UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DEFENDANT GLAXOSMITHKLINE LLC'S
REPLY REGARDING RIPENESS OF ITS OMNIBUS MOTION TO DISMISS AND/OR
MOTION FOR JUDGMENT ON THE PLEADINGS

I. INTRODUCTION

The issue before the Court is simple and ripe for determination. GSK's Motion presents the question of whether Plaintiffs' failure-to-warn claims are preempted by federal law when the pleadings and public record demonstrate that FDA has clearly and unequivocally rejected the pregnancy risk warning that Plaintiffs claim state law required. The Court can and should answer this question in the affirmative without delay.

The issue is resolved by FDA's recent consideration and rejection of a "Citizen's Petition," the formal request that FDA reclassify the pregnancy category applicable to Zofran® and change the warnings to healthcare providers of the alleged risks of birth defects in children whose mothers used the medicine. Following FDA's review and analysis, it concluded that the pregnancy warnings in Zofran®'s labeling were appropriate when the medicine was initially approved 25 years ago and that the label "remains appropriate today." Regardless of Plaintiffs' view of the merits of that decision, FDA's explicit consideration and rejection of the labeling changes advocated by Plaintiffs give the Court the unique ability to consider GSK's preemption defense at the pleadings stage. The Court does not need to predict, under *Wyeth v. Levine*, whether FDA "would not have approved" Plaintiffs' suggested warnings—it knows that FDA did not. This motion—this MDL—is in a different posture from *Levine*, because, here, FDA has already made that determination. As a result, the Court can properly decide the preemption question now.

Plaintiffs miss the mark in arguing that the Court cannot take judicial notice of FDA's official response and that a "developed evidentiary record" is somehow necessary for the Court to consider the legal question of federal preemption. The only relevant fact here is that FDA actually considered and rejected any and all additional or different pregnancy warnings regarding birth defects—the warnings Plaintiffs advocate in this litigation. Plaintiffs' disagreement with

FDA's determination or the underlying data is beside the point. Discovery that seeks to second-guess FDA's decision is irrelevant and unwarranted. In short, Plaintiffs provide no compelling reason why this Court cannot and should not resolve GSK's legal defense of preemption now.

II. ARGUMENT

A. Preemption Is a Pure Legal Question That Can Be Resolved at the Pleadings Stage.

1. FDA's Response to the Reichmann Petition provides the necessary basis for establishing preemption.

Plaintiffs are incorrect in declaring that dismissal in this context is "procedurally unavailable under Federal Rule of Civil Procedure 12." (Doc. 128 at 1.) There can be no dispute that preemption is a question of law appropriate for the Court's determination. *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 40 (1st Cir. 2015) (affirming district court's decision granting motion to dismiss based on preemption when "Plaintiffs' complaint [sought] to impose liability on Forest because of what Lexapro's FDA-approved label state[d] or fail[ed] to state"); *Dobbs v. Wyeth Pharms.*, 797 F. Supp. 2d 1264, 1267 (W.D. Okla. 2011) ("Where, as here, the moving party asserts entitlement to judgment because a claim is preempted by federal law, the motion presents only a legal question for the court . . . ."); *In re Incretin-Based Therapies Prods. Liab. Litig.*, No. 3:13-md-2452, 2015 WL 6912689, at *3 (S.D. Cal. Nov. 9, 2015) (same). The fact that FDA considered and rejected the labeling changes Plaintiffs advocate is established by FDA's Response,[1] and that fact properly forms the basis for GSK's Motion.

It is well-settled that a court may dismiss a case under Rule 12 when "the facts establishing [an affirmative] defense are definitely ascertainable from the complaint and other

[1] FDA's Response to Citizen Petition of James P. Reichmann ("FDA's Response") was attached to GSK's Memorandum in Support of Its Omnibus Motion to Dismiss and/or Motion for Judgment on the Pleadings ("GSK's Memorandum") as Exhibit A (Doc. 96-1).

allowable sources of information" and "those facts suffice to establish the affirmative defense with certitude." *Nisselson v. Lernout*, 469 F.3d 143, 150 (1st Cir. 2006). Indeed, "[i]t would be contrary to the object of the Rules of Civil Procedure, which is to save time, not to entertain a motion to dismiss where a complaint shows on its face an affirmative defense that defeats the claim or recovery on it." Cyclopedia of Federal Procedure, 5 Cyc. of Fed. Proc. § 15:129 (3d ed.). The affirmative defense of conflict preemption, whether under *Levine*, *Buckman*, or *Mensing*,[2] is no different. Plaintiffs present nothing more than unsupported diversions to suggest otherwise.[3]

Moreover, resolving preemption now furthers the purposes for which MDLs are specifically created—to foster efficiency by identifying and resolving common dispositive issues early and not wasting time, money, and energy, where, as here, doing so is appropriate and possible under the law. *See* Duke Law Center for Judicial Studies, Standards and Best Practices for Large and Mass-Tort MDLs, at 2-3 (2014) ("The objectives of an MDL proceeding should usually include: . . . reducing litigation costs; saving the time and effort of the parties, attorneys, witnesses, and courts; . . . streamlining key issues; and moving cases toward resolution (by trial, *motion practice*, or settlement).") (emphasis added); Manual for Complex Litigation, Fourth, § 22.6 (noting that "active case management is imperative" and that MDL judges should "identify preliminarily the critical threshold legal and factual issues"); *id*. at § 22.634 (listing whether a claim is legally barred as one of the issues that should be taken up earlier in the litigation). *See*

[2] *Wyeth v. Levine*, 555 U.S. 555 (2009), *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), and *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

[3] 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 stated, "This document relates to: All Actions." Every case pending in this MDL presents the same core issue, which is dispositive as to all of the cases. Plaintiffs do not point to any substantive differences in the cases that are relevant to the question before the Court. Finally, Plaintiffs assert that "hundreds" will have the "right to amend their complaints" if the Court proceeds to the substance of GSK's Motion, but, again, they provide no authority or justification for this professed "inefficiency." (Doc. 128 at 4.)

also In re Bisphenol-A (BPA) Polycarbonate Plastic Prods. Liab. Litig., 276 F.R.D. 336, 339 (W.D. Mo. 2011) ("The purpose of an MDL is to foster efficiency by having a single judge address and decide issues that will apply to all (or at least a significant number of) the transferred cases.").

Because FDA's Response provides the sole basis for GSK's Motion and the evidence necessary for the Court to resolve the preemption inquiry, the Court can and should do so at the pleadings stage. The fact that Plaintiffs may be disappointed with the substance or preemptive effect of FDA's decision does not impact this Court's ability and duty to resolve a legal issue properly asserted in a Rule 12 motion.

2. The Court can and should take judicial notice of FDA's action, as set forth in its Response to the Reichmann Petition.

FDA's Response to the Reichmann Petition[4] is a public record of the official position of the Agency and, as such, is properly before the Court. Not surprisingly, throughout their brief, Plaintiffs attempt to downplay this important determination by FDA by characterizing it as "a letter written by FDA employee Janet Woodcock." (Doc. 128 at 13.) That description is misleading, at best. The Reichmann Petition was submitted to FDA pursuant to 21 C.F.R. § 10.30, which allows a person to request the Commissioner of FDA to issue, amend, or revoke regulations and orders or take or refrain from taking other administrative actions. The FDA Commissioner is required by law to rule upon each petition within the time specified. *See* 21 C.F.R. § 10.30(e).[5] The Commissioner has delegated his authority to respond to citizen petitions relating to drug and biological product matters to the Director of FDA's Center for Drug

[4] The Citizen Petition of James P. Reichmann ("Reichmann Petition") was attached to GSK's Memorandum as Exhibit D (Doc. 96-4).

[5] FDA is required to give a written response that approves or denies the petition, or indicates why the Agency has been unable to reach a decision yet. "The decision will be placed in the public docket file and may also be in the form of a notice published in the Federal Register." *Id.*

Evaluation and Research, Dr. Janet Woodcock.[6] *See* FDA Staff Manual Guide 1410.30(1)(J), available at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM273849.pdf. Thus, in denying the Reichmann Petition, Dr. Woodcock was not simply "writing a letter"—she was performing an official function on behalf of the Agency, pursuant to authority from the Commissioner.

Plaintiffs' assertion that the Court may not take judicial notice of FDA's Response because it is the "subject of controversy" is incorrect. (Doc. 128 at 13-15.) Under Federal Rule of Evidence 201(b), the Court may judicially notice an adjudicative fact that is "not subject to reasonable dispute" in that it is "capable of accurate and ready determination by resort to sources whose accuracy cannot be reasonably questioned." Plaintiffs do not dispute the accuracy of the fact that FDA's Response demonstrates that FDA considered and rejected the request for a different warning for this product. Instead, they dispute FDA's *conclusions* regarding Zofran®'s alleged "propensity to cause birth defects" and the Agency's *diligence,* suggesting that FDA failed to consider material information. These issues are not implicated by the Motion and are thus not before the Court. While FDA's thorough discussion regarding the lack of scientific support for Plaintiffs' claims is indicative of the hurdles they may later face in establishing general causation if this litigation were to proceed, GSK's current Motion does not ask the Court to determine this issue. Preemption does not depend on whether FDA was correct in concluding, as they did, that there is insufficient data to find a safety concern with regard to the use of Zofran® during pregnancy (the truth of the matter asserted).

Instead, as discussed below, the only relevant inquiry is whether FDA considered the issue. (*See infra* section IIB.) FDA's Response simply demonstrates that the Agency did, in fact,

[6] The Center for Drug Evaluation and Research is the division of the Agency that is responsible for regulating prescription drugs. About the Center for Drug Evaluation and Research, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ (last visited Jan. 12, 2016).

consider the adequacy of Zofran®'s pregnancy warnings and validated the sufficiency of the labeling. The Court can and should judicially notice this adjudicative fact. *See, e.g.*, *LoConte v. Forest Labs., Inc.*, No. 14-13848-NMG, 2015 WL 3751422, at *3 (D. Mass. June 15, 2015) ("A court therefore may take judicial notice of facts outside the complaint when adjudicating a motion to dismiss based on an affirmative defense," which included in that instance "FDA-approved drug labels"); *Novartis Pharms., Corp. v. Wockhardt USA LLC*, No. 12-cv-3967, 2013 WL 5770539, at *5 (D.N.J. Oct. 23, 2013) (noting the propriety of taking judicial notice of FDA's response to a citizen petition).[7]

B. *Levine* Does Not Mandate Deciding Preemption Only After Fact Discovery.

The linchpin of Plaintiffs' argument is that preemption can only be decided upon a fully developed evidentiary record. (*See* Doc. 128 at 1, 4, 5, 10.) But Plaintiffs provide no authority for this sweeping assertion and why it should govern this set of facts. Plaintiffs instead misconstrue the preemption inquiry under *Levine* in an attempt to justify discovery on matters irrelevant to the legal question currently before the Court—namely whether FDA's Response provides evidence that it did in fact consider and reject the warnings Plaintiffs propose. FDA answered that question when it squarely rejected the proposal of additional or different birth defect warnings for Zofran®, obviating the need for the discovery Plaintiffs seek.

1. Plaintiffs misconstrue the preemption inquiry under Levine.

Plaintiffs misinterpret the Supreme Court's analysis in *Wyeth v. Levine* to argue that a developed factual record is necessary to resolve a preemption motion. Nothing in *Levine* supports such a requirement. Instead, the Supreme Court held that state law failure-to-warn claims are preempted when there is "clear evidence that the FDA would not have approved" the

[7] The Court may properly consider matters of public record, "the authenticity of which are not disputed by the parties," without converting a motion to dismiss to one for summary judgment. *Watterson v. Page*, 987 F.2d 1, 3-4 (1st Cir. 1993).

warning that a plaintiff alleges state law requires.[8] *Levine*, 555 U.S. at 571. *Levine* did not hold that preemption motions may be resolved only after discovery, let alone that plaintiffs are "entitled" to certain discovery, as Plaintiffs suggest. Plaintiffs' claim that *Levine* set forth "four fact-specific considerations" that necessitate discovery prior to a ruling on preemption is similarly erroneous. (Doc. 128 at 6.) Neither *Levine* nor any case cited in Plaintiffs' Opposition holds that courts must consider these facts. These "considerations" are merely the Supreme Court's discussion and analysis of the evidence in that record on which Wyeth based its preemption motion. They are not clear evidence "factors" that this or any court must apply in every case.[9]

Since *Levine,* courts have repeatedly noted that the Supreme Court did not define "clear evidence," but instead left it to district courts to determine whether the evidence was sufficient. *See e.g.*, *Dobbs*, 797 F. Supp. 2d at 1270; *Rheinfrank v. Abbott Labs., Inc.*, No. 1:13–cv–144, 2015 WL 4743056, at *7 (S.D. Ohio Aug. 10, 2015). Even cases cited by Plaintiffs recognize as much. *See, e.g.*, *Mason*, 596 F.3d at 391 ("The Supreme Court, however, did not clarify what constitutes 'clear evidence.'"); *Koho v. Forest Labs., Inc.*, 17 F. Supp. 3d 1109, 1116 (W.D. Wash. 2014) (same). It comes as no surprise, then, that courts have characterized preemption under *Levine* as a "fact-based" inquiry, *i.e.*, one that depends on the particular FDA actions and warnings at issue. *See, e.g.*, *Koho*, 17 F. Supp. 3d at 1118 ("[T]he clear evidence standard is a

[8] As stated in GSK's Memorandum, "clear evidence" describes the requirement of an actual, as opposed to potential, conflict between state and federal law. It should not be construed to replace "preponderance of the evidence" as the standard of proof for preemption. (Doc. 96 at 12.)

[9] Plaintiffs' reliance on *Mason v. SmithKline Beecham*, 596 F.3d 387, 392-93 (7th Cir. 2010), for the proposition that "courts uniformly concur . . . 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" is likewise flawed. (Doc. 128 at 9.) Not only did Plaintiffs fail to respond to the differences GSK discussed in its opening brief between this case and *Mason* (Doc. 96 at 17), but the Seventh Circuit did not describe or limit the specific evidence necessary to prevail on a preemption motion. Nor has any other court. Just like they did with *Levine*, Plaintiffs want this Court to hold that the specific facts of *Mason* somehow set the legal standard for preemption—one that they themselves admit is specific to the facts of each case.

fact based inquiry that depends on the express type of warning at issue and the particular facts of each case."); *Dobbs*, 797 F. Supp. 2d at 1270 ("[T]he evidence in this case must be evaluated in the context of the FDA's regulation of the warnings accompanying antidepressants, including Effexor, as applied to the facts of this case."). That preemption is a case-specific inquiry does not mean that a "fully developed factual record" is required to resolve the question. It simply means that the facts and evidence necessary to answer the "clear evidence" question will vary from case to case. As discussed below, the unique circumstances present here—a current and official statement by FDA rejecting the very warnings Plaintiffs seek in this litigation—provide the necessary evidence to resolve this Motion now.

2. The only fact relevant to the preemption inquiry is FDA's Response to the Reichmann Petition, which provides clear and conclusive evidence that FDA rejected Plaintiffs' proposed warnings.

The *only* question before this Court is whether FDA's actions demonstrate that it considered and rejected the pregnancy and birth-defect related warnings that Plaintiffs claim state law required. *Levine*, 555 U.S. at 571; *see also, e.g.*, *In re Incretin-Based Therapies*, 2015 WL 6912689, at *4 n.5 (noting that conflict preemption involves an analysis of what FDA has done, if anything, in addressing the need for a warning on a particular drug); *In re Byetta*, No. JCCP-4574, 2015 WL 7184655, at *5 (Cal. Super. 2015) ("The only prism through which the adequacy of the label is to be examined for federal preemption purposes is via the action or inaction of the FDA such that one can conclude that a [proposed warning] would have been rejected (or was rejected in actual fact) by the FDA during the relevant period."). FDA has answered that question. In its Response to the Reichmann Petition, FDA expressly and unequivocally rejected the precise change to Zofran®'s pregnancy and birth-defect related warnings that Plaintiffs seek in this litigation. In fact, FDA concluded that *any* additional warnings on the topic could be misleading. FDA's Response at 19. After a thorough and

independent review of the scientific evidence, FDA determined that the Zofran® label appropriately described the risk of birth defects when Zofran® was approved in 1991 and that the label remains appropriate today. *Id.* at 18. This official agency statement—which is properly before the Court—demonstrates that FDA would have rejected the warnings at issue because FDA, in fact, already considered and rejected those warnings.

Plaintiffs nevertheless assert that any decision on preemption would be premature. Plaintiffs claim that they are "entitled" to discover evidence regarding: (1) GSK's knowledge of Zofran®'s alleged propensity to cause birth defects, including animal teratogenicity studies conducted after Zofran®'s approval; and (2) GSK's interactions with FDA. (Doc. 128 at 6-10.) But this evidence is irrelevant to the preemption inquiry, which is only focused on what FDA would have done with Plaintiffs' proposed warnings—not what evidence it considered. *See In re Incretin-Based Therapies*, 2015 WL 6912689, at *17 (The preemption standard "does not mandate which data the FDA must consider in evaluating a . . . labeling change. The relevant consideration is whether the FDA considered the *safety concern* challenged by a plaintiff.") (emphasis in original). Plaintiffs cite no authority to the contrary.

Moreover, this case does not require the historical digging necessary to decide the issue as in *Levine* and *Mason*. In those cases, the courts were faced with the hypothetical question of what FDA *would have* done with the warnings proposed by the plaintiffs. *Id.*; *Mason*, 596 F.3d at 395-96. The manufacturers relied on the regulatory history of the drugs, including past communications with FDA about the pertinent risks, in an attempt to convince the courts that FDA would have rejected a warning had it been presented with one. *Levine*, 555 U.S. at 572-73; *Mason*, 595 F.3d at 394-96. In stark contrast, FDA's actions here are current and known. This Court need not review regulatory correspondence to predict whether FDA "would not have

approved" the warnings at some hypothetical time. It already knows that FDA "did not" approve them. Moreover, subjecting GSK to costly—and ultimately unnecessary and irrelevant—discovery that would only delay the proceedings and waste the resources of the parties and the Court runs counter to the Supreme Court's teachings and the purposes for which MDLs are created. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007) ("[W]hen the allegations in a complaint, however true, could not raise a claim of entitlement to relief, 'this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court.'"); 28 U.S.C. § 1407(a) (permitting transfer to an MDL court to "promote the just and efficient conduct of such actions").

In addition, any attempt by Plaintiffs to use discovery to call into question the propriety of FDA's rejection of birth-defect warnings is impermissible. "[T]he question posed by *Wyeth v Levine* is NOT to second guess whether the FDA should have allowed [a label change]." *In re Byetta*, 2015 WL 7184655, at *5 (emphasis in original). Accordingly, Plaintiffs may not avoid preemption by arguing that FDA's determination is wrong or by speculating that FDA might have decided the issue differently had it evaluated different facts. *See Rheinfrank*, 2015 WL 4743056, at *11 (rejecting as "speculative" argument that FDA might have allowed a warning change based on different data); *In re Fosamax (Alendronate Sodium): Prods. Liab. Litig.*, No. 08–08, 2014 WL 1266994, at *9 (D.N.J. Mar. 26, 2014) (what FDA might have done in the face of different evidence is "purely speculation"). As the First Circuit aptly explained, state tort law claims that are, by their nature, "a second guess of an FDA judgment," are preempted. *In re Celexa & Lexapro*, 779 F.3d at 41.

3. The evidence Plaintiffs claim is necessary is also irrelevant under Buckman.

The discovery Plaintiffs seek is irrelevant for yet another reason: it raises issues that would be preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).[10] Plaintiffs claim they need evidence regarding what GSK knew about birth defects and whether GSK provided this information to FDA, presumably for the purpose of establishing that GSK withheld data from FDA that would have altered its decisions. (Doc. 128 at 8.) As an initial matter, Plaintiffs are incorrect in asserting that a drug manufacturer has "exclusive" access to information regarding non-FDA approved uses for medicines. FDA rules require holders of New Drug Applications to report adverse experiences with the drug, including those derived from clinical investigations, studies, reported scientific literature, and unpublished scientific papers, regardless of the indication for which the medicine was used. *See, e.g.*, 21 C.F.R. §§ 314.80, 314.81.

In any event, the inquiry Plaintiffs envision is irrelevant in light of *Buckman*. A discovery expedition into whether GSK provided information to FDA in accordance with its legal obligations could only lead to a theory of liability that is preempted by *Buckman*. *See In re Trasylol Prods. Liab. Litig.*, 763 F. Supp. 2d 1312, 1330 (S.D. Fla. 2010) (evidence that manufacturer of prescription drug failed to adequately or timely provide information to FDA "is generally irrelevant to Plaintiffs' state-law claims," including negligence and failure-to-warn, and is preempted by *Buckman* for a fraud-on-the-FDA claim); *see also In re Incretin-Based Therapies*, 2015 WL 6912689, at *17 (holding that plaintiffs' "arguments are preempted to the extent they are based on Defendants failure to comply with FDA reporting requirements"); *Rheinfrank*, 2015 WL 4743056, at *11-12 ("Plaintiffs' argument that Abbott withheld certain

[10] Plaintiffs do not argue that a ruling on preemption on *Buckman* grounds is premature; in fact, Plaintiffs' Opposition fails to mention *Buckman* at all.

information or misrepresented the results of studies in its 2005 and 2007 submissions to the FDA appears to be a fraud-on-the-FDA theory, which is preempted."); *U.S. ex rel. Ge v. Takeda Pharm. Co. Ltd.*, No. 10-11043-FDS, 2012 WL 5398564, at *6 (D. Mass. Nov. 1, 2012) (noting that "FDA exercises discretion in its enforcement procedures"), *aff'd*, 737 F.3d 116 (1st Cir. 2013). This type of evidence is simply not relevant and, more importantly, would not save Plaintiffs' claims from preemption.

III. CONCLUSION

Plaintiffs present no reason why this Court should not consider GSK's Motion at the pleadings stage. FDA's Response to the Reichmann Petition is properly before this Court to demonstrate that FDA considered the pregnancy warnings that Plaintiffs allege were inadequate and concluded that the label was appropriate when Zofran® was initially approved and that the label remains appropriate today. The fact that Plaintiffs may dispute FDA's conclusion is immaterial. Discovery is unnecessary and would represent nothing more than an improper attempt to second guess FDA's judgment and analysis. The Court should therefore proceed to the merits of GSK's Motion.

Respectfully submitted,

GLAXOSMITHKLINE LLC,

By its attorneys,

/s/ Madeleine M. McDonough
Madeleine M. McDonough
Jennifer Stonecipher Hill
SHOOK, HARDY & BACON L.L.P.
1155 F Street NW, Suite 200
Washington, D.C. 20004
Telephone: (202) 783-8400
Facsimile: (202) 783-4211
mmcdonough@shb.com
jshill@shb.com
Admitted pro hac vice

Mark D. Seltzer (BBO # 556341)
Joshua S. Barlow (BBO # 667472)
NIXON PEABODY LLP
100 Summer Street
Boston, MA 02110
Telephone: 617-345-1000
Facsimile: 617-345-1300
mseltzer@nixonpeabody.com
jbarlow@nixonpeabody.com

George W. Vien (BBO # 547411)
DONNELLY, CONROY & GELHAAR LLP
260 Franklin Street, Suite 1600
Boston, MA 02110
Telephone: 617-720-2880
Facsimile: 617-720-3554
gwv@dcglaw.com

Dated: January 12, 2016

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document, which was filed with the Court through the CM/ECF system, will be sent electronically to all registered participants as identified on the Notice of Electronic Filing ("NEF") and paper copies will be sent via first class mail to those identified as non-registered participants.

/s/ Madeleine M. McDonough
Madeleine M. McDonough