BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: Valsartan NDMA Contamination Litigation	)	MDL No. 88

PLAINTIFF ROBERT KRUK'S BRIEF IN SUPPORT OF MOTION TO TRANSFER ACTIONS TO THE DISTRICT OF NEW JERSEY PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

Movant, Robert Kruk, plaintiff in the action *Kruk v. Zhejiang Huahai Pharmaceutical Co. et al.*, No. 18-cv-005944 (N.D. Ill.), hereby submits this Brief in support of his Motion to Transfer Actions to the District of New Jersey Pursuant to 28 U.S.C. § 1407 for Coordinated or Consolidated Pretrial Proceedings. Movant hereby seeks to transfer all 11 actions listed in the Schedule of Actions filed concurrently herewith to the Federal District Court for the District of New Jersey for coordinated consolidated pretrial purposes.

For the convenience of the parties and witnesses, to streamline discovery, to prevent certification of overlapping classes and inconsistent class certification rulings, and to promote the just and efficient pretrial conduct of these cases, the 11 Scheduled Actions, and all other subsequently-filed related actions, should be transferred to a single court for coordination or consolidated pre-trial proceedings. The District of New Jersey has a strong nexus to the conduct at issue, is convenient for parties, witnesses, and counsel, and is capable of handling multi-district litigation. Accordingly, Movant respectfully requests that the Scheduled Actions be transferred to Judge Freda L. Wolfson of the District of New Jersey.

BACKGROUND

On August 29, 2018, Movant filed a class action suit against Zhejiang Huahai Pharmaceuticals Co., Ltd., Prinston Pharmaceutical, Inc., Solco Healthcare U.S., LLC, Huahai US

Inc., and Wal-Mart Stores, Inc. in the Northern District of Illinois, asserting claims for (i) violations of the Illinois Consumer Fraud and Deceptive Business Practices Act, (ii) strict products liability, (iii) failure to warn, (iv) breach of contract, (v) breach of implied warranty of merchantability, (vi) unjust enrichment, (vii) fraudulent concealment, (viii) conversion, (ix) negligence, and (x) gross negligence. *Kruk*, No. 18-cv-005944 (N.D. Ill. Aug. 29, 2018). The *Kruk* action is pending before Judge Harry D. Leinenweber in the Northern District of Illinois.

Movant's class action arises out of his purchase of the generic drug Valsartan, which has been revealed to contain a carcinogenic chemical. In addition to Movant's class action complaint, nine other class action complaints have been filed against Valsartan manufacturers, distributors, and marketers in federal courts nationwide.

The Valsartan Recall

Valsartan is a generic prescription drug mainly used to treat hypertension, high blood pressure, congestive heart failure, and to prevent heart attacks. It was originally marketed and sold under the brand name Diovan.

On July 13, 2018, the U.S. Food & Drug Administration ("FDA") announced a voluntary recall ("the Recall") of several brands of Valsartan-containing generic medications. The Recall was due to the presence of an organic chemical known as *N*-nitrosodimethylamine ("NDMA") in the recalled products. The United States Environmental Protection Agency classifies NDMA as a probable human carcinogen, and NDMA is also listed as a "priority toxic pollutant" in federal regulations. *See* 40 CFR § 131.36. NDMA is not currently produced in pure form or used commercially in the United States, and was formerly used in the production of, among other things, liquid rocket fuel. According to the EPA, in animal studies of various species including rats and

mice, exposure to NDMA has caused tumors of the liver, respiratory tract, kidney, and blood vessels. The Recall was expanded to additional Valsartan products on July 27, 2018.

The Source: Zhejiang Huahai Pharmaceuticals Co., Ltd.

Zhejiang Huahai Pharmaceuticals Co., Ltd. ("Zhejiang") is a Chinese drug manufacturer, and has served as a contract Valsartan manufacturer for numerous American drug distributors, including its American subsidiaries. The Recall traced the presence of NDMA in American Valsartan products back to Zhejiang's manufacturing facilities, which have had numerous quality-control issues with the FDA dating back to at least 2007. Other regulators have agreed with the FDA—a recent inspection of Zhejiang valsartan manufacturing facilities by European Union found that Zhejiang failed to comply with Good Manufacturing Practice, an international standard designed to minimize the risks involved with pharmaceutical production.[1]

Pending Valsartan Litigation

In addition to Movant's class action, there are nine other class actions and one individual action pending in District Courts across the country, for a total of eleven cases. Five of the eleven actions are pending in the District of New Jersey. Each of the Scheduled Actions assert claims stemming from the purchase of NDMA-contaminated Valsartan under breach of warranty theories, common law fraud, and state consumer protection laws where available. Additionally, several of the actions, including Movant's, bring product liability claims against certain domestic and international Valsartan manufacturers.

[1] *See* EUROPEAN MEDICINES AGENCY, *EU Inspection Finds Zhejiang Huahai Site Non-Compliant for Manufacture of Valsartan* (Sept. 28, 2018), https://www.ema.europa.eu/en/news/eu-inspection-finds-zhejiang-huahai-site-non-compliant-manufacture-valsartan-ema-national.

More Claims Anticipated

Significantly, these filed cases represent only a small sample of the cases that will eventually be filed, as the Recall and other government investigations of the scope of NDMA contamination are still in their infancy. For example, regulators have only recently begun investigating other Chinese Valsartan manufacturers.[2] It is reasonable to expect that more cases will be filed as the public becomes increasingly aware that a generic drug meant to treat heart disease—the leading cause of death for Americans[3]—has been contaminated with a carcinogen, possibly for years.

ARGUMENT

The eleven actions that comprise the Scheduled Actions under this Panel's consideration seek to hold defendant Valsartan manufacturers, distributors, marketers, and retailers liable for producing, distributing, and selling defective, NDMA-contaminated Valsartan drugs to consumers nationwide. Even though "there are relatively few parties and actions at present, efficiencies can be gained from having these actions proceed in a single district"—the District of New Jersey. *In re First Nat'l Collection Bureau, Inc., Tel. Consumer Protection Act (TCPA) Litig.*, 11 F. Supp. 3d 1353, 1354 (J.P.M.L. 2014).

I. The Eleven Scheduled Actions Should Be Transferred And Consolidated.

Section 1407 of the United States Code provides: "When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings." 28 U.S.C. § 1407(a). The

[2] *See* EUROPEAN MEDICINES AGENCY, *Update on Medicines Containing Valsartan from Zhejiang Tianyu: Company No Longer Authorized to Manufacture Valsartan Active Substance for EU Medicines Due to Presence of NDMA* (Aug. 2, 2018), https://www.ema.europa.eu/news/update-medicines-containing-valsartan-zhejiang-tianyu-company-no-longer-authorised-manufacture.

[3] CTRS. FOR DISEASE CONTROL AND PREVENTION, *Heart Disease Facts*, https://www.cdc.gov/heartdisease/facts.htm (last visited Oct. 21, 2018).

presence of common factual questions often necessitates transfer under § 1407 in order to prevent duplication of discovery and the possibility of inconsistent pretrial rulings. *In re Eastern Airlines, Inc. Flight Attendant Weight Program Litig.*, 391 F. Supp. 763, 764 (J.P.M.L. 1975); *Manual for Complex Litigation, Fourth* § 20.131 (2004) (Section 1407's objectives are served if transfer and consolidation would "eliminate duplication in discovery, avoid conflicting rulings and schedules, reduce litigation costs, and save the time and effort of the parties, the attorneys, the witnesses, and the courts."). Transfer under § 1407 does not require complete identity or even majority of common factual or legal issues as a prerequisite to transfer. *In re Rembrandt Techs., L.P.*, 493 F. Supp. 2d 1367, 1369 (J.P.M.L. 2007); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 173 F. Supp. 2d 1377, 1379 (J.P.M.L. 2001).

A. The Claims In Each Scheduled Action Involve Common Questions Of Law And Fact Concerning The Manufacture, Distribution, And Sale Of The Same Allegedly Defective Drug.

Each Scheduled Action arises from a common factual core: the plaintiff purchased Valsartan, only to discover after the Recall that the purchased Valsartan was contaminated by NDMA, a dangerous carcinogen. Thus, each action depends on establishing on the fact that the purchased Valsartan was in fact contaminated by NDMA. The majority of the Actions name either Huahai US, Inc., Prinston Pharmaceutical, Inc. and Solco Healthcare U.S., LLC, Zhejiang's American subsidiaries, as defendants, but the Actions vary slightly in terms of other named Valsartan manufacturers, distributor defendants, and retailer defendants. However, each Action names at least one New Jersey-based defendant.

Additionally, while the plaintiffs in each of the class actions assert claims for breach of warranty, fraudulent concealment, and negligence, some of the class actions bring additional

product liability claims. The individual action, *Gentry v. Solco Healthcare U.S., LLC*, brings unique claims for loss of consortium.

However, such variance does not weigh against transfer, as the presence of differing facts or "differing legal theories is not significant when the actions still arise from a common factual core." *In re Blue Cross Blue Shield Antitrust Litigation*, 908 F. Supp. 2d 1373, 1376 (J.P.M.L. 2012); *In re Ford Motor Co. Speed Control Deactivation Switch Prods. Liability Litig.*, 398 F. Supp. 2d 1365, 1366 (J.P.M.L. 2005); *see also Convergent Tel. Consumer Prot. Act Litig.*, 981 F. Supp. 2d at 1387 (citing *In re: Satyam Computer Servs., Ltd., Sec. Litig.*, 712 Supp. 2d 1381, 1382 (J.P.M.L. 2010).

Here, the questions common to all suits arise from the same alleged Valsartan manufacturing defects. The common questions include:

1) Whether the Valsartan drugs sold by the defendants were in fact contaminated with NDMA;

2) Whether the defendants knew or should have known that their Valsartan drugs were contaminated with NDMA prior to the Recall;

3) Whether defendants' conduct constitutes a breach of any warranty or warranties recognized by law;

4) Whether plaintiffs are entitled to recover damages from defendants, including compensatory damages and/or punitive or exemplary damages;

5) If damages are available to plaintiffs, the method or methods by which such relief should be determined.

Coordination is therefore appropriate and necessary given the significant number of common questions of law and fact present in this potential litigation. This necessity is particularly clear because all actions rely on allegations that plaintiffs purchased the same contaminated, defective drug. Even though each of the Scheduled Actions may have some individualized aspects, whether that be a unique defendant or unique claim, "[d]iscovery with respect to any case-specific issues

can also proceed concurrently with discovery on common issues," such as the circumstances surrounding the Recall and the common issues listed above. *In re Ford Motor Co. Speed Control Deactivation Switch Prods. Liability Litig.*, 398 F. Supp. 2d at 366. Typically, the Panel does not need to determine the exact manner or extent of coordination, leaving that determination to the transferee court. *In re Pre-filled Propane Tank Antitrust Litig.*, 53 F. Supp. 3d 1383, 1383 (J.P.M.L. 2014).

Regardless of the presence of minor differences, the Scheduled Actions should be consolidated due to the overlapping classes pled in the putative class actions. Each of the class actions seeks to represent essentially the same class: a nationwide class of individuals who purchased Valsartan. Coordination is thus necessary to prevent inconsistent rulings on competing class definitions. The fact that the class definitions are roughly identical points to the centrality of the key factual issue present in each Action: the putative class members purchased Valsartan prior to realizing, as a result of an FDA investigation, that Valsartan was contaminated with NDMA.0

As the Panel has repeatedly held: "In many situations, we are hesitant to bring together actions involving separate defendants and products, but where, as here, the actions stem from the same government investigation and there is significant overlap in the central factual issues, parties, and claims, we find that creation of a single MDL is warranted." *In re Walgreens Herbal Supplements Mktg. & Sales Practices Litig.*, 109 F. Supp. 3d 1373, 1375 (J.P.M.L. 2015). The Scheduled Actions all arise from the FDA's investigation of Valsartan manufacturing practices, which culminated in the Recall. Thus, the Actions, even the individual action, stem from the same government investigation such that their central factual issues overlap. Therefore, the Actions should be consolidated.

B. Consolidation Serves The Best Economic And Equitable Interests Of The Parties, Counsel, And Judiciary.

Here, coordination serves the best interests of the parties, parties' counsel, and the judiciary by conserving economic resources and equitably preventing inconsistent rulings. Unless the plaintiffs' claims are centralized and coordinated, the parties and courts will be forced to spend a great deal of time and effort replicating actions for pretrial discovery matters. Furthermore, the parties may be prejudiced by various courts entering contradictory orders ruling on discovery and evidentiary issues common to all claims. Such disparate rulings will lead to more litigation and, ultimately, to incongruous results and inconsisent precedent. In contrast, coordination avoids the pitfalls of piecemeal litigation by resolving disputes related to common issues in one singular ruling. *In re StarLink Corn Products Liability Lit.*, 152 F.Supp.2d 1378, 1380 (J.P.M.L. 2001).

Centralized pretrial proceedings work to conserve the time, effort, and financial resources of the judiciary and the parties, while simultaneously eliminating the possibility of inconsistent rulings from sister courts in parallel proceedings that might impair the equitable and orderly administration of justice. *See, e.g., In re Pradaxa (Dabigatran Etexilate) Prods. Liab. Litig.*, 883 F. Supp. 2d 1355, 1356 (J.P.M.L. 2012) ("Centralization will eliminate duplicative discovery; prevent inconsistent pretrial rulings; and conserve the resources of the parties, their counsel and the judiciary."); *In re DePuy Orthopaedics, Inc*., 753 F. Supp. 2d 1378, 1379 (J.P.M.L. 2010) ("Centralization under Section 1407 will eliminate duplicate discovery, prevent inconsistent trial rulings on discovery and other issues, and conserve the resources of the parties, their counsel and the judiciary.").

Moreover, in litigation bearing both common and unique issues of fact, it is important that the actions be allowed to go forward before a single judge who can establish a pretrial plan under which pretrial proceedings with respect to any non-common issues proceed concurrently with

pretrial proceedings on common issues. *In re Smith Patent Litig*., 407 F. Supp. 1403, 1404 (J.P.M.L. 1976). *See also In re Nexium (Esomeprazole) Prods. Liab. Litig.*, 908 F. Supp. 2d 1362, 1363 (J.P.M.L. 2012) (stating that "[t]he transferee court can employ any number of pretrial techniques – such as establishing separate discovery and/or motion tracks" to manage individual questions of fact). In addition, if the actions are not centralized in one location, counsel for all parties will be forced to litigate actions in several different courts concurrently, and scheduling conflicts will likely result. Finally, it is essential to ensure that all parties have access to the same essential documents without concerns over duplication of costs and effort or inconsistencies in document production.

Each of the scheduled Actions will necessarily require investigation of Valsartan manufacturing processes, the breadth and scale of NDMA contamination, and the effects thereof. Additionally, plaintiffs in each of the scheduled Actions will predictably seek information on when and how defendants learned or became aware of any contamination. It is also likely that each case will involve at least some contested discovery issues. Thus, there is a clear danger of inconsistent discovery rulings absent consolidation.

C. Transfer And Consolidation Will Not Burden Or Prejudice Any Of The Parties To The Scheduled Actions.

All of the Scheduled Actions remain essentially at the starting line. Each case is at the exact same litigation stage, as none of the class action complaints have been answered. Only one defendant, the Harvard Drug Group, LLC, has filed an answer in the *Gentry* individual action. Transfer and consolidation now, before any dispositive motions are filed or the discovery process begins, is essential to prevent inconsistent rulings.

In fact, the most noteworthy activity thus far is that defendants have already successfully transferred at least one case, *Duffy v. Solco Healthcare U.S., LLC, et al.*, from the Southern District

of New York to the District of New Jersey, and have sought to transfer Movant's action to the District of New Jersey as well. Because each case is in such an early stage, significant time and effort can be conserved by conducting centralized discovery under one judge.

II. The Proper Transferee Forum For These Cases Is The United States District Court For The District Of New Jersey.

The criteria used by the Judicial Panel on Multidistrict Litigation in determining the most appropriate transferee forum under 28 U.S.C. § 1407 include: the convenience of the parties and witnesses; the relative degree of progress achieved in pending actions; the location of parties, witnesses, and documents; the likelihood that a given district's location would enhance the prospects for cooperation among the federal and state courts; and, when no clear choice emerges from these factors, the preference of the majority of the parties. *In re Factor VIII or IX Concentrate Blood Prods. Liab. Litig*., 853 F. Supp. 454, 455 (J.P.M.L. 1993); *In re New Mexico Natural Gas Antitrust Litig*., 482 F. Supp. 333, 337 (J.P.M.L. 1979). For example, in the phenylpropanolamine (PPA) MDL, the Panel selected a transferee court based in part on the fact that it was "a major metropolitan court that (i) is not currently overtaxed with other multidistrict dockets, and (ii) possesses the necessary resources to be able to devote the substantial time and effort to pretrial matters that this complex docket is likely to require." *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 173 F. Supp. 2d 1377, 1379-80 (J.P.M.L. 2001).

A. Judge Wolfson Of The District Of New Jersey Has The Experience To Properly Conduct This Litigation.

The District of New Jersey and Judge Wolfson in particular have significant experience handling multidistrict litigation involving deceptive sales actions as well as products liability actions. *See, e.g., Fosamax (Alendromate Sodium) Products Liability Litigation (No. II)*, MDL Docket No. 2243 (D.N.J. 2018); *In Re: Johnson & Johnson Talcum Powder Products Marketing,*

Sales Practices and Product Liability Litigation, MDL Docket No. 2738 (D.N.J. 2016); *Plavix Marketing, Sales Practices and Products Liability Litigation (No. II)*, MDL Docket No. 2418 (D.N.J. 2013) (all product liability MDLs currently assigned to Judge Wolfson). Currently, five of the eleven Scheduled Actions are located in the District of New Jersey. Judge Wolfson is presently presiding over four of these actions, including *Erwin v. Prinston Pharmaceutical Inc., et al.*, No. 18-cv-13447 (D.N.J), as well as *O'Neill v. Solco Healthcare U.S. Inc., et al.*, No. 18-cv-14841 (D.N.J.). Thus, the District of New Jersey, and particularly Judge Wolfson's docket, is the appropriate transferee court for this multidistrict litigation.

B. The District of New Jersey Is An Efficient Forum.

The District of New Jersey has consistently served as a favored transferee court and is currently managing only 14 MDLs.[4] The District of New Jersey has significant experience handling MDLs, and has consistently shown its ability to handle and resolve complex multidistrict products liability litigation, like this case, in an expeditious and fair manner, having terminated a total of 62 MDLs since 1972.[5]

C. Transfer Serves The Convenience Of The Parties And Witnesses.

"[T]ransfers shall be made by the judicial panel on the multidistrict litigation authorized by this section upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a).

Each of the Scheduled Actions names as defendants New Jersey entities responsible for the manufacture, distribution, and marketing of defective Valsartan. Indeed, the primary defendants

[4] JUDICIAL PANEL ON MULTIDISTRICT LITIGATION, *Pending MDLs by District as of October 15, 2018*, at 2. Available at http://www.jpml.uscourts.gov/pending-mdls-0.
[5] JUDICIAL PANEL ON MULTIDISTRICT LITIGATION, *Multidistrict Litigation Terminated Through September 30, 2017*, at 13–14. Available at http://www.jpml.uscourts.gov/statistics-info.

likely to have discoverable information relating to the Valsartan manufacturing process, marketing practices, and other material issues are headquartered in New Jersey. Therefore, transferring the Scheduled Actions to New Jersey is essential to prevent unnecessary and repetitive travel and expense during the conduct of each of the Actions.

Furthermore, several of the defendants named in the Scheduled Actions prefer consolidation in the District of New Jersey. Defendants successfully transferred the *Duffy* action to the District of New Jersey from the Southern District of New York, and defendants in Movant's action have similarly moved to transfer his class action from the Northern District of Illinois to the District of New Jersey.

D. New Jersey Is A Geographically Accessible Forum.

As explained above, the District of New Jersey is already the site of nearly half of the Scheduled Actions and, not coincidentally, the home of the majority of the named defendants. For plaintiffs and defendants residing in other jurisdictions, however, each division is within an hour's drive or train ride from either New York City or Philadelphia, two of the nation's largest cities and transportation hubs with international airports and expansive hotel and restaurant options. Expert witnesses and counsel would find New Jersey a convenient location to reach for hearings, depositions, and any possible trial.

CONCLUSION

For the foregoing reasons, pursuant to 28 U.S.C. § 1407, Movant respectfully requests that the Scheduled Actions listed in the contemporaneously-filed Schedule of Actions, and all similar or subsequently-filed related actions, be transferred and consolidated before Judge Freda L. Wolfson of the District of New Jersey.

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Respectfully Submitted,

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