UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE : ZOFRAN® (ONDANSETRON) PRODUCTS LIABILITY LITIGATION	MDL No. 1:15-md-2657-FDS This document relates to: All Actions

DEFENDANT GLAXOSMITHKLINE LLC'S
MEMORANDUM IN SUPPORT OF ITS MOTION FOR ENTRY OF AN ORDER CONCERNING PRODUCT IDENTIFICATION

Defendant GlaxoSmithKline LLC ("GSK"), pursuant to Rules 16 and 26 of the Federal Rules of Civil Procedure and Local Rules 16.1(f) and 26.3, hereby moves for entry of an Order concerning product identification, a fundamental and threshold question in this MDL. GSK specifically seeks documentation of product identification to establish whether a Plaintiff used GSK's brand-name Zofran® or another company's generic ondansetron product. As this Court has already noted, product identification is "surely a fair threshold question." *See* MDL Status Conference Transcript (Nov. 17, 2015) at 15:16-22, attached as Exhibit B. The importance of product identification is further magnified here given the substantial number of companies selling generic ondansetron. Requiring disclosure of product information now—information that Plaintiffs should already possess—is the most sensible and fair way to proceed with initial discovery in this litigation. It will allow for a meaningful and fair assessment of the viability (or lack thereof) of the cases before time and money are expended on cases and claims that can and should be dismissed at an early stage. *See In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig*., 756 F.3d 917, 938 (6th Cir. 2014) (stating that an "overwhelming majority" of courts held that brand-name manufacturers cannot be liable to plaintiffs who ingested other

manufacturers' drugs). Beginning the outset of discovery with product identification therefore fulfills the directive of Rule 1 of the Federal Rules of Civil Procedure that the Rules "should be construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding." It is also consistent with the purpose of an MDL—to ensure the "just and efficient" resolution of pretrial proceedings. *See* 28 U.S.C. § 1407(a). In addition, product identification information is a prerequisite to the master pleadings process, as the claims and underlying theories of those who used GSK's product will vary from those who seek to hold GSK liable for use of another company's product.

GSK therefore requests that the Court order Plaintiffs to provide product identification information as set forth in the [Proposed] Order Concerning Product Identification, attached as Exhibit A.

I. LEGAL STANDARD

Federal Rules of Civil Procedure 16 and 26(b), (c) and (d) "vest the trial judge with broad discretion to tailor discovery narrowly and to dictate the sequence of discovery." *Crawford-El v. Britton*, 523 U.S. 574, 598-99 (1998) (noting that "the court may postpone all inquiry" regarding certain matters "until discovery has been had on objective factual questions such as whether the plaintiff suffered any injury"). In order to facilitate the "efficient completion of discovery" and to best develop "information needed for a realistic assessment of the case," Local Rule 26.3 also specifically affords the trial judge "discretion to structure discovery activities by phasing and sequencing the topics which are subject to discovery." The court's control over the execution of discovery exists so that "[t]he trial judge can therefore manage the discovery process to facilitate prompt and efficient resolution of the lawsuit." *Crawford-El*, 523 U.S. at 598-99. Similarly, "[f]ederal district courts enjoy wide discretion in their crafting of the pretrial process." *Berkovitz*

v. Home Box Office, Inc., 89 F.3d 24, 28 (1st Cir. 1996). The Judicial Panel on Multidistrict Litigation has explained that, because "[e]ach multidistrict litigation is unique, . . . transferee judges have broad discretion to determine the course and scope of pretrial proceedings." *In re Light Cigarettes Mktg. & Sales Practices Litig.*, 856 F. Supp. 2d 1330, 1332 n.2 (J.P.M.L. 2012).

II. ARGUMENT

A. Product Identification Is a Threshold Issue Impacting All Cases.

Product identification is a fundamental and pressing issue in this MDL. Because product identification is "surely a fair threshold question," the Court recognized that "collection of product identification evidence" should be among the first discovery measures that the parties consider, since it is "relatively less complicated" than other types of discovery. *See* MDL Status Conference Transcript (Nov. 17, 2015) at 15:16-22, attached as Exhibit B. The Court's recognition has been endorsed in commentary on MDL practices and procedures. *See* Duke Law School Center for Judicial Studies, *MDL Standards and Practices*, at 7-8 (Sept. 11, 2014) ("*MDL Standards*") ("For example, in MDL proceedings in which product identification is an overarching issue, the transferee judge might consider 'establish[ing] an early focus on evidence of product exposure."); *see also* Manual for Complex Litigation, Fourth, § 11.422 (instructing that "initial discovery" should focus on matters that "appear pivotal" and should target "information that might facilitate settlement negotiations or *provide the foundation for a dispositive motion*") (emphasis added).[1]

[1] Beginning with product identification is also consistent with the newly amended "proportionality" standard—providing that parties may only obtain relevant and non-privileged discovery that is also "proportional to the needs of the case." Fed. R. Civ. P. 26(b) (2015). Before engaging in merits discovery, Plaintiffs should disclose what product they claim is at issue. While the 2015 Amendments only recently went into effect on December 1, 2015, "[b]y order of the United States Supreme Court, these amendments 'govern . . . insofar as just and practicable, [in] all proceedings then pending.'" *Gilbert v. Rare Moon Media, LLC*, No. 15-MC-217-CM, 2016 WL 141635, at *4 n.4 (D. Kan. Jan. 12, 2016) (quoting Fed. R. Civ. P., Orders of the Supreme Court of the United States Adopting and Amending Rules (Apr. 29, 2015)); *Carr v. State Farm Mut. Auto. Ins. Co.*, No. 3:15-cv-1026-M, 2015 WL 8010920, at *3-*10 (N.D. Tex. Dec. 7, 2015) (same).

Product identification is especially important here because a significant number of Plaintiffs likely used generic ondansetron products sold by companies other than GSK. In 2006, FDA approved the first generic version of ondansetron, and the market for generic versions quickly blossomed. In 2007, GSK's sales of Zofran® declined by 88% in the United States due to generic competition. *See* GlaxoSmithKline plc, 2007 Annual Report (Form 20-F), 2008 WL 10046482, at *66 (Feb. 29, 2008). Today, generic ondansetron in its various forms is among the most widely distributed generic drug products available. No fewer than 30 different companies currently manufacture different forms of generic ondansetron. *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. Of the more than 200 complaints pending in this litigation, Plaintiffs in at least 153—over half—allege or allude to use of generic ondansetron. Only 68 Plaintiffs assert exclusive use of brand-name Zofran®. Many complaints contain allegations that are vague, ambiguous, or that otherwise make it impossible to know for certain which product(s) those Plaintiffs actually used.

The lack of product identification information unfairly impacts GSK's ability to plan for future discovery and dispositive motion practice. GSK is entitled to know whether its product was even consumed to meaningfully proceed in this MDL.[2] For purposes of initial discovery, GSK requests only that Plaintiffs complete a straightforward, one-page "Product Identification Disclosure,"[3] identifying and documenting the ondansetron product(s) that each Plaintiff claims to have used. Plaintiffs should already possess such information, as they presumably needed it to bring these lawsuits in the first place, consistent with their obligations under the Federal Rules.

[2] The fact that some Plaintiffs may claim that GSK is liable for injuries allegedly caused by a generic manufacturer's product does not relieve them of their obligation to identify the product they allegedly ingested. GSK is still entitled to know the legal theory on which each Plaintiff intends to proceed.

[3] The Product Identification Disclosure is not intended to substitute for Plaintiffs' Fact Sheets ("PFS"), which GSK anticipates will be served as part of subsequent discovery. The threshold issue of product identification should not be delayed as part of the PFS process.

Providing product identification information will cause Plaintiffs little to no burden and will guide the Court and the parties in determining the most efficient and fair course of pretrial proceedings, including the structure of and procedures for master pleadings.

B. Addressing Product Identification Now Preserves Judicial and Party Resources.

Requiring Plaintiffs to disclose what product they used now will promote efficiency and preserve the resources of the parties and the Court. Some or all of Plaintiffs' claims may be subject to early dismissal because they never actually used GSK's product. Indeed, there is a "mountain of authority" establishing that name-brand manufacturers should not be liable for claims arising from generic drugs. *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1253 (11th Cir. 2013); *see also In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig*., 756 F.3d 917, 938 (6th Cir. 2014) (noting that an "overwhelming majority of courts" have held that brand-name manufacturers cannot be liable to plaintiffs who ingested other manufacturers' drugs); *In re Darvocet, Darvon & Propoxyphene Products Liability Litig.*, No. 2:11-MD-2226-DCR, 2012 WL 3610237, at *2 (E.D. Ky. Aug. 21, 2012) *aff'd sub nom.* 756 F.3d 917 (6th Cir. 2014) ("There is no theory of product liability under which a defendant can be held liable for an injury caused by a product it did not sell, manufacture, or otherwise supply to the plaintiff."); *Madden v. Teva Pharma. USA, Inc.*, No. 0087, 2012 WL 4757253, at *1 (Pa. Com. Pl. Phila. Cty. Oct. 1, 2012) (recognizing that "courts across the country have overwhelmingly refused to allow claims against the manufacturer of a name-brand medication for damages allegedly caused by the use of another manufacturer's generic-equivalent medication on both legal and policy grounds").

Other pharmaceutical MDLs facing similar product identification issues have required that plaintiffs provide product identification information at the outset of the litigation. For example, in the *Darvocet, Darvon and Propoxyphene* litigation (MDL No. 2226), the Eastern

District of Kentucky addressed product identification in the first CMO it issued. In the Order, the court permitted limited initial discovery on product identification. *See* Darvocet CMO 1, attached as Exhibit C (discussing document requests and interrogatories on the issue of product identification). All other discovery was stayed. Over the course of the next year, the court dismissed brand manufacturers from over 100 actions because the plaintiffs either did not use the brand manufacturer's product or were unable to properly identify the company that marketed, sold, or manufactured the product that the plaintiffs claimed to have ingested. *See, e.g.*, Orders dismissing brand defendants, attached as Exhibit D. The use of early product identification discovery, therefore, resulted in the appropriate dismissal of brand manufacturers in cases where plaintiffs were unable to show adequate product identification, and prevented needless and costly merits discovery.

Similarly, here, identifying such cases early will ensure that the parties do not expend resources on legally nonviable cases and claims. And the Court will not be forced to oversee unnecessary discovery or to decide needless motions. Addressing product identification now is consistent with the mandate of Rule 1; that is, that the Federal Rules "should be construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding." Fed. R. Civ. P. 1. It also furthers the purpose for which this MDL was created—to "conserve the resources of the parties, their counsel, and the judiciary." Transfer Order, MDL No. 2657 (Oct. 13, 2015) (JPML Dkt. #116).

C. Product Identification Is a Prerequisite to Master Pleadings.

Product identification should be addressed now—before the Court considers the use of master pleadings. Indeed, the master pleadings will be guided by the legal theories that are advanced by each Plaintiff. For example, Plaintiffs who used a generic product cannot rely on a

master complaint that alleges theories of liability based on ingestion of brand-name Zofran®. If a master complaint is intended to capture the allegations and legal theories at issue, it must reflect the fact that some Plaintiffs did not use GSK's product. Thus, which product is at issue—GSK's product or a generic product sold by another company—is information that must be known and disclosed before turning to master pleadings.

The uncertainty created by lack of product identification is illustrated by a number of individual complaints that provide vague allegations as to the specific product at issue. *See, e.g.*, Complaint and Jury Demand at ¶ 90, *Faciane v. GlaxoSmithKline LLC*, No. 1:16-cv-10055-FDS (D. Mass. Jan. 14, 2016) (alleging use of "Zofran **and/or** ondansetron") (emphasis added), attached as Exhibit E. This type of pleading does not provide GSK "fair notice of what the . . . claim is and the grounds upon which it rests," as required by Fed. R. Civ. P. 8(a)(2). *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Basic product identification information is critical to allowing the parties to fully and fairly evaluate the structure of and procedures for master pleadings. Identifying this information should, therefore, precede consideration of master pleadings.

III. CONCLUSION

For the foregoing reasons, GSK respectfully requests that this Court enter an Order requiring Plaintiffs to identify and document the ondansetron product(s) that each Plaintiff claims to have used, as set forth in the [Proposed] Order Concerning Product Identification, attached as Ex. A**.**

Dated: February 22, 2015

Respectfully submitted,

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By its attorneys,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing Memorandum in Support of GlaxoSmithKline LLC's Motion for Sequenced Discovery, which was filed with the Court through the CM/ECF system, will be sent electronically to all registered participants as identified on the Notice of Electronic Filing ("NEF") and paper copies will be sent via first class mail to those identified as non-registered participants.

/s/ Madeleine M. McDonough
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