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 CASES**	)	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION FOR ENTRY OF AN ORDER REQUIRING PRODUCT IDENTIFICATION PRIOR TO MASTER PLEADINGS AND INITIAL FACT SHEET DISCOVERY

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I. INTRODUCTION

In a mass tort product liability MDL such as this, product identification is but one item of discovery that, with the rarest of exception, is obtained initially through the Plaintiff and Defense fact sheet process. Nevertheless, in a departure from countless MDL product liability litigations before this, Defendant GlaxoSmithKline, LLC ("GSK") proposes a process that is cumbersome, inefficient and unnecessarily would tilt the playing field to the advantage of GSK and to the prejudice of Plaintiffs. GSK's request for what it labels a "Product Identification Disclosure" ("PID Disclosure") at this early juncture seeks to construct an unnecessary hurdle for the families involved in these cases to navigate, and unfairly prejudices their ability to prosecute their claims in this MDL. Whatever the procedure for the discovery of product identification, it should not be one that confers an unfair advantage to a party or one that can be manipulated to prejudice a party.

Plaintiffs do not contest that the identification of the drugs they ingested as either Zofran in its branded form or its generic form is important and they intend to so identify them. Indeed, Plaintiffs themselves have proposed a Plaintiffs' Fact Sheet with an earlier, more comprehensive production of product identification information. Disregarding this traditional and efficient process for product identification production, GSK proffers a complicated eight-step mandate that would stall the filing of complaints, potentially encourage unwarranted dismissals, and thus prevent Plaintiffs with viable claims from participating in this litigation. Of course, this is the advantage GSK seeks. Yet this novel approach and its harsh consequences contravene Rule 26 discovery and would actually *delay* the receipt of the very information Plaintiffs intend to provide in their pleadings, fact sheets and core discovery. GSK's proposed process will take anywhere from 90 days to 180 days for initial discovery to commence.

Further, the GSK proposal is manifestly one sided. First, it requires product identification information for all Plaintiffs, including those minor Plaintiffs who were born before 2007 when GSK owned exclusivity over Zofran, which was the only version of ondansetron on the market. Under any construct, GSK's proposed process should not apply to those plaintiffs. Second, GSK's proposal unfairly prejudices the Plaintiffs by denying them any product identification information that rests exclusively within GSK's possession. GSK knows where and to which obstetricians it marketed its products for morning sickness. Dismissal of a family's case without the benefit of this information would be improper. Yet, under GSK's novel construct, that is precisely the outcome that would occur.

Finally, the practical effect of such dismissals creates an administrative burden for this Court – dismissals without prejudice followed by the subsequent re-filing of cases once product information is obtained. This would not only delay this Court's ability to assess the true volume and nature of cases before it, but hinder the efficient conduct of these proceedings.

In contrast to the potential harm to plaintiffs forced to participate in a burdensome product identification process, and the concomitant burden on this Court, GSK suffers no prejudice if its Motion is denied, as the issue of product identification at this stage is simply not dispositive, and GSK will obtain this information in due course.

II. BACKGROUND

Any consideration of a product identification proposal that goes against the grain of most every product liability litigation before it must also be viewed against the backdrop of *this* MDL. This MDL was created to coordinate claims brought by mothers who ingested the drug ondansetron: both the brand version Zofran, exclusively manufactured and marketed by GSK, *and* its generic equivalent, ondansetron. The product identification issue concerning brand

versus generic ondansetron is a relevant consideration, and Plaintiffs recognize that this inquiry needs to be answered. GSK's PID proposal, however, obscures two critical and undisputed facts.

First, GSK was the *only* manufacturer of ondansetron – branded "Zofran" by GSK – until December 31, 2006. Thus, as to any complaint involving the birth of a child with defects prior to mid-2007, GSK is the only possible manufacturer. GSK's proposed order, under any construct, should not apply to these plaintiffs. Again, Plaintiffs' proposed fact sheet would identify any information that would demonstrate Zofran proof of use prior to mid-2007.

Second, this case presents a fact pattern unlike any other pharmaceutical case involving generic versions of a brand drug. Here, Plaintiffs will prove (and GSK implicitly has conceded in the largest healthcare fraud settlement in U.S. history) that GSK's pervasive illegal and fraudulent conduct marketing for an untested, unapproved and virtually experimental use gives rise to its liability for injuries based on the ingestion of generic ondansetron by mothers after 2007. The identity of the specific generic manufacturer that supplied the drug is irrelevant if the mother alleges a theory of liability against GSK based upon its misrepresentations about the drug and its creation of the market for the drug by its conduct.

Plaintiffs are proposing a sequence for the filing of pleadings, responsive pleadings and initial discovery by way of fact sheets, as is contemplated by case precedent and *The Manual for Complex Litigation, 4th*.[1] Plaintiffs plan to file (1) a Master Complaint setting forth the global factual and legal allegations pertinent to all cases before this Court; (2) a Short Form Complaint, by which individual Plaintiffs may adopt those relevant counts of a Master Consolidated

[1] *Manual for Complex Litigation (Fourth)*, 2004 WL 259063, at *6 (Model CMO) ("Each plaintiff whose case has been transferred to this court shall have _____ days from the entry of this order to complete and serve on defendants a plaintiff fact sheet and an authorization for release of medical records. Counsel shall meet and confer to agree on an electronic format for completion of the Fact Sheet."). Plaintiffs continue to attempt to reach an accord with GSK as to the sequence of such pleadings through negotiation, but in the event that this cannot be accomplished, Plaintiffs will file their plaintiff and defendant fact sheet proposals on March 18, 2016, in accordance with this Court's orders.

Complaint and by which Plaintiffs will provide relevant core information about their claims, including product identification information; and (3) a Plaintiffs' Fact Sheet after the filing of such Complaint, which will include even more specific product identification and other information, including names of prescribing doctors, pharmacies and hospitals. The parties are currently negotiating the precise content of the Plaintiff Fact Sheet. Under Plaintiffs' proposal, from Short Form Complaint to Plaintiffs' Fact Sheet, all of the necessary product identification information would be produced within 30 days after filing the Short Form Complaint.

Thereafter, Plaintiffs expect that GSK will provide its Defendant Fact Sheet, within 30 days, with information that is available only to GSK. The Defendant Fact Sheet is also the subject of months' long negotiation.[2] Plaintiffs suggest that GSK's disclosures will include information concerning, *inter alia*, the sales and marketing of GSK's Zofran to those physicians identified by individual plaintiffs. Further, third-party discovery of former sales representatives and the witnesses involved in the two Department of Justice investigations and resolutions with GSK arising from its Zofran marketing will shed light on these product identification and generic liability issues.

In contrast to this traditional, fair and orderly process, GSK offers a one-sided approach to product identification. Under its approach, each MDL Plaintiff is required to complete the GSK-suggested "PID Disclosure" under penalty of perjury within 30 days of filing her complaint. If a Plaintiff is unable to provide *any* of the information called for within 30 days,

[2] To underscore the inefficiencies and delay in the GSK proposals, if a Plaintiff is missing information and has to rely upon "other evidence" as GSK calls it, the GSK PID process will initially take 90 days. Assuming Plaintiff's "other evidence" satisfies GSK, GSK would then finally address its own discovery obligations. Yet, under GSK's current defense fact sheet proposal, it would have an additional 90 days for completion of a defense fact sheet ("DFS") that could provide information bearing on product identification: "GSK will serve a completed DFS on Plaintiff's counsel as identified in the Plaintiff Fact Sheet ("PFS") no later than 90 days after a complete and verified PFS and a product identification disclosure documenting use of Zofran® has been served on GSK." *See*, GSK Proposed Defense Fact Sheet, Exhibit A. This would result in 180 days – a full six months – until just the basic product identification information is exchanged.

such as the NDC codes for the drug ingested, or does not yet have the specific "dispensation" proof required by the PID Disclosure, under GSK's proposal, the company would not be obligated to provide any further product identification information it may have in its possession. Thus, that Plaintiff would face *dismissal* of her case, without the benefit of *any* discovery from GSK.

GSK's proposal would result in the dismissal of viable claims for lack of documentary proof generated at least ten years ago, even though other evidence, such as doctors' records that reflect prescription but not "dispensation," or the Plaintiff's testimony, can itself satisfy any product identification requirement. As set forth herein, Plaintiffs have proposed a tried and trusted vehicle for product identification: disclosure of product information and other relevant claimant information in a Short Form Complaint and Plaintiff Fact Sheet. *See* Plaintiffs' Proposed Case Management Order, "Master Pleadings and Fact Sheets," Doc. No. 156, attached as Exhibit B. GSK's PID Disclosure Order and its burdensome compliance protocol are, therefore, unnecessary.

III. LEGAL STANDARD

Federal Rule of Civil Procedure 1 provides that the Rules should be construed and administered by the court to secure the "just, speedy and inexpensive determination of every action and proceeding." The goals of mass tort case management "parallel the goals of Federal Rule of Civil Procedure 1." *Manual for Complex Litigation (Fourth)* § 22.2. As the *Manual* instructs, mass tort case management "must keep the litigation moving efficiently" and thus the "challenge for the judge is to avoid excessive delay while preserving the right to a fair trial". *Id.* One of the threshold inquiries for the Court is to identify the number of potential claimants. *Id.*

Federal Rule of Civil Procedure 26(b)(1) requires discovery that considers the following factors: (i) the importance of the issues at stake in the litigation; (ii) the amount in controversy;

(iii) the parties' relative access to relevant information; (iv) the importance of the discovery in resolving the issues; and (v) whether the burden or expense of the proposed discovery outweighs the likely benefit. Fed. R. Civ. P. 26(b)(1). These factors entail analysis of all the information provided by both parties and consideration of "all the other factors in reaching a case-specific determination of the appropriate scope of discovery." Fed. R. Civ. P. 26(b)(1) Advisory Committee's Note.[3] Given the case here, the additional burden GSK seeks to impose is far outweighed by any benefit that may be derived from identifying Zofran versus its generic version without the benefit of any discovery.

IV. ARGUMENT

A. PLAINTIFF FACT SHEETS ARE THE APPROPRIATE MECHANISM FOR PRODUCT IDENTIFICATION IN CASES SUCH AS THIS.

The potential for confusion surrounding product identification in a large pharmaceutical litigation is neither new nor unique. MDL Courts routinely utilize fact sheets to elucidate facts from both plaintiffs and defendants concerning the specific drug ingested. *See In re Vioxx Prods. Liability Litig.*, MDL 1657, *In re Propulsid Prods. Liability Litig.*, MDL 1355, *In re Xarelto (Rivaroxaban) Prods. Liability Litig.*, MDL 2592. Indeed, in the *In re Risperdal and Invega Products Liability Litigation* (hereinafter "Risperdal"), there are dozens of generic versions of the brand drugs at issue, and Plaintiff Fact Sheets are mandated for initial product identification. *See* Risperdal-Philadelphia Plaintiff's Fact Sheet, attached hereto as "Exhibit C;"

[3] All of the proportionality factors weigh against the imposition of the PID Disclosure. Most importantly, the administrative burden regarding the practical execution of the proposed order, such as numerous dismissals and re-filings due to difficulty of obtaining records, likely outweighs the benefit of providing product identification in this manner. Furthermore, this PID Disclosure should not be required because the burden of compliance also outweighs the likely benefit, especially considering the same product identification information will be provided by the Short Form Complaint and the Plaintiff Fact Sheet. Finally, the PID Disclosure requires dismissal as the consequence for failure to comply, which goes against the important issues at stake in this litigation – the opportunity of young children and their parents to seek redress in the Courts for the alleged tortious conduct of the defendant.

see also Risperdal-Los Angeles Plaintiffs' Fact Sheet, attached hereto as "Exhibit D." Similarly in *In re Testosterone Replacement Therapy Products Liability Litigation,* MDL 2545 (hereinafter "Testosterone"), another mass tort with generic equivalents of the brand drug in issue, the court is employing a "product description" option similar to that which has been proposed by the Plaintiffs in Zofran: in the Fact Sheet, if the Testosterone plaintiff cannot "presently recall the name of the drug" in the nascent days of his case, he may identify the product by "Type: (Patch, Gel, Injection, Tablets, Pellets or Capsules)." *See* Testosterone Plaintiffs' Fact Sheet, attached hereto as "Exhibit E." In still another mass tort litigation that had thousands of women who ingested both brand and generic versions of postmenopausal hormone therapy, the Plaintiffs' Fact Sheet provided a detailed product information section where Plaintiffs would list, NDC code, Manufacturer, Description of the pills used and the generic or brand name. *See,* Plaintiffs' Fact Sheet in *In re Hormone Therapy Litigation*, Mass Tort Program, Phila. Court of Common Pleas, Nov. Term 2003, No. 00001, Sec. IX, p. 44, attached hereto as "Exhibit F."

These processes, embraced by numerous MDL and state courts, ensure that the Plaintiff families are protected in situations where definitive product identification is not immediately available. *See also* Plaintiffs' Fact Sheet from *In re Paxil Products Liability Action*, MDL 1574 attached hereto as "Exhibit G."; Plaintiffs' Fact Sheets from *In re Zimmer Durom Hip Cup Prods. Liab. Litig.,* MDL 2158 and *In re Stryker Rejuvenate and ABG II Hip Implant Products Liab. Litig.,* MDL 2441 attached hereto as "Exhibit H" and "Exhibit I" respectively; Plaintiffs' Fact Sheet from *In re Fresenius GranuFlo/NaturaLyte Dialysate Prods. Liab. Litig.*, MDL 2428 attached hereto as "Exhibit J." Plaintiffs' Fact Sheet from *In re: Yasmin and YAZ (Drospirenone) Marketing, Sales Practices and Prods. Liab. Litig.*, MDL 2100, attached hereto as "Exhibit K."

GSK ignores this substantial precedent but cites a single case to support its novel proposal: *In re Darvocet, Darvon and Propoxyphene Products Liability Litigation*, MDL 2226. However, the *Darvocet* case is easily distinguishable from Zofran litigation. In *Darvocet*, Plaintiffs did not seek to hold the brand manufacturer liable for promoting a drug for unapproved use by an untested population, as is the case here. Rather, the generic manufacturers and brand manufacturers were named as defendants based upon the same product liability theories. The pleadings against the various defendants neither shed light as to which defendants were responsible for a particular plaintiff's injury, nor asserted a viable legal theory upon which to proceed against brand or generic manufacturers for ingestion of a generic drug. As discussed above, that is not the case before this Court.[4]

Moreover, even the Darvocet order only permitted the defendants to send discovery requests tailored to product identification within 15 days of a filing. It did not create a separate form to be verified by the plaintiffs, nor did it provide a vehicle for dismissal should plaintiffs be unable to produce the *complete* set of evidentiary records requested by defendants only weeks after filing a Complaint. Instead, it merely allowed defendants to conduct discovery through interrogatories and document requests which sought: pharmaceutical records indicating NDC codes; photocopies of pill bottles; affidavits from pharmacist regarding the NDC code, manufacturer, or distributor of the product prescribed; and, any other "circumstantial evidence" upon which plaintiffs will rely to prove PID.

B. THE DELAY AND PREJUDICE TO PLAINTIFFS UNDER GSK'S PROPOSED PID ORDER IS UNWARRANTED.

GSK suffers no harm if this Court denies its Motion. GSK will obtain product identification information in a timely and orderly fashion to allow it to conduct discovery, file

[4] There are only 6 cases which name a generic defendant.

dispositive motions and prepare its defense. By contrast, an order requiring the Plaintiffs to adhere to the process GSK proposes or suffer dismissal of their cases is unfairly prejudicial and will substantially delay the progress of this MDL.

By way of just one illustration, MDL Plaintiff Kelly Roberts was prescribed GSK brand Zofran while pregnant with her son, in late 2005.[5] Plaintiff's Complaint alleges that Kelly's ingestion of Zofran caused her minor son, C.R., to be born with a cleft palate. As a result of those birth defects, C.R. has undergone at least eight surgeries and suffers from possibly permanent ear and dental damage, as well as developmental difficulties. *See* Roberts Complaint, ¶¶ 12-14. Mrs. Roberts, like many mothers already or soon to be in this litigation, is at a disadvantage in obtaining medical records that meet GSK's PID Disclosure criteria because her ingestion of the drug is further back in time than most medical facilities and pharmacies are obligated to maintain records. Plaintiff and her counsel have spent approximately several months attempting to track down the pharmacy records, medical records, and insurance records from 2005 that would ideally contain the NDC Code or prescription for Zofran. Plaintiff and her husband frequented several different pharmacies due to the locations of their home and workplaces around that time, all of which were identified by Plaintiff and sent records requests. Nevertheless, because of the 2005 ingestion, none of the pharmacies were able to provide records. Importantly, however, Plaintiff's Ob/Gyn records are available and do reference a Zofran prescription. Still, to date, there is no record of a "dispensation" of Zofran to Mrs. Roberts.

Under GSK's proposed PID Disclosure process, counsel for the Roberts Plaintiffs are obligated to engage in this cumbersome and inefficient process: (i) first, presumably complete a

[5] *See* Excerpts from Roberts Complaint, 5:15-cv-01411, Doc No. 1, attached hereto as "Exhibit L."

Short Form Complaint that would inevitably include some product identification information; (ii) second, fill out GSK's PID Disclosure within 30 days of filing the Complaint; (iii) third, also complete a Plaintiff's Fact Sheet within 30 days of filing the Complaint, that would include product identification information; (iv) fourth, send GSK counsel a letter explaining the absence of a response regarding NDC Code in their PID Disclosure; (v) fifth, await a letter from GSK counsel reminding them of the lack of NDC Code and the deficiency within the PID disclosure; (vi) sixth, meet and confer with GSK counsel regarding the fact that pharmacy records are rarely kept for more than 10 years; (vii) seventh, somehow attempt to cure that "deficiency" of the lack of "dispensation" records within 14 days of the letter GSK sent; (viii) and, finally, within 60 days later provide "records, affidavits, and/or other evidence" on which Plaintiff relies to support the Ob/Gyn record that shows she was prescribed Zofran. At the conclusion of this lengthy process – up to 90 days in many instances – Plaintiff will be faced with a Motion to Dismiss because GSK did not receive the NDC Code its Order contemplates. And remarkably, all of this would be required under the GSK proposal *despite the fact that GSK was the only maker of ondansetron at the time of Plaintiff's ingestion of the drug in 2005 and despite the fact that Plaintiff's doctors wrote in records that she was prescribed Zofran.*

Rather than deny Plaintiffs like Ms. Roberts the ability to prove their cases, Plaintiffs respectfully suggest that this Court allow Plaintiffs to gather information in discovery. GSK will have an opportunity in due course to file motions for summary judgment, which are the proper procedural mechanisms for product identification proof issues. *See Santiago v. Sherwin-Williams Co.*, 782 F. Supp. 186, 188 (D. Mass. 1992) (stating the general rule that summary

judgment is the stage at which defendant can seek dismissal if the plaintiff cannot establish who or what caused her injury) (citing *Garside v. Osco Drug, Inc.*, 895 F.2d 46, 49 (1st Cir. 1990)).[6]

C. GIVEN THE NATURE OF THE SPECIFIC CLAIMS AGAINST GSK IN THIS LITIGATION, THE PID DISCLOSURES GSK PROPOSES AT THE OUTSET OF THIS CASE ARE UNWARRANTED.

Of course, the threshold question of product identification is not as simple as whether a GSK-manufactured product was ingested. (Def. Br., Doc. No. 96, at 1-2).[7] Simply ascertaining whether a Plaintiff ingested a GSK-manufactured pill is still not dispositive of the claims.[8] There are nearly two hundred meritorious claims pending in this MDL against GSK based upon established state laws that allow families to hold GSK liable under negligent misrepresentation principles even though the mother ingested the generic version of Zofran. Thus, while the distinction between generic versus brand at the commencement of a claim is certainly a relevant inquiry, it is not the end of the day for all plaintiffs. As such, Plaintiffs request that this Court deny GSK's Motion for Entry of its Order Concerning Product Identification and alternatively allow the parties to move forward with discovery as Plaintiffs suggest.

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[6] To shift the burden of proof required by the summary judgment standard to Plaintiffs at the outset of the case is in contradiction of the suggested process for the management of mass torts. The "*Managing Multidistrict Litigation in Products Liability Cases*" pocket guide recommends that in cases that are not yet "mature" mass torts, and where "liability is seriously disputed," it is appropriate to "focus initial discovery toward matters bearing on the defendants' liability to all plaintiffs, perhaps initially only requiring plaintiffs to provide basic information on exposure and damages." *See* Rothstein, Barbara J., "Managing Multidistrict Litigation in Products Liability Cases: A Pocket Guide for Transferee Judges," FJC – Judicial Panel on Multidistrict Litigation, 2011 at 31, available at http://www2.fjc.gov/sites/default/files/2012/MDLGdePL.pdf. The Zofran MDL is not yet "mature," and "liability is seriously disputed."

[7] References to page numbers on ECF docket entries refer to the page number listed at the bottom of the pages, as opposed to the page numbers auto-generated by the ECF system in the header of the document.

[8] *See generally Wyeth, Inc. v. Weeks*, 159 So.3d 649, 677 (Ala. 2014) ("In the context of inadequate warnings by the brand-name manufacturer placed on a prescription drug manufactured by a generic manufacturer, it is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce because the manufacturing process is irrelevant to misrepresentation theories based, not on manufacturing defects in the product itself, but on information and warning deficiencies, when those alleged misrepresentations were drafted by the brand-name manufacturer and merely repeated, as allowed by the FDA, by the generic manufacturer.").

A careful review of those complaints on file alleging that a mother took "ondansetron" reveals that all but six seek to hold GSK exclusively liable for the resultant birth defects to their children.[9] Plaintiffs are pursuing claims that include, *inter alia*, two legal theories: (i) claims for product liability under various theories based on Plaintiffs' use of brand Zofran; and (ii) negligent misrepresentation or other similar claims for Plaintiffs who ingested generic ondansetron based upon GSK's promotion of Zofran for an unapproved and unintended use.[10] In fact, of the filed Complaints that fall into this latter category, 73% of them arise under the laws of four states that *expressly* allow for claims against GSK based upon use of a generic equivalent.[11] The plain language of these complaints makes it clear that each plaintiff seeks to hold GSK liable for illegally promoting Zofran, an oncology anti-nausea drug, to pregnant women without proper testing for safety and efficacy.[12] At this juncture, such notice is all that is

[9] There are only six cases in the MDL that name a generic defendant because most of the plaintiffs who ingested generic ondansetron are **not** alleging claims against the generic manufacturer. They are alleging claims against GSK, the brand manufacturer, for negligent misrepresentation. *See* n. 4.

[10] *See Strickland v. GSK*, No. 1:15-cv-13688-FDS, Doc. No. 1, Compl. ¶¶ 167-68.

[11] As of the date of filing of this response, there are approximately 230 total Complaints. There are approximately 68 Complaints alleging brand use. (Doc. No. 160, at 4). There are also 169 Complaints alleging claims against GSK alleging claims of misrepresentation and other state law theories under state law that expressly allows for these claims. For example, in *Wyeth, Inc. v. Weeks*, the Alabama Supreme Court held that brand manufacturers may be liable for fraud or misrepresentation based on statements made in connection with the manufacture or distribution of a brand-name drug, by a plaintiff claiming physical injury from a generic drug manufacturer. 159 So.3d 649, 676 (Ala. 2014). There are a total of 142 Alabama Complaints alleging claims of misrepresentation and other theories for generic use, due to a statutory change that went into effect on November 1, 2015 which caused plaintiffs who ingested generic drugs to bring negligent misrepresentation claims against the brand manufacturer by that date. GSK acknowledged that "about three-fourths of those cases [all cases in the MDL] were filed from Alabama on the eve or right around the date that the statute of limitations was about to expire on innovator liability." *See* MDL Status Conference Transcript (Jan. 14, 2015) at 11:24-25-12:1-2. There are 7 such cases filed under California law and 3 under Illinois, which explicitly allow claims against GSK as discussed above. Plaintiffs contend that GSK is liable for generic ingestion based upon this same reasoning.

[12] *See Strickland v. GSK*, No. 1:15-cv-13688-FDS, Doc. No. 1, Compl. ¶¶ 167-68.

required. *See* Fed. R. Civ. P. 8(a)(2). GSK will be able to make dispositive motions at the appropriate time.[13]

V. CONCLUSION

The issue before this Court is how to conduct the initial stages of fact discovery and product identification efficiently and without unduly prejudicing one party. The Plaintiffs are the only litigants who have proposed such a process, and that process is consistent with the protocol employed by most other mass torts with similar complexity of fact and legal issues. For the foregoing reasons, GSK's Motion should be denied and this Court should accept Plaintiffs' Proposed Case Management Order, "Master Pleadings and Fact Sheets," which sets a schedule and process through which the parties can effectively address product identification and commence the discovery phase of this litigation.

Dated: March 8, 2016

Respectfully submitted,

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[13] At the 30 day-after pleading stage, the critical early question is what state does Plaintiff claim to have consumed the drug and what year, which will be provided by Plaintiffs' Short Form Complaint. If Plaintiff's ingestion was prior to 2007, after which GSK's brand Zofran went off patent, GSK knows that this is a brand case. *See* MDL Status Conference Tr. (Nov. 17, 2015) at 13:3-9 ("Zofran was first approved in 1991 as a brand name product. It's been on the market for 24 years. There's actually never been any litigation like this in that whole time, but it went generic in 2007. . . ."). If Plaintiff's ingestion was 2007 or after, then Plaintiffs' proposed product identification disclosures and sequence will timely provide GSK enough information to evaluate the merits of that individual's Short Form Complaint and respond to it.

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CERTIFICATE OF SERVICE

I, Robert K. Jenner, hereby certify that on this 8th day of March, 2016, I electronically filed the foregoing with the Court using the CM/ECF system and thereby delivered by electronic means to all registered participants as identified on the Notice of Electronic Filing.

/s/ **Robert K. Jenner**
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