FULBRIGHT
& Jaworski L.L.P.
Attorneys at Law

Jeremy A. Mercer
Partner

Southpointe Energy Complex • 370 Southpointe Boulevard, Suite 300 • Canonsburg, Pennsylvania 15317
jmercer@fulbright.com • Direct: 724 416 0440 • Main: 724 416 0400 • Facsimile: 724 416 0404

May 2, 2012

Karen Reid Bramblett, Prothonotary
Superior Court of Pennsylvania
Philadelphia Office
530 Walnut Street
Suite 315
Philadelphia, PA 19106

Re: Superior Court of Pennsylvania Eastern District, Case No. 82 EDA 2012; In Re: Reglan®/Metoclopramide Litigation

Dear Ms. Bramblett:

Enclosed for filing in the above-referenced matter are:

1. An original unbound Brief for Amici Curiae The Chamber of Commerce of The United States of America and Generic Pharmaceutical Association in Support of Appellants and Reversal ("Brief of Amici Curiae");

2. Six bound copies of the Brief of Amici Curiae; and,

3. A CD containing a .pdf file of the Brief of Amici Curiae.

I also enclose one additional bound copy of the Brief of Amici Curiae to be date-stamped and returned to me in the self-addressed stamped envelope, which I have also provided.

If you have any questions, please contact me at 724-416-0440.

Best regards,

Jeremy A. Mercer /MPG

Jeremy A. Mercer

JAM/tal
Enclosures
cc: Liaison Counsel identified on Certificate of Service (w/brief only) (via e-mail only)

IN THE SUPERIOR COURT OF PENNSYLVANIA
EASTERN DISTRICT

No. 82 EDA 2012

IN RE REGLAN®/METOCLOPRAMIDE LITIGATION

On Appeal from the November 18, 2011 Order of the Court of Common Pleas of Philadelphia County, Jan. Term 2010, No. 01997, As Amended on December 16, 2011

BRIEF FOR AMICI CURIAE THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND GENERIC PHARMACEUTICAL ASSOCIATION IN SUPPORT OF APPELLANTS AND REVERSAL

Robin S. Conrad
Rachel Brand
NATIONAL CHAMBER LITIGATION CENTER, INC.
1615 H. Street, N.W.
Washington, D.C. 20062
(202) 463-5337

Counsel for Amicus Curiae Chamber of Commerce of the United States of America

Robert Billings
GENERIC PHARMACEUTICAL ASSOCIATION
777 Sixth Street, N.W., Suite 510
Washington, D.C. 20001
(202) 249-7100

Counsel for Amicus Curiae Generic Pharmaceutical Association

Jonathan S. Franklin
Mark Emery
FULBRIGHT & JAWORSKI L.L.P.
801 Pennsylvania Ave., N.W.
Washington, D.C. 20004
(202) 662-0466

Jeremy A. Mercer (PA 86480)
FULBRIGHT & JAWORSKI L.L.P.
370 Southpointe Blvd., Suite 300
Canonsburg, Pennsylvania 15317
(724) 416-0440

Counsel for Amici Curiae

May 2, 2012

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES:

CONSTITUTIONAL PROVISION:

STATUTES:

REGULATIONS:

OTHER AUTHORITIES:

INTEREST OF AMICI CURIAE

The Chamber of Commerce of the United States of America (the "Chamber") is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. Chamber members transact business throughout the United States and a large number of countries around the world. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. The Chamber regularly files amicus briefs in significant preemption cases such as this.

The Generic Pharmaceutical Association ("GPhA") is a nonprofit, voluntary association representing more than 100 manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. GPhA's members provide American consumers with safe, effective, and affordable generic drugs. Their products account for nearly 80% of all prescriptions dispensed in the United States, and they save consumers and the U.S. healthcare system more than $160 billion each year. GPhA's core mission is to improve the lives of consumers and patients by providing timely access to affordable prescription medicines.

SUMMARY OF ARGUMENT

When the U.S. Supreme Court issues a federal preemption decision like *Pliva v. Mensing*, 131 S. Ct. 2567 (2011), *amici* and their members have a strong interest in ensuring that the Court's ruling is correctly and uniformly applied throughout the United States. The Supremacy Clause of the U.S. Constitution is implicated in two important ways in this case, both of which serve the overriding interest of businesses in maintaining certainty in the law. First, decisions

like *Mensing* implement the Supremacy Clause by ensuring that when Congress has acted within its enumerated powers to displace state law in favor of a federal rule, regulated businesses are governed by that uniform federal standard rather than the various and changing standards of 50 different states. Second, the Supremacy Clause confers upon the U.S. Supreme Court the fundamental role of ensuring that federal law—including the law of preemption—is applied uniformly throughout the Nation. *Amici* urge this Court to uphold both interests in this case. Under *Mensing*, the duties of generic pharmaceutical manufacturers with regard to warnings are to be determined by a uniform federal arbiter—the Food and Drug Administration ("FDA")—and that uniformity would be destroyed by allowing plaintiffs to easily circumvent that ruling and avoid a prompt dismissal by re-characterizing their claims through the kind of artful pleading at issue in this case. And allowing such circumvention would likewise undermine the central authority of the U.S. Supreme Court by delaying and frustrating courts' application of one of its key decisions.

As plaintiffs made clear at the outset of this case, their complaint raises prototypical failure-to-warn claims. Although plaintiffs have attempted to rename these claims in the wake of *Mensing*, the claims are still preempted by federal law just as much as they were when the plaintiffs called them by different names. The claim that generic manufacturers must follow a state law duty to communicate "adequate" or "effective" warnings is still an alleged failure to ***warn***, and imposes the same "impossible" choice that the claims in *Mensing* did, requiring generic manufacturers to change their labeling, when the essential underpinning of the federal system requires that generic and brand products (including their labels) be exactly the same. The claim that manufacturers have a duty to communicate or disseminate approved warnings in a manner more to the liking of plaintiffs' counsel is likewise preempted, because all such

communications are also within the FDA's purview. The claim that manufacturers failed to timely update their labels to match the brand company's labeling is preempted because federal law does not authorize a private suit to police FDA's enforcement of its own regulations. Finally, the claim that state law imposes on a generic manufacturer a duty to "withdraw" from the market if it could not obtain updated labels was considered and rejected in *Mensing*.

The trial court's plan to allow all plaintiffs to delay disposition of their claims until the summary judgment stage is thus not only inconsistent with *Mensing*, but would subject the pharmaceutical industry to unnecessary and unmeritorious proceedings at immense cost. *Mensing* rejected, on a motion to dismiss, the argument that the adequacy of generic pharmaceutical warnings is a question of state law. This Court should do likewise. Allowing these 2,000 cases to nevertheless proceed in light of that binding precedent would impose inordinate litigation costs on the defendants that are not only unnecessary but contrary to federal law as announced by the Supreme Court in *Mensing*.

The federal pharmaceutical regulatory regime ensures that there will be uniform nationwide warnings based on reasoned, informed, expert determinations made by the FDA. This regime also ensures that affordable generic drugs are made widely and quickly available by permitting generic manufacturers to produce drugs without incurring costs that are unnecessary and do nothing to further the goal of producing less expensive drugs for consumers. Accordingly, the statute and FDA's implementing regulations require each generic drug to be "the same" as its branded equivalent in all material respects—including the chemical composition of its active ingredient, its dosage form, its strength, its routes of administration, the rate and extent to which it delivers the active ingredients to patients, and the content and nature of warnings.

Plaintiffs nevertheless contend that they should be permitted to proceed in this case based on invented state law duties, sue these defendants under the failure-to-warn laws of all 50 states and continue to impose on defendants the significant costs associated with that litigation through summary judgment and beyond. If that contention is accepted, manufacturers would be subjected to different, and possibly conflicting, duties imposed by various state laws. The Supreme Court already decided that is not the law and the futile exercise plaintiffs propose would impose unnecessary costs upon generic drug manufacturers and waste the limited resources of the court system.

ARGUMENT

I. THE TRIAL COURT FAILED TO IMPLEMENT BINDING U.S. SUPREME COURT PRECEDENT.

A. Under *Mensing*, The FDCA, Not State Failure-To-Warn Law, Is The Law Of The Land.

Under the Supremacy Clause, federal law is "the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Therefore, all conflicts between federal and state laws must be resolved in favor of federal law. *Werner v. Plater-Zyberk*, 2002 PA Super 42, 799 A.2d 776, 788 (2002). Since *McCulloch v. Maryland*, 4 Wheat. 316, 17 U.S. 316 (1819), it has been settled that state law that conflicts with federal law is "without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). State law is preempted, among other ways, when compliance with both federal and state regulations is "impossible." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). In *Mensing*, the Supreme Court applied the Supremacy Clause to hold that state laws attempting to impose liability due to alleged inadequacies in federally-mandated generic drug labeling conflict with, and thus are preempted by, federal law.

Mensing involved the same drug that is at issue in this case—generic metoclopramide, also sold under the brand name Reglan. The Supreme Court broadly held that federal drug regulations directly conflict with, and thus preempt, state law claims that manufacturers allegedly failed to provide adequate warnings for metoclopramide. 131 S. Ct. at 2572.

As did the plaintiffs in *Mensing*, plaintiffs here allege that when used over long periods of time, metoclopramide and Reglan cause a neurological disorder called tardive dyskinesia. The *Mensing* plaintiffs alleged that the generic drug manufacturers were liable for failing to provide adequate warning labels with their products. *Id.* In effect, as the Supreme Court noted, the allegations were that state law required additional or stronger warnings for those products. *Id.* at 2574. The manufacturers argued that it was impossible to simultaneously comply with federal law (to be the same) and the state law duties (to provide additional warnings). *Id.* at 2573. The Supreme Court agreed. *Id.* at 2572.

As the Supreme Court observed, federal law imposes "far more complex drug labeling requirements" than the state laws. *Id.* at 2574. Congress has long required manufacturers to obtain federal approval to market new drugs under the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, a process that requires lengthy and expensive testing for all proposed drugs. In 1984, Congress enacted the Hatch-Waxman Amendments to the FDCA, which permitted generic manufacturers to obtain FDA approval to produce and sell generic drugs by showing equivalence to an approved brand name drug. Pub. L. No. 98-417, 98 Stat. 1585 (1984); 21 U.S.C. § 355(j)(2)(A). Under that law, a generic manufacturer is required to show, among other things, that the proposed labeling for its generic product is "the same as the labeling approved for the [brand name] drug." 21 U.S.C. § 355(j)(2)(A)(v).

The *Mensing* plaintiffs alleged that manufacturers violated state law by failing to take several actions that, according to those plaintiffs, would not have violated federal law. First, the plaintiffs claimed that manufacturers should have used the FDA's "changes-being-effected" ("CBE") process, which permits drug manufacturers to "add or strengthen a contraindication, warning [or] precaution," 21 C.F.R. § 314.70(c)(6)(iii)(A), or to "add or strengthen and instruction about dosage and administration that is intended to increase the safe use of the drug product," 21 C.F.R. § 314.70(c)(6)(iii)(C). *See Mensing*, 131 S. Ct. at 2575. However, the Supreme Court ultimately deferred to FDA's position that its CBE process does not permit generic manufacturers to "unilaterally strengthen their warning labels." *Id.* The CBE process can only be used by a generic manufacturer to change its label to match an updated brand-name label or to follow the FDA's instructions. *Id.* Therefore, CBE changes made unilaterally by a generic manufacturer to change a warning would violate the FDCA and FDA's regulations that require the generic labels to match the brand labels. *Id.* Since this conflict makes simultaneous compliance with federal and state law impossible, federal law prevailed and plaintiffs' claim that manufacturers could alter their warnings via the CBE process was preempted. *Id.* at 2577.

Similarly, the plaintiffs also claimed that the manufacturers could have sent communications known as "Dear Doctor" letters to prescribing physicians and other healthcare professionals, warning them of risk information. *See* 21 C.F.R. § 200.5. The Supreme Court again deferred to the FDA's own interpretation of its regulations, which classified "Dear Doctor" letters as "labeling." *Mensing*, 131 S. Ct. at 2576; *see also* 21 U.S.C. § 321(m); 21 C.F.R. § 202.1(*l*)(2). If generic drug manufacturers unilaterally sent such letters, "that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" *Mensing*, 131 S. Ct. at 2576 (citing Br. for United States as

Amicus Curiae Supporting Respondents, *Pliva v. Mensing*, Nos. 09-993, 09-1039 and 09-1501 ("U.S. *Mensing* Br.") at 19; 21 C.F.R. § 314.150(b)(3)). Since this conflict makes simultaneous compliance with federal and state law impossible, federal law prevailed and plaintiffs' claim that generic drug manufacturers could unilaterally send "Dear Doctor" letters was preempted. *Id.* at 2578.

Finally, plaintiffs (and the FDA, which participated as amicus), contended that generic drug manufacturers could have proposed stronger warning labels to the FDA, and if the FDA agreed, it would work with the brand name drug manufacturer to create a new label for both the brand name and generic drug. *Id.* at 2578. Assuming (but not deciding) that such a duty existed, the Supreme Court nonetheless held that a state law claim based on such a duty to warn was preempted by federal law because it would be impossible for the manufacturers to comply with state law as well as FDCA and FDA regulations. As the Supreme Court concluded, "the question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Id.* at 2579. Before manufacturers could satisfy state law by changing labels, it would be necessary for the FDA to permit them to do so, but "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 2580.

Mensing did not recognize or leave open any room for unilateral warning activity by the generic manufacturers. The majority opinion concluded that the tort claims were preempted because "state law imposed a duty on the Manufacturers to take certain action, and federal law barred them from taking that action," and "***the only action*** that the Manufacturers could ***independently*** take—asking for the FDA's help—is not a matter of state-law concern." *Id.* at

2581 (emphasis added). The four dissenting Justices characterized the court's holding to be that "federal law immunizes generic-drug manufacturers from ***all*** state-law failure-to-warn claims because they cannot unilaterally change their labels." *Id.* at 2582 (Sotomayor, J., dissenting) (emphasis added). And the majority opinion's closing note—far from suggesting that innovation or artfulness in the pleading of state law claims might avoid federal preemption—signaled just the opposite view: it is "different federal statutes and regulations" that may "lead to different pre-emption results" and "Congress and the FDA retain the authority to change the law and regulations if they so desire." *Id.* at 2582.

Mensing is the law of the land and it cannot be circumvented in this case. When the U.S. Supreme Court holds that state law conflicts with federal law, this Court must follow that precedent. *Hubbard v. United States*, 514 U.S. 695, 713 n.13 (1995) ("We would have thought it self-evident that the lower courts must adhere to our precedents."). A determination by the Supreme Court is "binding upon the state courts, and must be followed, any state law, decision, or rule to the contrary notwithstanding." *Chesapeake & O. Ry. Co. v. Martin*, 283 U.S. 209, 221 (1931); *Commonwealth v. Ware*, 446 Pa. 52, 56, 284 A.2d 700, 702 (1971) ("[A] state court is not free to ignore the dictates of the United States Supreme Court on federal constitutional matters because of its own conclusion that those dictates are 'ill-considered.'"). As the Pennsylvania Supreme Court has held, "[i]t is fundamental that by virtue of the Supremacy Clause, the State courts are bound by the decisions of the Supreme Court with respect to the federal Constitution and federal law, and must adhere to extant Supreme Court jurisprudence." *Council 13, ex rel. Fillman v. Rendell*, 604 Pa. 352, 375-76, 986 A.2d 63, 77 (2009) (citations omitted). *Mensing* squarely holds that the content and adequacy of generic pharmaceutical warnings should be determined by the FDA, not state law. *Amici* urge this Court to follow that

straightforward ruling and direct dismissal of the plaintiffs' complaint. The defendants in this case should not be forced to bear the extraordinary costs of continuing to litigate these 2,000 cases when the U.S. Supreme Court has already held that the claims are preempted.

B. Plaintiffs Should Not Be Permitted to Delay Dismissal By "Pleading Around" *Mensing*.

As numerous courts have held, *Mensing* compels dismissal of claims such as those raised by plaintiffs here.[1] Before *Mensing*, plaintiffs openly stated that their claims are failure-to-warn claims. R. 358a. After *Mensing*, and having been given the opportunity to amend their claims, all plaintiffs have done is make cosmetic changes, to relabel their claims as "failure-to-communicate" claims. But the new verbiage cannot change the underlying nature of the claims; alleging that defendants failed to communicate warnings is simply a different way of saying that they failed to warn. If plaintiffs can avoid the dictates of *Mensing* simply by recasting their claims in different language, thereby delaying dismissal and subjecting the defendants to

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1 *See, e.g.*, *Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir. 2011) (vacating district court order and remanding for judgment in favor of defendants based on *Mensing*); *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011), *cert. denied* 566 U.S. --, 2012 WL 592900 (Apr. 30, 2012) (same); *Mensing v. Wyeth*, 658 F.3d 867 (8th Cir. 2011) (dismissing metoclopramide failure-to-warn claims under *Mensing*); *Gaeta ex rel. A.G. v. Perrigo Pharmaceuticals Co.*, No. 09–15001, 2012 WL 605678 (9th Cir. Feb. 27, 2012), *aff'g* 562 F. Supp. 2d 1091 (N.D. Cal. 2008) (affirming summary judgment for defendant based on *Mensing* reversal of Ninth Circuit's prior opinion); *In re Accutane Prod. Liab. (Plevniak)*, MDL 1626-IBD, 2011 WL 6224546, at *2 (M.D. Fla. Nov. 9, 2011) ("any state-law claim involving a generic drug label or warning is preempted and must be dismissed with prejudice under *Mensing*."); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, MDL 2226, 2012 WL 718618 (E.D. Ky. Mar. 5, 2012); *In re Fosamax Prods. Liab. Litig. (No. II)*, MDL No. 2243, Civ. No. 08–008, 2011 WL 5903623, at *6-8 (D.N.J. Nov. 21, 2011) ("Plaintiffs' claims of failure to warn are squarely preempted by *Mensing*."); *In re: Pamidronate Prods. Liab. Litig.*, Nos. 09-MD-2120, 10-CV-1860, -- F. Supp. 2d --, 2012 WL 272889, at *3 (E.D.N.Y. Jan. 30, 2012) (claim that "defendants should have altered the labeling of pamidronate to provide stronger warnings about the drug's possible adverse side effects" was preempted under *Mensing*).

significant litigation burdens, then any other plaintiff could do the same in any other case. Such a holding would be directly contrary to *Mensing*.

Plaintiffs now claim that *Mensing* "foreclosed only claims requiring generic manufacturers to unilaterally change their drug's warning label to include information different from and additional to the brand manufacturer's approved FDA label." Appellants' Br., App. A, Trial Court's November 18, 2011 Opinion ("Op.") at 3-4 (citing Plaintiffs' Memorandum of Law in Support of Their Response in Opposition to the Master Preliminary Objections at 4). From that flawed premise, their complaint alleges that defendants are liable under at least three different state law-derived duties: (1) the alleged requirement to give "adequate" warnings or to "effectively" communicate warnings or risks to physicians and patients; (2) the alleged requirement to "timely" update generic labels to reflect FDA-approved labeling; and (3) the alleged requirement to "withdraw" a product from the market until the FDA approves "adequate" warnings. *See, e.g.*, Plaintiffs' Third Amended Master Long Form Complaint ("MC") ¶¶ 117, 118, 135, 150, 158; Op. 4.[2]

All of these claims are preempted under *Mensing*, just as they were before the wording changes in the complaint. The first set of claims are preempted because they impose the same "impossible" conflict on generic manufacturers, requiring "labeling" communications that violate the FDA's "sameness" requirement and, contrary to *Mensing*, cannot be done

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2 Plaintiffs raise a number of other claims, including design defect; negligence and negligence per se; fraud; intentional misrepresentation and suppression; constructive fraud; breach of express and implied warranties and unfair and deceptive trade practices. These claims are also fundamentally failure-to-warn claims that are preempted by federal law under *Mensing* because they would require a labeling change. *See Del Valle v. Pliva, Inc.*, No. B:11–113, 2011 WL 7168620, at *5 (S.D. Tex. Dec. 21, 2011) ("This 'kitchen sink' approach . . . does not obscure the fact that all of these claims are based upon the purported failure of the generic drug defendants to warn of the dangers of long-term use of the drug.").

"independently" of federal review and discretion. The remainder collide with well-established law that such claims are preempted because there is no private cause of action to police the FDA's enforcement of its own regulations.

1. Plaintiffs' "Failure-To-Communicate" Claims Are Preempted Under *Mensing*.

Plaintiffs claim that generic manufacturers are liable for "failure to give ***adequate*** warnings and/or to ***effectively*** communicate adequate warnings to physicians (or to their patients)." *See, e.g.*, MC ¶ 128 (emphasis added); *see also* ¶ 135 (failure to give "timely and adequate warnings," including generic defendants' failure "to effectively and adequately communicate the warnings in the label to physicians and patients").[3] An "adequate warning," according to the complaint, "requires both proper language describing the nature and rate of the risk, the nature of the harm that might be encountered and the ways to avoid that harm." *Id.* at ¶ 117. Moreover, to be an "adequate warning," the drug prescriber and user must allegedly "be made aware of those warnings—requiring effective communication of the warnings." *Id.* Plaintiffs allege that the generic manufacturers had "many different ways to ensure that the actual warning language was effectively communicated to physicians and patients," such as through "proper delivery" of the existing approved label or "***other FDA approved means of communication***." *Id.* (emphasis added).

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[3] Plaintiffs also allege that the manufacturers breached a duty "to ensure that adequate warnings were provided to the medical community, Plaintiffs' physicians, Plaintiffs, and/or other foreseeable metoclopramide users," MC ¶ 111, and that they were "required to ensure that the existing labels were effectively communicated to physicians and patients," *id.* at ¶ 117. They allege that manufacturers were required by state law to "ensure that warnings they disseminated or relied on to be disseminated to the medical community . . . were actually and effectively communicated to physicians and patients," and to take a number of other steps to evaluate usage, stay informed of drug safety research and engage in testing. *Id.* at ¶ 118.

The allegation that the manufacturers were required to provide more "adequate" or "effective" warnings of drug hazards, which plaintiffs understand to mean the use of "proper language describing the nature and rate of the risk," *id.* at ¶ 117, is simply a claim that the approved warning itself is improper and that the manufacturers have a duty to change the label to something more "adequate" or "effective." That is exactly the kind of claim that *Mensing* considered and held preempted by federal law. *See Mensing*, 131 S. Ct. at 2578 ("it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same").

The same conclusion applies to plaintiffs' repackaged contention that the defendants failed to comply with a purported state law duty to adequately "communicate" warnings through various "FDA approved means of communication." MC ¶ 117. In *Mensing*, the Supreme Court expressly held that "Dear Doctor" letters—which are communications about warnings other than through the physical product label—are nonetheless "labeling" that is equally subject to FDA approval. 131 S. Ct. at 2576. If generic drug manufacturers unilaterally sent such letters, "that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" *Id.* (citing U.S. *Mensing* Br. at 19); 21 C.F.R. § 314.150(b)(3)). Because of this danger, a generic manufacturer "is not free to change its approved labeling at will." Br. for United States as Amicus Curiae, *Pliva v. Mensing*, Nos. 09-993 & 09-1039 at 12 ("U.S. *Mensing* Cert. Br.") (citing 21 C.F.R. § 314.70(a)); *see also* U.S. *Mensing* Br. at 16 ("FDA has consistently taken the position that [a generic drug manufacturer] may not unilaterally change its approved labeling"). Giving deference to the FDA's interpretation of its own regulations, the Supreme Court concluded that any unilateral

communications by generic manufacturers through "Dear Doctor" letters would violate federal law, and therefore any state duties to do so were preempted. *Mensing*, 131 S. Ct. at 2575-76.

Plaintiffs contend that their "failure to communicate" claims are simply allegations that defendants failed to communicate warnings by "proper delivery" of the existing approved label or "other FDA approved means of communication that did not require language different from the [approved brand] label." MC ¶ 117. Such claims are still preempted under *Mensing*.[4] The FDA interprets "labeling" to include not just what is on the physical package, but also a vast array of communications regarding drugs, including printed, audio or visual matter. *See* 21 C.F.R. § 202.1(*l*)(2). Generic manufacturers' labeling must be precisely the "same" as the communications from the brand name manufacturers. *Mensing*, 131 S. Ct. 2575; 21 U.S.C. § 355(j)(2)(A); 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992) ("[T]he [generic drug's] labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for [generic drug] approval.").[5]

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4 *See Morris v. Wyeth, Inc.*, No. 3:09–CV–854, --- F. Supp. 2d ---, 2011 WL 4973839, at *2 (W.D. La. Oct. 19, 2011) (claims based upon alleged failure to use other "FDA-recommended communication tools" are preempted); *Guarino v. Wyeth*, No. 8:10-cv-2885-T-30TGW, --- F. Supp. 2d ---, 2011 WL 5358709, at *3 (M.D. Fla. 2011) ("[T]he Supreme Court specifically rejected Plaintiff's failure-to-communicate argument that generic drug manufacturers . . . should have sent "Dear Doctor" letters providing additional warnings to prescribing physicians."); *Darvocet*, 2012 WL 718618, at *4 n.9 (noting that "[s]everal courts have held failure-to-communicate claims to be preempted" in light of *Mensing*'s statement that generic drug manufacturers are not free to send "Dear Doctor" letters containing new drug warning information) (citing cases).

5 As defendants have explained, the relevant test is "sameness" not "consistency." *See* Brief for Appellants at 31-32 (discussing 21 C.F.R. § 201.100(d)(1)); *see also Turek v. General Mills, Inc.*, 662 F.3d 423, 426-27 (7th Cir. 2011) (Posner, J.) (as to FDA food labeling regulation that forbid states from imposing requirement "that is not identical" to FDA regulation, "[e]ven if the disclaimers that the plaintiff wants added would be consistent with the requirements imposed by the [FDCA], ***consistency is not the test; identity is***.")

The communications plaintiffs envision are thus regulated by federal law, and FDA alone is empowered to determine whether a proposed communication satisfies the mandates of the federal regulations it has the sole authority to enforce. *See* 21 U.S.C. § 352 (defining "misbranded drugs and devices"); *id.* at §§ 331, 332, 334(a), (b) (defining prohibited acts and penalties); *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) ("Congress intended that the [FDCA] be enforced exclusively by the Federal Government.") (citing 21 U.S.C. § 337(a)). As the FDA explained to the Supreme Court in *Mensing*, any assertion based on a generic drug manufacturer's "failure to communicate warnings to their customers" is "something ultimately in FDA's control." U.S. *Mensing* Cert. Br. 19.

A claim is not preempted only if "the private party could ***independently*** do under federal law what state law requires of it." *Mensing*, 131 S. Ct. at 2579 (emphasis added). "[W]hen a party cannot satisfy its state duties ***without*** the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party ***cannot independently satisfy those state duties for pre-emption purposes***." *Mensing*, 131 S. Ct. at 2580-81 (emphasis added). The fact that all means of labeling communications for generic drugs are "something ultimately in FDA's control," U.S. *Mensing* Br. 19, means that the nature and content of generic pharmaceutical warnings are solely within the FDA's ambit, and therefore are squarely preempted under *Mensing*. This issue should be decided now, and there is no reason for the Court to permit the claims to proceed to summary judgment.

2. Plaintiffs' "Failure-To-Update" Claim Is Preempted.

Plaintiffs also claim that generic manufacturers were "negligent in failing to include information present in the [brand label] and in failing to implement changes to their own labels to ensure that the information they provided was current and not outdated." MC ¶ 158. Plaintiffs allegedly suffered injuries because "FDA approved label changes in 2003 (warning of

use in geriatric patients) and 2004 (warning therapy should not exceed 12 weeks) were never included on some generic manufacturers' labels." Op. at 3. As a preliminary point, no such state law duty to update FDA-approved labels appears to exist. *See Gross v. Pfizer, Inc.*, No. 10–cv–00110–AW, 2011 WL 5865267, at *4 (D. Md. Jan. 27, 2011) (court not "aware of any such cause of action" for failure-to-update labels).[6]

But in any event, any failure-to-update claim boils down to an allegation that certain generic manufacturers failed to comply with FDA guidelines by failing to update their labels, and therefore is preempted. Federal labeling requirements are enforced exclusively by the FDA, not private parties, and therefore state law claims to compel agency enforcement of its own regulations are preempted. *Buckman*, 531 U.S. at 347; 21 U.S.C. § 337(a).; *see Fulgenzi v. Pliva, Inc.*, No. 5:09CV1767, 2012 WL 1110009, at *7 (N.D. Ohio Mar. 31, 2012) (holding that allegation that manufacturers failed to "include the FDA approved warning . . ." should be dismissed because "[t]here is no private cause of action for violations of FDA regulations"). In *Buckman*, the Supreme Court held that claims that defendants failed to satisfy disclosure requirements under state law (described as "fraud-on-the-FDA" claims) were preempted, stating that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." 531 U.S. at 347 (citing *Boyle v. United Technologies Corp.*, 487 U.S. 500, 504-05

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6 Furthermore, such a claim, even if it could be shown to be viable under some state's law, would be facially unsound in this case, where the allegation is that all pre-2009 "black box" labels were inadequate, *see* MC ¶¶ 119-122. No facial liability would attach for failure to update the allegedly inadequate 2004 label. *See Del Valle*, 2011 WL 7168620, at *8; *Gross*, 2011 WL 5865267, at *4; *Bowman v. Wyeth, LLC*, No. 10–1946, 2012 WL 684116, at *7 (D. Minn. Mar. 2, 2012) ("there is no duty for a manufacturer to provide an ***inadequate*** warning"); *Morris*, 2012 WL 601455, at *4 ("it is impossible to construe a facially plausible claim . . . because PLIVA's warning label would have been inadequate even if it had complied with the 2004 revision").

(1988) (allowing preemption of state law by federal common law where the interests at stake are "uniquely federal" in nature)). The FDCA creates no private right of action permitting private plaintiffs to change government policy in the guise of tort suits. *Id.* at 352-53. Thus, federal law preempts plaintiffs' state law claims seeking to police manufacturers' compliance with FDA regulations. Such a theory should not cause the Court to delay a ruling on preemption, given the costs at stake.

3. Plaintiffs' "Failure-To-Withdraw" Claim Is Preempted.

Finally, plaintiffs also allege that the defendants were "entitled to withdraw [their] metoclopramide product from the market at any time, but failed to do so in a timely and responsible manner." MC ¶¶ 150, 158. Again, there is no such state law duty to compel manufacturers to withdraw from the market when the FDA has authorized the manufacturers to sell drugs in interstate commerce. *See Lance v. Wyeth*, 2010 PA Super 137, 4 A.3d 160, 167 (2010) (joining the "majority of modern jurisdictions that have decided not to impose a common law duty to recall on a manufacturer"); *Gross*, 2011 WL 5865267, at *3 ("The Court is aware of no state law duty that would compel generic manufacturers to stop production of a drug that under federal law they have the authority to produce."); *Moore v. Mylan*, No. 1:11–CV–03037–MHS, --- F. Supp. 2d ---, 2012 WL 123986, at *10 n.14 (N.D. Ga. Jan. 5, 2012) (negligence claims alleging that a generic manufacturer had a duty to cease selling its product are preempted, and would conflict with FDA authority to determine what drugs can be sold in interstate commerce); *Coney v. Mylan Pharmaceuticals, Inc.*, No. 6:11–cv–35, 2012 WL 170143, at *5 (S.D. Ga. Jan. 19, 2012) (rejecting "withdrawal" argument as "tantamount to conferring supremacy upon the state law").

Moreover, the "failure-to-withdraw" claim has been made and rejected in *Mensing* and in numerous lower courts. The argument failed when presented to the U.S. Supreme Court on

rehearing in *Mensing*. *See* Respondents' Petition for Rehearing, *Pliva, Inc. v. Mensing*, No. 09-993, 2011 WL 2874547 at *1; *see also* Appellants' Br. 37-38. On remand, the Eighth Circuit expressly repudiated its statement in its earlier opinion that supported that view. *See Mensing*, 658 F.3d 867, *vacating portion of earlier opinion* at 588 F.3d 603, 611 (8th Cir. 2009) ("The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product."). As one court has succinctly stated, the argument that generic defendants could have removed their product from the market was "essentially a re-argument of *Mensing*" and to accept that argument, a court "would have to directly contravene binding law." *Fosamax*, 2011 WL 5903623, at *6 n.5. A theory so unsupported and soundly rejected should not cause the Court to delay a ruling on preemption any further, given the extraordinary costs at stake.

4. Nothing In Plaintiffs' Rephrased Claims Justifies The Enormous Burdens That Deferral Of The Preemption Issue Would Impose.

In sum, plaintiffs' rephrased claims fail to avoid *Mensing*'s preemptive reach and are otherwise unmeritorious. Moreover, there is no reason to wait until summary judgment or trial to review these issues and correct the trial court's errors. No further information is needed to determine that plaintiffs' claims are preempted. There is no justification for testing the claims under the laws of all 50 states on summary judgment, given that the U.S. Supreme Court has already held that a uniform federal standard applies and has done so in a decision involving the same drug, the same mandated federal warning, the same defendants, and the same basic claims.

If plaintiffs' preempted claims are not dismissed now, the benefit of the uniform standard decreed by the Supreme Court will effectively be lost in these cases. The trial court's refusal to vindicate the defendants' federal preemption defense, if left undisturbed, will subject these

defendants to enormous burdens resulting from the very disuniformity that federal law has sought to prevent. Forcing the generic manufacturers to re-wage the *Mensing* battle against 2,000 plaintiffs, wielding various and contradictory interpretations of the laws of 50 states, would impose unfair and crippling litigation burdens through additional discovery, motion practice, and protracted uncertainty. Just as the Supreme Court did in *Mensing*, numerous courts have dismissed state law claims based on *Mensing* without any particularized examination of laws of the plaintiffs' states. *See supra* note 1. This Court should do the same. Federal preemption is an issue of federal law, and the word of the final authority on federal law, the U.S. Supreme Court, is binding and should be given effect without needless examination of varying state laws.

II. THE TRIAL COURT'S RULING CONTRAVENES THE FEDERAL REGULATORY REGIME.

In creating the federal pharmaceutical regulatory regime, Congress intended to establish uniform nationwide warnings based on the expert views of the FDA, and also to ensure that low cost drugs are widely available by permitting generic manufacturers to produce drugs without having to replicate testing and approval processes already engaged in by the brand name manufacturers. Plaintiffs' contention that they can simply "plead around" *Mensing*, if accepted, would contravene that federal regulatory regime.

According to the FDA, if a generic manufacturer believes that a new label is warranted, "it should provide adequate supporting information to the FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised." U.S. *Mensing* Br. 20 (quoting 57 Fed. Reg. at 17,961). This "orderly process" reconciles the statutory mandates that generic drugs not be misbranded, but bear labeling the "same" as the labeling approved for the brand name drug. *Id.* at 20. The FDA's regulatory interpretations of "labeling" are broad, and necessarily

so, because the FDA places "a very high priority [on] assuring consistency in labeling" in order to "minimize any cause for confusion among health care professionals and consumers as well as to preclude a basis for lack of confidence in the equivalency of generic versus brand name products." U.S. *Mensing* Br. 4 (citations omitted).

Under plaintiffs' view, however, manufacturers' dissemination of information to health care providers and consumers must be driven by state laws that purportedly impose a duty to communicate what individual juries would view as "adequate" or "effective" warnings, rather than by the orderly and uniform federal process developed by the FDA. If accepted, that would threaten the FDA's uniform regulatory role and its interest in preserving the "therapeutic equivalency" of generic drugs. Allowing each plaintiff to plead the law of his or her domicile, and thereby avoid immediate dismissal, would make the frustration of the FDA's goals all the more likely. If these 2,000 plaintiffs may pursue failure-to-warn claims under the laws of 50 different states, manufacturers would be subjected to different, and potentially conflicting, duties arising from various state laws. That directly contradicts the federal regulatory regime and it was specifically rejected in *Mensing*.

Allowing this result would make the orderly dissemination of information about FDA-approved drugs more complicated, more expensive, and practically impossible for the regulated manufacturers. Other courts have recognized this irrefutable point:

> To allow each of the 50 states to set out the duty to warn under its own law would lead conceivably to 50 different regulations for the same generic drug. This would effectively make it impractical for a drug manufacturer to comply with each state and thereby impact the production of medications. The need for uniformity from one source of the law concerning generic drugs is an important reason for preemption of this area by federal law.

Leitzen v. Teva Pharmaceuticals USA, Inc., No. II-L-4 (Ill. Cir. Ct. Feb. 15, 2012) (unpublished Memorandum Order at 3).

Allowing plaintiffs to avoid immediate dismissal by relying upon cacophony of 50 different legal regimes to govern the adequacy of pharmaceutical warnings would also threaten to seriously interfere with the FDA's regulation of generic drugs. In *Buckman*, the Court found that state law fraud-on-the-FDA claims in connection with applications for approval of medical devices were preempted by the federal statutory scheme, which empowered the FDA to punish and deter fraud against the administration, and that that authority was used "to achieve a somewhat delicate balance of statutory objectives." 531 U.S. at 348. Such a balance could be "skewed" by permitting state law claims. *Id.* The court held that "[a]s a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress . . . ." *Id.* at 350. Such "litigation would exert an extraneous pull on the scheme established by Congress." *Id.* at 353. That same danger is present here, as the FDA efforts to establish a single, effective process for the intake of information that could lead to updated labeling—as well as procedures for the effective communication of such warnings—may be undermined as generic drug manufacturers are faced with the prospects of absorbing significant litigation costs defending against improper state law claims.

In fact, the legal regime contemplated by plaintiffs has not only been rejected by *Mensing* and would raise regulatory impossibility problems, it is likely to lead to ***less*** adequate and effective communications of warnings and information. If manufacturers were required to provide communications of warnings that suited each of the 50 states' laws, providers and consumers of prescription drugs—many of whom may purchase or use drugs in various states—may receive numerous notices each year regarding the same drug. As the Seventh Circuit observed in holding that the FDCA preempted certain state law packaging requirements, "[i]t is

easy to see why Congress would not want to allow states to impose disclosure requirements of their own on packaged food products, most of which are sold nationwide. Manufacturers might have to print 50 different labels, driving consumers who buy food products in more than one state crazy." *Turek*, 662 F.3d at 426. The cacophony of warning information would be more than annoying, it could endanger patient health. The stream of communications from generic manufacturers may "backfire" and "such information overload could cause [providers] to simply tune out this communication." *See* Brenna Jenny, et al., *Did Failure-To-Warn Claims Against Generic Manufacturers Survive* Mensing*?*, J. L. Med. & Ethics 165, 168-69 (2012).

The underlying purpose of the federal regulatory scheme is to ensure that low cost drugs are widely available by permitting generic manufacturers to produce drugs without having to incur unnecessary costs and therefore to bring much-needed drugs to market at lower costs. *Mensing*, 131 S. Ct. at 2582 ("it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public"). Subjecting manufacturers to varied state law duties, including additional state-imposed duties to gather information and disseminate it to health care providers and consumers, will impose significant costs, thereby defeating one of the primary purposes of the generic labeling laws. Indeed, plaintiffs expressly allege that manufacturers should "withdraw" from the market if they cannot comply with additional state law duties to warn. *See* MC ¶¶ 150, 158. That would undermine Congress's goals of expanding the drug market.

If the complex federal drug labeling scheme is to be altered, that should be left to Congress and the FDA, not individual juries proceeding under varied state laws. As *Mensing* noted with respect to the different outcomes yielded by the different regulatory schemes that govern brand name and generic drug labels, it is Congress and the FDA that have authorized and

implemented the current labeling regime and "different federal statutes and regulations may . . . lead to different pre-emption results," 131 S. Ct. at 2582, and "[a]s always, Congress and the FDA retain the authority to change the law and regulations if they so desire." *Id.* Whether or not changes to the regulatory framework are advisable is a question properly addressed through legislative and regulatory channels, not litigation under state law.

CONCLUSION

For the foregoing reasons, the Court should reverse the order below.

Respectfully submitted,

/MPG

Jeremy A. Mercer (PA 86480)
FULBRIGHT & JAWORSKI L.L.P.
370 Southpointe Blvd., Suite 300
Canonsburg, Pennsylvania 15317
(724) 416-0440

Jonathan S. Franklin
Mark Emery
FULBRIGHT & JAWORSKI L.L.P.
801 Pennsylvania Ave., N.W.
Washington, D.C. 20004
(202) 662-0466

Counsel for Amici Curiae

Robin S. Conrad
Rachel Brand
NATIONAL CHAMBER LITIGATION CENTER, INC.
1615 H. Street, N.W.
Washington, D.C. 20062
(202) 463-5337

Counsel for Amicus Curiae Chamber of Commerce of the United States of America

Robert Billings
GENERIC PHARMACEUTICAL ASSOCIATION
777 Sixth Street, N.W., Suite 510
Washington, D.C. 20001
(202) 249-7100

Counsel for Amicus Curiae Generic Pharmaceutical Association

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CERTIFICATE OF SERVICE

I certify that on May 2, 2012, the foregoing brief was served by E-Mail on all parties in the above captioned matter and/or their counsel of record through and with the agreement of the following:

Plaintiffs' Liason Counsel:

Raymond Peppelman (PA 17484)
GILLIGAN & PEPPELMAN
1223 North Providence Road, Floor 3
Media, PA 19063
Tel: 610-726-1288
Fax: 610-566-0808
ray@gandplaw.us

Rosemary Pinto (PA 53114)
FELDMAN & PINTO
1604 Locust Street, 2R
Philadelphia, PA 19103
Tel: 215-546-2604
Fax: 215-546-9904
rpinto@feldmanpinto.com

Stewart Eisenberg (PA 32151)
EISENBERG, ROTHWEILLER,
WINKLER, EISENBERG & JECK
1634 Spruce Street
Philadelphia, PA 19103
Tel:215-268-7153
Fax:215-546-0118
stewart@erlegal.com

L. Leonard Lundy (PA 9895)
LUNDY LAW
1635 Market Street, 19th Floor
Philadelphia, PA 19103
Tel: 215-567-3000
Fax.: 215-246-9239
llundy@lundylaw.com

Defendants' Liaison Counsel:

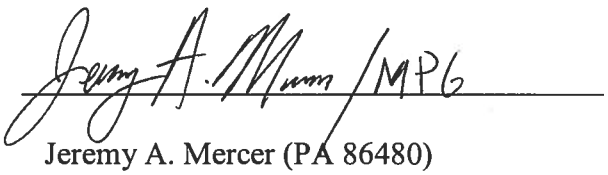
Henninger S. Bullock (NY 4084224)
MAYER BROWN LLP
1675 Broadway
New York, NY 10019
Tel: 212- 506-2528
Fax: 212-849-5528
hbullock@mayerbrown.com

Robert Boston (PA 85825)
CAMPBELL, CAMPBELL, EDWARDS &
CONROY
690 Lee Road, Suite 300
Wayne, PA 19087
Tel: 610-964-1900
Fax: 610-964-1281
rboston@campbell-trial-lawyers.com

Walter "Pete" Swayze, III (PA 59101)
SEGAL MCCAMBRIDGE SINGER
MAHONEY, LTD.
1818 Market Street, Suite 2600
Philadelphia, PA 19103
Tel: 215-972-8015
Fax: 215-972-8016
pswayze@smsm.com
mgrossman@smsm.com

Raymond Williams (PA 90771)
DLA PIPER US LLP
One Liberty Place
1650 Market Street, Suite 4900
Philadelphia, PA 19103
Tel: 215-656-3368
Fax: 215-656-3301
raymond.williams@dlapiper.com

Ernest F. Koschineg (PA 83350)
KENT MCBRIDE
1617 JFK Blvd., Suite 1200
Philadelphia, PA 19103
Tel: 215-568-1800
Fax: 215-568-1830
ekoschineg@kentmcbride.com



Jeremy A. Mercer (PA 86480)
FULBRIGHT & JAWORSKI L.L.P.
370 Southpointe Blvd., Suite 300
Canonsburg, Pennsylvania 15317
(724) 416-0440