

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: ZOFRAN (ONDANSETRON))	MDL No. 1:15-md-2657-FDS
PRODUCTS LIABILITY LITIGATION)	
_____)	
)	
THIS DOCUMENT RELATES TO:)	
)	
ALL CASES)	
_____)	

PLAINTIFFS’ PROPOSAL FOR SEQUENCE AND EFFECT OF MASTER PLEADINGS

The Court has directed the parties to submit proposals with respect to the sequence and effect of master pleadings. (Doc. No. 162). The parties were not able to reach an agreed proposal for the sequence of master pleadings and therefore Plaintiffs submit this proposal. Based upon the proceedings to date, this case is now ripe to follow the usual procedural course of mass tort product liability MDL litigation, whereby Plaintiffs file a Master Consolidated Complaint, Defendant files a Master Answer, and individual short form complaints for each individual action follow thereafter. Accordingly, Plaintiffs respectfully submit the following proposal and supporting reasons.

I. SEQUENCE OF MASTER PLEADINGS

A. PLAINTIFFS’ MASTER AND SHORT FORM COMPLAINTS

1. Plaintiffs will file and serve their Master Consolidated Complaint (“Master Complaint” no later than April 14, 2016.
2. Plaintiffs will serve on GSK, but not file, their proposed Short Form Complaint no later than April 14, 2016.
3. To promote an efficient filing process for present and future Plaintiffs, all parties will file a Short Form Complaint. The short form complaint will:
 - (a) incorporate by reference the Plaintiffs’ Master Complaint;
 - (b) identify those named Defendants that apply and appear in the Master Complaint;

(c) identify the product ingested – Zofran, Ondansetron, and/or Ondansetron Hydrochloride

(d) identify the form of product used for Zofran, Ondansetron and/or Ondansetron Hydrochloride oral tablet, orally disintegrating tablet, injectable, oral solution or other);

(e) identify the state in which the drug at issue was ingested and the state in which the minor child was born;

(f) identify the District Court and Division in which Plaintiff would have otherwise filed the Complaint absent the Court’s Direct Filing Order, MDL Order No. 6;

(g) identify the injury(ies) claimed;

(h) check the box(es) to identify the legal claims asserted; and

(i) add any additional legal counts, Defendants and supporting allegations.

4. By May 3, 2016, two weeks prior to the Court’s May 17, 2016 status conference, GSK will provide its suggested edits to Plaintiffs’ proposed Short Form Complaint so that the parties can bring any unresolved issues before the Court during the May 17, 2016 status conference.

B. DEFENDANT’S MASTER ANSWER AND RESPONSES TO SHORT FORM COMPLAINTS

1. GSK shall file and serve its Master Answer to Plaintiffs’ Master Complaint by May 17, 2016.¹
2. GSK’s Master Answer to Plaintiffs’ Master Complaint will be deemed its answer to individual Short Form Complaints. The filing of GSK’s Master Answer will eliminate GSK’s obligation to file individual answers to individual complaints in this MDL, absent further Order of the Court or agreement by the Parties on Answer obligations.
3. Other than the Master Answer set out above, the Defendant’s obligation to file any responsive pleading to a Short Form Complaint that is filed in or transferred to this proceeding will be stayed until further Order of the Court.

¹ The proposed timing reflects the anticipated proposal of GSK, which based on meet and confer to date, does not align with Plaintiffs’ proposal. To date, it appears that GSK maintains its position that it can file yet another 12(b)(6) motion in this litigation. Therefore, Plaintiffs will need to see GSK’s final position before filing any Master Complaint. If, however, GSK will agree to the usual course, and file a Master Answer, Plaintiffs would be in a position to move this timeline up.

II. EFFECT OF MASTER PLEADINGS IN AN MDL

A. MASS TORT MDL COURTS FAVOR A MASTER CONSOLIDATED COMPLAINT, TO WHICH AN ANSWER, AND NOT A MOTION TO DISMISS, PROMOTES THE EFFICIENCY SOUGHT IN MDL COORDINATION.

In MDL product liability practice, a Master Complaint serves as a tool to promote efficiency in the context of coordinated proceedings. Judge Eldon Fallon, who has now presided over four mass tort MDLs, *In re Propulsid*, *In re Vioxx*, *In re Chinese-Manufactured Drywall*, and *In re Xarelto*, has explained the foundation for the Master Complaint in an MDL context and explained its function as a procedural device necessary to achieve efficiency:

Master complaints are often used in complex litigation, although they are not specifically mentioned in either the Federal Rules of Civil Procedure or in any federal statute. They seem to be grounded instead in the general provisions of Rule 42(a) of the Federal Rules of Civil Procedure. Rule 42(a) broadly authorizes district courts to consolidate actions pending before the court and to make such orders “as may tend to avoid unnecessary costs or delay.” Courts have interpreted Rule 42(a) to authorize the filing of a unified or master complaint in cases consolidated both for pretrial discovery and for trial. In both situations, consolidation is not supposed to “merge the suits into a single cause, or change the rights of the parties, or make those who are parties in one suit parties in another.” Rather, consolidation is intended only as a procedural device used to promote judicial efficiency and economy.

....

If a master complaint in this MDL were viewed as a traditional complaint in a single plaintiff proceeding, many significant and perhaps unintended consequences would follow **In light of these concerns, the master complaint should not be given the same effect as an ordinary complaint. Instead, it should be considered as only an administrative device to aid efficiency and economy.**

In re Propulsid Prods. Liab. Litig., 208 F.R.D. 133 (E.D. La. 2002) (emphasis added).²

² See also *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 454 (E.D. La. 2006) (“[A] master complaint is only an administrative device used to aid efficiency and economy and, thus, should not be given the status of an ordinary complaint.”); *In re Digitek Prods. Liab. Litig.*, 2009 WL 2433468 at *8 (S.D. W.V. Aug. 3, 2009) (“The administrative nature of a master complaint and its focus on facilitating management of the litigation, as opposed to being a primary operative pleading, has been considered in analyzing the motions to dismiss. Since it is uncertain how a master complaint should be treated when it is challenged via Rule 12(b)(6), the document has been read and

Given the Master Complaint's purpose of administrative efficiency and coordination, courts have refused to consider motions to dismiss Master Complaints when doing so would require rulings to determine the sufficiency of each individual plaintiff's factual allegations. *See In re Nuvaring Prods. Liab. Litig.*, No. 4:08MD1946 RWS, 2009 WL 4825170, at *2 (E.D. Mo. Dec. 11, 2009) (“[C]ase-specific rulings on the sufficiency of the plaintiffs’ allegations “are neither the purpose, nor the forte of a court presiding over a multi-district litigation.”). In the *Trasylol Products Liability Litigation*, when faced with an attempt to dismiss several counts of the master pleadings, Judge Middlebrooks went so far as to say:

The Court cannot envision the task of adequately pleading the consolidated master complaint in a manner which would satisfy Defendants, without completely removing the compromise and attempt at efficiency the Parties and I had in mind in allowing the filing of the Consolidated Master Complaint. At this stage of the litigation I prefer to assess the sufficiency of plaintiffs’ claims with substantial leniency, especially when the information that may or may not support Plaintiffs’ claims is largely within the control of the Defendants.

In re Trasylol Prods. Liab. Litig., No. 08–MD–1928, 2009 WL 577726, at *8 (S.D. Fla. Mar. 5, 2009) (observing as well that a dismissal at such an early juncture of the litigation would be “ill-serving” the goal of consolidated proceedings which is, in part, an “efficient, just, and consistent resolution to the issues presented herein”).

Sound reasons support special treatment of a Master Consolidated Complaint. First, a Master Complaint cannot, of course, feasibly include the Plaintiff-specific allegations for all of the Plaintiffs in an MDL. Second, product liability actions such as this implicate state substantive law, and moving to dismiss a Master Complaint based on characterizations of state

construed at this point in the litigation in light of its procedural purpose.”); *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 56 (D.N.J. 2009) (“In the absence of . . . consent, the majority of courts treat consolidated complaints filed in multi-district litigations as a procedural device rather than a substantive pleading with the power to alter the choice of law rules applicable to the plaintiffs’ claims.”).

law in the absence of a filed claim from a Plaintiff in that state calls for an advisory opinion and violates the case-or-controversy requirement. Federal courts may not give opinions “advising what the law would be upon a hypothetical state of facts.” *Chafin v. Chafin*, 133 S. Ct. 1017, 1023 (2013); *see also* *McInnis-Misenor v. Maine Med. Ctr.*, 319 F.3d 63, 70 (1st Cir. 2003) (“The ripeness doctrine seeks to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements.”) (internal quotation marks omitted).

Third, to allow a Defendant to move to dismiss a Master Complaint would overlook the fact that the substantive law of each Plaintiff’s home state will govern that Plaintiff’s claims, and in many instances, that state law varies for a given legal claim. Each Plaintiff is deemed the master of his or her Complaint, and each has a due process right to application of a substantive state law that has “sufficient contact or aggregation of contacts” to his or her claim. *Allstate Ins. Co. v. Hague*, 449 U.S. 302, 308 (1981) (“In order to ensure that the choice of law is neither arbitrary nor fundamentally unfair, the Court has invalidated the choice of law of a State which has had no significant contact or significant aggregation of contacts, creating state interests, with the parties and the occurrence or transaction.”); *see also* *In re Asbestos Prods. Liab. Litig. (No. VI)*, 278 F.R.D. 126, 129 (E.D. Pa. 2011) (observing that “administering cases in multidistrict litigation is different from administering cases on a routine docket” and “regardless of how massive or complex the litigation is, . . . each [party] is entitled to a full and fair day in court as to the merits of its claims and defenses”). Thus, treating a Master Complaint as more than an administrative procedural device runs the risk of depriving individual Plaintiffs their rights to individualized consideration.

B. GSK SHOULD NOT BE AFFORDED A SECOND OPPORTUNITY TO FILE A MOTION TO DISMISS AFTER IT ALREADY MOVED AGAINST “ALL ACTIONS” – ASSERTING ONLY A CLEAR EVIDENCE PREEMPTION DEFENSE.

GSK will propose that the Master Complaint should be treated as a substantive complaint to which it can move to dismiss on 12(b)(6) or 12(c) grounds. Principles of fundamental fairness, efficiency and prejudice dictate that GSK not be given a second bite at the apple. Although it is conceivable that a motion to dismiss a Master Complaint could be entertained if raised against an issue common to all Plaintiffs’ claims, that circumstance is not present here. GSK already filed such a Motion to Dismiss and/or Motion For Judgment on the Pleadings based on an assertion of federal preemption, and the Court has already resolved that motion. Additionally, GSK has already answered at least 35 of the Complaints filed in or transferred to the MDL. (DE 96, at p. 12, n.8). If there was a clear legal basis to move to dismiss every Plaintiffs’ claim at the pleading stage, GSK would not have answered any.

Moreover, GSK made a strategic decision at the outset of this case to go all-in on a 12(b)(6) and 12(c) Motion to Dismiss on one issue and one issue only: federal preemption. When it chose to file that motion, GSK took the position that the similarity of the complaints filed to date was the equivalent of a Master Complaint, and therefore it sought relief applying to “All Cases.” In filing its “Omnibus Motion,” GSK stated:

Plaintiffs suggest that it is not clear which complaints are subject to GSK’s Motion (Doc. 128 at 4.) But as specifically stated in GSK’s Motion, GSK seeks dismissal of “all causes of action against it in this multidistrict litigation.” (Doc. 95 at 1.) To prevent any ambiguity, the case caption of GSK’s Omnibus Motion to Dismiss and/or Motion for Judgment on the Pleadings state, “This Document relates to: All Actions.” **Every case pending in this MDL presents the same core issue, which is dispositive as to all cases. Plaintiffs do not point to any substantive difference in the cases that are relevant to the question before the Court.**

See, Def.’s Reply Br. (doc. no. 131, at 3, fn.3). (Emphasis added.)

Under Federal Rule of Civil Procedure 12(g), “a party that makes a motion under this rule must not make another motion under this rule raising a defense or objection that was available to the party but omitted from its earlier motion.”³ Fed. R. Civ. P. 12(g). This rule is intended to avoid piecemeal litigation tactics, where a defendant seeks dismissal of all claims on one ground, loses, and then seeks dismissal anew on another ground. *See id.* Advisory Comm. Note to 1966 Amendment (“This required consolidation of defenses and objections in a Rule 12 motion is salutary in that it works against piecemeal consideration of a case.”). This waiver principle applies as well to amended complaints that do not assert new and materially different legal claims. *See Rowley v. McMillan*, 502 F.2d 1326, 1333 (4th Cir. 1974) (“An unasserted defense available at the time of response to an initial pleading may not be asserted when the initial pleading is amended.”); *Pruco Life Ins. Co. v. Wilmington Trust Co.*, 616 F. Supp. 2d 210, 215 (D.R.I. 2009) (same).

In GSK’s initial motion under Rule 12(b)(6) and 12(c), it claimed over and over that all claims brought by Plaintiffs were the same – simply a variation of failure to warn – and as such, those claims should be dismissed on preemption grounds. If GSK found every claim to be the same in all actions, it had every opportunity within its dispositive motion to challenge Plaintiffs’ claims on other legal grounds as well. It did not. And now GSK wants a do-over. Remarkably, GSK wants this opportunity despite the fact that it represented to the Court that a Master Complaint was not the appropriate vehicle for a Motion to Dismiss:

³ Rule 12(h)(2) and (3) created exceptions to this waiver principle; namely (a) an exception allowing the defense of failure to state a claim on which relief can be granted to be reasserted in an answer, a motion for judgment on the pleadings or at trial; and (b) an exception concerning lack of subject matter jurisdiction. Here, GSK has already moved to dismiss claims through a motion to dismiss and a motion for judgment on the pleadings. Therefore, these exceptions to Rule 12(g)’s waiver principle do not apply.

Ms. McDonough: ... We don't have a master pleading, although we talked about it at one point as possibly helpful for administrative purposes, **but the whole idea of a master pleading is actually not necessarily for purposes of dismissal**, and I think in this case, it's not even helpful or necessary...

See, Tr. of Jan. 17, 2016 Status Conf. at p. 8, ln. 18-24. (Emphasis added.) GSK told the Court that everything could be decided then on the current dispositive motion, and that if a master pleading were filed it would not be used for dismissal purposes. It would be fundamentally unfair and prejudicial to the Plaintiffs to allow GSK to reverse course and be given a second opportunity to move to dismiss the claims when it represented plainly that all the issues relating to plaintiffs legal claims were ripe and before the Court for dispositive motion on "All Actions" according to GSK. GSK summarized the procedural posture it understood very clearly before the Court on January 17, 2016:

Ms. McDonough: So really where we are are 200 cases that really boil down to is there a subject to dismissal claim on failure to warn? And I really think it cuts across all of these cases. **It's the gist of every single case, and I think it can be decided now, and I think it should be decided not under Rule 12, under the reasoning of the cases cited for judicial efficiency, threshold streamlining of issues and MDL coordination.**

See, Tr. of Jan. 17, 2016 Status Conf., at p. 10, ln. 18-25. (Emphasis added.) In short, GSK had its shot and took it. To permit GSK another opportunity would invite repeated reconsideration of issues after they have been decided. GSK was right about one thing: MDL coordination calls for judicial efficiency. Plaintiffs' plan achieves that and allows the parties and the Court to move on with the substance of the litigation, without serial motions on issues that GSK had the chance to address and strategically chose not to.

In summary, Plaintiffs propose to file a Master Complaint as a summary of the allegations common to all Plaintiffs, followed by each Plaintiff's filing of a Short Form Complaint that adopts the common allegations and adds that particular Plaintiff's individualized

allegations and specific legal claims arising under that Plaintiff's home state. Should an issue arise later in this litigation whereby a critical mass of Plaintiffs from a given state present a legal claim not already challenged by GSK, then the parties can confer and together with the Court, outline a procedure for summary proceedings or motion practice relative to a given issue. That is the most efficient procedure. Until there is a case or controversy to address, the appropriate course is a Master Complaint, a Master Answer and Short Form Complaints. Therefore, Plaintiffs respectfully request this Court grant Plaintiffs' Proposed MDL Order, which achieves an efficient and legally sound master pleadings sequence.

Dated: March 11, 2016

Respectfully submitted,

/s/ Robert K. Jenner

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CERTIFICATE OF SERVICE

I, Robert K. Jenner, hereby certify that on this 11th 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

Robert K. Jenner

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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IN RE: ZOFTRAN (ONDANSETRON))	MDL NO. 1:15-md-2657-FDS
PRODUCTS LIABILITY LITIGATION)	HON. F. DENNIS SAYLOR, IV
)	
This document relates to:)	
)	
All Actions)	
)	

[PROPOSED] MDL Order No. XX
(Master Pleadings)
[Date]

The Court hereby ORDERS as follows:

I. PLAINTIFFS’ MASTER AND SHORT FORM COMPLAINTS

- a. Plaintiffs shall file and serve their Master Complaint no later than March 31, 2016.
- b. Plaintiffs shall serve on GSK, but not file, their proposed Short Form Complaint no later than March 31, 2016.
- c. To promote an efficient filing process for present and future Plaintiffs, all parties will file a Short Form Complaint. The short form complaint will:
 - (a) incorporate by reference the Plaintiffs’ Long Form Master Complaint;
 - (b) identify the named Defendants;
 - (c) identify the product ingested – Zofran, Ondansetron and/or Ondansetron Hydrochloride
 - (d) identify the form of product used for Zofran, Ondansetron and/or Ondansetron Hydrochloride (oral tablet, orally disintegrating tablet, injectable, oral solution or other);
 - (e) identify the state in which the drug at issue was ingested and the state in which the minor child was born;
 - (f) identify the District Court and Division in which Plaintiff would have otherwise filed the Complaint absent the Court’s Direct Filing Order, MDL Order No. 6;
 - (g) identify the injury(ies) claimed;

- (h) check the box(es) to identify legal claims asserted; and
- (i) add any additional legal counts, Defendants and supporting allegations.

d. By April 7, 2016, one week prior to the Court's April 14, 2016 status conference, GSK will provide its suggested edits to Plaintiffs' proposed Short Form Complaint so that the parties can bring any unresolved issues before the Court during the April 14, 2016 status conference.

II. DEFENDANT'S MASTER ANSWER AND RESPONSES TO SHORT FORM COMPLAINTS

- e. GSK shall file and serve its Master Answer to Plaintiffs' Master Complaint by April 21, 2016.
- f. GSK's Master Answer to Plaintiffs' Master Complaint will be deemed its answer to individual Short Form Complaints. The filing of GSK's Master Answer will eliminate GSK's obligation to file individual answers to individual complaints in this MDL, absent further Order of the Court or agreement by the Parties on Answer obligations.
- g. Other than the Master Answer set out above, the Defendant's obligation to file any responsive pleading to a Short Form Complaint that is filed in or transferred to this proceeding is hereby stayed until further Order of the Court. Before filing any motion to dismiss or for judgment on the pleadings, Defendant must meet and confer with Co-Lead Counsel for Plaintiffs and attempt to resolve the motion amicably. Any such motion must include a signed certification that a good faith effort was made undertaken to resolve the motion without the Court's intervention.
- h. The Court will decide whether oral argument is necessary.

So Ordered this ___ day of _____ 2016.

F. Dennis Saylor, IV
United States District Judge