BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: CHANTIX (VARENICLINE) MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	MDL-_____

BRIEF IN SUPPORT OF PLAINITFF COUNTY OF MONMOUTH'S MOTION FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. § 1407

Plaintiff, the County of Monmouth,[1] respectfully submits this Brief in Support of its motion for transfer and consolidation of related actions in the District of New Jersey, under 28 U.S.C. § 1407.

I. INTRODUCTION

Pursuant to 28 U.S.C. § 1407, Plaintiff, the County of Monmouth, seeks an Order (i) transferring to the District of New Jersey the eight actions and any other tag-along actions asserting similar or related claims against Pfizer, Inc. involving contaminated, defective, or adulterated Chantix (or varenicline) drug products that contained a carcinogenic substance, n-nitroso-varenicline, and were adulterated, that may be subsequently filed in or removed to the federal courts, (ii) consolidating eight class actions for pretrial discovery and class certification purposes. Transfer and consolidation in the District of New Jersey is necessary under § 1407 to promote efficient management of this litigation because:

- The actions involve nearly identical factual allegations that Pfizer's Chantix drug products were adulterated or defective in that they contain the presence of n-nitroso-

[1] *County of Monmouth v. Pfizer, Inc.*, No. 3:22-cv-2050 (D.N.J.).

varenicline, a human carcinogen, and the actions bring largely duplicative legal claims. Thus, discovery in all of the related actions will necessarily focus on the same documents, witnesses, and other evidence pertaining to Pfizer's manufacture and testing of Chantix products, Pfizer's knowledge of problems regarding the presence of nitrosamines in its products, and any steps Pfizer took or should have taken to address any known contamination or adulteration issues. Absent consolidation, duplicative discovery and potentially conflicting dispositive legal rulings may result.

- The actions involve overlapping putative classes, as the six actions seek to certify overlapping classes of consumers, and the two actions seek to certify overlapping classes of third-party payors ("TPPs").[2] Absent consolidation, at least eight federal district courts could issue five conflicting class certification rulings.
- The District of New Jersey is where Plaintiff, County of Monmouth, is located, and is where Pfizer has admitted that multiple percipient witnesses are located.

These actions, relating to nitrosamine contamination, present nearly identical circumstances that led this Panel to consolidate cases under § 1407 into at least four other recent MDLs involving the contamination and adulteration of prescription and over-the-counter drug products with carcinogenic contaminants: *See In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, MDL No. 19-2875 (D.N.J.); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, MDL No. 20-2924 (S.D. Fla.); *In re Johnson & Johnson Sunscreen Marketing, Sales Practices & Prods. Liab. Litig*., MDL No. 3015 (S.D. Fla.); *In re Procter & Gamble Aerosol Products Marketing and Sales Practices Litigation*, MDL No. 3025 (S.D. Ohio).

[2] The eight cases are listed on the Schedule of Actions filed with the accompanying Brief as Exhibit "A." The Complaints (without exhibits) in the Actions and their related docket sheets are attached to the Brief as Exhibits "A-1" through "A-8."

II. BACKGROUND

A. Factual Background

Defendant Pfizer, Inc. manufactures and sells the smoking-cessation brand-name drug Chantix. Chantix, generically known as varenicline, was approved by the FDA in May 2006. Pfizer has continuously manufactured, marketed, and sold Chantix since, until very recently due to the recalls (discussed more below) without any generic competition. Due in part to Pfizer's patent exclusivity, the price of Chantix has steadily climbed since its launch. For instance, in 2018 the price for a 30-day supply of Chantix was approximately $485. Pfizer's total sales in 2018 alone were at least $997 million.

Non-party Apotex, Inc. (whose United States headquarters is in Florida), manufactured and sold a generic version of Chantix in Canada. In October 2020, Health Canada informed Apotex, Inc., about the presence of nitrosamines in Chantix and its generic equivalents—specifically a nitrosamine known as N-nitroso-varenicline. Nitrosamines are genotoxic compounds and known human carcinogens. Nitrosamines are not new; their chemical structures have been well-defined for decades, and the industry has been aware of the formation of nitrosamines during drug manufacturing for decades. Nitrosamines are not an active ingredient in Chantix or any other drug; indeed, nitrosamines have been used as intentional poisons and to induce cancer in laboratory animals.

Because nitrosamines are not active or inactive components of Chantix (or any drug, for that matter), the presence of nitrosamine contaminants in a drug such as Chantix renders it adulterated and misbranded under federal and analogous state laws, and therefore economically worthless and illegal to sell. The presence of nitrosamine contamination also led to the massive recalls of popular hypertension drugs valsartan, losartan, and irbesartan in 2018 and 2019, and the

recall of blockbuster stomach medication Zantac (i.e., ranitidine) in 2019. The recalls of those other products due to nitrosamine or other carcinogenic contamination are the subject of at least four different multi-district litigations: *See In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, MDL No. 19-2875 (D.N.J.); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, MDL No. 20-2924 (S.D. Fla.); *In re Johnson & Johnson Sunscreen Marketing, Sales Practices & Prods. Liab*. Litig., MDL No. 3015 (S.D. Fla.); *In re Procter & Gamble Aerosol Products Marketing and Sales Practices Litigation*, MDL No. 3025 (S.D. Ohio).

Despite hearing from Health Canada about nitrosamine contamination at least as early as October 2020, Pfizer did not institute any recall in the United States until June 2021. And even at that time, Pfizer only recalled a few lots of Chantix, implying the nitrosamine contamination was not a product-wide issue. It expanded its recall to a couple of other lots a few weeks later, but again stopped well short of instituting a product-wide recall. Finally, in September 2021—almost a year after first hearing from Health Canada about nitrosamine contamination in Chantix—Pfizer announced it was recalling all lots of Chantix "due to the presence of a nitrosamine." Partially released results of FDA's own testing found N-nitroso-varenicline in Pfizer's Chantix at staggeringly high levels between 155-474 ppm, which is well above the 0.15-0.47 range referenced by the FDA.[3] The FDA has since specially authorized Apotex to import its generic version of Chantix into the United States and sell it here due to Pfizer's contaminated product and recalls.[4] This demonstrates the FDA believes there is a proper way to make appropriate varenicline-containing drugs that are not contaminated with nitrosamines like Pfizer's Chantix product.

[3] *See, e.g.*, Laboratory analysis of varenicline products, *at* https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-varenicline-products.
[4] *See* Apotex Ltr., *at* https://www.apotex.com/products/us/downloads/hpl/apo_vare_fct_hcl.pdf.

B. Procedural History of the Pending Actions

Plaintiff County of Monmouth filed its proposed class action on behalf of all TPPs nationwide who reimbursed for Chantix on April 8, 2022. Plaintiff County of Monmouth asserts claims for breach of express and implied warranty, fraud, negligent misrepresentation, violation of consumer protection laws, negligence, negligence per se, and unjust enrichment.

A prior proposed class action, also filed on behalf of TPPs, is currently pending in the Southern District of Florida (*MSP*). Another six proposed class actions filed on behalf of consumers are pending across the country, including in the Eastern District of Pennsylvania, the Northern District of California, the Southern District of Illinois, and the Southern District of Florida.[5]

Although Plaintiff knows of no other related cases pending, Pfizer is best situated to inform the Panel whether there are any other class actions in federal district courts that raise the same or similar claims.

III. ARGUMENT

A. Transfer of the Pending Class Actions for Coordinated Pretrial Proceedings is Proper

The principal goals of 28 U.S.C. § 1407 are to avoid duplicative discovery, prevent inconsistent or repetitive rulings, promote efficient management of litigation, and conserve the resources of the parties, counsel, and the courts. *See* MANUAL FOR COMPLEX LITIGATION (FOURTH) § 22.33 at 367 (4th ed. 2004). These goals are best served by transferring the above-identified cases for coordinated pretrial proceedings. 28 U.S.C. § 1407 authorizes this Panel to transfer and consolidate two or more civil cases for coordinated pretrial proceedings upon the determination

[5] At the time of this petition, it appears one of the Southern District of Florida cases may be transferred to the Southern District of New York.

that (i) they "involv[e] one or more common questions of fact," (ii) transfer will further "the convenience of the parties and witnesses," and (iii) transfer "will promote the just and efficient conduct of the action." 28 U.S.C. § 1407(a). The aim of § 1407 is to "eliminate duplication in discovery, avoid conflicting rulings and schedules, reduce litigation cost, and save the time and effort of the parties, the attorneys, the witnesses, and the courts." *Gelboim v. Bank of America Corp.*, 574 U.S. 405, 410 (2015) (internal quotations and citation omitted). Transfer of the Related Actions for consolidated or coordinated pretrial proceedings will satisfy each of these requirements and will advance § 1407's underlying objectives.

Here, § 1407's requirements for transfer are satisfied. The above-referenced class actions against Pfizer are based on the same or substantially similar questions of law and fact. In addition, transfer will promote the convenience of the parties and efficiency in the pretrial proceedings by eliminating duplicative discovery and the potential for inconsistent rulings, including determinations on class certification. Indeed, because all of the actions assert complex, yet virtually identical claims and allegations requiring substantial discovery into highly technical aspects of Pfizer's manufacturing and testing of Chantix, they are ideal candidates for transfer for coordinated or consolidated pretrial proceedings. *See e.g.*, *In re: Xarelto (Rivaroxaban) Prod. Liab. Litig*., 65 F. Supp. 3d 1402, 1405 (J.P.M.L. 2014) (consolidation appropriate where issues concerning development, manufacture, regulatory approval, labeling, and marketing of product are common to all actions, transferring to Plaintiff's choice forum).

1. The related actions involve common questions of fact.

The first requirement of § 1407 — that actions involve common questions of fact — is satisfied. The factual issues to be determined in each of the actions proposed for transfer and coordination arise from the same course of conduct by Pfizer and are, therefore identical for pretrial

purposes.[6] Common questions of fact and law at issue in the related actions include, but are not limited to, the following:

a. Whether Pfizer's Chantix drugs were contaminated with nitrosamines or similar contaminants;

b. Whether Pfizer's Chantix drugs containing nitrosamines or similar contaminants were adulterated and/or misbranded;

c. Whether Pfizer violated current good manufacturing practices regarding the manufacture of Chantix;

d. Whether Pfizer falsely claimed that its unapproved varenicline-containing drugs were the same as Chantix and thus therapeutically and pharmacologically interchangeable;

e. Whether Pfizer affirmatively misrepresented or omitted facts regarding its compliance with current good manufacturing practices;

f. Whether Pfizer made express or implied warranties of "sameness" to Plaintiffs and class members regarding its drugs;

g. Whether Pfizer's varenicline-containing drugs were, in fact, "the same" as Chantix consistent with such express or implied warranties;

h. Whether Plaintiffs and other class members have been injured as a result of each Defendant's unlawful conduct, and the amount of their damages;

i. Whether a common damages model can calculate damages on a class-wide basis;

j. When Plaintiffs' and class members' causes of action accrued; and

[6] Although all of the pending cases are substantially similar, Section 1407 does not require a "complete identity or even [a] majority" of common questions of fact to justify transfer. *In re Zyprexa Prods. Liab. Litig.*, 314 F. Supp. 2d 1380, 1381 (J.P.M.L. 2004).

k. Whether Pfizer fraudulently concealed Plaintiffs' and class members' causes of action.

Even a cursory review of the pleadings reveals that the factual issues to be determined in each of the actions are nearly identical, making transfer to a single forum highly appropriate. *See In re Neurontin Mktg & Sales Practices Litig.*, 342 F. Supp. 2d 1350, 1351 (J.P.M.L. 2004) (finding existence of common issues to warrant transfer where "[a]ll actions were purported class actions involving allegations that common defendants have engaged in the illegal promotion and sale of the drug Neurontin"); *In re Ephedra Prod. Liab. Litig.*, 314 F.Supp. 2d 1373, 1375 (J.P.M.L. 2004) ("Common factual questions arise because these actions focus on alleged side effects of ephedra-containing products, and whether defendants knew of these side effects and either concealed, misrepresented or failed to warn of them."); *In re Fluoroquinolone Prod. Liab. Litig.*, 122 F. Supp. 3d 1378, 1380 (J.P.M.L 2015) (common factual questions arose out of allegations against defendant manufacturer, consolidating to plaintiff's choice forum).

2. Consolidating the class actions will further the convenience of the parties and the witnesses.

Consolidation of the related class actions would likewise satisfy the second requirement of Section 1407 because it will serve the convenience of the parties and witnesses. At present, all of the pending cases are in their infancy, having been filed in 2021 If these cases continue to proceed separately, there will be substantial duplicative discovery because of the many overlapping issues of fact and law. Indeed, discovery in all of the related actions will necessarily focus on documents, witnesses and other evidence pertaining to Pfizer's manufacture, distribution, and sale of carcinogen-laced Chantix drugs, Pfizer's knowledge of problems regarding the Chantix drugs, and any steps Pfizer took to address any known contamination. These subjects are complex and highly technical and will require substantial discovery and entail significant expense. Because these

actions arise from a common core of factual allegations, there is a strong likelihood of duplicative discovery demands and redundant depositions. Consolidation of the actions would enable a single District Judge to establish a single pretrial schedule, thereby minimizing inconvenience to witnesses and expense to parties. *See In re Fisher-Price Rock 'N Play Sleeper Marketing, Sales Practices, & Products Liab. Litigation*, 412 F.Supp.3d 1357, 1360 (J.P.M.L. 2019 (consolidation "expeditiously places all related actions before a single judge who can ensure that pretrial proceedings are conducted in a streamlined manner leading to the just and efficient resolution of all actions"). Indeed, the Panel in the last few years has repeatedly recognized that nearly identical nitrosamine or other carcinogenic contamination issues merit coordination. *See In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, MDL No. 19-2875 (D.N.J.); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, MDL No. 20-2924 (S.D. Fla.); *In re Johnson & Johnson Sunscreen Marketing, Sales Practices & Prods. Liab*. Litig., MDL No. 3015 (S.D. Fla.); *In re Procter & Gamble Aerosol Products Marketing and Sales Practices Litigation*, MDL No. 3025 (S.D. Ohio).

3. Transfer and consolidation will promote just and efficient conduct of the related actions.

For these same reasons, transfer and coordination of the related cases would also promote the just and efficient adjudication of the actions. The related actions all raise common questions of fact and law. Plaintiffs in each action will likely seek to depose many of the same individuals and request production of a substantially similar set of documents. Failure to consolidate these actions would, therefore, result in unnecessary and duplicative discovery; witnesses would have to appear for multiple depositions and Pfizer would have to negotiate and produce multiple sets of overlapping documents. Consolidation and coordination of the actions would avoid this

needless waste of resources and confer benefits upon both the plaintiffs as well as Pfizer.[7]

Also, the fact that all actions are seeking to certify overlapping classes opens the possibility of inconsistent rulings on certification issues, which weighs heavily in favor of transfer and consolidation. Lastly, the defects at issue are complex and highly technical and will necessarily require extensive use of experts and a substantial amount expensive discovery. *See In re Power Morcellator Products Liab. Litigation*, 140 F. Supp. 3d 1351, 1353 (J.P.M.L. 2015) (the fact that "[d]iscovery, including expert discovery, will overlap with respect to these common issues" supports centralization).

To avoid the possibility of inconsistent rulings (including inconsistent determinations on class certification) and duplicative discovery, as well needless taxation on the judicial system, the actions should be consolidated before the same court. *See In re Fairlife Milk Products Marketing & Sales Practices Litig.*, 396 F.Supp.3d 1370, 1371 (J.P.M.L. 2019) ("Centralization thus will eliminate duplicative discovery; prevent inconsistent pretrial rulings, particularly with respect to class certification; and conserve the resources of the parties, their counsel, and the judiciary.").

B. The Related Actions Should Be Transferred to the District of New Jersey for Coordinated or Consolidated Pretrial Proceedings

Transfer and centralization will also serve the overall "convenience of parties and witnesses" consistent with § 1407(a). *See, e.g., In re Zantac (Ranitidine) Prods. Liability Litig*.,

[7] This Panel has routinely recognized that consolidating litigation in one court benefits ***both*** plaintiffs and defendants. For example, pretrial transfer would reduce discovery delays and costs for plaintiffs and permit plaintiffs' counsel to coordinate their efforts and share the pretrial workload. *See, e.g., In re Phenylpropanolamine (PPA) Prods. Liab. Litig*., 173 F. Supp. 2d 1377, 1379 (2001) ("And it is most logical to assume that prudent counsel will combine their forces and apportion their workload in order to streamline the efforts of the parties and witnesses, their counsel and the judiciary, thereby effectuating an overall savings of cost and a minimum of inconvenience to all concerned.").

MDL No. 2924, 2021 WL 5848067, at *1 ("Transfer of an action, however, is appropriate if it furthers the expeditious resolution of the litigation taken as a whole, even if some parties to the action experience inconvenience[.]"); *In re Nat'l Prescription Opiate Litig.*, 2018 U.S. Dist. LEXIS 170489, at *2–3 (J.P.M.L. Oct. 3, 2018) (noting that the JPML looks to the "overall convenience of the parties and witnesses, not just those of a single plaintiff or defendant in isolation"). As stated above, the elimination of duplicative discovery would significantly increase convenience for the parties and witnesses. The District of New Jersey is an appropriate transfer district.

Plaintiff County of Monmouth is a third-party payor ("TPP"), and as a TPP, it paid the vast majority of the purchase price for the Chantix dispensed to its insureds. As such, County of Monmouth and the proposed TPP class have the most at stake and represent the largest claims. Plaintiff County of Monmouth is located in New Jersey and the data and documents relevant to the County of Monmouth's purchase of Chantix are located in New Jersey—as are the witnesses with knowledge regarding those purchases and the information that the County of Monmouth relied on when making those purchases. *In re: Xarelto (Rivaroxaban) Prod. Liab. Litig.*, 65 F. Supp. 3d 1402, 1405 (J.P.M.L 2014) (transferring cases to district where several plaintiff actions were already pending and plaintiffs were located). Thus, New Jersey contains the bulk of the relevant witnesses, documents, and records. It is also serviced by multiple airports and all major airlines, and would be accessible and convenient for all parties, witnesses, and attorneys.

Further, there would be little gained by transferring the case to Pfizer's headquarters in New York. This case is about the manufacturing and testing of Chantix, both of which were done

overseas in Ireland and Germany—not New York.[8] Judge Shipp, to whom Plaintiff County of Monmouth's case is assigned, is an able jurist well-situated to oversee an MDL involving Chantix.

IV. CONCLUSION

For the above reasons, Plaintiff County of Monmouth respectfully requests that this Panel transfer the above-listed cases and any subsequently filed cases raising similar claims to the District of New Jersey for coordinated pretrial proceeding before the Honorable Michael A. Shipp.

Dated: August 31, 2022

Respectfully Submitted,

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[8] *See, e.g.*, PR NEWS WIRES, *Pfizer site named pharmaceutical facility of the year* (announcing Pfizer's Germany facility as 'facility of the year' for its Chantix production) (Ex. B hereto); PHARMACEUTICAL TECHNOLOGY, *Pfizer, New Containment Facility, Germany* (Apr. 29, 2008) https://www.pharmaceutical-technology.com/projects/pfizerdeutschland/ (noting Pfizer manufactured Chantix in Ireland (Ex. C hereto).