BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: Zofran (Ondansetron) Products Liability Litigation	:	**MDL No. 2657**

RESPONSE OF PLAINTIFF TOMISHA LECLAIR TO DEFENDANT'S MOTION FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. § 1407, AND JPML RULE 7.2, FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

Comes now, Plaintiff Tomisha LeClair, individually and on behalf of her minor child A.S., the named plaintiff in *LeClair v. GlaxoSmithKline LLC*, filed in the U.S. District Court for the District of Massachusetts ("Plaintiff"), and respectfully submits this response to the motion of Defendant GlaxoSmithKline LLC ("GSK" or "Defendant") to transfer pending and future Zofran® (ondansetron) product liability actions for coordinated pretrial proceedings.

Plaintiff agrees with GSK that the Panel should transfer the actions for coordinated pretrial proceedings under Section 1407, but Plaintiff disputes GSK's proposed forum. MDL coordination is appropriate because the cases proposed for transfer all arise from children born with birth defects after having been exposed to Zofran when their mothers innocently ingested the drug during pregnancy. Although 12 Zofran actions were pending when GSK petitioned the Panel for MDL coordination, there are now approximately 31 actions involving more than two dozen law firms. This renders informal coordination impractical despite the best effort of all counsel involved. The difficulties in coordination will increase with additional case filings.

Although Plaintiff agrees that MDL coordination is warranted, Plaintiff disagrees with GSK's proposal to transfer the actions to the Eastern District of Pennsylvania in Philadelphia,

Pennsylvania, which has no pending cases. GSK asserts that Philadelphia would be convenient for GSK because one of its two main offices is there. Several more appropriate venues, however, such as the District of Massachusetts, the Northern Districts of Ohio and California, and the Eastern District of Louisiana, have pending cases and offer capable jurists with substantial MDL experience. As discussed below, the District of Massachusetts has the strongest nexus to this litigation, and it is the forum with the most advanced Zofran litigation.

STATEMENT OF FACTS

I. PERTINENT BACKGROUND ON ZOFRAN

A. LIMITED FDA APPROVAL OF ZOFRAN

Zofran is a prescription drug approved by the U.S. Food and Drug Administration for the prevention of chemotherapy-induced nausea and vomiting, radiation therapy-induced nausea and vomiting and post-operative nausea and/or vomiting. The FDA has never approved Zofran to treat morning sickness or any other condition in pregnant women. GSK, however, has illegally marketed Zofran as a safe and effective treatment for morning sickness in pregnant women. GSK never conducted any studies to establish the safety or efficacy of Zofran for that sensitive population, and, in fact, it excluded pregnant women from its clinical trials used to support its application for FDA approval.

B. GSK'S FRAUDULENT OFF-LABEL PROMOTION OF ZOFRAN FOR THE TREATMENT OF MORNING SICKNESS IN PREGNANT WOMEN

At all relevant times, GSK has known that the safety of Zofran for use in human pregnancy has not been established. Before its patents expired in 2006, Zofran was one of the most expensive drugs available in the U.S. market. With more than six million annual pregnancies in the United States since 1991 and an estimated 70-85% incidence of pregnancy related nausea, the absence of a prescription medication that was FDA approved to treat

pregnancy related nausea presented a lucrative business opportunity for GSK to expand its sales of Zofran. GSK seized that opportunity.

At least as early as January 1998, despite available evidence showing that Zofran presented an unreasonable risk of harm to babies exposed to Zofran prenatally, GSK launched a marketing scheme to promote Zofran to obstetrics and gynecology (Ob/Gyn) healthcare practitioners across the country as a safe and effective treatment for morning sickness in pregnant women. In support of its off-label marketing efforts, GSK offered and paid substantial remuneration to healthcare providers and "thought leaders" to induce them to promote and prescribe Zofran to treat morning sickness.

1. FDA Warning Letter to GSK

On March 9, 1999, the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC) notified GSK that the FDA had become aware of GSK's promotional materials for Zofran that violated the Federal Food Drug and Cosmetic Act and its implementing regulations. The FDA reviewed the promotional material and determined that "it promotes Zofran in a manner that is false or misleading because it lacks fair balance."

GSK's off-label marketing at issue included promotional statements relating to the effectiveness of Zofran, such as "Zofran Can," "24-hour control," and other promotional messages. But the promotional labeling failed to present any information regarding the risks associated with use of Zofran. In its March 9, 1999 letter, the FDA directed GSK to "*immediately cease distribution of this and other similar promotional materials for Zofran that contain the same or similar claims without balancing risk information*."

GSK disregarded this FDA mandate. For example, as early as 2000, GSK's marketing materials in widely circulated Ob/Gyn trade journals misleadingly emphasized Zofran's "Pregnancy Category B" designation as suggestive of safety for use in pregnancy. This

created a false impression on the part of healthcare practitioners that the safety of Zofran use in pregnancy had been established. GSK's materials failed to disclose its internal information showing the risks of birth defects associated with Zofran treatment during pregnancy. Furthermore, in contrast to GSK's promotion of Zofran for pregnancy nausea in the United States, in Canada, GSK recommends against use of Zofran during pregnancy, noting, "The safety of ondansetron for use in human pregnancy has not been established. Ondansetron is not teratogenic in animals. However, as animal studies are not always predictive of human response, the *use of ondansetron in pregnancy is not recommended*." (Emphasis added).

2. GSK's Misleading Promotion of Zofran to Obstetricians and Gynecologists for Treating Morning Sickness

When the FDA first approved Zofran to treat cancer patients, GSK's Oncology Division sales force had primary responsibility for marketing and promoting the drug. Beginning in at least January 1998, GSK set out to expand its Zofran sales to obstetricians and gynecologists ("Ob/Gyn's") by promoting Zofran as an established safe and effective treatment for morning sickness. GSK's initial strategy in this regard required its sales force to create new relationships with Ob/Gyn's by adding them as "new accounts." While this strategy had some success, it was inefficient compared to a revised promotional strategy that would enable GSK to leverage its Consumer Healthcare Division's already established relationships with Ob/Gyn's. Thus, GSK's Oncology Division began partnering with GSK's Consumer Healthcare Division to promote Zofran.

Specifically, in or about 2001, GSK's Oncology Division finalized a co-marketing agreement with GSK's Consumer Healthcare division under which sales representatives from GSK's Consumer Healthcare division would market Zofran to Ob/Gyn's. At the time, GSK's Consumer Healthcare sales force already had established relationships with, and routinely called

on, Ob/Gyn's to promote and provide samples of another GSK product, Tums®, specifically for the treatment and prevention of heartburn during pregnancy. GSK's network for promoting Tums afforded it an efficient additional avenue for promoting Zofran for use in pregnancy.

GSK's primary purpose in undertaking this co-marketing arrangement was to promote Zofran to Ob/Gyn's during GSK's Consumer Healthcare sales force's visits to their offices. Although some Ob/Gyn's performed surgeries and could order Zofran for post-operative nausea, the central focus of GSK's co-marketing effort was to promote Zofran for the much more common condition of morning sickness in pregnancy, thus increasing sales and profits. GSK's Zofran sales representatives received incentive-based compensation that included an annual salary and a quarterly bonus. The bonus amount was determined by each sales representative's performance in the relevant market and whether s/he attained or exceeded quarterly sales quotas. The more Zofran sold by a GSK sales representative or prescribed by a provider in that representative's sales territory, the greater his or her compensation and other incentives would be. As a result of GSK's fraudulent marketing campaign, Zofran achieved blockbuster status by 2002 and became the number one most prescribed drug for treating morning sickness in the United States. In 2002, sales of Zofran in the United States totaled $1.1 billion, while global Zofran sales were approximately $1.4 billion in 2002.

3. GSK's Settlements with the Department of Justice for Unlawfully Promoting and Offering Financial Incentives to Doctors to Prescribe Zofran for Use in Pregnancy

In 2012, GSK entered a civil settlement with the United States to resolve allegations that GSK:

> **(a) "promoted the sale and use of Zofran for a variety of conditions other than those for which its use was approved as safe and effective by the FDA (including hyperemesis and pregnancy-related nausea)"**
>
> **(b) "made and/or disseminated unsubstantiated and false representations about the safety and efficacy of Zofran concerning the uses described in subsection (a) [hyperemesis and pregnancy-related nausea]"**
>
> **(c) "offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zofran."**[1]

The settlement covered improper promotional conduct that was part of a plan to maximize highly profitable Zofran sales without due regard to laws designed to protect patient health and safety. As part of the same plan, GSK's promoted financial incentives to potential Zofran prescribers.

In 2005, this practice led to a separate $149 million settlement between GSK and the United States.[2] Examples of this marketing include the following: In or around 1993, a GSK marketing document sent to all of its sales and marketing personnel nationwide advised that they should emphasize the financial benefits to the providers from prescribing Zofran. Specifically, "[b]y using a 32 mg bag [of Zofran], the physician provides the most effective dose to the patient and increases his or her profit by $___ in reimbursement." GSK's marketing focus on profits to the prescribers misleadingly aimed to shift prescribers' focus from the best interests of patients to personal profit. For example, GSK marketed

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[1] GSK Settlement Agreement, at p. 5 (June 27, 2012), Attached as Exhibit A.

[2] FDA Enforcement Manual Newsletter, *GSK Pays $149 Million To Resolve AWP Investigation Over Marketing of Two Antinausea Pharmaceuticals*, (Nov. 2005), Attached as Exhibit B.

Zofran beginning in the 1990s as "convenient" and offering "better reimbursement" to prescribers. GSK detailed this plan in a marketing document for its Zofran premixed IV bag entitled "Profit Maximization – It's in the Bag."

C. THE RISK OF BIRTH DEFECTS FROM PRENATAL ZOFRAN EXPOSURE

Since at least 1992, GSK has had mounting evidence showing that Zofran presents an unreasonable risk of harm to babies who are exposed to the drug during pregnancy. GSK has been aware that Zofran readily crosses mammalian and human placental barriers during pregnancy. At least as early as 1992, GSK began receiving reports of birth defects associated with the use of Zofran by pregnant women. By 2000, GSK had received at least 32 reports of birth defects arising from Zofran treatment in pregnant women. In addition, three recent epidemiological studies have reported a two-fold, statistically significant increase in the incidence of specific birth defects in children of mothers who ingested Zofran during pregnancy compared with unexposed children.

II. POSTURE OF PENDING ZOFRAN CASES

There are 33 actions filed in different federal courts throughout the country with the involvement of more than two dozen law firms. Of these, five cases are pending in the Northern District of Alabama, Southern Division; four cases are pending in the U.S. District Court for the District of Massachusetts; three cases pending in the Northern District of Ohio; two cases in the Southern District of Illinois; and one case in each of the following Districts: the Northern District of California; the Southern District of Ohio; the Northern District of Alabama, Eastern Division; the Southern District of Alabama; the District of Montana, Billings Division; the Eastern District of Texas, Texarkana Division; the Eastern District of Arkansas, Western Division; the Western District of Louisiana; the Eastern District of Louisiana; the Southern District of New York; the

District of Southern Texas; the Southern District of Mississippi; and the District of Southern Florida. Similar actions will be filed in or removed to federal courts in the future.

ARGUMENT

III. TRANSFER AND PRETRIAL COORDINATION OF THE ZOFRAN ACTIONS WILL PROMOTE THE GOALS OF 28 U.S.C. § 1407.

Transfer under Section 1407 is appropriate where: (i) "civil actions involving one or more questions of fact are pending in different districts;" (ii) transfer and coordination "will promote the just and efficient conduct of such actions"; and (iii) transfer and coordination will serve "the convenience of parties and witnesses." 28 U.S.C. §1407(a). As set forth below, each requirement is satisfied.

A. THE ACTIONS INVOLVE COMMON ISSUES OF FACT.

The cases proposed for transfer all arise from children born with birth defects after having been exposed to Zofran when their mothers innocently ingested the drug during pregnancy. The cases present complex, material and disputed questions concerning the development, testing, manufacturing and marketing of Zofran, as well as GSK's knowledge regarding the drug's adverse effects in prenatally exposed children, and GSK's responses to that knowledge. These questions are common among all of the cases proposed for transfer and center on the following:

- GSK's pre-market investigation of Zofran's potential to cause birth defects;
- GSK's post-marketing surveillance of Zofran's potential to cause birth defects;
- GSK's knowledge of and responses to post-market reports of Zofran-related birth defects;
- GSK's warnings to healthcare providers and consumers concerning the risks of Zofran use during pregnancy;
- The nature and extent of the GSK's marketing of Zofran for use in pregnancy;
- The nature and extent of the GSK's offering of financial incentives to physicians to induce them to prescribe Zofran;
- GSK's communications with its sales and marketing personnel, consultants, and key opinion leaders engaged to promote Zofran;
- GSK's knowledge of prescriptions of Zofran for treating pregnancy related nausea;

The cases also presents complex medical and legal issues concerning Zofran's propensity to cause specific birth defects, the type and severity of the damages to children exposed to Zofran *in utero*; and legal ramifications of GSK's misleading promotion of Zofran for morning sickness without FDA consideration or approval of the drug for that condition.

Although the actions present some individualized factual issues, "Section 1407 does not require a complete identity or even a majority of common factual issues as a prerequisite to centralization." *In re Zimmer Durom Hip Cup Prods. Liab. Litig.*, 717 F. Supp. 2d 1376, 1378 (J.P.M.L. 2010). Instead, where, as here, the underlying factual and legal allegations are sufficiently similar, "[t]ransferee judges have demonstrated the ability to accommodate common and individual discovery tracks, gaining the benefits of centralization without delaying or compromising consideration of claims on their individual merits." *In re Yamaha Motor Corp. Rhino ATV Prods. Liab. Litig.*, 597 F. Supp. 2d 1377, 1378 (J.P.M.L. 2009). Courts have applied this dual discovery approach in other pharmaceutical product liability actions. *See, e.g.*, *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 655 F. Supp. 2d 1343, 1344 (J.P.M.L. 2009); *In re Vioxx*, 360 F. Supp. 2d 1352, 1353-54 (J.P.M.L. 2005).

B. CONSOLIDATION WILL PROMOTE EFFICIENCY.

Because the cases share common questions of fact and implicate overlapping discovery, coordination before a single judge is the most efficient way to proceed. In each of the 33 pending actions, plaintiffs will likely seek much of the same discovery from GSK. MDL coordination will avoid the costly duplication of efforts and inconsistent rulings that would otherwise occur. The Panel has consistently recognized that Section 1407 coordination is the

preferred way to manage individual lawsuits that raise similar questions regarding a defendant's development, design, and testing of a particular prescription medication or device.[3]

C. CONSOLIDATION WILL SERVE THE CONVENIENCE OF THE PARTIES AND WITNESSES.

MDL coordination will reduce the cost of the litigation and enable the parties to more effectively focus resources on the core issues in the litigation. Furthermore, creation of the MDL will enable the parties to maximize these benefits. No discovery of GSK has taken place, and no dispositive motion practice has occurred. These factors favor MDL consolidation, which will allow the parties, counsel and an MDL judge to develop a coordinated discovery and case management plan. *See In re: Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 780 F. Supp. 2d 1379, 1382 (J.P.M.L. 2011) ("Since all the actions in this docket are at an early stage, transfer to another district should not be disruptive.").

In sum, coordination of these actions is appropriate because it would avoid duplicative discovery, prevent inconsistent pretrial rulings by multiple judges and conserve the resources of the parties, their counsel and the judiciary.

IV. THE ZOFRAN MDL SHOULD BE VENUED IN MASSACHUSETTS.

Several considerations favor transferring Zofran cases for pre-trial proceedings to the District of Massachusetts: (i) Boston has the strongest nexus to the Zofran litigation; (ii) the Honorable F. Dennis Saylor, IV has already begun to address initial case management matters in Plaintiff's action and is presiding in two other related Zofran cases; and (iii) Boston is a convenient forum.

[3] *See, e.g., In re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prods. Liab. Litig.*, 787 F. Supp. 2d 1358, 1360 (J.P.M.L. 2011); *In re DePuy Orthopaedics, Inc., ASR Hip Implant Prods. Liab. Litig.*, 753 F. Supp. 2d 1378 (J.P.M.L. 2010); *In re Prempro Prods. Liab. Litig.*, 254 F. Supp. 2d 1366, 1367 (J.P.M.L. 2003); *In re A.H. Robins Co. "Dalkon Shield" IUD Prods. Liab. Litig.*, 406 F. Supp. 540, 542 (J.P.M.L. 1975).

A. THE DISTRICT OF MASSACHUSETTS HAS THE STRONGEST NEXUS TO THE ZOFRAN LITIGATION.

The District of Massachusetts is where GSK was prosecuted and entered two separate settlements with the United States based on its illegal marketing of Zofran, one in 2005 for $150 million and another in 2012, when GSK paid a record $1 billion to the United States for illegally marketing various drugs, including Zofran for pregnancy related nausea, as part of a civil settlement with the U.S. Department of Justice. That District also embraces the Boston University's Children's hospital, where Plaintiff's child was treated and where other similarly situated children from around the country travel to be treated for Zofran-related birth defects. In addition, the Boston University Slone Epidemiology Center and the Massachusetts Department of Health have conducted epidemiology studies in that District reporting Zofran's risk of birth defects. Finally, the District is accessible to the parties, important third-party witnesses, and is a convenient middle ground between GSK's U.S. operations and the company's operations in England, where, according to GSK's publicly available new drug application files, GSK's parent company participated in the design, testing, and manufacturing of Zofran and thus generated evidence relevant to this litigation. For all these reasons, the District of Massachusetts has the strongest nexus to the Zofran litigation.

B. THE DISTRICT OF MASSACHUSETTS HAS THE MOST PENDING ZOFRAN CASES.

The District Court of Massachusetts also has the second most pending Zofran cases with four: *Tomisha LeClair individually and on behalf of A.S. v. GSK, LLC,* 1:15-cv-10429-FDS (D. Mass. Feb. 16, 2015) (the "*LeClair* case"), *Leila Benzaghou and Toufik Bourkiche, individually and on behalf of H.B. v. GSK, LLC,* 1:15-cv-12973 (D. Mass. July 17, 2015) (the "*Benzaghou* case"), and *Kim Duong v. GSK*, 1:15-cv-11672-IT (D. Mass. April 17, 2015) (the "*Duong* case"); *Beth Botelho and Scott Mello, Individually and as Parents and Natural Guardians of M.M, a*

Minor v. GlaxoSmithKline, LLC, No. 1:15-cv-13002 (D. Mass. July XX, 2015) (the "*Botelho*" case). The *LeClair*, *Benzaghou* and *Botelho* cases are before Judge Saylor, and the other likely will soon be as well. This factor, too, favors transfer there.

C. JUDGE SAYLOR HAS THE MOST CASES, THE MOST ADVANCED PENDING CASE, AND THE SKILL AND EXPERIENCE TO MANAGE A ZOFRAN MDL.

The Honorable F. Dennis Saylor, IV has more Zofran cases than any other judge. Plaintiff anticipates that initial case management orders will be issued in August 2015. Judge Saylor is a highly skilled and experienced jurist. This Panel has previously expressed its confidence in Judge Saylor's ability to "steer [an MDL litigation] on a prudent course." *See* Order dated Jan. 12, 2013, *In re New England Compounding Pharmacy, Inc., Prods. Liab. Litig.*, MDL No. 2419 (D. Mass.).[4] He received a Bachelor of Science degree from Northwestern University in 1977 and a law degree from Harvard Law School in 1981. Before his appointment to the bench, Judge Saylor spent 17 years in private practice in Boston. He also served as an Assistant U.S. Attorney for the District of Massachusetts for three years and as Special Counsel and Chief of Staff to the Assistant Attorney General in the Criminal Division of the U.S. Department of Justice in Washington, D.C. Given his qualifications and experience, Judge Saylor is well qualified to manage a Zofran MDL.

D. THE DISTRICT OF MASSACHUSETTS IS A CONVENIENT VENUE.

Boston is a conveniently located forum. There are numerous daily flights to and from Boston and most major cities, including Philadelphia, which GSK has identified as the "likely" location of some of its witnesses.[5] Relevant evidence was generated in GSK's affiliate offices in England and Canada, making Boston a convenient middle ground for its various offices. In any

[4] Judge Saylor also is presiding in MDL 2375, *In re Body Science LLC Patent Litig.*, which currently includes six cases. *See* JPML, MDL Statistics Report – Distribution of MDL Dockets by District, at http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-July-15-2015.pdf

[5] *See* Def. Br. at 13.

event, the location of documents in many complex litigation matters should not be primary venue consideration in the current e-discovery age because the majority of document productions today are delivered in electronic format.[6]

E. THE FACT THAT ONE OF GSK'S OFFICES IS LOCATED IN PHILADELPHIA IS NOT A DISPOSITIVE FACTOR.

The location of a defendant's headquarters has been but one of many factors considered by the Panel and is far from the decisive factor as suggested by GSK. The Panel has transferred recent MDLs to venues outside of a defendant's corporate headquarters.[7] GSK misplaces reliance on several cases when it overemphasizes the significance of this factor.[8] Unlike in the

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[6] *See generally* The Sedona Conference, *The Sedona Principles: Best Practices Recommendations & Principles for Addressing Electronic Document Production*, at 1 (2d ed. 2007) ("The explosive growth and diversification of electronic methods for recording, communicating, and managing information has transformed the meaning of the term 'document.' While twenty years ago PCs were a novelty and email was virtually nonexistent, today more than ninety percent of all information is created in an electronic format."); *See generally* FED. R. CIV. P. 26(b)(2) advisory committee's note (2006) ("Electronic storage systems often make it easier to locate and retrieve information . . . .The volume of – and ability to search – much electronically stored information means that in many cases the responding party will be able to produce information from reasonably accessible sources that will fully satisfy the parties' discovery needs.")

[7] *See In re: Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Prods. Liab. Litig.(No. II)*, 997 F. Supp. 2d 1354, 1356 (J.P.M.L. 2014); *In re: Xarelto (Rivaroxaban) Prods. Liab. Litig.*, 65 F.Supp 3d 1402, 1405 (J.P.M.L. 2014); *In re: Am. Med. Sys., Inc., Pelvic Repair System Prods. Liab. Litig*., 844 F.Supp. 2d 1359, 1361 (J.P.M.L. 2012); *In re: ACTOS Prods. Liab. Litig.*, MDL No. 2299 (Aug. 3, 2012).

[8] *See* Def. Br. at 14. In each case cited, the Panel acknowledged considerations other than the location of the defendant's headquarters as supporting transfer to a particular district. *See 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 because centralization in that district "also likely will facilitate coordination with approximately 40 actions alleging injuries from the use of Benicar, Benicar HCT, or Azor that have been consolidated in the Superior Court of New Jersey Law Division before Judge Nelson Johnson"); *In re Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prods. Liab. Litig.*, 53 F. Supp. 3d 1379, 1380 (J.P.M.L. 2014) (although the MDL was established in the district where the defendant was headquartered, all parties agreed to the Southern District of Indiana because more than 50 percent of the pending cases were located there and almost all of them were before the judge who was ultimately assigned the MDL); *In re: LivingSocial Mktg. and Sales Practices Litig.*, 807 F. Supp. 2d 1379, 1380 (J.P.M.L. 2011) (choosing the District of District Columbia because the parties agreed it was the most appropriate forum, there was also a case pending in that district, and defendant was headquartered there); *In re: Google Inc. Street View Elec. Comc'ns Litig.*, 733 F. Supp. 2d 1381, 1382 (J.P.M.L. 2010) (choosing the Northern District of California because most of the responding parties supported that district and it is where the defendant was headquartered); *In re Apple iPod nano Prods. Liab. Litig.*, 429 F. Supp. 2d 1366, 1368 (J.P.M.L. 2006) (choosing the Northern District of California because all responding parties agreed on the forum, more than 50 percent of the actions were filed there, and it is where the defendants headquarters were located); *In re Medtronic, Inc., Implantable Defibrillators Prods. Liab. Litig.*, 408 F. Supp. 1351, 1352 (J.P.M.L. 2005) (choosing the District of Minnesota because the district "provides a centrally located forum for actions filed in several locations nationwide," it had two pending cases, and it is where the defendant was headquartered); *In re St. Jude, Inc., Silzone Heart Valves Prods. Liab. Litig.*, 2001 WL 36292052,

cases cited by GSK, here, no factor other than asserted convenience to GSK favors transfer to the Eastern District of Pennsylvania. Specifically, GSK asserts that it "maintains co-centralized U.S. pharmaceutical operations and offices in the Eastern District of Pennsylvania [and Raleigh-Durham, North Carolina]," and 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 this District." *See* Def. Br. at 13 & n. 9 (emphasis added).

GSK's assertion that the Eastern District of Pennsylvania is a convenient forum for GSK should not be assigned meaningful value in this case. ***First***, GSK has not asserted that its corporate headquarters are located in that district or even that a majority of its witnesses or documents are located there. ***Second***, on April 22, 2014, GSK's parent GlaxoSmithKline PLC (GSK) and Novartis AG (Novartis) entered an agreement for the sale of GSK's oncology business, including the Zofran product line.[9] According to Section 2.3.1 of the Amended and Restated Agreement of Sale, GSK has transferred its Zofran-related books and records to another company, Novartis:

> The Assets to be sold under this Agreement [include]:
> (i) the Transferred Books and Records[10];
> . . . .
> (iv) subject to and in accordance with Schedule 6, all Product Approvals (other than those relating to manufacturing), Product Expansions and all

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at *1-2 (Apr. 18, 2001) (choosing the District of Minnesota which had the most pending cases because it is geographically centrally located, its favorable caseload conditions, and is where the defendants were headquartered).

[9] The Amended and Restated Agreement of Sale (dated Nov. 21, 2014), Attached as Exhibit C.

[10] Under the Amended and Restated Agreement of Sale, "'Transferred Books and Records' means all books, ledgers, files, reports, plans, records, manuals and other materials (in any form or medium) to the extent of, or maintained predominantly for, the Business by the Seller's Group (other than emails), including (without limitation) all books, records and other materials relating to the research, development and pre-clinical trials for each of the Products and the Product Expansions but excluding: (i) any such items to the extent that: (A) they are related to any Excluded Assets or Excluded Liabilities, (B) they are related to any corporate, Tax, human resources or stockholder matters of the Seller or its Affiliates, (C) any Applicable Law prohibits their transfer or (D) any transfer thereof otherwise would subject the Seller or any of its Affiliates to any material liability; (ii) any laboratory notebooks to the extent containing research and development information unrelated to the Business; and (iii) in relation to Products other than the Key Products, any books and records that are more than 5 years old containing, in whole or in part, research and development information (other than any laboratory notebooks, books or records described in this paragraph iii) that are maintained for the Business by the Seller's Group)." *Id.* at 22 (emphasis added).

> other permits, licences, certificates, registrations, marketing or other authorisations or consents issued by a Governmental Entity Exclusively Related to the Business[11];
> (v) subject to and in accordance with Schedule 6, all Marketing Authorisation Data;
> (vi) all Commercial Information;
> (vii) all Medical Information;
> . . . .
> (ix) the Business Goodwill; and
> (x) all other property, rights and assets owned by any member of the Seller's Group and Exclusively Related to the Business at Closing (other than any property, rights and assets of the Business Sellers or the Company expressly excluded from the sale under this Agreement).[12]

Among the books and records that GSK transferred to Novartis appears to be its clinical trials and safety database for Zofran.[13] According to the Agreement, transferred books and records include materials related to the research, development and pre-clinical trials of each product, including Zofran.[14] Additionally, the Agreement contemplates Novartis's access to GSK's electronic "data room," which includes GSK's documents and information pertaining to its products.[15] Finally, Novartis's U.S. headquarters for its Institutes for BioMedical Research, is located in Cambridge, Massachusetts, where it maintains a 1.2 million square-foot pharmaceutical campus embraced by the District of Massachusetts. Novartis's Cambridge facility is home to its oncology research department, and Zofran is now one Novartis's oncology products.[16] Under these circumstances, the fact that GSK maintains an office in Philadelphia should not be entitled to significant weight.

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[11] Under the Amended and Restated Agreement of Sale, the term "'Business' means the business of the Seller's Group (including the Company) of research and development (including any studies or trials (whether or not undertaken with third parties)) relating to the Products and the Commercialization of the Products but excluding (i) the Manufacturing of the Products and (ii) the Seller Pipeline." *Id.* at p. 4. The term "Products" means the products set out under the heading "Products" in Part 1 of Schedule 1 of the Agreement, including Zofran products sold in the United States. *Id.* at 17.

[12] Amended and Restated Agreement of Sale, Ex. C, at pp. 28-29.

[13] *Id.* at p. 60.

[14] *Id.* at p. 22.

[15] *Id.* at p. 60.

[16] Novartis Institutes for BioMedical Research (NIBR) in Cambridge, MA. www.nibr.com., Attached as Exhibit D.

CONCLUSION

Plaintiff respectfully requests that the Panel issue an order transferring all actions listed in the Schedule of Actions, as well as any subsequently filed related actions, for coordinated and consolidated pretrial proceedings to the District of Massachusetts, or in the alternative, to a jurist in the Northern District of Ohio or California, or the Eastern District of Louisiana, each of which has pending Zofran litigation.

Dated: July 28, 2015

Respectfully submitted,

/s/ M. Elizabeth Graham

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