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

PLAINTIFFS' OPPOSITION TO GSK'S MOTION FOR SEQUENCED DISCOVERY AND COUNTER-PROPOSAL FOR TARGETED DISCOVERY

I. INTRODUCTION

GSK's proposal, euphemistically entitled a "Motion for Sequenced Discovery," is by all accounts a "Motion to Litigate the Zofran MDL by Reverse Bifurcation." GSK proposes a reverse bifurcation discovery plan where scientific causation must be established before any of the sordid evidence of GSK's liability for its overpromotion of a dangerous drug for an unapproved use to doctors and pregnant women can be discovered. This backwards approach to discovery accomplishes exactly the opposite of its alleged purpose: instead of allowing for greater efficiency, it obfuscates necessary, proportional discovery and will result in a substantially longer and messier litigation.

For as long as there have been civil liability actions, there has existed an ordinary pattern of developing the evidence necessary for both sides to prove the elements of their case: discovery is exchanged that is relevant to both liability and causation, then defendants may choose to move for summary judgment, and thereafter the parties – either simultaneously, or if material facts remain – commence expert discovery. While mass tort litigation is an extension of the traditional civil action, it still adopts the standard discovery protocol. Thus, Courts presiding

over coordinated mass tort actions overwhelmingly follow this traditional and sensible protocol to this day.

With its motion, GSK urges this Court to reject the traditional sequence of discovery as inappropriate for this litigation. Instead, GSK again offers that preemption is a complete legal defense that must be prioritized over all else. GSK devotes nine pages of its moving papers to a subjective recitation on the state of the science, weaving in self-serving and improper summary judgment-like argument at this early stage of the litigation, conveniently before Plaintiffs can demonstrate to the Court evidence of GSK's deceit and orchestrated misrepresentations that resulted in Zofran's ubiquitous presence in obstetricians' and gynecologists' offices. While GSK is anxious to paint only its opinions on the science and legal issues of this case, those opinions run counter to the well-founded allegations of the Master Complaints and are an insufficient basis for reverse bifurcation of this litigation.

Reverse bifurcation is a rarely-used tool which gained popularity within asbestos litigation, wherein defendants for decades concealed the harmful nature of asbestos. As liability became a virtual certainty in most every case, switching the order of the presentation of evidence in asbestos trials became a logical decision. Scientific causation stood alone as the only contested issue in those asbestos cases. Of course here, GSK does not concede liability – in fact, GSK vehemently denies it has done anything wrong relating to its Zofran conduct. Therefore, this contested liability evidence must be discoverable along with other relevant and discoverable information in GSK's files that may support – or contradict – Plaintiffs' claims. Ignoring Plaintiffs' negligent misrepresentation claims and the need to engage in a *thorough* review of the evidence in GSK's possession relating to Zofran will result in a longer, motion-saturated

discovery process that precludes Plaintiffs from their right to a proportional and complete investigation of their claims.

II. PLAINTIFFS' PROPOSAL FOR TARGETED DISCOVERY

GSK is unaware of and uninterested in Plaintiffs' proposal for discovery in this case. Plaintiffs learned this the hard way when they were rebuffed from any joint effort, whatsoever, for a discovery plan. District of Massachusetts Local Rule 16.1 advises that at the outset of a litigation, the parties should submit a "joint statement" proposing a pretrial schedule along with a "joint discovery plan scheduling the time and length for all discovery events."[1] The Rule encourages an attempt at finding common ground on a discovery path before placing more motion practice before the Court. Plaintiffs hoped to work with GSK in developing a joint discovery plan, but instead were blindsided on June 1, 2016 when they learned that GSK had created a plan of its own for submission to the Court on June 3, 2016, regardless of Plaintiffs' position. Plaintiffs remain amenable to discussing with GSK the makeup of a reasonable and mutual discovery plan, along with all of its inherent complexities. Nevertheless, as a result of the surprising instant motion and the accompanying unilateral proposal to one-sided discovery, Plaintiffs' hand is now forced into providing an alternative to GSK's plan for reverse bifurcation. Therefore, Plaintiffs respectfully submit Plaintiffs' Plan for Targeted Discovery, attached as Exhibit A. This proposal is created from the mold of the most commonly used discovery plans which permit targeted, proportional discovery of Plaintiffs' claims to be followed in due course with an expert discovery phase. Plaintiffs' Plan for Targeted Discovery is fair and reasonable to both sides and most importantly, efficient and economical in the management of this MDL.

[1] *See* District of Massachusetts Local Rule 16.1 (2015).

A. Framework for Plaintiffs' Proposed Targeted Discovery Plan

Plaintiffs' Plan for Targeted Discovery lays out a fairly routine discovery plan consistent with this Court's desire to treat this MDL, when and where feasible, as an ordinary and individual civil action, modified of course for the scale of a product liability case that involves decades of misconduct and includes hundreds of plaintiffs. Plaintiffs' Plan is tethered to the rules allowing for discovery. It does not arbitrarily cap the number of Defendants' or Plaintiffs' discovery requests, nor does it arbitrarily seek to limit the number of depositions of document custodians. Instead, it allows Plaintiffs to start with and serve the basic discovery requests that will outline this MDL. It also allows GSK (and any future Defendants) to choose between specific discovery responses to document requests, or a business records production to the whole of the document requests.

Plaintiffs' Plan also achieves what is glaringly omitted from Defendants' plan: efficiency. Rather than dividing discovery into two potentially elongated timeframes, as GSK proposes, Plaintiffs' Plan recognizes that most often discovery requires the logical multi-tasked effort of discovery related to both liability and causation. After all, Plaintiffs' Master Complaints sound in negligence. And the legal requirements of a negligence case require proof of both liability and harm: as a seller of pharmaceutical prescription drugs, GSK had certain **duties**;[2] GSK **breached** those duties in a variety of ways, but most centrally through its negligent misrepresentations surrounding Zofran;[3] although GSK never sought approval to market and sell Zofran as a treatment for nausea and vomiting in pregnancy, it nevertheless promoted the drug as such through a series of misrepresentations that Zofran was appropriate and safe for use among pregnant women and safe for obstetricians and gynecologists ("Ob/Gyns") and other doctors to

[2] *See* Plaintiffs' Master Brand Complaint, 5/31/16, Doc. No. 255, ¶¶ 64,74-75
[3] Doc. 255 at ¶¶ 72-86

prescribe during pregnancy;[4] as a result of the widespread and false information that GSK disseminated, doctors widely prescribed Zofran to pregnant women;[5] this misconduct caused women to take a drug they believed to be safe during pregnancy; Zofran **caused** harm, namely birth defects in the babies born to the pregnant users of Zofran;[6] and, the birth defects these children suffered as a result of Zofran allow these children (and in certain instances their parents) to recover compensatory **damages** for their injuries and treatment thereof.[7] Further, given GSK's egregious deceitful conduct – conduct that GSK acknowledged as part of the largest civil healthcare fraud in United States history – Plaintiffs also maintain a **punitive damages** claim.[8]

It is axiomatic that given Plaintiffs' burden of proof to establish each of the elements of their claims, they will need discovery to do so. And of course, rather than split discovery into discrete time frames where segregated elements of proof can be discovered (despite the overlapping evidence of duty, breach and causation does not allow for such evidence to be sanitized and separated), Plaintiffs' Plan recognizes that this evidence is inextricably intertwined and that efficiency dictates the elements be discovered together.

Plaintiffs' Plan is straightforward, targeted, time-saving, cost-saving, and logical. The highlights of the Plan, attached as Exhibit A are as follows:

- The parties have a mutual obligation to exchange Fact Sheets that address specific facts relating to individual cases.

[4] See id. at ¶¶ 27-39.
[5] See id. at ¶ 36.
[6] See id. at ¶¶ 40-46.
[7] See id. at ¶ 86.
[8] See id. at ¶¶ 153-158.

- Plaintiffs will narrow the scope of discovery through two initial 30(b)(6) depositions: (1) Corporate Structure of GSK and its related entities responsible for Zofran over the years; and (2) Electronically Stored Information relating to Zofran.[9]
- Plaintiffs will serve initial sets of targeted discovery that pose specific requests and interrogatories intended to specifically address the allegations of Plaintiffs' Master Complaints.
- GSK will be entitled to respond to Plaintiffs' discovery requests either through specific document productions tethered to each request or through a general business records production of all documents that may relate to Plaintiffs' requests.
- Plaintiffs and GSK will cooperate with state court jurisdictions on discovery to help reduce duplicative effort.
- The parties will be required to bring Privilege Log disputes to the Court as often as practical to avoid large accumulations of multiple disputes.
- No limitations will be placed on discovery (including the number of custodians, depositions or discovery requests) until there is some showing of abuse or that Plaintiffs' discovery efforts are unrelated to proving the claims in their Complaint.

B. Plaintiffs' Targeted Discovery Plan is Consistent with the Vast Majority of Pharmaceutical Mass Tort Litigations

Reverse bifurcation is an infrequently used discovery method that is limited to fact patterns that warrant special treatment of a litigation. If used at all, it is usually reserved for

[9] *See* Plaintiffs' Response in Opposition to Defendant GlaxoSmithKline LLC's Motion for Protective Order Concerning Plaintiffs' Rule 30(b)(6) Deposition Notices, simultaneously filed on this date.

trials wherein liability is not in dispute and causation is the principal issue to be determined.[10] Since GSK is attempting to deviate from the standard discovery protocol employed in mass tort litigations, one would expect the supportive examples cited by GSK would share some unique element with the Zofran litigation that justifies the reverse bifurcation exception. That is not the case.

Four out of the six cases cited by GSK in favor of their preemption course involved Premarket Approval (PMA) medical devices which, by a specific federal statutory scheme inapplicable here, may preempt state law tort claims unless an exception applies.[11] The remaining two preemption cases cited by GSK involved another medical device and an opinion construing a prison official's qualified immunity defense.[12] Not a single one of these cases involved a pharmaceutical product or MDL.

In re Incretin Mimetics Products Liability Litigation (hereinafter *Incretin*) is oft-cited in GSK's recent preemption briefing. *Incretin* stands out amongst other pharmaceutical MDLs for the sheer scope of review done by the Federal Drug Administration (FDA) and other regulatory

[10] *See* Edward F. Sherman, Segmenting Aggregate Litigation: Initiatives and Impediments for Reshaping the Trial Process, 25 REV. LITIG. 691, 703 n. 46 (2006) ("Reverse bifurcation can be useful where the parties have excellent information about the likelihood of success on the issue of liability and the real sticking points are the individual issues of causation and damages").

[11] *See* Doc. 263 at 15. *See Pinsonneault v. St. Jude Med. Inc.*, 2014 WL 2879754 (D. Minn. June 24, 2014) (Riata leads at issue were a PMA Class III product and this litigation was not a MDL); *Hesik v. Boston Scientific Corp*., No. 1:12-cv-00014 (D.S.C. Oct. 3, 2013) (pacemaker implant at issue was a PMA Class III product and this was not a MDL); *Barlow v. Guidant Corp.*, No. 2:09-01161 (S.D. W.Va. Apr. 12, 2011) (implantable defibrillator at issue was a PMA Class III product and this discovery plan was entered into before case was transferred to MDL); *Riegel v. Medtronic, Inc.*, 2002 WL 34234093 (N.D.N.Y. Mar. 18, 2002) (catheter at issue was a PMA Class III product and this was not a MDL).

[12] *See* Doc. 263 at 15. *See Burgos v. Satiety, Inc.*, 2011 WL 1327684 (E.D.N.Y. Apr. 5, 2011) (stomach stapling device at issue fell under Investigation Device Exemption (IDE) with requirements analogous to PMA process. GSK provides no case management plan illustrating extent of discovery limits but merely cites one sentence in opinion narrowing post-12(b)(6) analysis discovery). *See also Crawford-El v. Britton*, 523 US 574 (1998) (Court was interpreting qualified immunity defense).

bodies prior to the issuance of the Order relied upon by GSK;[13] a compilation of analysis described by the trial judge as "unprecedented" and "comprehensive."[14] *In re Viagra Products Liability Litigation* involved an agreed-upon proposed schedule and protocol between the parties.[15] GSK also cites *In re Bextra & Celebrex Marketing Sales Practices and Product Liability Litigation*, in particular "PTO 21"/Dkt No. 1098, but omits the facts that "PTO 21" at no place includes any language "limiting" discovery to general causation nor expressly skipping liability discovery.[16]

The inclusion of the *In re Phenylpropanolamine (PPA) Products Liability Litigation* MDL (hereinafter *PPA*) is truly puzzling. First, the date of GSK's relied upon "CMO 12" is December 20, 2002, approximately 16 months after the cases were transferred to the Western District of Washington; yet, GSK somehow claimed that the MDL "order[ed] expert discovery and *Daubert* hearings within the first year of litigation."[17] Second, GSK and "CMO 12" omit the actual dates by which expert discovery or *Daubert* hearings must occur, so the Plaintiffs and Court are left to guess as to the actual duration of time between the start of the MDL – August 18, 2001, per the JPML transfer order – and expert discovery. Third, and *most importantly*, GSK conveniently ignored the 35-page "CMO 1" dated January 29, 2002, which sets deadlines for extensive factual discovery of the defendants in the litigation which would presumably have

[13] Specifically, in the summer of 2013 alone, the European Medicines Agency, American Diabetes Association, European Association for Study of Diabetes, International Diabetes Foundation, American Association of Clinical Endocrinologists, and the FDA (twice) issued statements or presented studies finding no link between incretin-based therapies and pancreatic cancer.
[14] *See In re Incretin*, 142 F. Supp. 3d 1108, 1112 (S.D. Cal. Nov. 19, 2015) (holding plaintiffs' claims preempted due to "unprecedented" set of facts of case).
[15] *See* "Exhibit E" to GSK's Motion for Sequenced Discovery, Doc. No. 262.
[16] *See* "Exhibit G" to Doc. 262. PTO 21 was preceded by PTO 20 which discussed other case-specific discovery. Further, PTO 21 stated "[a]ny case in which plaintiff alleges an injury other than a serious cardiovascular event . . . due to ingestion of Celebrex is not subject to this Order." *See id.*
[17] *See* Doc. 262 at 16.

occurred prior to any expert phase.[18] Consequently, *PPA* actually supports the rejection of GSK's reverse bifurcation plan.

It is noteworthy that since 1998 there have been approximately 158 product liability MDLs ordered by the JPML.[19] GSK cites to only three in which reverse bifurcation was adopted. Without question, the overwhelming majority of pharmaceutical mass torts have followed a path of discovery consistent with the core elements of a negligence case: duty, breach, causation, then damages. That path allows for initial discovery on defendant's liability to proceed without limitation to certain areas that address only *some* of Plaintiffs' claims. Examples from just a few recent litigations which did not reverse bifurcate or place abnormal restrictions on the parties' discovery process are instructive:

- *In re: Avandia Marketing, Sales Practices and Products Liability Litigation*, MDL No. 1871, 2:07-md-01871-CMR (E.D. Pa). *See* Report and Recommendations of the Special Master as to Discovery Plan, dated 9/11/08, attached hereto as Exhibit D-1 (setting parameters for non-restricted factual discovery including 30(b)(6) depositions before exchange of expert reports);
- *In re Yasmin and Yaz (Drospirenone) Marketing, Sales, Practices and Relevant Products Liability Litigation*, MDL No. 2100, 3:09-md-02100-DRH-PMF (S.D. Ill). *See* Minutes of Status, filed 3/4/10, attached hereto as Exhibit D-2 (documenting defendants' production of over 10 million pages of documents soon after start of MDL); *see also*

[18] *See* "CMO 1" for *In re PPA Litigation*, dated 1/29/02, attached hereto as Exhibit B. Incredibly, "CMO 1" even references the "ongoing" document production by some of the defendants in prior state litigation, providing further evidence of the body of factual discovery established before any expert discovery commenced.

[19] *See* MDL Case Report, Judicial Panel on Multidistrict Litigation, Report Date 6/22/16, attached hereto as Exhibit C (report generated via JPML's "Live" website, available at http://www.jpml.uscourts.gov/). Estimated total omits case with status of "motion withdrawn" or "denied by panel."

"CMO 18", dated 6/10/10, attached hereto as Exhibit D-3 (detailing sales and marketing custodial files to be produced in conjunction with DFS);

- *In re Vioxx Products Liability Litigation*, MDL No. 1657 (E.D. La). *See* Pretrial Order No. 17, dated 6/21/05, attached hereto as Exhibit D-4 (setting discovery parameters including RFPs, 30(b)(6) depositions, and acknowledging documents already produced);
- *In re Fresenius GranuFlo & NaturaLyte Dialysate Products Liability Litigation*, MDL No. 1:13-md-2428-DPW (D. Mass). *See* "CMO 2" (and "Exhibit A" to "CMO 2"), dated 10/1/13, attached hereto as Exhibit D-5 (setting early deadlines for written discovery and "rolling document production" and explicitly postponing expert discovery until later date);
- *In re Cook Medical, Inc., IVC Filters Marketing, Sales Practices and Product Liability Litigation*, MDL No. 2570, Case No. 1:14-ml-2570-RLY-TAB (S.D. Ind). *See* Case Management Plan and "CMO 2", dated 11/25/14 and 3/4/15, respectively, attached hereto as Exhibit D-6 (setting parameters for fact discovery including 30(b)(6) depositions and a bellwether protocol where expert discovery followed fact discovery);
- *In re Bard IVC Filters Product Liability Litigation*, MDL No. 15-02641-PHX-DGC (D. Ariz). *See* "CMO 8", dated 2/2/16, attached hereto as Exhibit D-7 (setting parameters for conclusion of factual discovery period predating expert discovery phase. Phase 2 of fact discovery beginning only 8 months into litigation).

One of the most recent MDL litigations that shares important parallels to the Zofran case provides instructive guidance. In *In re Testosterone Replacement Therapy Products Liability Litigation* (hereinafter *Testosterone*) defendants moved the court to adopt a very similar

discovery plan which limited plaintiffs to "general causation only" discovery.[20] The *Testosterone* defendants attempted to produce only discovery related to research and development, regulatory affairs, and safety/pharmacovigilance in the first phase of discovery, and conveniently set *Daubert* briefing and the motion hearing for one month *before* the end of non-general causation (sales, marketing, and other) document production.[21] The similarities do not end there. The purported rationale for the defendants' backwards science approach was the alleged "overwhelming" weight of the science, both from independent studies and very recent FDA position statements, against a connection between testosterone replacement therapies (TRTs) and cardiovascular problems.[22] Like here, the core of the plaintiffs' claim in *Testosterone* is that the defendants created a market through deceptive marketing and overpromotion, creating widespread use of a drug that carried with it significant risks.

Judge Kennelly of the Northern District of Illinois was "not persuaded" that bifurcation was appropriate or necessary. In fact, in ruling against bifurcation, Judge Kennelly reasoned that despite the defendants' suggested aim of efficiency, their process was *not likely* to be more efficient "or result in a quicker resolution of the case."[23] And it's a good thing, too: the FDA issued a Safety Announcement in March 2015 – only four months after Judge Kennelly's ruling – requiring TRT "manufacturers to add information to the labeling about a possible increased

[20] *See Testosterone* Defendants' Proposed Case Management Plan, submitted as "Exhibit D" to *Testosterone* Plaintiffs' Memorandum in Support of Proposed Unified Case Management Plan, which is attached hereto as Exhibit E.
[21] Specifically, "general causation only" discovery would be produced by 5/29/15; plaintiffs' expert reports would be due 10/1/15; plaintiffs' *Daubert* opposition would be due by 4/22/16 with a hearing on 7/1/16; and then, possibly, the *Testosterone* defendants would produce "non-general causation" discovery (sales and marketing) by 8/1/16. Sounds familiar.
[22] *See Testosterone* Defendants' Memorandum in Support of Their Proposed Case Schedule, pp 4-8, attached hereto as Exhibit F.
[23] *See* Transcript of *Testosterone* Case Management Hearing, dated 10/24/14, pp 49-50, attached as Exhibit G.

risk of heart attack and strokes . . . ." [24] [25]

Plaintiffs' proposed plan is the type most favored by MDL Courts in litigations of this type. It is targeted. It does not favor one side. It does not ask Plaintiffs to discover the case with only one eye open. It suggests and requires that the parties can multitask in order to efficiently and economically discover liability and causation at the same time. It provides safeguards to ensure that the parties remain on target and that the discovery itself is targeted to the claims of the litigation.

III. GSK'S REVERSE BIFURCATION PLAN WHOLLY IGNORES PLAINTIFFS' THEORY OF NEGLIGENT MISREPRESENTATION AND IS OTHERWISE DISPROPORTIONAL, INEFFICIENT, AND ARBITRARY.

A chief reason that the overwhelming majority of courts reject reverse bifurcated discovery is the inevitable **inefficiency** that will result from a longer, more litigious process. GSK proposes a plan that asks this Court to endorse a piecemeal approach to this litigation. It suggests that this Court enter an Order telling Plaintiffs to ignore discovery on liability even if it overlaps with science, and to press a lengthy pause on liability discovery in the event that Plaintiffs fail to muster scientific evidence. Of course, what GSK does not address is the entirely

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[24] *See* FDA Drug Safety Communication, Safety Announcement, dated 3/3/15, available at http://www.fda.gov/Drugs/DrugSafety/ucm436259.htmhttp://www.fda.gov/Drugs/DrugSafety/ucm436259.htm.

[25] Just on June 23, 2016, a Court presiding over the consolidated *Risperdal* litigation in California underscored the dangers of a limited discovery plan like GSK:

> The Court is inclined to deny the motion for summary judgment re failure-to-warn/federal preemption for reasons adequately set forth in the [Proposed] Order recently supplied by plaintiffs.
>
> The most notable development since argument was had on May 19, 2016 is the belated disclosure by Janssen (at the Court's specific request and not by the deadline set for same) of the actual terms of the 1996 request by Janssen to the FDA. It was a market-expanding request by its nature, not a purely precautionary warning/precaution to the prescribing community.

In re Risperdal and Invega Product Liability Claims, JCCP 4775, Los Angeles Superior Court, June 23, 2016, Hon. William Highberger, attached hereto as Exhibit H. Allowing GSK to dictate what it believes is the relevant discovery to preemption and causation is unfortunately akin to the fox watching the henhouse. Plaintiffs should not have to be a sleuth in discovery to demonstrate their claims.

likely scenario under its Reverse Bifurcation plan that Plaintiffs *do* demonstrate that Zofran can cause birth defects in the population that ingests the drug. Then what? Eighteen months of an MDL will have been stalled waiting for an entirely new lengthy phase. The approach is wrong and inefficient.

A. Foregoing Important Liability Discovery until 2017 will Result in a Longer, Litigious Discovery Process.

GSK's Reverse Bifurcation plan mandates that discovery of "any claims remain[ing] following the resolution of *Daubert* and dispositive motions" may commence upon "future Order of the Court," which effectively means after the expert and summary judgment deadlines that it has slotted for November and December 2017. Those "other claims" would include Plaintiffs' negligent misrepresentation claims, consequently stalling core discovery for an inexplicable amount of time.

1. Reverse Bifurcation prevents Plaintiffs from taking proportional discovery on behalf of the majority of cases pending in this MDL.

Time and again, GSK has deliberately mischaracterized Plaintiffs' case as a traditional negligent failure to warn case. The refrain is simple and self-serving: GSK is being sued solely because of the company's failure to warn of the risk of birth defects on the drug's label.[26] This refrain continues in complete disregard for the very clear allegations of *negligent misrepresentation* espoused in the numerous individual plaintiffs' complaints, and now, the

[26] "Now they can identify claims that are couched differently, have different words, but they really do boil down to a failure to warn." *See* Transcript of 1/14/16 Status Conference, statement by Madeleine McDonough, Esq., attached hereto as Exhibit I. *See also* GSK Memorandum in Support of Omnibus Motion to Dismiss, Doc. No. 96, pp 17-18, 20.

Master Brand and Master Generic Complaints filed with this Court.[27] In this case, negligent misrepresentation is derived not from the lack of a warning in the Physicians' Desk Reference (PDR) or on the bottle, but instead it is based on GSK's deliberate off-label sales and marketing to the medical community for unapproved indications and unapproved audiences, thereby *creating the market* for the use of Zofran in pregnant women. Negligent misrepresentation is a distinct cause of action that is dependent on a different set of facts which are unlikely to be contained in regulatory and pharmacovigilance files.

GSK's proposal to reverse bifurcate discovery would effectively stall the discovery necessary for the majority of the cases currently in the MDL. The states which have already embraced a version of "brand liability" for generic use – California, Illinois, Vermont, and Alabama (before the legislature's curious intervention) – have done so on the shoulders of the negligent misrepresentation theory,[28] and there are already cases in this MDL which will presumably see the application of one of those state's law on negligent misrepresentation. GSK's plan would see that none of these cases begin to discover evidence necessary to support their claims until *late 2017 or early 2018*, well after GSK will have sought dismissal for preemption – presumably for all claims pled, including negligent misrepresentation – or filed some other dispositive briefing.

GSK's plan should be revealed for what it truly is: on a broad scale, an effort to avoid or delay the necessary discovery for the majority of the filed cases, and on a small scale, an effort to

[27] *See* Doc. No. 255 at ¶¶ 29-30 ("… GSK launched a marketing scheme to promote Zofran to obstetrics and gynecology healthcare practitioners and consumers as a safe and effective treatment for pregnancy-related nausea . . . . In support of its misleading efforts . . . GSK offered and paid substantial remuneration to healthcare providers . . . .); *id.* at ¶¶ 71-86 (listing Second Cause of Action – Negligent Misrepresentation and enumerating allegations in support). *See also* Plaintiffs' Master Generic Complaint, 5/31/15, Doc. No. 256 at ¶¶ 77-92. These citations are not exhaustive of all allegations in the Complaints related to negligent misrepresentation.

[28] *See Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 653 (Ala. 2014); *Conte v. Wyeth, Inc*., 168 Cal. App. 4th 89 (Cal.Court.App.2008); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 703 (D. Vt. 2010); *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 710 (N.D. Ill. 2014).

never produce the discovery related to sales and marketing. It is no secret that GSK has settled the DOJ's claims against the company that dealt specifically with the company's sales and rampant off-label marketing for Zofran and other drugs. As a result, that evidence never saw the light of the day. In many MDLs, sales and marketing is a relevant but not necessarily crucial element to liability and causation. Here, evidence of off-label promotion and other sales and marketing efforts that can be found in the custodial files of GSK employees bears directly upon Plaintiffs' theories of liability. The Zofran Plaintiffs clearly are entitled to this discovery.

2. Reverse Bifurcation will necessarily result in a longer and more litigious discovery process.

GSK's reverse bifurcation plan guarantees a fact discovery period that persists well beyond 2018. Since, as described above, negligent misrepresentation will have to be proven in most cases in this litigation, and negligent misrepresentation turns on facts not normally discoverable in the limited clinical and pharmacovigilance files that GSK offers, GSK's plan will actually have Plaintiffs beginning core factual discovery after the conclusion of its proposed *Daubert* schedule at the end of 2017. There is no legitimate reason for parsing out factual liability discovery in such a manner.

GSK is also trying to sell this Court on the notion that its plan is in the interest of efficiency. In reality, trying to navigate a discovery process that is restricted to GSK's subjective understanding of "general causation" and areas "necessary for preemption" will inevitably lead to the opening of a veritable Pandora's Box of motion practice. For every custodial file, deposition, interrogatory, and request for production, the parties and Court would have to determine whether the particular area falls under the umbrella – if GSK has its way, a cocktail umbrella – of preemption or general causation discovery. This inevitable complication was foreseen by Judge Kennelly when faced with this issue:

> "My general experience with bifurcated discovery is **it's just a nice way of bringing up disputes about what goes into what box**."[29]

Avoiding discovery disputes in their entirety is unlikely, but it is entirely possible to considerably limit the amount and scope of the disputes as to what constitutes appropriate preemption and medical causation discovery by simply declining GSK's backwards proposal and proceeding in the normal, orderly fashion.

3. The specifics of GSK's Reverse Bifurcation plan are completely arbitrary.

In addition to all its other foundational problems, the Reverse Bifurcation plan restricts Plaintiffs to a severely limited number of depositions, interrogatories, requests for production of documents, and custodial files. Plaintiffs took no part in the formulation of these figures, but did strive to inquire as to the foundation and rationale for the figures after first seeing the plan on June 1. After GSK announced to Plaintiffs in a June 1 correspondence that its case management proposal would be submitted by June 3, Plaintiffs requested "meet & confers" on June 2 and June 3 with the hopes of substantively discussing the specifics of GSK's unconventional discovery plan and the goal of formulating a joint discovery plan.[30]

While the Plaintiffs came with questions about the specific provisions of the plan – for example, inquiries were made as to *how many* custodial files GSK identified before dictating the extremely low limit of *seven* to which Plaintiffs would be given access – GSK had no interest in making progress towards a mutual discovery plan. GSK could not give *any* rationale for its severely limited number of custodial files, depositions (seven), and written discovery requests (**twenty**) beyond maintaining that those numbers are what GSK believes is "appropriate." When Plaintiffs persisted to ascertain what was the denominator of documents and custodians from

[29] *See* Ex. G at 49-50 (emphasis added).
[30] *See* Correspondence from Jennifer Hill, Esq., dated 6/1/16, attached hereto as Exhibit J.

which GSK was dictating these limits, GSK shut down the discussion, telling Plaintiffs that such questions did not "move the ball forward." Given our distance on almost every single issue, and the refusal of GSK to seriously consider Plaintiffs' issues – let alone, suggestions – Plaintiffs requested on the morning of June 3 that the CMO not be submitted until real progress was made. Hours later, GSK submitted the Motion to which Plaintiffs now respond.[31]

B. There is no Compelling Argument on Science or Preemption That Would Justify the Inefficiencies and Prejudices Caused by Reverse Bifurcation.

GSK's lengthy and wholly unnecessary recitation of their favored science arguments is a thinly veiled attempt to re-litigate their preemption motion, only five months after its dismissal and without any discovery in between. Since GSK's self-serving dissertation on science is biased and not the subject of the debate on the issue of ***how and when*** discovery should proceed, Plaintiffs decline to take the bait and use the memorandum in opposition to outline the substantive underpinnings of the scientific (or liability) case. This is neither the time nor forum for that substantive weighing of the evidence. Suffice it to say that GSK misstates the scientific evidence upon which Plaintiffs will rely, omits the basic scientific allegations pled in the Master Complaints, and employs an incredibly flawed study to mischaracterize the state of the science.[32]

Just as GSK could not cite to any MDLs as pointed precedent for reverse bifurcation here, it similarly failed to point to any secondary authority that actually suggests there is logic to putting science before liability discovery in this case. In what is surely coincidence, GSK cites

[31] Brazenly attached to its Motion is a Rule 7.1 Certification which avers that the parties conferred "in a good faith attempt to narrow the issues of dispute without success." *See* GSK's Motion for Sequenced Discovery, Doc. 262 at 2.

[32] *See* Doc. 255 at ¶¶ 20-21 ("Among patients who ingested Zofran, the drug has caused sometimes fatal cardiac arrhythmias such as QT prolongation and Torsade de Pointes . . . . Defendants have been aware of these facts at all relevant times, but they failed have failed to inform healthcare providers, their patients, or the public of the impact of these potentially life-threatening conditions on the developing embryo and fetus"). *See also id*. at ¶¶ 45, 46 (discussing the animal studies and adverse event reports in GSK's possession that demonstrate a link between Zofran and birth defects).

to the exact same two provisions of the Complex Litigation Manual that were unsuccessfully employed by the *Testosterone* defendants in their motion for reverse bifurcation: §§ 11.422 and 22.634.[33] However, the Manual is not intended to be a tool to usher defendants to a more expedient summary judgment stage, but instead a guide to ensure a fair and balanced discovery phase: "[i]n determining appropriate limits, the court will need to balance efficiency and economy against the parties' need to develop an adequate record for summary judgment or trial."[34]

As demonstrated above, GSK's plan will lead to inefficiency and expansion of the discovery process, whereas Plaintiffs *require* the basic discovery that GSK attempts to restrict in order to meet their burden for general and specific causation. General causation in this case will be proven not just by the published medical studies, but also by data from animal studies, cell studies, and other internal analyses conducted by GSK or its affiliates, which at this time are in the possession of GSK. Plaintiffs need ample time in order to digest the 530,000 pages produced on June 10 and June 13 in the NDA/IND files for Zofran. However, it is important to note that the NDA/IND files address only Zofran's on-label uses, and that GSK excluded pregnant women from the clinical trials conducted to support FDA approval of the drug. Plaintiffs thus require more leeway in the discovery process to determine the nature and scope of GSK's additional, relevant scientific evidence beyond that which was submitted to the FDA decades ago for a separate treatment population than the Plaintiffs. Moreover, in view of GSK's affirmative marketing of Zofran to treat pregnancy-related nausea, it is reasonable to expect that much of GSK's internal and external scientific and medical communications about Zofran's risks and

[33] See Exhibit F, pp 1, 9.
[34] *See* MANUAL FOR COMPLEX LITIGATION (Fourth) § 11.422 (2004). *See also* § 22.87 ("Generally, the more novel, complex, and central the scientific or technical issues, **the more time the parties will need to conduct discovery, prepare expert reports**, and brief the issues for *Daubert* hearing") (emphasis added).

benefits for use in pregnancy flowed through the sales and marketing departments. Therefore, it is premature to entertain scientific arguments *four months from now* when GSK has yet to provide all the scientific discovery relevant to the issue of causation.

Stuffing this Court's docket with expedited science discovery is clearly a tactic to avoid responsive, proportional discovery of all the relevant areas of inquiry laid out in Plaintiffs' Complaints – so too is GSK's red herring preemption argument. A preemption track will not "narrow" the litigation as GSK suggests, since their proposal deliberately withholds relevant discovery that could be derived from custodians in the sales and marketing departments. Such discovery is vital for two reasons: 1) it contains information relevant to Plaintiffs' failure to warn claims,[35] and 2) it contains information necessary for Plaintiffs' negligent misrepresentation claims, which turn on GSK's actions in creating the off-label market for Zofran and are therefore not subject to a preemption ruling.[36] If the negligent misrepresentation claims cannot be extinguished in preemption briefing, and are unquestionably pertinent to the litigation as a whole, then a great deal of time would be wasted in attempting to narrow the initial discovery phases knowing full well that discovery will have to be visited at some point. Instead, this discovery along with other *proportional* liability discovery should be commenced immediately

[35] *See, e.g., Smith v. Pfizer Inc.*, No. 3:05-0444, 2010 WL 1754443, at *2 (M.D. Tenn. Apr. 30, 2010) ("[E]vidence of a national marketing scheme to promote Neurontin's off-label benefits is not 'independent from the acts upon which' the plaintiff seeks to impose liability. As described above, any such scheme bears directly on the plaintiff's negligence claim, because it affects the defendants' duty to test the safety of their drug for off-label uses and label it accordingly").

[36] This lawsuit is as much about GSK's conduct as it is the physical product of Zofran. *But for* GSK's conduct and misrepresentations, there would not be a market for Zofran use in pregnant women. So, when GSK circumvented the FDA and FDCA to promote Zofran for use in pregnant women, it forfeited the ability to claim blanket preemption protection under the FDCA against any theory of negligence. In this litigation involving clear off-label promotion, negligent misrepresentation and traditional failure to warn are distinct legal claims and cannot be couched together. *See, e.g., Knipe v. SmithKlineBeecham*, 583 F. Supp. 2d 602, 619 (E.D. Pa. Sep. 30, 2008) (finding in off-label Paxil pediatric-use case that negligent misrepresentation claims based on off-label promotion were distinguishable from traditional failure to warn claims and therefore could not be subsumed under the state's strict Product Liability Act).

so that a full record can be established before GSK attempts any further dispositive motions on one or more of Plaintiffs' claims.

IV. CONCLUSION

GSK seeks a reverse bifurcation plan for discovery that precludes Plaintiffs from proportional, relevant investigation into the core claims of this case. Therefore, Plaintiffs hereby request that GSK's Plan be denied and Plaintiffs' Plan for Targeted Discovery be entered.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 24, 2016 the foregoing Opposition To GSK's Motion For Sequenced Discovery And Counter-Proposal For Targeted 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/ Tobias L. Millrood