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' RESPONSE IN OPPOSITION TO GLAXOSMITHKLINE LLC'S RULE 12 MOTION TO DISMISS AND/OR FOR JUDGMENT ON THE PLEADINGS PERTAINING TO PROCEDURAL RIPENESS

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I. INTRODUCTION

Defendant GlaxoSmithKline, LLC's ("GSK's") request to dismiss all cases at the initial pleadings stage is unripe, unprecedented and violates established federal law. GSK has not cited a single case in which a court has addressed the so-called "clear evidence" preemption exception at the pleading stage, and Plaintiffs' research has disclosed no case in which a court upheld a clear evidence affirmative defense prior to any discovery. Indeed, every case cited by GSK addressing the issue did so based on a summary judgment or trial record.

As with all pharmaceutical products liability actions involving branded drugs, application of the narrow "clear evidence" exception to the general rule against federal preemption requires a fact-intensive inquiry based upon a developed evidentiary record. Plaintiffs before this Court all allege that they suffered birth defects caused by exposure to the drug Zofran®, which GSK falsely and misleadingly marketed as a safe and effective treatment for Plaintiffs' pregnancy related nausea. Because GSK has never sought approval from the U.S. Food and Drug Administration ("FDA") to market Zofran for this experimental purpose, and because discovery in this litigation has not yet begun, GSK has exclusive control of much of the evidence relevant to the foreseeable risks of Zofran use during pregnancy.

The U.S. Supreme Court in *Wyeth v. Levine* and its progeny have deemed this type of evidence essential to an assessment of the affirmative defense of "clear evidence" preemption. Notwithstanding, GSK urges dismissal of *all* individual claims in this MDL at the pleading stage based upon its affirmative defense. Its request must be denied at this juncture, as it is procedurally unavailable under Federal Rule of Civil Procedure 12 and premature based upon the lack of evidence before the Court.

GSK's arguments in support of dismissal of these complaints under Rule 12 all are premised upon its incorrect assertion that this Court may judicially notice statements contained

in a single letter, the Woodcock Letter.[1] Judicial notice of these statements is unsupported because the facts and opinions asserted therein are in reasonable dispute, and, independently, because the statements are offered for the truth of the matter asserted. Moreover, consideration of the Woodcock Letter without analysis of any other contextual evidence that will be developed in this case would contravene established law. Accordingly, GSK's motion is critically flawed, premature and procedurally misguided. In the interest of efficiency, fairness and the orderly process of this MDL, Plaintiffs respectfully request this Court deny this Motion.

II. BACKGROUND PERTINENT TO PROCEDURAL RIPENESS

This newly created MDL proceeding coordinates the individual claims of more than 200 children and their mothers seeking to recover from the damage GSK has caused their families. There are no class action allegations in any of the Complaints. As alleged, these families suffer hardships as a result of the serious birth defects caused by prenatal exposures to Zofran, GSK's brand name for the oncology drug ondansetron.[2] Zofran is a drug for which GSK initially sought and received FDA approval for the treatment of chemotherapy induced nausea suffered by cancer patients. Given this specific indication, it is not surprising that GSK did not disclose to the FDA data on the safety of the drug for healthy pregnant mothers or their babies. Pregnant mothers were specifically excluded from the clinical trials GSK sponsored to obtain FDA approval.[3] Following GSK's launch of Zofran, GSK did not provide safety information after its decision to market the drug to obstetricians for the treatment of pregnancy related nausea and vomiting, otherwise known as morning sickness. The testing that GSK has conducted to

[1] On October 27, 2015, Janet Woodcock of the FDA wrote a letter in response to a private citizen's petition concerning information relating to Zofran. That letter, attached to GSK's Motion to Dismiss as Exhibit A, is herein referred to as the Woodcock Letter.

[2] Zofran is an oncology drug designed for the treatment of nausea associated with chemotherapy and radiotherapy in cancer patients. The drug's only other indication is for prevention of post-operative nausea in certain instances. (*LeClair v. GSK*, No. 1:15-cv-10429-FDS, Compl. ¶ 1.)

[3] *Id.* ¶ 3.

evaluate the risks of Zofran during pregnancy is in GSK's exclusive control.[4] Notwithstanding, GSK undertook an unprecedented nationwide marketing initiative to promote this drug as a prophylactic treatment for morning sickness.

At the time GSK petitioned for MDL centralization, there were only a few dozen cases pending. Today there are hundreds of cases centralized before this Court, and Plaintiffs are filing new cases weekly. Indeed, with the volume of new complaints growing and the responsive obligations of GSK increasing, counsel for GSK wrote Plaintiffs' Co-Lead Counsel on November 10, 2015 with a request attaching "a proposed order to stay all responsive pleading deadlines in the MDL *to allow us time to discuss the use of master pleadings*.[5]" With no opposition from Plaintiffs to a stay of responsive pleadings, on November 18, 2015, the Court issued MDL Order Number 4, stating that, "[i]n the interests of judicial economy, all deadlines to file responsive pleadings are stayed in all transactions to this Court in this multi district proceeding pending further order of this Court." There were many sound reasons that supported the stay, including the fact that a Plaintiffs' Steering Committee had not yet been appointed and a determination of whether a master pleading would be filed had not been made. Nevertheless, despite GSK Counsel's November 10, 2015 representation and despite this Court's Order, on December 11, 2015, GSK filed the instant Motion. (Doc. No. 96.)[6] The Court directed the Plaintiffs to address the ripeness of the Motion first.

This Court can deny GSK's Motion to Dismiss based purely on the inefficiencies that would result if GSK is permitted to move forward procedurally and substantively with its

[4] *Id.* ¶ 142.
[5] *See* November 10, 2015 e-mail from Madeleine McDonough to Co-Lead Counsel, attached as Exhibit A. (Emphasis added.)
[6] 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.

motion. GSK did not identify all specific complaints on which it moves against. Though it is aware of more than 200 cases pending at this point, GSK cites to only three within its Motion and carefully and very generally uses the language "Plaintiffs" throughout. Should this Court allow GSK to move forward on the substance of its motion, hundreds of Plaintiffs have the right to amend their complaints to correct the mischaracterizations of "Plaintiffs" claims within the instant Motion. This invites inefficiency. Furthermore, as set forth below, GSK's proffered arguments in support of the sweeping application of its affirmative defenses are premature. GSK's affirmative defense may be considered only after analysis of a properly developed evidentiary record. As such, Plaintiffs request that this Court deny GSK's Motion.

III. THE LEGAL STANDARD APPLICABLE TO THIS MOTION MANDATES ITS DENIAL

Courts addressing motions to dismiss for failure to state a claim ordinarily consider only the four corners of the complaint, and are required to "assum[e] the truth of all well-pleaded facts contained in the operative version of the complaint and indulg[e] all reasonable inferences in the plaintiff's favor." *Ruiz-Sanchez v. Goodyear Tire & Rubber Co.*, 717 F.3d 249, 256 (1st Cir. 2013). Where an argument raised in an affirmative defense requires factual development, this "precludes resolving the contention through a Rule 12(b)(6) motion to dismiss," and an order of dismissal will be vacated on appeal. *Id.*

Under Rule 12(b)(6) and 12(c), the district court may properly consider only facts and documents that are part of or incorporated into the complaint and the answer itself. *Rivera v. Centro Medico de Turabo, Inc.*, 575 F.3d 10, 15 (1st Cir. 2009). Ordinarily, if matters outside the pleadings are considered at the 12(b)(6) or 12(c) stage, the motion must be decided under the more stringent standards applicable to a Rule 56 motion for summary judgment. Fed. R. Civ. P. 12(d). In that event, all parties must be given a reasonable opportunity to present all the material

that is pertinent to the motion. *Id.* Courts have adopted narrow exceptions to this rule for "documents, the authenticity of which are not disputed by the parties; for official public records; for documents central to Plaintiffs' claim; or for documents sufficiently referred to in the complaint." *Simon v. Abiomed, Inc.*, 37 F. Supp. 3d 499, 504 (D. Mass. 2014). Such documents may not, however, be considered for the "the truth of the matters asserted." *Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007). In all events, "a ruling on a motion for dismissal pursuant to Rule 12(b)(6) is not an occasion for the court to make findings of fact." *Id*.

IV. ARGUMENT

A. The Clear Evidence Standard Requires a Fact-Specific Analysis Based upon a Developed Evidentiary Record That is Not Present Here.

GSK should not be permitted to proceed with its Motion because the relief it seeks is dependent upon a fact-intensive record that can only be developed through discovery. GSK seeks to dismiss the entire litigation on a narrow exception to the rule against preemption that would in turn provide complete impunity to a pharmaceutical manufacturer that promotes its drug for an experimental purpose.[7] The fact that there is *no evidence* before this Court – much less a developed evidentiary record suggesting the *clear* evidence required under the relief GSK

[7] The Court has directed the parties to address only the ripeness issue at this stage. If GSK's Motion is permitted to proceed, it will likewise become clear substantively that an evidentiary record must be developed in order to consider the merits. The United States Supreme Court has established the general rule against allowing a drug manufacturer to invoke the affirmative defense of preemption in pharmaceutical cases in order to escape liability from its failure to warn of the harm caused by its products. Specifically, in *Wyeth v. Levine*, 555 U.S. 555 (2009), the Supreme Court addressed whether the Food and Drug Administration's (FDA's) approval of a pharmaceutical manufacturer's branded drug's warning label provides a preemption defense to failure to warn claims arising under state law. *Id.* at 558-59. The Court held that FDA's approval notwithstanding, there is no express or field preemption in the pharmaceutical liability context, as "manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Id.* at 578-79. Accordingly, GSK bears responsibility for its failure to comply with state law, unless it can prove, by "clear evidence," that a narrow exception to the general rule against preemption established in *Levine* is warranted. In other words, in order to invoke its preemption defense, GSK bears the burden to prove with "clear evidence" that, although it attempted to update its warnings to comply with state law, the FDA prohibited the manufacturer from doing so: "Absent clear evidence that the FDA would not have approved a change to [the drug's] label," the Court will not "conclude that it was impossible for [the manufacturer] to comply with both federal and state requirements." *Id*. at 571. GSK cannot meet this burden based upon the record now before this Court.

seeks – mandates a denial of GSK's Motion, as any analysis of the clear evidence standard necessarily is fact-intensive.[8] In *Wyeth v. Levine*, 555 U.S. 555 (2009), the Court identified four fact-specific considerations relevant to a clear evidence determination:

> (1) the manufacturer's knowledge and information concerning the risk in question, *id.* at 569-70;
>
> (2) whether the manufacturer supplied the FDA with an evaluation or analysis concerning the specific risks at issue;
>
> (3) whether the manufacturer attempted to give the kind of warning that plaintiff alleges was required under state law; and
>
> (4) whether the FDA precluded the manufacturer from doing so.

Id. at 572-73. As set forth herein, neither the Plaintiffs nor this Court has any evidence yet to perform this inquiry.

1. Plaintiffs Are Entitled to Discover and Present Evidence to This Court Pertaining to GSK's Knowledge Concerning Birth Defects.

First, Plaintiffs are entitled to discover and present to this Court what GSK knew about its drug's propensity to cause birth defects, as clear evidence determinations require consideration of the manufacturer's knowledge and information concerning the risk at issue. In *Levine*, the Court considered the manufacturer's information concerning the risk in question, including incident reports and "accumulating data" received by the company and the company's communication with the FDA about this information. *Id.* at 569-70. Consideration of the manufacturer's knowledge of the risk is necessary to a clear evidence determination because "manufacturers have superior access to information about their drugs, especially in the post-marketing phase as new risks emerge" and thus "manufacturers, not the FDA, bear primary

[8] *See Shipley v. Forest Labs., Inc.*, No. 1:06-CV-00048-TC, 2015 WL 4199739, at *10 (D. Utah July 13, 2015) ("[T]he clear evidence standard is a fact based inquiry."); *Koho v. Forest Labs., Inc.*, 17 F. Supp. 3d 1109, 1118 (W.D. Wash. 2014) (same); *Reckis v. Johnson & Johnson*, 28 N.E.3d 445, 457 (Mass. 2015) ("[A]pplication of the clear evidence standard is necessarily fact specific.").

responsibility for their drug labeling at all times." *Id.* at 578-79. GSK alone possesses this information, as Plaintiffs have yet to undertake any discovery in this newly created MDL.[9]

It is undisputed that the FDA has never approved Zofran for the treatment of pregnancy related nausea and vomiting. Nevertheless, in an effort to expand the market for the drug and increase its profits, GSK sales representatives marketed the drug to obstetricians nationwide. In such cases, consideration of the manufacturer's knowledge of the risk at issue could not be more essential as the FDA has not conducted its approval process with respect to the marketing of Zofran for morning sickness:

> The FDA drug approval process is "onerous and lengthy." The FDCA requires that drug manufacturers gain FDA approval prior to marketing or selling a drug in interstate commerce. *See* 21 U.S.C. § 355(a) [new drugs]. To gain FDA approval, a drug manufacturer must submit either a new-drug application ("NDA"), for a new drug, or a supplemental new-drug application ("sNDA"), *for a new treatment*. *See* 21 C.F.R. § 314.1 *et seq*. NDAs and sNDAs are subject to the same approval requirements. *See id.* The NDA or sNDA must include "full reports of [all clinical] investigations which have been made to show whether ... such drug is [safe for use and whether such drug is] effective in use." 21 U.S.C. § 355(b)(1)(A).

In re Celexa & Lexapro Mktg. & Sales Practices Litig., 779 F.3d 34, 35-36 (1st Cir. 2015) (emphasis added). Thus, while manufacturers have *superior* access to information about their drugs with respect to post-market risks of FDA-approved uses of the drug, *id.*, manufacturers have *exclusive* access to most information about non-FDA approved uses for which they market their drugs.[10] For this reason, discovery of this information is highly relevant to GSK's "clear evidence" preemption defense.

[9] In April 2014, GSK sold its "oncology drugs," including Zofran, to Novartis Pharmaceuticals Corporation. The future role of Novartis in this MDL is just one more reason the instant motion is not ripe.

[10] *See Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 553, 584-85 (E.D. Pa. 2008) (observing the "void in the authority of the FDA, which can neither independently regulate off label use nor require additional clinical trials" concerning a drug's use that a company has promoted off label).

2. Plaintiffs Suspect that GSK Was Involved in Animal Teratogenicity Studies in Japan that Reveal the Same Defects As Alleged Here.

Plaintiffs have not been privy thus far to any information that GSK holds regarding Zofran and the risk of birth defects. Notwithstanding, Plaintiffs have reason to believe that GSK has important evidence about the defects alleged here, and the link to Zofran. For example, Plaintiffs can point to several animal teratogenicity studies of Zofran conducted by GSK *after* the launch of Zofran sales in the United States with limited approval as an oncology drug.[11] At least one of the studies revealed Ventricular Septal Defects in fetuses from dams treated intravenously with ondansetron during organogenesis. These are the same cardiac birth defects that many Plaintiffs allege in their complaints.

Plaintiffs do not know whether GSK ever provided the FDA this or any other evidence of severe heart defects. What Plaintiffs do know, however, is that the Zofran warning labels and available marketing materials were silent as to such evidence. Furthermore, there is no evidence that anyone at the FDA ever considered these animal studies in conjunction with the Woodcock Letter. This is just one example to support the necessity of discovery in this litigation and denial of GSK's Motion.

3. Plaintiffs Are Entitled to Obtain and Present Evidence Concerning GSK's Interactions with the FDA.

Plaintiffs are entitled to discover and present to this Court evidence pertaining to what, if anything, GSK supplied to the FDA relevant to the risks of Zofran. *Levine* teaches that courts should consider whether the manufacturer shared with the FDA any of the manufacturer's information, evaluation, or analysis concerning the risk in question; whether the manufacturer attempted to update its warnings in any way based on its analysis of the risk; and whether the

[11] *See Torres v. GSK*, No. 1:15-cv-14247, Doc. No. 1, Compl.¶ ¶ 50, 69.

FDA precluded the manufacturer from doing so in view of the totality of available evidence, including that provided by the manufacturer. *Id.* at 572-73. Thus, in *Levine*, the Supreme Court considered the extensive regulatory history of the drug in question, including evidence of information exchange between the FDA and the manufacturer dating more than thirty years, from the drug's initial approval in 1955 through 1998, as well as the supplemental new drug applications and label changes proposed by the manufacturer. *Id.* at 563. The Plaintiffs should be permitted to present similar information to this Court before it analyzes the merits of GSK's preemption defense.

As the U.S. Court of Appeals for the Seventh Circuit observed,

> Since *Levine* is our intellectual anchor . . . *we must look at the long and fairly extensive administrative history of Phenergan and compare it to the administrative history of Paxil*. . . . *While the opinion in Levine covers the administrative history and record, the dissent delves even deeper*. . . . *The dissent then meticulously lists the various times the FDA considered a different warning label regarding the IV-push method. It begins in 1975 when several people from Wyeth and several members of the FDA met regarding Phenergan's label* . . . . [W]e *turn our attention to the administrative record of Paxil* and see if it is any more compelling.

Mason v. SmithKline Beecham Corp., 596 F.3d 387, 392-93 (7th Cir. 2010) (emphasis added).

Courts uniformly concur with the view that the clear evidence determination *must* be based on more than simply the evidence provided by the manufacturer, and thus have rejected arguments similar to the ones GSK now advances. *See id.* ("GSK highlights that the FDA had been thoroughly reviewing the data available about SSRIs and suicide and concluded there was not an increased risk of self-harm from SSRIs. In particular, GSK points out that on three separate occasions the FDA rejected a citizen petition for a labeling change for Prozac that would have included a warning about suicide. The FDA's rejection of the Prozac warnings, however, is not as clear-cut as GSK would have us believe."); *Miller v. SmithKline Beecham*

Corp., 381 F. App'x 776, 778 (10th Cir. 2010) ("After *Levine,* GSK must demonstrate that federal labeling requirements made it impossible to meet its state law duty to warn by proving that there was "clear evidence" that the FDA would have rejected GSK's labeling change had it unilaterally strengthened Paxil's warning label using the CBE supplement.")[12]

B. Every Court To Consider the Clear Evidence Standard Has Done So In the Context of a Motion for Summary Judgment or Post-Trial Motion.

Because *Levine*'s clear evidence standard requires evidentiary findings based upon a developed record, the earliest juncture at which the standard could be addressed is after discovery has occurred and the record before this Court is sufficiently developed on this issue. Every published opinion addressing the clear evidence standard has thus done so in the context of a motion for summary judgment or a post-trial motion.[13] Despite its sweeping proclamation

[12] *See also Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225, 1236-37 (9th Cir.) cert. granted, judgment vacated sub nom. *L. Perrigo Co. v. Gaeta*, 132 S. Ct. 497, 181 L. Ed. 2d 343 (2011) (reversed on other grounds based on *Pliva v. Mensing*) (considering whether the manufacturer "supplied the FDA with any 'evaluation or analysis concerning the specific dangers' posed by its drug); *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 2436, 2015 WL 7075916, at *21 (E.D. Pa. Nov. 13, 2015) (considering the company's knowledge of the risk in question and observing that, "[a]s *Wyeth* made clear, the onus has always been on McNeil to ensure its label accurately reflects the risks of Extra Strength Tylenol"); *Shipley v. Forest Labs., Inc.*, No. 1:06-CV-00048-TC, 2015 WL 4199739, at *10-11 (D. Utah July 13, 2015) (considering whether the manufacturer produced any evidence to show that it attempted to change its warnings for the drug in question or shared its knowledge of the risk with FDA through the CBE process); *Koho v. Forest Labs., Inc.*, 17 F. Supp. 3d 1109, 1118 (W.D. Wash. 2014) (considering whether defendant proposed any modifications to its drug label before the plaintiffs' injury); *In re Actos (Pioglitazone) Prod. Liab. Litig.*, No. 12-CV-00064, 2014 WL 60298, at *7, *22 (W.D. La. Jan. 7, 2014) (considering whether the "FDA, *had it been presented with a complete, accurate, and forthright description of the evidence,* would have chosen to *hide* from the medical community and the general public the possibility of an increased risk of the very serious side effect" of the drug in question) (emphasis in original); *McCarrell v. Hoffman-La Roche, Inc.*, No. A-3280-07T1, 2009 WL 614484, at *43-44 (N.J. Super. Ct. App. Div. Mar. 12, 2009) ("Roche does not . . . establish whether it advocated such a stronger warning, or whether the FDA would not have approved a stronger warning, both requirements for application of the *Wyeth* exception. The incomplete record supplied to us about the chronology of the FDA's review of Accutane's labeling is insufficient for us to evaluate, at least in the first instance, the preemption issues implicated by *Wyeth*.")

[13] *See*, *e.g., Wyeth v. Levine*, 555 U.S. 555, 561 (2009) (addressing post-trial motion asserting preemption under clear evidence standard); *In re Actos (Pioglitazone) Prods. Liab. Litig.*, No. 6:11-MD-2299, 2014 WL 4364832, at *18 (W.D. La. Sept. 2, 2014) (addressing clear evidence preemption based on trial record); *Schedin v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F. Supp. 2d 1125, 1133 (D. Minn. 2011), partially overruled on other grounds, *In re Levaquin Prod. Liab. Litig.*, 700 F.3d 1161 (8th Cir. 2012) (same); *Reckis v. Johnson & Johnson*, 28 N.E.3d 445, 460 (Mass. 2015) (same); *see also*, *e.g.*, *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 389, 392-93 (7th Cir. 2010) (applying clear evidence standard on appeal based on summary judgment record); *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 2436, 2015 WL 7075916, at *21-24 (E.D. Pa.

that this Court can properly consider GSK's Motion on the pleadings, GSK has not cited a single case in which a court has done so, and Plaintiffs' research has disclosed none. Indeed, *every* case cited by GSK addressing the clear evidence preemption standard did so on a summary judgment or trial record.[14] (Doc. No. 96 at pp. 8-9.)

GSK improperly relies on *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) to support its argument that the conclusions supporting application of the clear evidence exception to preemption are "ripe for determination at the motion to dismiss stage." (Doc. No. 96, at 8.). This reliance is misplaced because *Mensing* did not address preemption under the clear evidence standard. *Mensing* involved a conflict between state law and a federal law that required a generic manufacturer to use the same labeling as its brand-name counterpart. *Id.* at 2577. The Court in *Mensing* observed that the clear evidence exception was limited to branded drugs. *Id.* at 2593 n.8; *see also Shipley v. Forest Labs., Inc.*, No. 1:06-CV-00048-TC, 2015 WL 4199739, at

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Nov. 13, 2015) (addressing summary judgment record); *Shipley v. Forest Labs., Inc.*, No. 1:06-CV-00048-TC, 2015 WL 4199739, at *10-12 (D. Utah July 13, 2015) (same); *Koho v. Forest Labs., Inc.*, 17 F. Supp. 3d 1109, 1118-19 (W.D. Wash. 2014) (same); *Forst v. SmithKline Beecham Corp.*, 639 F. Supp. 2d 948, 952-55 (E.D. Wis. 2009) (same); *Hayes v. SmithKline Beecham Corp.*, No. 07-CV-0682-CVE-TLW, 2009 WL 4912178, at *4 (N.D. Okla. Dec. 14, 2009) (same).

[14] *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 864 (7th Cir. 2010) (addressing preemption based on trial record); *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 389 (7th Cir. 2010) (addressing summary judgment record); *In re Incretin-Based Therapies Prods. Liab. Litig.*, No. 13MD2452 AJB (MDD), 2015 WL 6912689, at *2 (S.D. Cal. Nov. 9, 2015) ("Defendants initially moved for summary judgment premised on conflict preemption in April 2014. (Doc. No. 410.) The Court denied the motion without prejudice and granted Plaintiffs' request for additional discovery pursuant to Federal Rule of Civil Procedure 56(d)."); *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1267 (W.D. Okla. 2011) ("Although the *Levine* [Court] did not review a summary judgment ruling, the court must apply the clear evidence standard to determine the propriety of granting *summary judgment*, as 'the inquiry involved in a ruling on a motion for summary judgment or for a directed verdict necessarily implicates *the substantive evidentiary standard of proof* that would apply at the trial on the merits.") (Emphasis added); *Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-CV-144, 2015 WL 4743056, at *6 (S.D. Ohio Aug. 10, 2015) (addressing clear evidence standard based on summary judgment record); *In re Fosamax (Alendronate Sodium): Prods. Liab. Litig.*, No. 08-08 JAP LHG, 2014 WL 1266994, at *2 (D.N.J. Mar. 26, 2014) (noting that the court heard oral argument on preemption issue based on a summary judgment record, but "reserved decision until a trial record had been established"); *In re Byetta Cases*, 2015 WL 7184655, at *3 (Cal. Super. Nov. 13, 2015) ("The motion before the Court is presented as a motion for summary judgment . . . . Accordingly, there are voluminous declarations and supporting exhibits and excerpts of discovery depositions and exhibits thereto."); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 951 F. Supp. 2d 695, 697 (D.N.J. 2013) (addressing preemption based on trial record); *Dorsett v. Sandoz, Inc.*, 699 F. Supp. 2d 1142, 1144 (C.D. Cal. 2010) (addressing summary judgment record);

*9 (D. Utah July 13, 2015) (noting that *Mensing* "is easily distinguishable because it involved a generic drug" and explaining difference between preemption defense arising from claim against manufacturers of generic drugs and the clear evidence standard applicable to branded drugs).[15]

Further, GSK's reliance on *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34 (1st Cir. 2015) to argue that a clear evidence determination is ripe now is equally unavailing. The Court in *Celexa* did not address the clear evidence standard. Indeed, "clear evidence" appears nowhere in the *Celexa* opinion, and the claims at issue there, unlike here, were based entirely on allegations of misconduct occurring before the FDA's initial approval of the drug. *Id.* at 41. By contrast, the clear evidence standard announced in *Levine* applies to claims involving a company's alleged failure to disclose risks that emerged *after* a drug's initial FDA approval. *See Levine*, 555 U.S. at 571.

Finally, GSK relies on additional inapposite cases involving express preemption under Section 514 of the Employee Retirement Income Security Act (ERISA)[16] and one involving the doctrine of *res judicata* barring re-litigation of a bankruptcy issue.[17] These cases have no bearing on the availability of the preemption defense in pharmaceutical cases, as articulated by the Supreme Court in *Levine.*

[15] The case of *Phelps v. Wyeth, Inc.*, 857 F. Supp. 2d 1114, 1118 (D. Or. 2012) does not support GSK's position either. As with *Mensing*, the clear evidence standard applicable in the branded drug context was not addressed in *Phelps*, which involved injuries arising solely from use of a generic drug.

[16] *See* Doc. 96, at 8 (citing *Tobin v. Nadeau*, No. CIV.A.03-11817-DPW, 2004 WL 1922134, at *5 (D. Mass. Aug. 30, 2004) (ERISA); *Kellerman v. Scovill Mfg. Co.*, No. CIV. 91-358-M, 1994 WL 529907, at *1 (D.N.H. July 19, 1994) (ERISA); *McCoy v. Mass. Inst. of Tech.*, 950 F.2d 13, 23 (1st Cir. 1991) (ERISA)).

[17] *See* Doc. 96, at 8 (citing *In re Colonial Mortgage Bankers Corp.*, 324 F.3d 12, 20 (1st Cir. 2003)).

C. GSK's Request That This Court Take Judicial Notice of the Woodcock Letter Is Improper And Cannot Serve As a Basis for Dismissal of Plaintiffs' Claims.

Notwithstanding GSK's efforts to shoehorn its Motion into a Rule 12 format, its Motion does not seek to test the adequacy of the pleadings filed by various Plaintiffs. Rather, GSK seeks to dispute the merit of Plaintiffs' factual allegations by offering extrinsic evidence of a letter written by FDA employee Janet Woodcock. GSK's preemption argument must fail as this letter is not properly before this Court and as the discussion contained in the correspondence is very much the subject of controversy.

Judicial notice is appropriate only for "facts outside the area of reasonable controversy," and a "high degree of indisputability is an essential prerequisite." Fed. R. Evid. 201(a) Advisory Committee's note.[18] Sound reasons support this requirement because "the effect of taking judicial notice under Rule 201 is to preclude a party from introducing contrary evidence and in effect, directing a verdict against him as to the fact noticed." 2 *Handbook of Fed. Evid.* § 201:1 (7th ed.). With respect to publicly available documents, judicial notice of correspondence such as the Woodcock letter, "is proper only for the fact of the documents' existence, and not for the truth of the matters asserted therein."[19] "If it were permissible for a court to take judicial notice of a fact merely because it has been found to be true in some other action, the doctrine of collateral estoppel would be superfluous." 2 *Handbook of Fed. Evid.* § 201:1 (7th ed.).

GSK touts Dr. Woodcock's statement that the evidence available to her concerning Zofran's birth defect risk "is not sufficient to conclude that there is an increased risk of birth

[18] Under Federal Rule of Evidence 201, a court may judicially notice an adjudicative fact only when the fact "is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b).

[19] *Passa v. City of Columbus*, 123 F. App'x 694, 697 (6th Cir. 2005); *Nadherny v. Roseland Prop. Co., Inc.*, 390 F.3d 44, 52 (1st Cir. 2004) (observing that facts adjudicated in a prior proceeding not involving the parties are not subject to judicial notice).

defects . . . among fetuses exposed to ondansetron" as dispositive to all of Plaintiffs' claims at the pleading stage, (Doc. No. 96, at 15), even though part of the proof of Plaintiffs' claims will be evidence in GSK's exclusive control, such as its own post-market teratogenicity studies. To the extent that GSK seeks dismissal of Plaintiffs' non-failure-to-warn claims, GSK further insinuates incorrectly that this Court may take judicial notice of statements in the letter for the truth of the matters asserted and thus conclusively find that Zofran exposure during pregnancy cannot cause birth defects. (*Id.*)[20]

First, all of the pleadings before this Court allege otherwise. For example, Plaintiff Tomisha LeClair alleges that (a) adverse event reports in GSK's possession, epidemiological and mechanistic studies, animal studies and placental transfer studies, all of which GSK had actual or constructive notice during the relevant time, demonstrate that Zofran exposure during pregnancy increases the risk of specific birth defects. (1:15-cv-10429-FDS, Doc. No. 9, ¶¶ 5, 6.)

Second, the Woodcock letter notably fails to consider material information such as, *inter alia*, any post-market data or safety analyses from GSK. Because discovery has not commenced, it is impossible for Plaintiffs to know the full scope or content of the information available concerning Zofran's propensity to cause harm. However, Plaintiffs clearly allege that their injuries are caused by GSK's drug, and its conduct related thereto.

[20] Plaintiffs all allege that GSK falsely, misleadingly and illegally marketed Zofran as a safe and effective treatment for Plaintiffs' pregnancy related nausea and illegally paid doctors to do the same. *See* (*LeClair v. GSK*, No 1:15-cv-10429-FDS, Doc. No. 9 ¶¶ 80, 81. GSK's liability for its affirmative misconduct in this regard does not depend on any alleged failure to warn.

Because the matter is disputed, the Court may not take judicial notice of the letter and may not consider the letter at this pleading stage. In order to do so, the present Motion would have to be converted to a motion for summary judgment. *Roth v. Jennings*, 489 F.3d at 509.[21]

GSK fails to cite any authority to support an alternative finding. Because the Woodcock Letter's contents are disputed, and it is not part of any Complaint, the Court's opinion in *Simon v. Abiomed, Inc.*, 37 F. Supp. 3d 499, 504 (D. Mass. 2014) is distinguishable. In *Simon*, by contrast, plaintiffs brought claims for securities fraud alleging that defendants downplayed and misrepresented to its investors an FDA investigation of its alleged off-label promotion while concurrently selling their own stock. *Id.* at 513-14. The Court considered Untitled Letters and Warning Letters from the FDA to the company, which were incorporated into and an integral part of the complaint. *Id.* at 504 and n.3. Defendant did not dispute the contents of the letters. *Id.* at 515. The FDA letters at issue had independent legal significance because they demonstrated that the FDA "took issue" with certain promotional materials and allegedly triggered the defendant's obligation to disclose to its shareholders that the FDA had been critical of the company. *Id.* at 515, 519-20. All of these factors set *Simon* apart from the present facts.

[21] *See also*, *e.g.*, *Gen. Elec. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1081 (7th Cir. 1997) (noting that a court may judicially notice a public record only "when an *undisputed* fact in the public record establishes that the plaintiff cannot satisfy the 12(b)(6) standard") (emphasis added); *Hardy v. Johns-Manville Sales Corp.*, 681 F.2d 334, 347 (5th Cir. 1982) ("Rule 201 relates to medical facts not subject to reasonable dispute . . . . Surely where there is evidence on both sides of an issue [of causation] the matter is subject to reasonable dispute. Judicial notice was therefore inappropriate here."); *Bruton v. Gerber Prods. Co.*, 961 F. Supp. 2d 1062, 1075 (N.D. Cal. 2013) (denying request for judicial notice of FDA letter where it was offered to dispute the merits of plaintiffs' allegations); *Ries v. Arizona Beverages USA LLC*, 287 F.R.D. 523 (N.D. Cal. 2012) (denying request for judicial notice of FDA correspondence rejecting a petition because the facts relating to the correspondence were in reasonable dispute).

V. CONCLUSION

GSK's request for consideration of extrinsic evidence without affording Plaintiffs discovery contravenes *Levine* and its progeny as well as First Circuit precedent interpreting Rule 12. The Court may not consider the Woodcock Letter for the truth of the disputed matters therein in the context of a Rule 12 motion. Accordingly, GSK's Motion must be denied.

Dated: January 5, 2016

Respectfully submitted,

/s/ Robert K. Jenner
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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I, Robert K. Jenner, hereby certify that on this 5th day of January, 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

Barone Baden, Kimberly

From: McDonough, Madeleine (SHB) <MMCDONOUGH@shb.com>
Sent: Tuesday, November 10, 2015 7:56 PM
To: Tobias L. Millrood (tmillrood@pbmattorneys.com); egraham@gelaw.com; Barone Baden, Kimberly
Subject: Zofran MDL - Submissions to the Court
Attachments: DC-#617305-v2-Pls_Proposed_Waiver_of_Service_Redlines.DOCX; DC-#617302-v1-Proposed_Responsive_Pleading_Stay_Order.docx; MDL_Order3Proposed_20151011 - Direct Filing - REDLINES.DOCX; Zofran - MDL Order No 2 - 11-10-15 (00836070xDB9C0).docx

Hi Tobi,

We are close on many of the issues that we've been discussing by email and phone. There have been multiple email threads going, and we have exchanged various drafts and proposals, so I thought it would make sense to consolidate the issues for clarity.

1. Proposed Agenda – I appreciate that we have been able to settle on most of the agenda items. At this point, I believe we would be better off submitting separate proposed agendas to the court and flagging the areas of agreement in our respective submissions. I am planning to submit GSK's proposed agenda tomorrow.

2. Order No. 2 (appointing lead counsel) – Attached are my suggested changes to Order No. 2. As I mentioned, I am only counsel for GSK. If you agree with my suggested changes, you have my permission to represent to the court that I, as counsel for GSK, do not oppose the attached motion.

3. Order No. 3 (Direct Filing) – I have attached my proposed changes to your proposed direct filing order.

4. Order No. 4 (Waiver of Service) – I have attached my proposed changes to your proposed waiver of service order.

5. Order No. 5 (Stay of Responsive Pleading) –Attached is a proposed order to stay all responsive pleading deadlines in the MDL to allow us time to discuss the use of master pleadings. Please let me know your thoughts on this and if I have your agreement to submit this to the court jointly. In any event, I plan to raise this issue with the judge during the conference.

Happy to discuss, as needed.

Many thanks.

Madeleine

Madeleine M. McDonough
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Mail Gate made the following annotations on Tue Nov 10 2015 18:55:31