the data, they decide and they express their reasons why some data is more important at arriving at their opinions than others.**

So long as they explain how they come to their opinions, and so long as they attempt to explain why they didn't think contrary data is not relevant to their opinion, then that's not objectionable.

His opinion about increased risk is not controversial. It's not an ipse dixit assertion that he makes. I think you also need to look at the whole picture. Like I said, like the Third Circuit has said, we're not looking for better experts and better opinions, we're just looking at what's there and whether or not methodology was followed.

And what he did in this is he employed the usual research in finding and discussing relevant animal studies, observational studies and other data. He does discuss the contrary data. **Noting the associational evidence, he**

> **moves on to the Bradford Hill Principles to render his conclusion of general causation.** He has an opinion as to how these chemicals can cause cancer. The alkylating agent or the activation, as he explains, of oncogenes. Accordingly, I find no problems with his methodology, and the motion to bar his testimony is denied.

(3/2/2022 Tr. 147:10-149:24, ECF 1959 (emphasis added)). Contrary to Defendants' gloss, Dr. Lagana, and all of Plaintiffs' experts, did not follow a random methodology. They followed the standard Bradford-Hill and/or weight of the evidence methodologies that the Third Circuit has affirmed are proper under *Daubert*/Rule 702. *In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation*, 858 F.3d 787, 795-797 (3d Cir. 2017) (holding: "[W]e accept that the Bradford-Hill and weight of evidence analyses are generally reliable." (citing *Milward v. Acuity Specialty Prods. Grp.*, 639 F.3d 11, 17-18 (1st Cir. 2011) (recognizing the role of judgment, and that "no one type of evidence must be present before causality may be inferred."))); *In re Avandia Marketing, Sales Practices & Products Liab. Litigation*, No. 2007–MD–1871, 2011 WL 13576, at *3 (E.D. Pa., Jan. 4, 2011) (noting: "Bradford-Hill criteria are used to assess whether an established association between two variables actually reflects a causal relationship. Because these criteria are so well established in epidemiological research, it appears that the experts often consider these factors without citation to Bradford–Hill."). And besides Dr. Britt who was excluded for applying an unreliable methodology similar to the one used to defend cigarette companies decades ago, Defendants' experts were

generally found to have applied the same methodology as Plaintiffs' experts grounded in the same set of peer-reviewed literature.

Defendants also criticize Judge Kugler for noting that an expert's decision to rely on certain peer-reviewed studies over others is a jury question. However, the 2023 Amendment does not stand for the proposition that Rule 702 gives the Court the final say on the correctness of an expert's opinion regarding the significance or import of a study. In fact, the Comments make it clear, as Judge Kugler explicitly stated himself, that, "[t]he evidentiary requirement of reliability is lower than the merits standard of correctness." (quoting *In re Paoli*, 35 F.3d at 744). Instead, the Comments explicitly state: "**It will often occur that experts come to different conclusions based on contested sets of facts. Where that is so, the Rule 104(a) standard does not necessarily require exclusion of either side's experts. Rather, by deciding the disputed facts, the jury can decide which side's experts to credit.**" (Emphasis added). This is exactly what Judge Kugler held here.[75]

Thus, Defendants' complaints regarding Judge Kugler's *Daubert*/Rule 702 decisions are really about his conclusions and not his analysis. To this end, Defendants point to the *In re Zantac (Ranitidine) Products Liability Litigation*

[75] To be clear, the predominance standard applies to whether the expert's opinion "is based on sufficient facts or data" in conjunction with the reasonable scientist standard, not to whether those facts, data, and related opinions are true in and of themselves. That second question is for a jury.

decision, currently on appeal, which they unsuccessfully raised with Judge Kugler. 644 F. Supp. 3d 1075 (S.D. Fla. 2022). Defendants disingenuously read and promote the decision because they like the outcome, while ignoring Judge Kugler's analysis that distinguished that decision on factual grounds, including that the contamination in that case was not the result of the manufacturing process, and in fact the level of contamination at issue in *Zantac* was dependent on environmental factors in dispute. To that point, the *Zantac* opinion uses 71 pages to discuss the plaintiffs' experts' opinions on the level of NDMA in Zantac and excludes all of those opinions. *Id.* at 1110-1181. Here, Plaintiffs are relying on Defendants' own testing of their valsartan to determine the levels at issue, rendering the *Zantac* case completely distinguishable, as Judge Kugler found.[76]

Defendants' final Hail Mary is an attempt to claim the scientific literature has materially changed since the initial *Daubert* decision. This is false. They cite a single study—Imène Mansouri, et al., *N-nitrosodimethylamine-Contaminated Valsartan and Risk of Cancer: A Nationwide Study of 1.4 Million Valsartan Users*, Journal of the Am. Heart Assoc. (2022)—that found patients exposed to contaminated valsartan

[76] Plaintiffs also note that the Delaware and California state courts have permitted the plaintiffs' experts to testify in their consolidated Zantac litigations, rejecting the same arguments accepted in the MDL in the decision that is on appeal to the Eleventh Circuit. *In re Zantac (Ranitidine) Litig.*, No. N22C-09-101 ZAN, 2024 WL 2812168, at *1 (Del. Super. Ct. May 31, 2024); *In re Rantidine Cases*, No. 21CV002172, 2023 WL 2725766 (Cal. Super. Mar. 23, 2023).

had a higher risk of liver cancer and melanoma. The study even states that the Gomm study, which was discussed by all the general causation experts and Judge Kugler above, "found an increased risk of liver cancer, 1.16-fold higher, which was very close to our findings." Consequently, the Mansouri study is consistent with the science throughout, and creates no basis for reevaluating Judge Kugler's general causation decisions.[77] In addition, Defendants fail to cite to any other studies published in the interim, which undercuts the reliability of their assertions as to the weight of scientific authority.

For these reasons, it is submitted that general causation should not be addressed once again, as this would do nothing more than further the Defendants' overall strategy to delay this litigation. In fact, Defendants claim that re-examination of the general causation questions is needed to advance the litigation to conclusion, while ignoring the fact that after the Court entered extensive *Daubert* decisions they failed to make any serious effort to move to resolution.

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[77] Defendants' failure to show any meaningful change in the science distinguishes their request from the one granted in *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Liab. Litig.*, No. CV 16-2738 (MAS) (RLS), 2024 WL 1914881, at *1 (D.N.J. Apr. 30, 2024) (ordering "Upon review of the parties' contentions. the Court is persuaded that the recent changes to Federal Rule of Evidence 702. the emergence of new relevant science, and the language of Chief Judge Wolfson's previous *Daubert* Opinion make a full refiling of Daubert motions appropriate."). Additionally, Judge Kugler never stated his general causation opinions were subject to revision in the manner that Judge Wolfson did in *Talc*.

Defendants' protestations to the contrary, the new amendment to Rule 702 merely clarifies the existing standard of expert admissibility. The amendment does not alter existing law and does not "impose[] any new, specific procedures." Fed. R. Evid. 702, advisory committee's note to 2023 amendment. Judge Kugler already applied the standard correctly in evaluating the reliability of Plaintiffs' class experts' methodologies. *See* ECF 2261 at 86-97 (noting, *inter alia*, that "the Court must thoroughly review the methodology of an expert and find it to have scientifically reliable underpinnings"), and in evaluating the reliability of Plaintiffs' liability experts in an order that post-dated the Rule 702 amendment (*see* ECF 2581 & 2582).

CONCLUSION

The parties greatly appreciate the Court's willingness to review this submission in advance of the upcoming status conference.

Dated July 9, 2024

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CERTIFICATE OF SERVICE

I hereby certify that I today caused to be served a copy of the foregoing on July 9, 2024, via ECF.

Dated: July 9, 2024

/s/ Gregory P. Coates