BEFORE THE UNITED STATES
JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: ZOFRAN® PRODUCTS LIABILITY LITIGATION	MDL No. _____

BRIEF IN SUPPORT OF DEFENDANT GLAXOSMITHKLINE LLC'S
MOTION FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. § 1407

Pursuant to 28 U.S.C. § 1407 and Rule 7.2(a) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, defendant GlaxoSmithKline LLC ("GSK") respectfully submits this memorandum of law in support of its motion for transfer of all currently filed federal cases in this litigation, and any subsequent "tag along" cases involving similar claims, to the United States District Court for the Eastern District of Pennsylvania.

Plaintiffs are minor children and their parents, who allege that the mothers ingested the defendant's prescription medication Zofran® while pregnant, and that the children were subsequently born with birth defects which plaintiffs attribute to the mothers' alleged use of Zofran®. At present, there are twelve federal actions, pending in ten separate judicial districts across the United States, alleging essentially the same conduct by GSK.[1] Defendant anticipates that more actions will be filed nationwide. Based on the numerous complex and common questions of fact involved, the compelling need to establish uniform and consistent standards in conducting pretrial discovery and motion practice, and because the most logical and convenient location for these proceedings is the Eastern District of Pennsylvania, GSK respectfully requests

[1] One case listed on the attached Schedule of Actions (*Ragland*) names GSK as the sole defendant and alleges that GSK is liable for injuries caused when the pregnant mother ingested a generic form of Zofran®.

that the Panel transfer all of these actions, including any similar cases subsequently filed, for coordinated proceedings there.

I. BACKGROUND

This motion for transfer involves twelve actions pending in ten different jurisdictions across the United States asserting common factual allegations and involving overlapping claims and legal issues. Based on plaintiff counsel advertising and information from plaintiff firms, GSK expects additional such actions to be filed in the federal courts.

A. Plaintiffs.

The plaintiffs in this litigation have filed civil actions arising from the alleged use of the prescription medication ondansetron, which for the past twenty-four years, GSK has manufactured and sold under the brand name Zofran®. Zofran® is a type of anti-emetic, a medication used to treat nausea and vomiting. The federal Food and Drug Administration ("FDA") has approved Zofran® for the treatment of nausea and vomiting related to chemotherapy and surgery, following a rigorous approval process.

Plaintiffs contend that their minor children suffered birth defects following the mothers' ingestion of Zofran® prescribed for treatment of severe morning sickness during pregnancy (a condition that can threaten the health of mother and baby). Plaintiffs all claim that the drug they allegedly ingested was defectively designed, manufactured, and/or marketed by GSK, resulting in serious physical injuries to their children, and that GSK failed to provide adequate warnings of the risks and dangers posed by Zofran®. Plaintiffs also allege that GSK improperly marketed Zofran® "off-label" to doctors for treating morning sickness during pregnancy without FDA approval.

Each of these pending federal cases presents a common core of facts, in that each (i) alleges exposure to mother and fetus; (ii) asserts injury and damages arising from alleged birth

defects of the minor plaintiff; and (iii) alleges the same or similar conduct by defendant. Indeed, the factual allegations in plaintiffs' complaints are nearly identical in numerous critical respects, including in several instances sharing the same typographical errors.

Plaintiffs in the twelve pending federal actions are geographically diverse, residing in eight different states located across the country: Massachusetts, Montana, Alabama, Arkansas, Louisiana, New Jersey, Ohio, and Texas. In addition, plaintiffs are represented by a regionally diverse group of law firms (in alphabetical order): Bonsignore Trial Lawyers, PLLC (Massachusetts and Nevada); Cory Watson Attorneys, P.C. (Alabama); David Hodges Law Firm (Arkansas); Edwards, Frickle & Culver (Montana); Gathings Law (Alabama); Grant & Eisenhofer P.A. (New York and Delaware); Haik, Minvielle & Grubbs, LLP (Louisiana); Harbatkin & Levasseur P.A. (New Jersey); Harrelson Law Firm, P.A. (Arkansas); Helland Law Firm (Montana); Herman, Herman & Katz, LLC (Louisiana); Janet, Jenner & Suggs, LLC (Massachusetts); Law Offices of Frank N. Dardeno, LLP (Massachusetts); Morrow, Morrow, Ryan & Bassett (Louisiana); Murray Law Firm (Louisiana); and Zoll, Kranz & Borgess, LLC (Ohio).

B. Defendant GSK.

The common, named defendant in all of these related cases is GSK. GSK is a Delaware limited liability company organized under the laws of the State of Delaware, and its sole member is GlaxoSmithKline Holdings (Americas) Inc. ("GSK Holdings"). GSK Holdings is a Delaware corporation with its headquarters and principal place of business in the State of Delaware. GSK has centralized U.S. pharmaceutical operations and offices in Philadelphia, Pennsylvania and Research Triangle Park in Raleigh-Durham, North Carolina. GSK is represented nationally by the law firm Shook, Hardy & Bacon L.L.P. with additional local counsel.

C. The Location and Status of the Actions.

Plaintiffs filed these pending federal cases in the following jurisdictions, all in this calendar year: On February 16, 2015, the *LeClair* plaintiff filed suit in the District of Massachusetts. *See* Schedule of Actions. On April 1, 2015, the *Hunter* plaintiff filed in the Northern District of Alabama. *Id.* On April 3, 2015, the *Marlenee* plaintiffs filed in the District of Montana. *Id.* On April 17, the *Duong* plaintiff filed in the District of Massachusetts, and the same day, the *Shonkwiler* plaintiff filed in the Eastern District of Texas. *Id.* On May 21, 2015, the *Cox* plaintiffs filed in Eastern District of Arkansas. *Id.* On June 8, 2015, the *Coughlin* plaintiffs filed in the Western District of Louisiana. On June 10, 2015, the *Regan* plaintiffs filed in the Northern District of Ohio. On June 23, 2015, the *Ragland* plaintiff filed in the Northern District of Alabama, and the *Roberts* plaintiff filed in the Southern District of Alabama. On June 26, 2015, the *Alexander* plaintiff filed in the Eastern District of Louisiana, and the *Mandoyan* plaintiffs filed in the District of New Jersey. None of these cases has advanced significantly through discovery, nor toward trial such that transfer would be unduly prejudicial or inefficient.

II. ARGUMENT

The Zofran® actions currently pending in different federal districts meet the requirements for transfer pursuant to 28 U.S.C. § 1407, and therefore, transfer of the above-referenced actions is warranted. Section 1407 authorizes the transfer of two or more civil actions, pending in different districts, for coordinated or consolidated pretrial proceedings, when (1) the "actions involv[e] one or more common questions of fact;" (2) transfer "will be for the convenience of parties and witnesses;" and (3) transfer "will promote the just and efficient conduct of such actions."

"The multidistrict litigation statute, 28 U.S.C. § 1407, was enacted as a means of conserving judicial resources in situations where multiple cases involving common questions of fact were filed in different districts." *Royster v. Food Lion (In re Food Lion),* 73 F.3d 528, 531-32 (4th Cir. 1996). Two critical goals of Section 1407 are to promote efficiency and consistency. *Illinois Municipal Retirement Fund v. Citigroup, Inc.*, 391 F.3d 844, 852 (7th Cir. 2004). The statute "was [also] meant to 'assure uniform and expeditious treatment in the pretrial procedures in multidistrict litigation'" and "[w]ithout it, 'conflicting pretrial discovery demands for documents and witnesses' might 'disrupt the functions of the Federal courts.'" *In re Phenylpropanolamine Prod. Liab. Litig.*, 460 F.3d 1217, 1230 (9th Cir. 2006) (quoting H.R. Rep. No. 1130, 90th Cong., 2d Sess. 1 (1968), *reprinted in* 1968 U.S.C.C.A.N. 1898, 1899). The alternative to appropriate transfer is "multiplied delay, confusion, conflict, inordinate expense and inefficiency." *Id.* (quoting *In re Plumbing Fixture Cases*, 298 F. Supp. 484, 495 (J.P.M.L. 1968)).

These actions assert overlapping claims, based on multiple common factual allegations, and will involve several common defenses. Consolidated pretrial treatment under Section 1407 will assist the parties and the courts in avoiding duplicative and conflicting rulings on the common issues in dispute. Granting this motion will also serve the convenience of the parties and witnesses and promote the just and efficient resolution of the litigation.

This Panel has frequently ordered the multidistrict transfer of multiple actions involving prescription medications. *See, e.g., In re: Benicar (Olmesartan) Products Liability Litigation*, 2015 WL 1518503 (J.P.M.L. Apr. 3, 2015); *In re Effexor Prods. Liab. Litig.*, 959 F.Supp.2d 1359 (J.P.M.L. 2013); *In re Tylenol Mktg., Sales Pracs. and Prods. Liab. Litig.*, 936 F.Supp.2d 1379 (J.P.M.L. 2013); *In re Zoloft Prods. Liab. Litig.*, 856 F.Supp.2d 1347 (J.P.M.L. 2012); *In*

re: Pradaxa (Dabigatran Etexilate) Prods. Liab. Litig., 883 F. Supp. 2d 1355 (J.P.M.L. 2012); *In re: Actos Prods. Liab. Litig.*, 840 F. Supp. 2d 1356 (J.P.M.L. 2011); *In re: Yasmin & Yaz Mktg. Prods. Liab. Litig*., 655 F. Supp. 2d 1343 (J.P.M.L. 2009); *In re: NuvaRing Prods. Liab. Litig*., 572 F. Supp. 2d 1382 (J.P.M.L. 2008); *In re: Vioxx Prods. Liab. Litig*., 360 F. Supp. 2d 1352 (J.P.M.L. 2005); *In re: Prempro Prods. Liab. Litig*., 254 F. Supp. 2d 1366 (J.P.M.L. 2003).

A. These Cases Involve Common Questions of Fact.

The first element of the Section 1407 transfer analysis is whether there are one or more common questions of fact. *See* 28 U.S.C. § 1407. The statute, however, 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).

Here, there is no question that these cases share a common core of operative factual allegations. Plaintiffs all allege that Zofran® can cause harm to developing babies through ingestion of the medication by a pregnant mother.[2] Each plaintiff alleges that GSK knew of this alleged risk yet failed to properly warn doctors or patients of the dangers.[3] Plaintiffs similarly rely on the same alleged FDA regulatory history, conduct, and labeling as a basis for their

[2] *See Coughlin* Compl. ¶ 51; *Cox* Compl. ¶¶ 24-26; *LeClair* Compl. ¶¶ 5-6; *Hunter* Compl. ¶¶ 10-11, 17; *Marlenee* Compl. ¶¶ 5-6; *Duong* Compl. ¶ 67; *Regan* Compl. ¶4; *Shonkwiler* Compl. ¶ 66; *Ragland* Compl. ¶¶ 5-6; *Roberts* Compl. ¶¶ 5-6; *Alexander* Compl. ¶¶ 5-6; *Mandoyan* Compl. ¶¶ 5-6.

[3] *See Coughlin* Compl. ¶ 51; *Cox* Compl. ¶ 25; *LeClair* Compl. ¶¶ 58, 142; *Hunter* Compl. ¶¶ 10, 70; *Marlenee* Compl. ¶ 139; *Duong* Compl. ¶ 176; *Regan* Compl. ¶60; *Shonkwiler* Compl. ¶ 169; *Ragland* Compl. ¶¶ 65, 71, 79; *Roberts* Compl. ¶¶ 65-66, 72-74; *Alexander* Compl. ¶¶ 61, 65, 74; *Mandoyan* Compl. ¶¶ 5-7, 89.

claims.[4] Plaintiffs each contend that GSK improperly designed, manufactured, and/or marketed Zofran®.[5]

GSK disputes that plaintiffs' claims have merit. Nonetheless, their factual theories and allegations reflect multiple alleged common issues. Indeed, several of the paragraphs in *Duong*, *Shonkwiler*, *Coughlin*, and *Alexander*, among other complaints, read essentially the same, word-for-word.[6] The *Duong* and *Shonkwiler* complaints also include identical typographical errors, which are, in turn, imbedded in language copied directly from the earlier *LeClair* complaint.[7] Because the factual assertions in each of the instant actions are nearly identical, and many

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[4] *See Coughlin* Compl. ¶ 31-33, 52-55; *Cox* Compl. ¶¶ 8-11; *LeClair* Compl. ¶¶ 34-36; *Hunter* Am. Compl. ¶¶ 27-30; *Marlenee* Compl. ¶¶ 22-30; *Duong* ¶¶ 129-135; *Regan* Compl. ¶¶23-25, 117; *Shonkwiler* ¶¶ 122-128; *Ragland* Compl. ¶¶ 35-36, 85-87; *Roberts* Compl. ¶¶ 29-34; *Alexander* Compl. ¶¶ 29-34; *Mandoyan* Compl. ¶¶ 95-97, 103-106.

[5] *See Coughlin* Compl. ¶ 31-33, 52-55; *Cox* Compl. ¶¶ 24-25, 30; *LeClair* Compl. ¶¶ 106-108; *Hunter* Am. Compl. ¶¶ 92-94; *Marlenee* Compl. ¶¶ 4, 5; *Duong* ¶¶ 22, 26; *Regan* Compl. ¶¶ 7, 84-88; *Shonkwiler* ¶¶ 23, 27; *Ragland* Compl. ¶¶ 110-111; *Roberts* Compl. ¶¶ 104-105; *Alexander* Compl. ¶¶ 104-105; *Mandoyan* Compl. ¶¶ 120-121.

[6] *Compare Shonkwiler* Compl. ¶ 130 ("Since at least the 1980s, when GSK received the results of the preclinical studies that it submitted in support of Zofran's NDA 20-007, GSK has known of the risk that Zofran ingested during pregnancy in mammals crosses the placental barrier to expose the fetus to the drug.") *with Duong* Compl. ¶ 137 (same) *with Ragland* Compl. ¶ 40 (same) *with Roberts* Compl. ¶ 36 (same) *with Alexander* Compl. ¶ 36 (same) *with Coughlin* Compl. ¶ 35 (same) *with* Marlenee Compl. ¶ 35 (substantively same) *with Mandoyan* Compl. ¶ 68 (same). Similarly, *compare LeClair* Compl. ¶ 3 ("Although the only FDA approval for this drug was for seriously ill patients, GSK marketed Zofran 'off label' since at least January 1998 as an established safe and effective treatment for the very common side effect of a normal pregnancy – pregnancy-related nausea and vomiting – otherwise known as 'morning sickness.'") *with Marlenee* Compl. ¶ 3 (same) *with Duong* Compl. ¶ 111 (substantively same) *with Shonkwiler* Compl. ¶ 130 (same); *with Coughlin* Compl. ¶ 3 (substantively same).

[7] *Compare Duong* Compl. ¶ 294 ("Plaintiff further demands that this Court order GSK to remove the Pregnancy Category B designation from its drug product labeling for Zofran no later than June 2015, and . . . fully and accurately summarize the risks of using Zofran during pregnancy fully **[sic]**; . . . accurately describe the data supporting that summary; and . . . fully and accurately describe the relevant information to help health care providers make informed prescribing decisions and counsel women about the risks associated with use of Zofran during pregnancy.") with *Shonkwiler* Compl. ¶ 187 (same).

important legal issues in dispute (for example, related to federal preemption, statute of limitations, and other defenses) will also be nearly identical, transfer and coordination or consolidation of these actions is highly appropriate. *See In re "Factor VIII or IX Concentrate Blood Prods." Prod. Liab. Litig.*, 853 F. Supp. 454, 455 (J.P.M.L. 1993).

Not all fact questions raised by these actions are common (e.g., specific causation of alleged injury), but while that is relevant to the transfer analysis, it is not necessary that the cases allege all of the exact same claims or injuries as a result of Zofran® ingestion. As the Panel has observed, "[a]lmost all personal injury litigation involves questions of causation that are plaintiff-specific. Those differences are not an impediment to centralization where common questions of fact predominate." *In re: Xarelto (Rivaroxaban) Prods. Liab. Litig.*, — F. Supp. 3d —, 2014 WL 7004048, at *1 (J.P.M.L. Dec. 12, 2014); *see also In re Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prods. Liab. Litig.*, 53 F. Supp. 3d 1379, 1381 (J.P.M.L. 2014) ("The Panel has rejected the argument that products liability actions must allege identical injuries to warrant centralization.")

In addition, all these actions rely upon similar legal theories of recovery. These theories include: negligence, strict products liability, misrepresentation, concealment, failure to warn, and breach of warranty. While not every cause of action is asserted in every one of the cases, and applicable state law will vary, the lawsuits all share related underlying legal theories of liability. And as the Panel has previously stated, "the presence of additional or differing legal theories is not significant when the actions still arise from a common factual core . . . ." *In re Oxycontin Antitrust Litig.*, 542 F. Supp. 2d 1359, 1360 (J.P.M.L. 2008).

Because numerous common issues of fact exist among these cases, the pending actions clearly satisfy the first element of the transfer analysis under Section 1407.

B. Transfer Will Serve the Convenience of the Parties and Prevent Duplicative Discovery.

The convenience of the parties and prevention of duplicative discovery also favor transfer. *See* 28 U.S.C. § 1407. If these cases continue to proceed separately, there will be substantial duplicative discovery because of the many overlapping issues of fact and law. Multiple cases could involve the repetitive depositions of the same company representatives, other current and former employees, and expert witnesses, as well as production of the same records, and responses to duplicative interrogatories and document requests in jurisdictions around the country. *See, e.g.*, *In re: Pilot Flying J Fuel Rebate Contract Litigation (No. II)*, 11 F. Supp. 3d 1351, 1352 (J.P.M.L. 2014) ("Centralization will avoid repetitive depositions of Pilot's officers and employees and duplicative document discovery regarding the alleged scheme"). Absent transfer, the federal court system will be forced to administer – and GSK will be compelled to defend – these related actions across multiple venues, all proceeding on potentially different pretrial schedules and subject to different judicial decision-making and local procedural requirements.

None of the pending cases have progressed to the point where significant efficiencies will be forfeited through transfer to an MDL proceeding. 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. *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."); *In re*

Baldwin-United Corp. Litigation, 581 F. Supp. 739, 741 (J.P.M.L. 1984) (same). As for GSK, national or "generic" expert depositions will be coordinated, document production will be centralized, and travel for its current and former employees will be minimized, since it will only have to appear in one location rather than multiple districts around the country.

While GSK anticipates additional filings, even the current level of litigation would benefit from transfer and coordinated proceedings, given the allegations of these complaints. *See In re First Nat'l Collection Bureau, Inc., Tel. Consumer Prot. Act (TCPA) Litig.*, 11 F. Supp. 3d 1353, 1354 (J.P.M.L. Apr. 8, 2014) ("Although there are relatively few parties and actions at present, efficiencies can be gained from having these actions proceed in a single district," such as "eliminat[ing] duplicative discovery; prevent[ing] inconsistent pretrial rulings . . . and conserv[ing] the resources of the parties, their counsel and the judiciary."); *In re Nutramax Cosamin Mktg. & Sales Practices Litig.*, 988 F. Supp. 2d 1371, 1371–72 & n.2 (J.P.M.L. 2013) (creating multidistrict litigation for three pending actions involving, similar to the present Zofran® actions, claims of false and misleading marketing of nutritional supplements); *In re: Zurn Pex Plumbing Products Liability Litigation*, 572 F.Supp.2d 1380, 1381 (J.P.M.L. 2008) (granting transfer and consolidation of three cases and six potential tag-alongs because of the "overlapping and, often, nearly identical factual allegations that will likely require duplicative discovery and motion practice. Centralizing these actions under Section 1407 will ensure streamlined resolution of this litigation to the overall benefit of the parties and the judiciary."); *In re Amoxicillin Patent & Antitrust Litig.*, 449 F. Supp. 601, 603 (J.P.M.L. 1978) (granting transfer and consolidation of three cases "[b]ecause of the presence of complex factual questions and the strong likelihood that discovery concerning these questions will be both complicated and time-

consuming, we rule that transfer under Section 1407 is appropriate at the present time even though only three actions are presently involved.").

In sum, transfer of these actions would serve the convenience of the parties and eliminate duplicative discovery, saving the parties—and the courts—significant time, effort, and money.

C. Transfer Will Promote the Just and Efficient Conduct of These Actions.

The Panel recognizes multiple factors as informing whether the just and efficient conduct of a litigation will be advanced by transfer, including: (i) avoidance of conflicting rulings in various cases; (ii) prevention of duplication of discovery on common issues; (iii) avoidance of conflicting and duplicative pretrial conferences; (iv) advancing judicial economy; and (v) reducing the burden on the parties by allowing division of workload among several attorneys. *See, e.g.*, *In re: Endangered Species Act Section 4 Deadline Litig.*, 716 F.Supp.2d 1369, 1369 (J.P.M.L. 2010); *In re Bristol Bay, Alaska, Salmon Fishery Antitrust Litigation*, 424 F. Supp. 504, 506 (J.P.M.L. 1976).

All of these factors will be advanced by transfer here. As the litigation stands now, there are twelve federal cases spread across ten jurisdictions—Massachusetts, Montana, Alabama – Northern District, Alabama – Southern District, Arkansas, Louisiana – Eastern District, Louisiana – Western District, New Jersey, Ohio, and Texas. Plaintiff counsel advertising suggests more cases will be filed in the future.[8] At least sixteen different plaintiffs' firms from

[8] Publicly available sources reflect that plaintiffs' counsel are aggressively advertising for more plaintiffs across the United States. *See, e.g.*, http://www.silversteingroup.net/mass-tort-ad-watch-blog (observing "Monthly mass tort ad spending targeting the anti-nausea drug Zofran and its manufacturer GlaxoSmithKline, increased by over 8,000% in February," and "[t]wenty-five law firms sponsored over 1,300 ads featuring Zofran last month . . . .") (last accessed June 7, 2015). Moreover, it is noteworthy that much of the advertising has contained inaccurate statements and misrepresentations concerning Zofran®, its regulatory history, and the state of the science on general causation—so much so that GSK has been forced to send numerous "cease

around the country represent plaintiffs in these cases. Under this *status quo*, ten different federal district courts will be ruling on the many common factual and legal issues presented in these cases. The presence of numerous counsel, plaintiffs, and courts currently involved in this litigation in every region of the country creates a clear risk of conflicting rulings, with the potential to generate significant confusion and conflict among the parties, as well as inconsistent obligations on the defendant.

The prospect of inconsistent rulings also encourages forum and judge shopping (including, for example, manipulation of non-congruent discovery limits, approaches to electronically stored information, and protective order issues). By contrast, a single MDL judge coordinating pretrial discovery and ruling on pretrial motions in all of these federal cases at once will help reduce witness inconvenience, the cumulative burden on the courts, and the litigation's overall expense, as well as minimizing this potential for conflicting rulings. *In re: Xarelto (Rivaroxaban) Prods. Liab. Litig.*, 2014 WL 7004048, at *1 ("Issues concerning the development, manufacture, regulatory approval, labeling, and marketing of Xarelto thus are common to all actions. Centralization will eliminate duplicative discovery; prevent inconsistent pretrial rulings; and conserve the resources of the parties, their counsel and the judiciary."); *In re Tylenol Mktg., Sales Pracs. and Prods. Liab. Litig.*, 936 F.Supp.2d at 1379 ("Centralization will . . . prevent inconsistent pretrial rulings (on *Daubert* issues and other matters) . . . .").

Transfer also will reduce the burden on the parties by allowing more efficient and centralized divisions of workload among the numerous attorneys already involved in this litigation, as well as those who join later. Plaintiffs themselves will reap efficiencies from being able to divide up the management and conduct of the litigation as part of a unified MDL process,

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and desist" letters to plaintiff personal injury firms requesting that they edit their website and other solicitations (and many have done so).

through a plaintiffs' steering committee or similar mechanism, instead of each plaintiffs' firm separately litigating its own cases on distinct and parallel tracks. *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 173 F.Supp.2d at 1379; *In re Tylenol Mktg., Sales Pracs. and Prods. Liab. Litig.*, 936 F.Supp.2d at 1379 ("Centralization will . . . conserve the resources of the parties, their counsel, and the judiciary.").

Accordingly, transfer to a single district court is appropriate for the just and efficient resolution of these cases.

D. The Proper Transferee Forum Is the Docket of Either the Honorable Cynthia M. Rufe or the Honorable Paul S. Diamond in the Eastern District of Pennsylvania.

The Eastern District of Pennsylvania best meets the objective of a forum that advances "the convenience of the parties and will promote the just and efficient conduct" of these actions. 28 U.S.C. § 1407. The Eastern District of Pennsylvania best meets these requirements because:

1. GSK maintains co-centralized U.S. pharmaceutical operations and offices in the Eastern District of Pennsylvania—in Philadelphia, Pennsylvania.[9] GSK employs well over 1,000 individuals in the Philadelphia metropolitan area and occupies over 200,000 square feet of office space in the Philadelphia Navy Yard Corporate Center. GSK's facility at the Philadelphia Navy Yard houses its marketing, communications, finance, IT, human resources, sales, administration, and other centralized functions. A significant portion of the witnesses and documents relating to the clinical development, regulatory history, and sales and marketing of Zofran® are likely located in the District. In light of these facts, the Eastern District of Pennsylvania is the natural and most efficient location for these coordinated proceedings.

[9] GSK's Philadelphia Navy Yard facility is one of its two locations in the United States where it maintains centralized pharmaceutical operations and offices, along with a large presence in the Research Triangle Park located in Raleigh-Durham, North Carolina.

The Panel frequently considers these criteria decisive. *See, e.g.*, *In re Benicar (Olmesartan) Prods. Liab. Litig.*, — F. Supp. 3d —, 2015 WL 1518503, at *2 (J.P.M.L. Apr. 3, 2015) (selecting District of New Jersey for multidistrict proceedings because "defendants, are headquartered in that district, and thus many witnesses and relevant documents are likely to be found there."); *In re Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prods. Liab. Litig.*, 53 F. Supp. 3d 1379, 1381 (J.P.M.L. 2014) (establishing MDL in Southern District of Indiana in part because "[defendant] Cook is headquartered in Indiana, where relevant documents and witnesses are likely to be found."); *In re: LivingSocial Marketing and Sales Practices Litig*., 807 F. Supp. 2d 1379, 1380 (J.P.M.L. 2011) ("LivingSocial is headquartered in the District of Columbia and, accordingly, the majority of relevant documents and witnesses are located there."); *In re: Google Inc. Street View Elec. Commc'ns Litig.*, 733 F. Supp. 2d 1381, 1382 (J.P.M.L. 2010) (transferring MDL proceedings to Northern District of California given that "The sole defendant, Google, is headquartered there, and most relevant documents and witnesses are likely located there."); *In re Apple iPod Nano Products Liab. Litig.*, 429 F. Supp. 2d 1366, 1368 (J.P.M.L. 2006) ("The Northern District of California is a likely source of relevant documents and witnesses inasmuch as Apple's headquarters are located there."); *In re Medtronic, Inc. Implantable Defibrillators Prods. Liab. Litig.*, 408 F. Supp. 2d 1351, 1352 (J.P.M.L. 2005) ("Because Medtronic has its headquarters within the District of Minnesota, relevant discovery may be found there."); *In re St. Jude Med., Inc. Silzone Heart Valve Prods. Liab. Litig.*, 2001 WL 36292052, at *2 (J.P.M.L. Apr. 8, 2001) (transferring "to the situs of the headquarters of the sole defendant in all actions [because] the district is likely to be a substantial source of witnesses and documents subject to discovery").

2. The Eastern District of Pennsylvania has significant experience handling multidistrict litigation involving pharmaceutical and medical device products liability actions. *See, e.g., In re Effexor Prods. Liab. Litig.*, 959 F.Supp.2d 1359 (J.P.M.L. 2013); *In re Tylenol Mktg., Sales Pracs. and Prods. Liab. Litig.*, 936 F.Supp.2d 1379 (J.P.M.L. 2013); *In re Zoloft Prods. Liab. Litig.*, 856 F.Supp.2d 1347 (J.P.M.L. 2012); *In re Avandia Mktg., Sales Pracs. and Prods. Liab. Litig.*, 543 F.Supp.2d 1376 (J.P.M.L. 2008); *In re Diet Drugs Prods. Liab. Litig.*, 990 F.Supp. 834 (J.P.M.L. 1998); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL No. 1014 (J.P.M.L. Aug. 4, 1994).

Specifically, GSK requests transfer to either Judge Cynthia M. Rufe or Judge Paul S. Diamond in the Eastern District of Pennsylvania. The Panel has recognized that Judge Rufe is "an experienced transferee judge" with "the ability to handle" multidistrict litigations. *In re Zoloft Prods. Liab. Litig.*, 856 F.Supp.2d at 1348. Judge Rufe is well versed in the nuances of multidistrict litigation, and GSK anticipates that she will justly and efficiently manage this litigation based on both her past and current experience. Likewise, Judge Diamond is fully qualified to handle this multidistrict litigation. He is an experienced jurist who has handled complex litigation including class actions and pharmaceutical industry litigation. His previous private law practice involved complex, multi-party cases. His work on the Advisory Committee on the Federal Rules of Civil Procedure is a further indication of his ability to effectively guide consolidated pretrial proceedings in this litigation.

At its core, this litigation involves allegations that plaintiffs' ingestion of prescription Zofran® during their pregnancies resulted in their children suffering from various congenital birth defects. Judge Rufe occupies an advantageous position for guiding this litigation because she currently oversees two other multidistrict proceedings involving alleged birth defects from

ingestion of prescription drugs during pregnancy. *See In re Effexor Prods. Liab. Litig.*, 959 F.Supp.2d at 1360 (citing Judge Rufe's experience with "parallel" claims involving birth defects and potential overlap with Zoloft litigation as grounds for transfer of Effexor multidistrict litigation to Judge Rufe); *In re Zoloft Prods. Liab. Litig.*, 856 F.Supp.2d 1347. Judge Diamond is also a jurist familiar with some of these issues by virtue of his experience presiding over litigation involving thalidomide birth defect claims brought from 2011-13. While these other matters involve different medications, the Panel previously has recognized that transferring actions to a judge who has already presided over litigation that may involve some similar issues is "likely to benefit the parties here, and to otherwise facilitate the just and efficient conduct of this litigation." *See In re Pella Corp. Architect and Designer Series Window Mktg., Sales Pracs. and Prods. Liab. Litig.*, 996 F.Supp.2d 1380, 1383 (J.P.M.L. 2014) (transferring actions to same judge already presiding over similar litigation "involving defects in various different windows (albeit windows manufactured by a different entity)"); *In re Pradaxa (dabigatran etexilate) Prods. Liab. Litig.*, 883 F.Supp.2d 1355, 1356 (J.P.M.L. 2012) ("Judge Herndon, an experienced MDL judge, has deftly presided over *In re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices & Products Liability Litigation*, 655 F.Supp.2d 1343 (J.P.M.L.2009), another large pharmaceutical products liability litigation.").

3. The Eastern District of Pennsylvania is geographically accessible to counsel and parties involved in this litigation. *See In re Impulse Monitoring, Inc. Aetna Intraoperative Monitoring Servs. Claims and ERISA Litig.*, 53 F.Supp.3d 1376, 1377 (J.P.M.L. 2014) (holding Eastern District of Pennsylvania is a "readily accessible district" for purposes of centralizing multidistrict litigation). As noted, the District is geographically central to GSK's major operational and research facilities in the United States, which are located in the District and in

Research Triangle Park, North Carolina, as well as multiple other GSK locations across the Eastern United States. Also, to the extent that any additional witnesses and documents may be located at facilities outside Pennsylvania, the Eastern District of Pennsylvania is centrally located and accessible such that locating multidistrict proceedings there will facilitate any needed discovery in these proximate locations. *See infra* II.D.1. Expert witnesses and counsel also would find Philadelphia a convenient location to reach for hearings and any possible bellwether trials. *See, e.g., In re Collecto, Inc. Tel. Cons. Prot. Act Litig.*, 999 F.Supp.2d 1373, 1374 (J.P.M.L. 2014) (transferring multidistrict litigation to District of Massachusetts because defendant's headquarters located there and "[t]his district also provides a geographically convenient forum for this nationwide litigation."); *In re Maxim Integrated Prods., Inc. Patent Litig.*, 867 F.Supp.2d 1333, 1336 (J.P.M.L. 2012) (transferring proceedings to Western District of Pennsylvania in part because district "is relatively geographically accessible").

4. Given the potential importance of federal-state coordination and cooperation, the Eastern District of Pennsylvania is particularly well suited to handle the Zofran® litigation given its history of working with the Complex Litigation Center established by the Philadelphia Court of Common Pleas. There are currently five state court claims or actions in this litigation pending against GSK, including two in the Philadelphia Court of Common Pleas. GSK anticipates that additional state court cases will be filed, and because GSK maintains a large presence in the Philadelphia metropolitan area, they may be filed in the Philadelphia Court of Common Pleas. Regardless of whether or how many state court actions ultimately may be filed in Philadelphia versus in other states, the District's experience in handling federal-state coordination of mass tort actions will be valuable in ensuring proper coordination with state court actions filed across the

United States. Centralizing this multidistrict litigation in the Eastern District of Pennsylvania will help facilitate the efficient disposition of parallel state court actions.

5. While no constituent action is currently pending in the Eastern District of Pennsylvania, the Panel regularly locates multidistrict litigation in districts for other reasons, including where a substantial number of witnesses and documents are located, despite the lack of a pending action in that forum. *See, e.g., In re Health Management Assos., Inc. Qui Tam Litigation (No. II)*, 11 F. Supp. 3d 1346, 1348 n.6 (J.P.M.L. 2014) ("Although no constituent action currently is pending in the District of District of Columbia, that is no impediment to its selection as transferee district."); *In re Nutramax Cosamin Mktg. and Sales Pracs. Litig.*, 988 F.Supp. 2d 1371, 1372 (J.P.M.L. 2013) (locating MDL in district even though no constituent action pending there because "[t]his district provides a geographically central forum for this nationwide litigation, and is convenient and accessible for the parties and witnesses. Nutramax is headquartered in the district, and thus relevant documents and potential witnesses are likely to be found there."); *In re Pella Window Mktg.*, 996 F.Supp.2d at 1382 ("Although no constituent action currently is pending in that district, that is no impediment to its selection as transferee district."); *In re Biomet M2A Magnum Hip Implant Prods. Liab. Litig.*, 896 F.Supp.2d 1339, 1340 (J.P.M.L. 2012) (granting transfer to Northern District of Indiana "even though no party suggested it and no plaintiff has yet filed a case there" because, *inter alia*, "many of the relevant documents and witnesses [were] likely found there"; and district was "relatively accessible" and centrally located); *In re: BP p.l.c. Secs. Litig.*, 734 F.Supp.2d 1376, 1379 (J.P.M.L. 2010) ("[T]hat no constituent action is currently pending in the Southern District of Texas is not an impediment to its selection as the transferee district."); *In re Southwestern Life Ins. Co. Sales Pracs. Litig.*, 268 F.Supp.2d 1377, 1378 (J.P.M.L. 2003) (holding that "[e]ven though no

constituent action is currently pending in the Northern District of Texas, we are persuaded that this district is an appropriate transferee forum for this litigation" where "relevant documents and witnesses are likely located there at or near Southwestern Life's Dallas home office."). It is also noteworthy that none of the federal actions have advanced significantly such that it would be inefficient to transfer them to this district. *In re: BP p.l.c. Secs. Litig.*, 734 F.Supp.2d at 1379 ("Since all the actions in this docket are at an early stage, transfer to another district should not be unduly disruptive.").

III. CONCLUSION

GSK respectfully requests that the Panel transfer the Zofran® actions described herein, as well as any similar "tag along" cases subsequently filed, to the Eastern District of Pennsylvania, and specifically to either Judge Cynthia M. Rufe or Judge Paul S. Diamond, for coordinated pretrial proceedings.

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Respectfully submitted,

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