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Rethinking Non-Failure-to-Warn Claims Against Generic Drug Manufacturers: An Argument for the Supreme Court to Reverse *Bartlett v. Mutual Pharmaceutical*

Jonathan A. Keller*

I. Introduction

The United States Constitution instituted the concept of federalism, a system of dual sovereignty between the federal and state governments.¹ Such a system sometimes positions state power against federal power, but other times allows for concurrent authority.² The Supremacy Clause of the Constitution resolves conflicts between federal and state law by providing that federal law “shall be the supreme Law of the Land.”³ In any preemption case, the critical question is always whether the relevant state and federal laws, either explicitly or implicitly, conflict—oftentimes a complex and difficult question to answer.⁴ In the last few years, the Supreme Court has dealt with the issue of preemption regarding the laws regulating prescription pharmaceuticals,⁵ catapulting product liability actions against drug manufacturers to the forefront of the debate over the role of federal regulation of prescription drugs.⁶

In 2009, the Supreme Court first addressed the preemption issue as it applied to the laws regulating brand-name drug manufacturers. In *Wyeth v. Levine*,⁷ the Court held that state law failure-to-warn claims were neither explicitly nor impliedly preempted by the federal laws governing prescription drug labeling.⁸ The Court conducted a detailed analysis of the Food,

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¹ THE FEDERALIST No. 51 (James Madison).

² *Id.*

³ U.S. CONST. art. VI, cl. 2.

⁴ Roger Pilon, *Into the Preemption Thicket Again-Five Times!*, 2011 CATO SUP. CT. REV. 263, 264 (2011).

⁵ See *Wyeth v. Levine*, 555 U.S. 555 (2009); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

⁶ Mary J. Davis, *The Battle over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1090 (2007).

⁷ 555 U.S. 555 (2009).

⁸ *Id.* at 555.

Drug, and Cosmetic Act (FDCA), a federal law, and concluded that it afforded brand-name manufacturers a way to comply with both their state law duty to strengthen the drug’s labeling and with federal regulations.⁹

Then, only two years later in 2011, the Supreme Court came to a seemingly opposite result in its application of preemption to the laws regulating generic drug manufactures. In *PLIVA v. Mensing*,¹⁰ the Court ruled that state law failure-to-warn claims against generic manufacturers were implicitly preempted by federal law based on a close reading of the FDCA.¹¹ In reaching its decision, the Court recognized that generic manufacturers are prohibited by statute from unilaterally changing their product labeling without prior Food and Drug Administration (FDA) approval.¹² Unlike brand-name manufacturers, generic manufacturers do not have the same regulatory mechanisms¹³ to account for new safety information and would violate federal law if they unilaterally change their warning labels.¹⁴

The Supreme Court’s decisions in *Wyeth* and *Mensing* have provided critical guidance illustrating how the preemption analysis should be applied to the laws regulating brand-name and generic drug manufacturers in the context of failure-to-warn claims. But, these two cases left unanswered the preemption question with respect to non-failure-to-warn claims against generic manufacturers.¹⁵ The federal district courts have struggled with this issue, but with near

⁹ *Id.* at 556–73.

¹⁰ 131 S. Ct. 2567 (2011).

¹¹ *Id.* at 2571.

¹² *Id.* at 2574–75 (“The FDA, however, tells us that it interprets its regulations to require that the warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of ‘sameness.’”); *see also* 57 Fed. Reg. 17961 (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.”).

¹³ *See also* 21 C.F.R. §§ 314.70(c)(3)–(6) (The FDA’s changes-being-effected process allows brand-name manufacturers to add or strengthen warnings and label instructions to increase the safe use of the drug. Brand-name manufacturers do not need to wait for FDA preapproval when making labeling changes through the CBE process; rather, they only need to file a supplemental application with the FDA. But, that process allows generic manufacturers to change its labels only when the brand label is concurrently changed).

¹⁴ *Mensing*, 131 S. Ct. at 2578–79 (2011).

¹⁵ *See* *Wyeth v. Levine*, 555 U.S. 555 (2009); *Mensing*, 131 S. Ct. 2567.

unanimity they have adopted a broad reading of *Mensing* based on its holding and reasoning.¹⁶ Specifically, the district courts have concluded that the rationales enunciated in *Mensing*, which preempted state failure-to-warn claims, apply with equal force to, and thus also preempt, state design defect claims against generic manufacturers.¹⁷

In May 2012, however, the United States Court of Appeals for the First Circuit broke ranks with every federal district court by upholding a district court's decision to allow a design

¹⁶ See *In re Pamidronate Products Liab. Litig.*, 842 F. Supp. 2d 479 (E.D.N.Y. 2012) (State law claims challenging the adequacy of generic drug labeling are preempted. Design defect claims are preempted because the "sameness" requirement in the labeling context applies equally to generic manufacturers with regards to the design of the drug. Negligent testing and breach of express warranty claims are warning claims in disguise and are preempted. Implied warranty claims are design defect claims in disguise and are preempted); *In re Fosamax (Alendronate Sodium) Products Liab. Litig. (No. II)*, No. 08-008 (GEB-LHG), 2011 WL 5903623 (D.N.J. Nov. 21, 2011) (The design of a generic drug, like its warnings, must be the same as the brand-name reference drug; therefore, design defect claims and negligent design claims are preempted. Negligence claims relating to generic drug warnings are preempted. Express warranty, fraud, misrepresentation, and consumer protection claims all attack a drug's labeling and are thus preempted); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654 (D. Md. 2011) (Negligence claims alleging that generic manufacturers had a duty to cease selling their product at all are preempted. Such a claim would directly conflict with FDA authority to determine what drugs can be sold in interstate commerce. Claims for concealing information from FDA are warning claims, and are preempted. Claims alleging failure to update do not exist at state law, and in any event are preempted); *Cooper v. Wyeth, Inc.*, No. 09-929-JJB, 2012 WL 733846 (M.D. La. Mar. 6, 2012) (Claims of inadequate post-marketing surveillance of drug's adverse effects are preempted. Claims that generic manufacturers had a duty to withdrawal its product from the market are preempted. The fact that defendant's generic product has been designated a reference listed drug does not establish that it may unilaterally change its warnings. Express warranty claims based on labeling are preempted. Design defect claims are not seen as really challenging the design of the drug, but rather only the warnings, and thus are preempted); *Johnson v. Teva Pharmaceuticals USA, Inc.*, No. 2:10 CV 404, 2012 WL 1866839 (W.D. La. May 21, 2012) (All warning claims preempted. Claims of failure to use additional forms of communication to provide warnings are preempted. Express warranty and design defect claim asserting an alternative package design are really warning claims in disguise and are preempted. Design defect claims challenging the composition of the drug itself are preempted because prior FDA approval is required to change it. A claim that the drug should have been removed from the market is preempted); *In re Darvocet, Darvon & Propoxyphene Products Liab. Litig.*, No. 2:11-MD-2226-DCR, 2012 WL 718618 (E.D. Ky. Mar. 5, 2012) (Marketing claims that generic manufacturers had a state duty to withdrawal its product from the market are preempted. Both design and warning claims are preempted since the "sameness" obligation applies to the design as well as to the warning requirement for generic drugs. Consumer fraud and express warranty claims all seek to change the label, and are preempted. Claims based on alleged violations of the FDCA are preempted as improper private rights of action); *Fulgenzi v. PLIVA, Inc.*, No. 5:09CV1767, 2012 WL 1110009 (N.D. Ohio Mar. 31, 2012) (State law claims challenging the adequacy of generic drug labeling are preempted. All non-failure-to-warn claims were inadequately pleaded, but even if they were, design defect claims would be preempted under the statute's "sameness" requirement. Claims for breach of express and implied warranties, misrepresentation, breach of undertaking, fraud, constructive fraud, fraudulent concealment, and intentional infliction of emotional distress all assert warning claims and are preempted. A claim that the drug should have been removed from the market is preempted).

¹⁷ See *In re Pamidronate*, 842 F. Supp. 2d 479; *In re Fosamax*, 2011 WL 5903623; *In re Darvocet*, 2012 WL 718618.

defect claim against a generic manufacturer.¹⁸ In *Bartlett v. Mutual Pharmaceutical*, the First Circuit rejected the generic manufacturer’s argument that, just as in the labeling context in *Mensing*, design defect claims against generic manufacturers are preempted since a generic manufacturer cannot unilaterally alter the composition of its drugs.¹⁹ Rather, the First Circuit found that there was no conflict between the federal and state law, and thus the design defect claim was not preempted.²⁰

The First Circuit erred in *Bartlett* because it openly departed from the Supreme Court’s reasoning in *Mensing*, which explained that because of a generic manufacturers’ “ongoing federal duty of sameness,” they are prevented from deviating in any material respect from their brand-name equivalents.²¹ Had the First Circuit faithfully applied the holding and reasoning in *Mensing*, it would have concluded that because the “impossibility” of changing a generic drug’s labeling under federal law led to the preemption of failure-to-warn claims, then the “impossibility” of changing a drug’s chemical composition under federal law would have also led to the preemption of design defect claims.²² Recognizing this tension between *Bartlett* and the Court’s prior decision in *Mensing*, the Supreme Court granted certiorari to review *Bartlett* and definitively answer whether non-failure-to-warn claims against generic manufacturers are preempted.²³

This Comment will focus on the viability of state law design defect claims against generic drug manufacturers, arguing that federal law preempts such claims. Part II of this Comment will begin by detailing the regulatory scheme under the FDCA, placing the preemption

¹⁸ *Bartlett v. Mut. Pharm. Co., Inc.*, 678 F.3d 30 (1st Cir. 2012).

¹⁹ *Id.* at 37–38.

²⁰ *Id.* at 37 (Court explained that because there was no federal law requiring Mutual to sell its generic drug, then a state law requiring Mutual to withdrawal the drug from the market would not conflict with federal requirements. Thus, the court concluded it was not impossible for Mutual to comply with both federal and state law).

²¹ *Mensing*, 131 S. Ct. at 2574–75.

²² See *infra* Part V.

²³ *Mut. Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 694 (2012).

issue in context.²⁴ In doing so, the FDCA and FDA regulations concerning drug manufacturers' ability to change their product labeling and composition post market will be examined and contrasted to the corresponding state law. Part III will discuss three product liability actions that an individual may bring against a drug manufacturer.²⁵ This part will specifically address the issues that arise when design defect claims are brought against drug manufacturers. Part IV will begin by setting forth the different types of preemption.²⁶ Then, it will examine *Wyeth v. Levine* and *PLIVA, Inc. v. Mensing*, the two high-profile Supreme Court cases that have addressed the issue of preemption with regards to prescription drugs. Part IV will then continue with an analysis of how courts have applied preemption in the wake of *Mensing*, with a particular focus on design defect claims. Part IV will conclude with an examination of the First Circuit's decision *Bartlett v. Mut. Pharm. Co., Inc.* and argue that the court erred by failing to hold that a design defect claim against the generic manufacturer was preempted.²⁷ Part V sets forth several reasons why the Supreme Court is likely to reverse *Bartlett*, and suggests that all design defect claims against generic drug manufacturers should be preempted.²⁸

Part II: The Prescription Drug Regulatory Framework

The FDCA regulates the sale and labeling of all prescription drugs in the United States.²⁹ A new prescription drug³⁰ cannot be sold in the United States without the FDA's prior approval.³¹ When the sponsor³² of a new drug has gathered enough evidence regarding the drug's safety and efficacy, the sponsor then submits a New Drug Application (NDA) to the FDA.

²⁴ See *infra* notes 29–64 and accompanying text.

²⁵ See *infra* notes 65–99 and accompanying text.

²⁶ See *infra* notes 100–158 and accompanying text.

²⁷ See *infra* notes 159–211 and accompanying text.

²⁸ See *infra* notes 212–251 and accompanying text.

²⁹ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2006).

³⁰ 21 U.S.C. § 321(p) (2009). A new drug is one that is not yet recognized as safe and effective to treat a particular medical condition. *Id.*

³¹ 21 U.S.C. § 355(a).

³² Often a brand-name drug manufacturer.

The purpose of the NDA is to provide the FDA with enough information to allow the agency to determine whether the drug is safe and effective for its proposed use.³³

An Abbreviated New Drug Application (ANDA) contains data that, when submitted to the FDA, provides for the review and approval of a generic drug.³⁴ Generic drug applications are termed an “abbreviated” process because those manufacturers are generally not required to include clinical data from test studies establishing the drug’s safety and efficacy. Once approved, the applicant may then manufacture and market the generic drug product.³⁵

A. New Drugs

In order to market a new prescription drug, the sponsor must submit a NDA, accompanied by extensive clinical and scientific studies verifying the drug’s safety and efficacy profile.³⁶ The NDA includes, among other disclosures, the safety and efficacy reports from the clinical trials, a list of all the components and composition of the drug, a description of the methods and controls used in manufacturing, processing, and packaging the drug, samples of the drug, and examples of intended labeling.³⁷ The FDA may deny the approval of a drug if it finds that the labeling is insufficient.³⁸

The brand-name manufacturer’s obligations continue after the FDA approves the drug. The manufacturers must maintain records, conduct additional testing as directed, and advise the FDA of significant adverse health consequences that are discovered following the drug’s introduction to the market.³⁹ Further, when new information about the safety of a drug becomes apparent to the sponsor, the brand-name manufacturer has an obligation to update its label to

³³ 21 U.S.C. § 355(b).

³⁴ *Id.*

³⁵ 21 C.F.R. § 314.50.

³⁶ 21 U.S.C. §§ 355(a)–(i).

³⁷ 21 U.S.C. § 355(b)(1).

³⁸ 21 U.S.C. § 355(c).

³⁹ 21 U.S.C. § 355(k)(1); 21 C.F.R. § 314.80.

reflect such warnings.⁴⁰ If the labeling change is “major,”⁴¹ the manufacturer must obtain FDA approval prior to implementing the change.⁴² On the other hand, “moderate [labeling] changes,”⁴³ may be implemented by the brand-name manufacturer before the FDA formally approves the proposed change.⁴⁴ Moderate labeling changes are implemented through the Changes Being Effected (CBE) procedure.⁴⁵

The Food and Drug Administration Amendments Act of 2007 (FDAAA)⁴⁶ amended the FDCA and gave the FDA additional tools to regulate prescription drugs.⁴⁷ The FDAAA added section 505(o) to the FDCA which authorizes the FDA to mandate additional post marketing studies and clinical trials for prescription drugs.⁴⁸ It also authorizes the FDA, under certain circumstances, to require a manufacturer to submit risk evaluation and mitigation strategies (REMS) to ensure that the drug’s benefits continue to outweigh its risks.⁴⁹ Lastly, the amendment gave the FDA the authority to require drug manufacturers to implement safety-related labeling changes (SLC).⁵⁰

B. Generic Drugs

In 1984 Congress passed the Drug Price Competition and Patent Term Restoration Act, (commonly referred to as the “Hatch-Waxman Act”), to reduce the cost and increase the speed of

⁴⁰ 21 C.F.R. § 201.80(e).

⁴¹ 21 C.F.R. § 314.70(b) (Major changes would include any alteration in the drug’s substance or production process which could adversely affect the identity, strength, purity, or potency of the drug, or a major label change).

⁴² 21 C.F.R. § 314.70(b).

⁴³ 21 C.F.R. § 314.70(c) (Moderate changes would include alterations to the drug substance or production process with a moderate possibility of adversely affecting the identity, strength, purity, or potency of a drug relating to safety or effectiveness and many label changes, such as strengthening warnings, deleting misleading or unsupported indications for use, or strengthening dosage or administration instructions).

⁴⁴ 21 C.F.R. §§ 314.70(c)(3), (6)(iii)(A)–(D).

⁴⁵ 21 C.F.R. §314.70(c)(6)(iii).

⁴⁶ Pub. L. No. 110-85, 121 Stat. 823 (2007).

⁴⁷ Pub. L. No. 110-85, 121 Stat. 823 (2007).

⁴⁸ 21 U.S.C. § 355(o)(3).

⁴⁹ 21 U.S.C. § 355-1.

⁵⁰ 21 U.S.C. §§ 355(o), 355–1(g), 333(f).

the approval of generic drugs.⁵¹ The Hatch-Waxman Act established the ANDA, an abridged process through which generic versions of brand-name drugs can be approved.⁵² Unlike brand-name sponsors, which must submit data from clinical trials demonstrating the safety and efficacy of their drug, the generic sponsor can “piggyback” on the information the brand-name sponsor already provided to the FDA.⁵³ The generic sponsor need only establish that its generic product is the same as the brand-name drug.⁵⁴

The primary difference between a NDA and an ANDA is that the latter generally does not require the extensive, and very expensive, pre-clinical and clinical studies that are the basis for establishing the drug’s safety and efficacy profile in the NDA process.⁵⁵ Under the ANDA process, the FDA will approve a generic drug for marketing upon proof that the drug is identical in active ingredient(s), dosage form, strength, route of admission, has the same labeling, and is bioequivalent to the brand-name drug.⁵⁶ In other words, the ANDA process focuses on establishing that the new generic drug is a copy of the brand-name drug in every significant respect, including its bioequivalence to the already approved brand-name drug.⁵⁷ A generic drug is considered bioequivalent to the brand-name drug when there is no significant difference in the rate and extent in which the drug becomes available in the body.⁵⁸ In particular, the FDA will determine whether the generic drug delivers the active ingredient(s) into the patients’

⁵¹ Pub. L. No. 98-417, 98 Stat. 1585 (1984).

⁵² Pub. L. No. 98-417, 98 Stat. 1585 (1984).

⁵³ 21 C.F.R. § 355(j)(2)(A).

⁵⁴ *Purepac Pharm. Co. v. FDA*, 354 F.3d 877, 879 (D.C. Cir. 2004); 21 C.F.R. § 355(j)(2)(A).

⁵⁵ 21 C.F.R. §314.94 (laying out the content and format of the ANDA).

⁵⁶ 21 C.F.R. §314.92(a)(1); 21 U.S.C. § 355(j)(2)(A).

⁵⁷ 21 C.F.R. §314.92(a)(1); 21 U.S.C. § 355(j)(2)(A).

⁵⁸ 21 C.F.R. § 320.1(e); *see also* *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 523 (E.D. Pa. 2006), *aff’d*, 521 F.3d 253 (3d Cir. 2008), *vacated*, 129 S. Ct. 1578 (2009) (noting that “[t]he ANDA applicant need only certify that the generic manufacturer will produce a bio-equivalent of the brand name drug and that the labeling and warnings of the generic drug are identical to that of the approved innovator drug”).

bloodstream in the same quantities and at the same rate when administered under similar conditions as the name-brand drug.⁵⁹

Furthermore, the generic sponsor must show that, with certain exceptions,⁶⁰ the labeling of the generic drug is the same as the brand-name drug's labeling.⁶¹ If the brand-name manufacturer makes a labeling change to its drug, the generic manufacturer must mirror that change in its corresponding drug labeling.⁶² If the brand-name manufacturer does not make a labeling change, however, the generic manufacturer may not unilaterally change its drug labeling.⁶³ In fact, the FDA's approval of an ANDA may be withdrawn if the labeling for the generic drug is no longer consistent with that of the brand-name drug referred to in the ANDA.⁶⁴

Part III: The Three Types of Product Defects

Product liability suits involving prescription drugs are state tort actions.⁶⁵ Under strict products liability theory, a manufacturer may be held liable via three distinct types of product defects: manufacturing defects, warning defects (as known as failure-to-warn claims), and design defects.⁶⁶

A. Manufacturing Defect Claim

A manufacturing defect is an unintended flaw in the product from the result of improper manufacturing.⁶⁷ Typically, the plaintiff will allege that the product ultimately produced was

⁵⁹ See 21 C.F.R. § 314.94(a)(7).

⁶⁰ 21 C.F.R. § 314.94(a)(8)(iv). It identifies the following differences as acceptable: “[D]ifferences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(4)(D) of the act.”

⁶¹ 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8)(iii).

⁶² See FDA, Guidance for Industry, Revising ANDA Labeling Following Revision of the RLD Labeling (May 2000) (ANDA Labeling Revision Guidance).

⁶³ 57 Fed. Reg. 17961 (1992); see also *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581–82 (2011).

⁶⁴ 21 C.F.R. § 314.150(b)(10).

⁶⁵ MARK HERRMANN & DAVID B. ALDEN, *DRUG AND DEVICE PRODUCT LIABILITY LITIGATION STRATEGY* 39 (2012).

⁶⁶ *Id.*

⁶⁷ *Id.* at 53.

different from what the manufacturer intended.⁶⁸ In assessing whether a manufacturing defect exists, the law focuses on whether the product was made in accordance with the manufacturer's own standards.⁶⁹ If the product is not in its "intended condition," it is defective and the manufacturer faces strict liability for injuries caused by the manufacturing defect.⁷⁰ There is generally no controversy over manufacturing defect law for prescription drugs.⁷¹

B. Failure-to-Warn Claim

A failure-to-warn defect exists when the manufacturer fails to provide adequate warnings regarding the risks associated with using the product.⁷² The *Restatement (Second) of Torts* explains that while some prescription drugs may be unavoidably unsafe, they are not "unreasonably dangerous" when "accompanied by proper directions and warnings."⁷³ When alleging a failure-to-warn, a plaintiff need only show that the manufacturer knew or should have known that use of the product carried risks which the manufacturer failed to warn the plaintiff against.⁷⁴

In failure-to-claims against drug manufacturers, the issue centers on the drug's labeling and whether the warning was adequate.⁷⁵ It is via the drug's labeling in which the manufacturer typically discloses the warnings regarding the drug.⁷⁶ The Supreme Court addressed whether failure-to-warn claims are preempted against drug manufacturers in *Wyeth*⁷⁷ and *Mensing*.⁷⁸ *Wyeth* held that failure-to-warn claims are not preempted against brand-name manufacturers

⁶⁸ *Id.*

⁶⁹ See generally RESTATEMENT (SECOND) OF TORTS § 402A (1965).

⁷⁰ RESTATEMENT (SECOND) OF TORTS § 402A(2)(a) (1965).

⁷¹ Grundberg v. Upjohn Co., 813 P.2d 89, 92 (Utah 1991) (explaining that this limitation on comment k immunity is universally recognized).

⁷² W. PAGE KEETON, PROSSER AND KEETON ON THE LAW OF TORTS, 697 (5th ed. 1984).

⁷³ RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

⁷⁴ W. PAGE KEETON, PROSSER AND KEETON ON THE LAW OF TORTS, 697 (5th ed. 1984).

⁷⁵ See *Wyeth v. Levine*, 555 U.S. 555, 563 (2009).

⁷⁶ *Id.* at 562.

⁷⁷ 555 U.S. 555 (2009).

⁷⁸ 131 S. Ct. 2567 (2011).

while *Mensing* explained such claims are preempted against generic manufacturers.⁷⁹ They left unanswered, however, the question of preemption as it applies to non-failure-to-warn claims against generic manufacturers.⁸⁰ Accordingly, since *Mensing* was decided, trial courts across the country have grappled with that unsolved issue and have had to interpret the breadth and scope of the Court’s decision.

C. Design Defect Claims

A design defect exists when the product is otherwise manufactured properly, but is nonetheless unreasonably dangerous because of its inherent design.⁸¹ Alleging a design defect claim depends heavily on whether the state it is brought under adheres to the *Second* or *Third Restatement of Torts*, and how that state specifically interprets the Restatement.

With respect to design defect claims for prescription drugs, comment *k* to section 402(A) of *Restatement (Second) of Torts* provides that a prescription drug, “properly prepared, and accompanied by proper directions and warning, *is not defective, nor is it unreasonably dangerous.*”⁸² Additionally, the seller of such a product will not be held strictly liable for the “unfortunate consequences” that may arise from its use “merely because [the manufacturer] has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.”⁸³ In a claim alleging the defective design of a prescription drug, comment *k* allows the manufacturer to escape strict liability if the risks associated with the prescription drug were unavoidable.⁸⁴ Once falling under comment *k*’s

⁷⁹ *Wyeth*, 555 U.S. at 555; *PLIVA v. Mensing*, 131 S. Ct. 2567, 2567 (2011).

⁸⁰ *See, Wyeth*, 555 U.S. 555; *Mensing*, 131 S. Ct. 2567.

⁸¹ HERRMANN, *supra* note 65, at 46.

⁸² RESTATEMENT (SECOND) OF TORTS § 402A, cmt. *k* (1965) (emphasis added).

⁸³ *Id.*

⁸⁴ *E.g. Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 657 (1st Cir. 1981) (explaining the protections from strict liability afforded by comment *k*).

protection, the prescription drug manufacturer is not held strictly liable on the basis of a defective design.⁸⁵

On its face, comment *k* would appear to preclude strict liability against design defect claims for prescription drugs that are properly manufactured and accompanied by appropriate warnings. In practice, however, the states have applied comment *k* in divergent ways,⁸⁶ leading to confusion as manufacturers face different standards depending on the jurisdiction.⁸⁷ Regardless of the approach taken, however, the comment *k* defense will not apply, and the manufacturer may be held strictly liable, if the drug was defectively manufactured or lacked adequate warnings.⁸⁸

⁸⁵ RESTATEMENT (SECOND) OF TORTS § 402A, cmt. b (1965).

⁸⁶ Courts confronted with claims of defectively designed drugs have generally adopted comment *k*, but have disagreed on the scope of protection that comment *k* affords prescription drugs. See *Brown v. Superior Court* (Abbott Labs), 751 P.2d 470, 476 (Cal. 1988). Most courts apply comment *k*'s protection from strict liability in a selective fashion, excepting from strict liability manufacturers of prescription drugs on a case-by-case basis. *Id.* However, a sizeable minority of courts apply comment *k*'s protections to all manufacturers of prescription drugs, excepting the manufacturers from strict liability on the basis of a defective design. *E.g.*, *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 90 (2d Cir. 1980); *Grundlerberg V. Upjohn Co.* 813 P.2d 89 (Utah 1991).

⁸⁷ See *e.g.*, *Grinage v. Mylan Pharms., Inc.*, 840 F. Supp. 2d 862 (D. Md. 2011); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011). In Pennsylvania, comment *k* bars strict liability failure-to-warn, manufacturing defect, and design defect claims for prescription drugs. *Lance v. Wyeth*, 4 A.3d 160, 165, 166 (Pa. Super. Ct. 2010) (“With our Supreme Court’s adoption of comment *k*, a design defect claim for strict liability is not cognizable under Pennsylvania law when it is asserted against a manufacturer of prescription drugs,” but the plaintiff’s “negligent design claim [wa]s not precluded by comment *k*, and [wa]s a valid cause of action upon which relief may be granted.”). In Washington, comment *k* bars strict liability only to design defect and failure-to-warn claims for prescription drugs. *Transue v. Aesthetech Corp.*, 341 F.3d 911, 915, 917 (9th Cir. 2003) (“Under Washington law, comment *k* affords a blanket exemption from strict liability for design defects in medical devices or products,” but “should not be construed to provide protection for manufacturing defect claims”). In California and Utah, plaintiffs may not pursue strict liability design defect claims for prescription drugs and devices. *Brown v. Super. Ct.*, 751 P.2d 470, 477 (Cal. 1988) (“We...conclude that (1) a drug manufacturer’s liability for a defectively designed drug should not be measured by the standards of strict liability; (2) because of the public interest in the development, availability, and reasonable price of drugs, the appropriate test for determining responsibility is the test stated in comment *k*.”). *Grundberg v. Upjohn Co.*, 813 P.2d 89, 99 (Utah 1991) (“In light of the strong public interest in the availability and affordability of prescription medications, the extensive regulatory system of the FDA, and the avenues of recovery still available to plaintiffs...we conclude that a broad grant of immunity from strict liability claims based on design defects should be extended to FDA-approved prescription drugs in Utah.”). In other states still, comment *k* amounts to an affirmative defense that a prescription drug manufacturer may invoke after showing either that the product is “unavoidably dangerous” or that its benefits outweigh its risk. *Georgia – Bryant v. Hoffman-La Roche, Inc.*, 585 S.E.2d 723, 728 (Ga. Ct. App. 2003) (“Comment *k* serves as an affirmative defense.”). *Nebraska – Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d., 827, 840 (Neb. 2000) (“We conclude that § 402 A, comment *k*, of the Second Restatement should be applied on a case-by-case basis and as an affirmative defense in cases involving prescription drug products.”).

⁸⁸ RESTATEMENT (SECOND) OF TORTS § 402A, cmt. *k* (1965).

Section 6(c) of the *Restatement (Third) of Torts* offers even less solace to plaintiffs injured by pharmaceuticals. It provides even more favorable protection to drug manufacturers by stating:

A prescription drug . . . is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug . . . are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug . . . for any class of patients.⁸⁹

Comment *b* to section 6(c) explains that a prescription drug manufacturer will be exempted from strict liability on the basis of a defective design if any reasonable health care provider would prescribe the drug to any class of patients.⁹⁰ Essentially, if a prescription drug confers a benefit upon a small class of patients, while harming other classes, it cannot be considered defectively designed.⁹¹ This reflects the judgment that as long as a drug provides a net benefit to at least one class of patients, it should be available on the market for a physician to prescribe.⁹²

Adding to the complexities of the design defect analysis for prescription drugs are several additional factors. First, the competing views of the *Restatement (Second)* and *(Third)*, as well as the opposing applications of comment *k*, illustrate the diverging view regarding judicial risk-utility review of prescription drug designs.⁹³ Additionally, the Restatements hold different views regarding the proper role of the FDA in reviewing prescription drug designs. Prescription drugs contain inherent risks and it is under the FDA's risk-benefit analysis in which the agency

⁸⁹ RESTATEMENT (THIRD) OF TORTS, PRODUCTS LIABILITY § 6(c) (1998).

⁹⁰ RESTATEMENT (THIRD) OF TORTS, PRODUCTS LIABILITY § 6(c), cmt. b (1998).

⁹¹ RESTATEMENT (THIRD) OF TORTS, PRODUCTS LIABILITY § 6(c), cmt. f (1998).

⁹² *Id.* (Explaining that if a reasonable physician determines a prescription drug to have sufficient utility to warrant its prescription, the prescription drug is not considered defectively designed).

⁹³ The Restatement (Third) takes the position that courts should not engage in the judicial review of prescription drug designs. Courts following the minority interpretation of Restatement (Second) agree with the Restatement (Third). *E.g., Brown v. Superior Court*, 751 P.2d 470, 470 (1988) (rejecting risk-utility review of prescription drug designs). However, the majority interpretation of the Restatement (Second) allow courts to review prescription drug designs. *Toner v. Lederle Laboratories, a Div. of Am. Cyanamid Co.*, 112 Idaho 328, 339–40 (1987). These courts apply comment *k* selectively, excepting from strict liability only manufacturers of those prescription drugs that supply an important social need. *Id.*

determines whether the drug's benefits outweigh its risk.⁹⁴ Some courts follow the approach of the Third Restatement and have declined to hold manufacturers of FDA-approved prescription drugs strictly liable on the basis of a defective design, deferring to the FDA-approval process.⁹⁵ However, most courts have held that FDA approval should not prevent judicial risk-utility review of prescription drug designs, or prevent a finding that a prescription drug has been defectively designed.⁹⁶

Furthermore, once a prescription drug is approved the design of the drug's chemical composition cannot be changed without further FDA permission.⁹⁷ Lastly, access to prescription drugs, and their use, are largely dictated by the recommendations and directions of physicians and other medical professionals.⁹⁸ As a result, case law addressing design defect claims against drug manufacturers has not been uniformly applied and varies significantly from jurisdiction to jurisdiction.⁹⁹

Part IV: The Development of Preemption as it Applies to Prescription Drugs

A. Introduction to Preemption

The Supremacy Clause of the U.S. Constitution provides that “the Laws of the United States shall be the supreme Law of the Land,” meaning that federal law will preempt and supersede conflicting state law.¹⁰⁰ There are two types of federal preemption. The first is express preemption. This occurs when a federal law contains language that, by its very terms, preempts state law.¹⁰¹ In such cases, a court first examines the language of the federal statute

⁹⁴ HERRMANN, *supra* note 65, at 48.

⁹⁵ Grundberg v. Upjohn Co., 813 P.2d 89,95 (Utah 1991).

⁹⁶ *E.g.*, Tobin v. Astra Pharm. Prod., Inc., 993 F.2d 528, 537–38 (6th Cir. 1993); Hill v. Searle Labs., 884 F.2d 1064, 1068 (8th Cir. 1989).

⁹⁷ HERRMANN, *supra* note 65, at 48.

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ U.S. CONST. art. VI, cl. 2.

¹⁰¹ *See* Cipollone v. Liggett Group, Inc., 505 U.S. 504, 548 (1992).

and determines if it should be read to preempt the state law.¹⁰² Then, the court must interpret the scope of the preemption language and determine if the state law falls within the scope of the intended preemption.¹⁰³

The second kind of preemption is implied preemption. Implied preemption occurs when Congress has not inserted express preemptive language in a federal law, but nonetheless, intended for the federal statute to preempt state law.¹⁰⁴ There are three different types of implied preemption. The first is conflict preemption, in which the conflict between federal and state law makes it impossible to comply with both laws simultaneously.¹⁰⁵ When this conflict exists, courts will conclude that Congress intended for the federal law to supersede the state law.¹⁰⁶ A second type of conflict preemption occurs when the state law undermines the objectives of the federal law.¹⁰⁷ In this situation, even though it may be possible to comply with both the state and federal law, the court will consider whether Congress intended to preclude state law from creating obstacles to the accomplishment of the federal law.¹⁰⁸ The court will examine the federal law and its legislative history to determine the purpose of the federal law, and whether the operation of the state law interferes with the objectives of the federal law.¹⁰⁹ Finally, there is field preemption.¹¹⁰ This occurs when Congress enacts broad legislation that is intended to occupy the entire field of regulation, leaving no room for state laws on the same subject.¹¹¹ The

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.* at 532–33.

¹⁰⁵ *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 871 (2000).

¹⁰⁶ *Id.* at 871–72.

¹⁰⁷ *Id.* at 873–74.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *See English v. Gen. Elec. Co.*, 496 U.S. 72 (1990).

¹¹¹ *Id.*

more comprehensive the federal law is, the more likely courts will find that Congress intended for the federal law to preempt the state law.¹¹²

The FDCA contains an express preemption clause relating to medical devices, but does not have a parallel provision governing pharmaceuticals.¹¹³ As such, courts have been forced to consider whether claims against drug manufacturers, especially failure-to-warn claims, are impliedly preempted.¹¹⁴ The Supreme Court has differentiated between cases involving brand-name drugs and those involving their generic counterparts.¹¹⁵ The Court has held that failure-to-warn claims involving brand-name drugs are not preempted because the manufacturer may alter its labeling without FDA approval pursuant to federal regulations.¹¹⁶ On the other hand, failure-to-warn cases involving generic drugs are preempted because generic drugs are required to be identical, both in labeling and design, to their brand-name counterparts.¹¹⁷

Wyeth and *Mensing* are the leading Supreme Court cases discussing preemption as it applies to the laws regulating prescription pharmaceuticals. Admittedly, these decisions only addressed the preemption of failure-to-warn claims against drug manufacturers, but the reasoning developed in these two cases can be extrapolated to design defect claims. There is no indication that a generic manufacturer's duty of "sameness" to the brand-name drug is somehow different in the design context than it is in the labeling context.

B. Failure-to-Warn Claims and Preemption

a. *Wyeth v. Levine*

¹¹² *Id.*

¹¹³ 21 U.S.C. § 360k(a) (2012).

¹¹⁴ *See, e.g.,* *Wyeth v. Levine*, 555 U.S. 555 (2009); *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011).

¹¹⁵ *Id.*

¹¹⁶ *Wyeth*, 555 U.S. at 555.

¹¹⁷ *Mensing*, 131 S. Ct. at 2567.

In *Levine*, the Supreme Court considered whether the FDA's approval of a drug labeling preempted state law products liability claims premised on the theory that the brand-name manufacturer failed to adequately warn consumers about the drug's known risks.¹¹⁸

In 2000, the plaintiff, Diana Levine, sought treatment for a migraine headache, and as part of her treatment, she received the brand-name drug Phenergan through an IV-push injection.¹¹⁹ Due to an error during administration, however, the drug entered Levine's artery, which ultimately led to gangrene and the amputation of her forearm.¹²⁰ At trial, Levine claimed that the label was defective because it failed to warn of the specific risks associated with the IV-push method.¹²¹ Wyeth countered that the FDA had approved the labeling and had rejected prior iterations which would have strengthened the warnings for inadvertent intra-arterial injection.¹²²

Levine brought a common law negligence and strict liability claims against Wyeth, the brand-name manufacturer of Phenergan.¹²³ A Vermont jury found for Levine and the court denied Wyeth's motion for judgment based on implied preemption.¹²⁴ The Supreme Court granted certiorari on the issue of whether the FDA's approval of a brand-name manufacturer's drug labeling preempts state law product liability claims premised on the theory that the drug's labeling failed to adequately warn of serious side effects.¹²⁵ Wyeth advanced two implied preemption arguments. First, Wyeth argued that it was impossible to comply with the state law duty to modify Phenergan's label without violating federal law, and second, that plaintiff's claim

¹¹⁸ *Wyeth*, 555 U.S. at 562.

¹¹⁹ *Id.* at 559.

¹²⁰ *Id.* at 560–61.

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Wyeth*, 555 U.S. at 563.

¹²⁵ *Id.* at 563–64.

created an obstacle to Congressional objectives by substituting a lay jury's decision about drug labeling for the expert judgment of the FDA.¹²⁶ The Court rejected both arguments.¹²⁷

With respect to the impossibility argument, the Court found that Wyeth could, in fact, have changed or strengthened its warning label pursuant to the FDA's Changes Being Effectuated (CBE) regulations.¹²⁸ These regulations permit a manufacturer to change its labeling without waiting for the FDA's approval.¹²⁹ The CBE regulations permit labeling changes, not only when a company acquires new safety information, but also when new analyses of previous data justifies a labeling change.¹³⁰ The Court found it significant that Levine had presented evidence of at least twenty similar adverse events and that Wyeth "could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug."¹³¹ Therefore, the Court held, it was possible for Wyeth to comply with both federal and state labeling requirements.

Wyeth's second preemption argument met a similar fate. The Court found that there was "[p]owerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."¹³² As the Court explained, if Congress thought state lawsuits would interfere with the FDA's objectives regarding drug labeling, it would have inserted an express preemption clause into the FDCA with regard to brand-name manufacturers.¹³³ The fact Congress did so for medical devices, but not for brand-name

¹²⁶ *Id.*

¹²⁷ *Id.* at 581.

¹²⁸ *Id.* at 568.

¹²⁹ *Id.* at 568 (quoting 21 C.F.R. §314.70(c)(6)(iii)(A), (C)).

¹³⁰ *Wyeth*, 555 U.S. at 569.

¹³¹ *Id.*

¹³² *Id.* at 575.

¹³³ *Id.*

prescription drugs, reinforces the conclusion that Congress did not intend to preempt failure-to-warn lawsuits.¹³⁴

Furthermore, the Court declined to defer to the preamble in the FDA’s 2006 regulation governing the content and format of prescription drug labels.¹³⁵ In the regulation, the FDA expressed its position that the approval of a drug’s labeling should preempt the state law duty to change the drug’s labeling.¹³⁶ Yet, the Court found this language to be “inherently suspect” because it was not included in the proposed regulation—only the final rule—and constituted a dramatic change in the agency’s prior position regarding preemption.¹³⁷

Having rejected Wyeth’s two preemption arguments, the Court affirmed the verdict. Thus, *Levine* established that conflict preemption does not apply to brand-name drug manufacturers in state law failure-to-warn claims.¹³⁸

b. PLIVA, Inc. v. Mensing

In *Mensing*, a 5-4 majority of the Supreme Court held that state law failure-to-warn claims against generic pharmaceutical manufacturers are impliedly preempted by federal law.¹³⁹ In reaching this decision, the Court accepted the FDA’s interpretation of its own regulations that generic manufacturers are prohibited from unilaterally changing or strengthening their product labeling without prior FDA approval.¹⁴⁰

Mensing involved two consolidated cases in which the plaintiffs, Gladys Mensing and Julie Demahy, alleged that they developed tardive dyskinesia, an often irreversible movement

¹³⁴ *Wyeth*, 555 U.S. at 575.

¹³⁵ *Id.* at 577.

¹³⁶ *Id.* at 580 (quoting 71 Fed. Reg. 3922, 3934–35).

¹³⁷ *Id.* at 580–81.

¹³⁸ *Id.* at 581.

¹³⁹ *PLIVA v. Mensing*, 131 S. Ct. 2567, 2570–71 (2011).

¹⁴⁰ *Id.*

disorder, as a result of taking the drug metoclopramide.¹⁴¹ The plaintiffs pursued state law failure-to-warn claims against the generic manufacturers of metoclopramide, alleging that the warnings for the drug failed to adequately disclose the risks of tardive dyskinesia.¹⁴² The generic manufacturers moved to dismiss, arguing that the FDA regulations required the warnings on their generic drugs to be the same as those of the brand-name product and that generic manufacturers are precluded from unilaterally changing the labeling without FDA approval.¹⁴³ Therefore, the generic manufacturers argued, the plaintiffs' failure-to-warn claims were preempted because it was impossible for them to unilaterally add the plaintiffs' proposed warnings without violating FDA regulations.¹⁴⁴

The two trial courts reached opposing conclusions on the generic manufacturers' motion to dismiss; one court granted the dismissal while the other allowed the suit to proceed.¹⁴⁵ On appeal, both the Fifth and Eighth Circuit Court of Appeals disagreed with the manufacturers and ruled in favor of the plaintiffs, finding that their claims were not preempted.¹⁴⁶ The Supreme Court then reversed, holding that the plaintiffs' failure-to-warn claims were in fact preempted by federal law.¹⁴⁷ The Court explained that while brand-name manufacturers are responsible for the labeling on their products, the Hatch-Waxman Amendments only require generic manufacturers to ensure that their warnings match those of the brand-name product.¹⁴⁸

First, the Court rejected the plaintiffs' argument that generic manufacturers were free to utilize the FDA's CBE regulations, which allow manufacturers to unilaterally add or strengthen a

¹⁴¹ *Id.* at 2572. Metoclopramide is the generic form of Reglan, a prescription drug used to treat various digestive track problems.

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Mensing*, 131 S. Ct. at 2572.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* at 2581–82.

¹⁴⁸ *Id.*

drug’s warnings before obtaining FDA approval.¹⁴⁹ In reaching this conclusion, the Court relied on the FDA’s position that the CBE process was unavailable to generic manufacturers because it would violate the requirement that the generic products’ warnings match those of the brand-name products.¹⁵⁰ Additionally, the Court also rejected the plaintiffs’ argument that the defendants were free to send warnings to physicians through “Dear Doctor” letters.¹⁵¹ Again, the Court’s position was based on the FDA’s interpretation that “Dear Doctor” letters constituted labeling under FDA regulations, and generic manufacturers cannot unilaterally add or strengthen warnings without prior FDA approval.¹⁵²

Significantly, the majority of the Court established the proper test for impossibility preemption. The Justices held that the “question for ‘impossibility’ is whether the private party could independently do under federal law what state law require[d] of it”¹⁵³ and that courts should not strain to find ways to reconcile federal law with seemingly conflicting state law.¹⁵⁴ Therefore, because the generic manufacturers could not independently change their drug’s labeling, the Court held that it was impossible for the generic manufacturers to add the plaintiffs’ proposed warning without violating FDA regulations.¹⁵⁵

C. Design Defect Claims and Preemption

Most pharmaceutical design defect claims devolve into claims asserting that either the FDA was wrong in approving the drug (which should either be preempted or barred by deference

¹⁴⁹ *Id.* at 2575; *see also* 21 C.F.R. §§ 314.70(c)(3)–(6) (FDA’s changes-being-effected process allows brand-name manufacturers to add or strengthen warnings and label instructions to increase safe use of the drug. Brand-name manufacturers need not wait for FDA preapproval when making labeling changes through the CBE process; they need only to file a supplemental application with the FDA. But that process allows generic manufacturers to change its labels only when the brand label is concurrently changed).

¹⁵⁰ *Mensing*, 131 S. Ct. at 2575.

¹⁵¹ *Id.* at 2576 (“Dear Doctor” letter is when a manufacturer sends a letter to physicians informing them of additional warnings regarding the drug).

¹⁵² *Id.*

¹⁵³ *Id.* at 2579.

¹⁵⁴ *Id.* at 2580.

¹⁵⁵ *Id.*

to the FDA’s decision to approve the drug) or the manufacturer wrongfully failed to withdraw the drug from the market (commonly termed the “failure-to-withdraw” theory).¹⁵⁶ Plaintiffs have asserted the latter theory, developed from state tort law, in an attempt to evade federal preemption.¹⁵⁷ Practically every court to consider the issue, however, has held that failure-to-withdraw claims are preempted because states cannot prohibit the sale and use of FDA approved drugs.¹⁵⁸

a. Preemption of Generic Manufacturer Claims After *Mensing*

¹⁵⁶ See *White v. Weiner*, 562 A.2d 378, 383 (Pa. Super. 1989).

¹⁵⁷ E.g., *Bartlett v. Mut. Pharm. Co., Inc.*, 678 F.3d 30, 37 (1st Cir. 2012).

¹⁵⁸ *Mensing* soundly rejected that approach, as this Court implicitly recognized on remand. See *Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011) (vacating 2009 opinion allowing a failure-to-withdraw theory). *Accord Smith v. Wyeth*, 657 F.3d 420 (6th Cir. 2011) (finding preemption in spite of plaintiffs’ failure-to-withdraw argument); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011) (“no state law duty that would compel generic manufacturers to stop production of a drug” could “exist, as it would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce.”); *Fullington v. PLIVA, Inc.*, 2011 WL 6153608, at *6 (E.D. Ark. Dec. 12, 2011) (removal from market claim preempted); *Coney v. Mylan Pharmaceuticals, Inc.*, 2012 WL 170143, at *5 (S.D. Ga. Jan. 19, 2012) (“Finding that state law prohibits [defendant] from doing what federal law explicitly requires [defendant] to do would be tantamount to conferring supremacy upon the state law.”); *Lyman v. Pfizer, Inc.*, 2012 WL 368675, at *4 (D. Vt. Feb. 3, 2012) (allegation that defendant “could have simply stopped selling the product” held preempted); *Moretti v. PLIVA, Inc.*, 2012 WL 628502, at *5–6 (D. Nev. Feb. 27, 2012) (liability for “continued distribution” held preempted); *Bowman v. Wyeth, LLC*, 2012 WL 684116, at *6 (D. Minn. Mar. 2, 2012) (rejecting “failure-to-withdraw” theory); *Cooper v. Wyeth, Inc.*, 2012 WL 733846, at *6 (M.D. La. Mar. 6, 2012) (“[i]f state law could require a generic drug manufacturer to wholly withdraw from the market based on the unreasonable danger of the product (which is all a successful failure to withdraw from the market claim could be), it necessarily must repudiate the label approved by the FDA.”); *Metz v. Wyeth*, 2012 WL 1058870, at *4 (M.D. Fla. Mar. 28, 2012) (removal from market claim preempted); *Fulgenzi v. PLIVA, Inc.*, 2012 WL 1110009, at *7 n.5 (N.D. Ohio Mar. 31, 2012) (“failure-to-withdraw” theory preempted); *Eckhardt v. Qualitest Pharmaceuticals, Inc.*, 2012 WL 1511817, at *6 (S.D. Tex. Apr. 30, 2012) (a state law requirement that the drug be completely withdrawn from the market, based solely on a theory that the federally mandated label was inadequate, would also impermissibly conflict with federal law and be preempted); *In re Reglan Litig.*, No. 289, 2012 WL 1613329 (N.J. Super. May 4, 2012) (rejecting the withdrawal argument and finding that “[t]he conflict between state and federal law would be much more pronounced if the state courts upheld a decision that an FDA-approved drug should not have been on the market”); *Johnson v. Teva Pharmaceuticals USA, Inc.*, No. 2:10 CV 404, 2012 WL 1866839, at *5 (W.D. La. May 21, 2012) (citing the *Mensing* petition for rehearing and subsequent Eighth Circuit proceedings and “likewise reject[ing] Ms. Johnson’s failure to withdraw argument”); *In re Darvocet, Darvon & Propoxyphene Products Liability Litigation*, 2012 WL 2457825, at *1 (E.D. Ky. June 22, 2012) (refusing to follow *Bartlett* and rejecting “failure-to-withdraw” theory); *Aucoin v. Amneal Pharmaceuticals, LLC*, 2012 WL 2990697, at *9 (E.D. La. July 20, 2012) (“[t]o require a generic manufacturer to remove a drug from the market would repudiate the label approved by the FDA.”); *Strayhorn v. Wyeth Pharmaceuticals, Inc.*, No. 11-2058-STA-CGC, 2012 WL 3261377 at *10 (W.D. Tenn. Aug. 8, 2012) (withdrawal theory “has not been adopted by the Supreme Court or other Circuits”); *Jacobsen v. Wyeth, LLC*, No. 10-823, 2012 WL 3575293, at *12 (E.D. La. Aug. 20, 2012) (“To require a generic manufacturer to remove a drug from the market would repudiate the label approved by the FDA.”); *Moore v. Mylan, Inc.*, 840 F. Supp.2d 1337, 1352 n.14 (N.D. Ga. 2012) (“any such state law duty [to cease marketing a drug] would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce.”).

Plaintiffs have attempted to distinguish their design defect claims from failure-to-warn claims, which the Supreme Court in *Mensing* definitively held are preempted against generic drug manufacturers.¹⁵⁹ For example, plaintiffs have asserted that failure-to-warn claims are based on a duty to change the drug's labeling (conduct that federal law prevents) while design defect claims are based on a duty to stop selling the drug (conduct that federal law permits).¹⁶⁰ But this is nothing more than wordplay. Stating that a failure-to-warn claim imposes liability because a manufacturer failed to change its drug's labeling is merely another way of stating that liability is imposed because the manufacturer sold a product with a defective label.¹⁶¹ Thus, plaintiffs will argue that generic manufacturers have two options to avoid liability: either change the drug's labeling or stop selling the drug.¹⁶² But since the former is preempted by *Mensing*, generic manufacturers are then faced with choosing the latter option or potentially face liability.

Likewise, under a design defect claim, in which the plaintiff asserts that the manufacturer sold a defectively designed product, state law offers the same two options: either change the drug's design or stop selling the drug. And because the Hatch-Waxman Amendments equally preclude labeling and design changes by generic drug manufacturers, state law in both cases seeks to impose liability for selling a product that generic manufacturers cannot lawfully change.¹⁶³ As a result, the only way for generic manufacturers to avoid liability is to stop marketing its drug.¹⁶⁴

It is because of this interplay that the rejection of the failure-to-withdraw theory by *Mensing* cannot be limited to the failure-to-warn context. Otherwise, plaintiffs could always

¹⁵⁹ *Mensing*, 131 S. Ct. at 2581.

¹⁶⁰ See *Bartlett v. Mut. Pharm. Co., Inc.*, 678 F.3d 30 (1st Cir. 2012).

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ *Id.* at 5.

¹⁶⁴ *Id.*

argue that the defendants were able to stop selling their products, and this rationale would prevent defendants from ever successfully asserting conflict preemption.¹⁶⁵ Thus, the Supreme Court’s reasoning in *Mensing* must extend to design defect claims against generic manufacturers “because every products [liability] case begins with a sale,” and “[w]ithout one, there is no basis to sue-and no need for a preemption defense.”¹⁶⁶ Specifically, by asserting that there was a state-law duty not to market the drug, the claim arguably conflicts with, and is preempted by, the FDA’s approval of the drug for sale.¹⁶⁷

For this reason, the overwhelming majority of federal courts have held that the principles espoused in *Mensing* also impliedly preempt design defect claims against generic manufacturers.¹⁶⁸ These decisions have expanded upon *Mensing*’s “duty of sameness,” holding that federal law not only requires generic and brand-name pharmaceutical products to have identical labeling, but they must also share the same product design.¹⁶⁹ Because generic manufacturers cannot unilaterally change the design of their drugs without FDA approval, courts have held that design defect claims are also impliedly preempted under the principles established in *Mensing*.¹⁷⁰

Notably, these preempted claims include: failure-to-withdraw from the market;¹⁷¹ claims alleging negligent concealment of important safety information;¹⁷² negligent failure to test and

¹⁶⁵ *Id.*

¹⁶⁶ *Bartlett*, 678 F.3d at 5.

¹⁶⁷ *HERRMANN*, *supra* note 65, at 51.

¹⁶⁸ *See, e.g., In re Pamidronate*, 842 F. Supp. 2d 479; *In re Fosamax*, 2011 WL 5903623; *In re Darvocet*, 2012 WL 718618.

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011); *Johnson v. Teva Pharmaceuticals USA, Inc.*, No. 2:10 CV 404, 2012 WL 1866839 (W.D. La. May 21, 2012); *Cooper v. Wyeth, Inc.*, No. 09-929-JJB, 2012 WL 733846 (M.D. La. Mar. 6, 2012).

¹⁷² *Gross*, 825 F. Supp. 2d at 659.

negligent failure to inspect;¹⁷³ failure to monitor the safety of the drug and report findings to the FDA;¹⁷⁴ fraud, negligent misrepresentation, and fraudulent concealment claims;¹⁷⁵ breach of express warranty;¹⁷⁶ and design defect claims¹⁷⁷ (with the exception of *Bartlett v. Mutual* discussed *infra*).

b. Design Defect Claims Come to Forefront of Preemption Debate

The design defect claim, in particular, has assumed substantial importance since the Supreme Court decided to review the *Bartlett* decision. In most jurisdictions, plaintiffs have difficulty asserting design defect claims against pharmaceutical manufacturers for two primary reasons. First, many jurisdictions require plaintiffs to prove that a safer alternative design exists.¹⁷⁸ Second, many jurisdictions have adopted comment *k* to the *Restatement (Second) of Torts*, section 402A, which immunizes manufacturers of “unavoidably unsafe” products where the product is accompanied by an adequate warning.¹⁷⁹ In the vast majority of pharmaceutical cases, either the plaintiffs cannot prove that a safer alternative exists or the defendants can establish the affirmative defense that the drug was accompanied by adequate warnings.

However, *Bartlett* poses neither of these issues: the court did not require proof of an alternative design of the drug,¹⁸⁰ and the defendants abandoned their comment *k* defense on the

¹⁷³ *Id.*

¹⁷⁴ *Cooper*, 2012 WL 733846; *Moretti v. Mut. Pharm. Co.*, 852 F.Supp.2d 1114, (D. Minn. 2012); *Moretti v. PLIVA, Inc.*, No. 2:08–CV–00396–JCM, 2012 WL 628502 (D. Nev. Feb. 27, 2012).

¹⁷⁵ *Grinage v. Mylan Pharms., Inc.*, 840 F.Supp.2d 862 (D. Md. 2011); *In re Darvocet, Darvon & Propoxyphene Products Liab. Litig.*, No. 2:11–MD–2226–DCR, 2012 WL 718618 (E.D. Ky. Mar. 5, 2012); *Bowman v. Wyeth, LLC*, No. 10–1946 (JNE/SER), 2012 WL 684116 (D. Minn. March 2, 2012); *Metz v. Wyeth, LLC*, No. 8:10–CV–2658–T–27AEP., 2012 WL 1058870 (M.D. Fla. 2012).

¹⁷⁶ *In re Pamidronate Products Liab. Litig.*, 842 F. Supp. 2d 479 (E.D.N.Y. 2012); *In re Fosamax (Alendronate Sodium) Products Liab.Litig. (No. II)*, No. 08–008 (GEB–LHG), 2011 WL 5903623 (D.N.J. Nov. 21, 2011); *Fisher v. Pelstring*, 817 F. Supp. 2d 791, 819–820 (D.S.C. 2011); *Johnson*, 2012 WL 1866839; *Morris v. Wyeth*, No. 09–0854, 2012 WL 601455 (W.D. La. Feb. 23, 2012); *Cooper*, 2012 WL 733846; *In re Darvocet*, 2012 WL 718618.

¹⁷⁷ *In re Pamidronate*, 842 F. Supp. 2d 479; *In re Fosamax*, 2011 WL 5903623; *Grinage*, 840 F.Supp.2d 862; *Metz*, 2012 WL 1058870; *Moore v. Mylan Inc.*, 840 F.Supp.2d 1337 (N.D. Ga. 2012).

¹⁷⁸ *Diluzio-Gulino v. Daimler Chrysler*, 385 N.J. Super 434, 440–41 (App. Div. 2006).

¹⁷⁹ *See, e.g., Grinage*, 840 F. Supp. 2d 862; *Gross*, 825 F. Supp. 2d 654.

¹⁸⁰ *Bartlett v. Mut. Pharm. Co., Inc.*, 678 F. 3d 30, 35–36 (1st Cir. 2012).

eve of trial.¹⁸¹ Consequently, the only remaining defense to the plaintiff's design defect claim was federal preemption. *Bartlett* explained, however, that unlike the state law at issue in *Mensing*, which required the generic manufacturer to change the label of the drug in question, nothing in New Hampshire law required Mutual Pharmaceutical to alter the drug's design.¹⁸² Rather, New Hampshire law required the generic manufacturer to stop selling the drug if it is unreasonably unsafe.¹⁸³ The court in *Bartlett* explained that a state law prohibiting the sale of Mutual's drug does not raise the issue of preemption because nothing in federal law affirmatively requires Mutual to the market its drug.¹⁸⁴ The First Circuit's analysis circumvented the issue of preemption, but in doing so the court created a larger problem. The state law effectively forces generic manufacturers out of the market, undermining the public policy of making low cost generic drugs available. The Supreme Court granted *certiorari* to definitively resolve the issue of conflict preemption as applied to the laws regulating generic drug manufacturers.¹⁸⁵

c. *Bartlett v. Mutual Pharmaceutical*

In *Bartlett v. Mutual*, the plaintiff suffered toxic epidermal necrolysis after taking sulindac, a generic version of the non-steroidal anti-inflammatory drug Clinoril.¹⁸⁶ Plaintiff sued the drug's generic manufacturer in New Hampshire state court alleging several claims of action.¹⁸⁷ Mutual removed the case to the U.S. District Court for the District of New Hampshire where the federal judge dismissed all but the design defect claim.¹⁸⁸ Additionally, Mutual waived its comment *k* defense to the design defect claim, presumably in a failed effort to prevent the jury from becoming prejudiced by learning about the warnings and risks associated with the

¹⁸¹ *Id.* at 36.

¹⁸² *Id.* at 37.

¹⁸³ *Id.*

¹⁸⁴ *Id.* at 38.

¹⁸⁵ *Bartlett v. Mut. Pharm. Co., Inc.*, 678 F.3d 30 (1st Cir. 2012).

¹⁸⁶ *Id.* at 34.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

drug.¹⁸⁹ At trial, plaintiff argued that sulindac’s risks outweighed its benefits, thus making it unreasonably dangerous to consumers.¹⁹⁰ The jury found in favor of the plaintiff and awarded her over \$21 million dollars.¹⁹¹

On appeal to the U.S. Court of Appeals for the First Circuit, Mutual contended that Bartlett’s claim should have failed as a matter of law because the plaintiff did not establish a defect in the drug.¹⁹² The defendant also argued that the claim was preempted because the FDCA required sulindac’s design to be the “same” as the brand-name drug’s design.¹⁹³ With respect to the requirements for a design defect claim, Mutual argued that New Hampshire law, which follows the *Restatement (Second) of Torts* section 402A, required that a plaintiff prove that the product was in a “defective condition,” as well as “unreasonably dangerous.”¹⁹⁴ The First Circuit rejected this argument.¹⁹⁵ Instead, it held that the district court properly allowed the plaintiff to establish that sulindac was defective solely by showing the drug was “unreasonably dangerous” due to its risk of causing toxic epidermal necrolysis.¹⁹⁶

Next, the First Circuit dealt squarely with the generic manufacturer’s preemption argument. The First Circuit stated that the Supreme Court in *Wyeth* adopted a “general no-preemption rule” and concluded that *Mensing*’s preemption did not apply outside the failure-to-warn context.¹⁹⁷ Yet, applying *Wyeth*’s reasoning to a design defect claim involving a generic manufacturer presents several issues the court failed to resolve. The *Wyeth* decision involved

¹⁸⁹ *Id.* at 36.

¹⁹⁰ *Id.* at 35.

¹⁹¹ *Bartlett*, 678 F.3d at 35.

¹⁹² *Id.*

¹⁹³ *Id.* at 35–36.

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ *Bartlett*, 678 F.3d at 38.

preemption of brand-name drug manufacturers, not generic manufacturers.¹⁹⁸ Accordingly, it would have been more appropriate for the First Circuit to apply the reasoning established in *Mensing*. *Mensing*, like *Bartlett*, involved a claim against a generic manufacturer, and even though *Mensing* involved a failure-to-warn claim and *Bartlett* a design defect claim, there is no logical rationale to distinguish between those two claims when asserted against a generic manufacturer. The Hatch-Waxman Act precludes drug manufacturers “from unilaterally altering either the label or design of their generic products,” thus both type of claims should be preempted under *Mensing*.¹⁹⁹

The court also failed to recognize that the statutes and regulations that govern brand-name drugs are meaningfully different from those that govern generic drugs.²⁰⁰ As a result, the First Circuit was quick to state that *Mensing* merely carved out an exception to *Wyeth*’s presumption against preemption.²⁰¹ But this is simply wrong because the Supreme Court in *Mensing* refused to apply such a presumption against generic drug manufacturers, the same type of drug manufacturers involved in *Bartlett*.²⁰² The First Circuit even acknowledged that targeting the drug’s design, instead of its labeling, did not provide a conceptually coherent basis for distinguishing *Mensing*.²⁰³

Nonetheless, the court was not persuaded by the defendant’s argument that preemption should extend to design defect claims because a generic manufacturer cannot unilaterally alter the composition of its drug.²⁰⁴ The court’s reasoning was quite simple—the generic

¹⁹⁸ See *Wyeth v. Levine*, 555 U.S. 555 (2009).

¹⁹⁹ *Bartlett*, 678 F.3d at 37.

²⁰⁰ *Id.*

²⁰¹ *Id.* at 38.

²⁰² *Id.*

²⁰³ *Id.* (Just as *Mensing* held that federal law precludes manufacturers from altering a generic drug’s labeling, the First Circuit conceded that under federal law “Mutual cannot legally make Sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway)”).

²⁰⁴ *Id.*

manufacturer could have chosen to not market the drug at all, an argument also known as the failure-to-withdraw from the market theory.²⁰⁵ Thus, the court held that the design defect claim was not preempted because, even though the generic manufacturer was precluded from changing the drug's composition, the manufacturer could have decided not to market the drug.²⁰⁶ The court, however, conceded that this rationale was impossible to square with *Mensing*, where the same failure-to-withdraw argument was made and rejected by the Supreme Court.²⁰⁷ The court stressed that design defect claims against generic manufacturers and the possible preemption of such a claim is an issue of "exceptional importance" that needs a definitive answer from the Supreme Court.²⁰⁸

On November 30, 2012, the Supreme Court answered the First Circuit's calling and granted Mutual's writ of certiorari.²⁰⁹ The Court will decide whether "federal [law] does not preempt state law design-defect claims targeting generic pharmaceutical products because the conceded conflict between such claims and the federal laws governing generic pharmaceutical design allegedly can be avoided if the makers of the generic pharmaceuticals simply stop making their products."²¹⁰ The Supreme Court should find that the failure-to-withdraw claims, and thus design defect claims, are preempted. States simply cannot prohibit the marketing and sale of

²⁰⁵ *Bartlett*, 678 F.3d at 38.

²⁰⁶ *Id.*

²⁰⁷ *Id.* Admitting that this claim is "in tension" with "[*Mensing*]'s rationale" because "a generic maker can avoid defective warning lawsuits as well as design defect lawsuits by not making the drug." *Id.* The court somehow suggested that the "Supreme Court might be less ready to deprive *Bartlett* of her remaining avenue of relief... despite what the Supreme Court made of similar arguments in the labeling context."

²⁰⁸ *Id.*

²⁰⁹ *Mut. Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 694, i (2012).

²¹⁰ *Id.*

FDA approved drugs.²¹¹ For this reason, as well as others to be explained below, it is likely the Supreme Court will reverse the First Circuit’s decision.

Part V: Supreme Court is Poised to Reverse *Mensing*

The Supreme Court is poised to adjudge whether design defect claims are preempted against generic manufacturers, as well as the broader question of how far the reasoning in *Mensing* extends. *Bartlett* was wrongly decided for a multitude of reasons, and re-opens avenues of liability that the Supreme Court closed in *Mensing*.²¹² In *Mensing*, the Court was clear that generic drug manufacturers are required under federal law to produce drugs that are the “same as” their brand-name counterparts and any state law requirement that conflict with this federal duty of “sameness” is preempted.²¹³

A. *Bartlett* was Wrong to Minimize the Holding in *Mensing*

In *Bartlett*, the First Circuit cited to *Wyeth* as authority against preemption,²¹⁴ but that decision actually supports the finding of preemption for generic manufacturers. In *Wyeth*, the Court held that failure-to-warn claims were not preempted because the CBE regulations allowed brand-name manufacturers to unilaterally strengthen their drugs’ labeling.²¹⁵ The same, however, is not true for generic manufacturers. Federal statutes and regulations that apply to brand-name manufacturers are meaningfully different than those that apply to generic manufacturers.²¹⁶ The Hatch-Waxman Act’s “sameness” mandate expressly precludes generic

²¹¹ *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011); *Johnson v. Teva Pharmaceuticals USA, Inc.*, No. 2:10 CV 404, 2012 WL 1866839 (W.D. La. May 21, 2012); *Cooper v. Wyeth, Inc.*, No. 09-929-JJB, 2012 WL 733846 (M.D. La. Mar. 6, 2012).

²¹² See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

²¹³ *Id.* at 2474–75.

²¹⁴ *Bartlett*, 678 F.3d at 37 (“[T]he Supreme Court rejected implied preemption, saying that ‘Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness’ and that state law serves as a ‘complementary form of drug regulation.’”) (citing *Wyeth v. Levine*, 555 U.S. 555, 575, 578 (2009)).

²¹⁵ *Wyeth*, 129 S. Ct. at 1196-99 (citing 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C)).

²¹⁶ *Mensing*, 131 S. Ct. at 2582 (In explaining why its decision was not contrary to *Levine*, the Court noted that “[i]t is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are

manufacturers from unilaterally altering either the labeling or design of their generic products.²¹⁷ Consequently, it was ill-founded for the court in *Bartlett* to find *Wyeth* controlling in light of the Supreme Court’s holding in *Mensing*.

Furthermore, the dissenting justices in *Mensing* reiterated the limitation of *Wyeth*’s applicability to generic drug cases.²¹⁸ They explained that:

[A] drug consumer’s right to compensation for inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic drug. If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings under our opinion in *Wyeth*. If, however, she takes a generic drug, as occurs 75 percent of the time, she now has no right to sue.²¹⁹

This passage clearly expresses the distinction between *Wyeth* and *Mensing*. For example, if the plaintiff took a brand-name drug, then according to *Wyeth*, the failure-to-warn claim is not preempted.²²⁰ If the plaintiff, however, took a generic drug, then according to both the majority and dissenting Justices in *Mensing* the plaintiff cannot sue the generic manufactures.²²¹ Accordingly, *Mensing* is not, as the First Circuit stated, a narrow exception to a general rule announced in *Wyeth*.

B. Generic Manufacturers are Precluded From Changing the Design of Their Drugs

Although the *Mensing* decision only addressed failure-to-warn claims,²²² its reasoning applies with equal force to design defect claims. In *Mensing*, the Supreme Court held that state law claims involving generic drugs are preempted where the plaintiff alleges that the generic

meaningfully different than those that apply to generic drug manufacturers” and “different federal statutes and regulations may, as here, lead to different pre-emption results”).

²¹⁷ *Id.* at 2574 & n.2 (explaining that the statute requires each generic drug to be “identical [to its branded equivalent] in active ingredients, safety, and efficacy” as well as in “the safety and efficacy labeling”).

²¹⁸ *Mensing*, 131 S. Ct. at 2592 (Sotomayor, J., dissenting).

²¹⁹ *Id.* (emphasis added).

²²⁰ *Id.*

²²¹ *Id.*

²²² *See Mensing*, 131 S. Ct. at 2567.

manufacturer should have changed aspects of its product which the manufacturer could not have unilaterally done without violating federal law or FDA regulations.²²³

Given that generic manufacturers are legally bound to use the brand-name drug's design, an overwhelming number of federal courts have held that state law product liability claims alleging the drug was defectively designed are also preempted under *Mensing*.²²⁴ The identical "duty of sameness" that precludes generic manufacturers from unilaterally changing its drug labeling also precludes generic manufacturers from unilaterally changing the design of its drugs. The First Circuit admitted that a generic manufacturer could not legally alter the composition of its drug, but still refused to find that this preempted a design defect claim.²²⁵ Instead, the First Circuit sidestepped the preemption issue by explaining that Mutual was not held liable for failing to change sulindac's design, but rather, was held liable for selling an unreasonably dangerous

²²³ *Id.* at 2581.

²²⁴ See also *Aucoin v. Amneal Pharmaceuticals, LLC*, No. 11-1275, 2012 WL 2990697 (E.D. La. July 20, 2012) ("Defendant could not alter the design of the drug without violating federal law and this duty of sameness, making it impossible for Defendant independently to comply with both federal and state law. As such, this Court joins numerous other lower courts that have considered this issue and found the failure-to-warn reasoning of *Mensing* equally applicable to a design defect claim."); *In re Fosamax (Alendronate Sodium) Products Liab. Litig.* (No. II), No. 08-008 (GEB-LHG), 2011 WL 5903623 (D.N.J. Nov. 21, 2011) (holding that plaintiff's design defect and implied warranty claims were preempted because federal law requires generic drugs to contain the same active ingredient as their brand-name equivalent); *In re Pamidronate Products Liab. Litig.*, 842 F. Supp. 2d 479 (E.D.N.Y. 2012) (holding that *Mensing's* "duty of sameness" preempts state law design defect claims against generic drug manufacturers); *In re Darvocet, Darvon & Propoxyphene Products Liab. Litig.*, No. 2:11-MD-2226-DCR, 2012 WL 718618 (E.D. Ky. Mar. 5, 2012) (rejecting design defect claims because "the Generic Defendants, bound by their 'ongoing federal duty of sameness,' were powerless to change" the product's design) (quoting *Mensing*, 131 S. Ct. at 2575); *Metz v. Wyeth, LLC*, No. 8:10-CV-2658-T-27AEP., 2012 WL 1058870 (M.D. Fla. 2012) (holding that a claim that the defendant should have redesigned the generic drug product were preempted); *Lyman v. Pfizer, Inc.*, No. 2:09-cv-262, 2012 WL 368675 (D. Vt. Feb. 3, 2012) (holding that plaintiff's design defect claim was preempted because generic drugs are required by federal law to be bioequivalent to the reference listed drug); *Grinage v. Mylan Pharms., Inc.*, 840 F.Supp.2d 862 (D. Md. 2011) (holding that design defect claims based on the consumer expectations test were preempted under *Mensing*); *Johnson v. Teva Pharm. USA, Inc.*, No. 2:10 CV 404, 2012 WL 1866839 (W.D. La. May 21, 2012) (holding that federal law prevents generic manufacturers from unilaterally changing the design of generic drugs); *Eckhardt v. Qualitest Pharm. Inc.*, 858 F.Supp.2d 792 (S.D. Tex. 2012) (holding that plaintiff's design defect claim was preempted because generic manufacturers are "not free to unilaterally pursue a safer alternative design"); *Stevens v. PLIVA, Inc.*, No. 6:10-0886, 2011 WL 6224569 (W.D. La. Nov. 15, 2011) ("Under the same federal law analyzed in *Mensing*, a generic pharmaceutical product must be the same as [its branded equivalent] in active ingredients, safety and efficacy and hence, as was the case with labeling, federal law pre-empts state laws imposing the duty to change a drug's design.").

²²⁵ See *Bartlett v. Mut. Pharm. Co., Inc.*, 678 F.3d 30, 37 (1st Cir. 2012).

product.²²⁶ And since federal law does not require Mutual to market sulindac, a state law that prohibits generic manufacturers from selling the drug, if it is unreasonably dangerous, would not be preempted. As the Comment will explain in detail below, such an assertion is fundamentally flawed.

C. Preemption Cannot be Premised on a “Failure-to-Withdraw” Claim

In *Bartlett*, the court held that even though a generic manufacturer is precluded from altering the composition of their drugs, they could have avoided liability for a defectively designed product by declining to sell their drugs altogether.²²⁷ The First Circuit asserted that because the FDCA did not prevent Mutual from selling sulindac, a claim arising out of the manufacturers failure to do so would not be preempted under *Mensing*.²²⁸ Yet this assertion, which even the *Bartlett* court conceded is fundamentally inconsistent with the reasoning in *Mensing*,²²⁹ has consistently been rejected by the Supreme Court and other circuits.²³⁰

In their petitions to the Supreme Court, the plaintiffs in *Mensing* argued that their failure-to-warn claims were not preempted because of the same “failure-to-withdraw” from the market theory asserted in *Bartlett*.²³¹ The Court rejected their petition, and on remand, the Eighth Circuit interpreted the Supreme Court’s ruling in *Mensing* to encompass the plaintiffs’ failure-to-withdraw claims and vacated the portion of its earlier opinion that embraced the theory.²³² In doing so, the Eighth Circuit understood that if the Supreme Court viewed the failure-to-withdraw

²²⁶ *Id.*

²²⁷ *Id.* at 38.

²²⁸ *Id.*

²²⁹ *Id.* (“To refuse preemption here is consistent with *Wyeth* but in tension not with the holding but with part of *PLIVA*’s rationale; a generic maker can avoid defective warning lawsuits as well as design defect lawsuits by not making the drug.”).

²³⁰ See *Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011) *cert. denied*, 132 S. Ct. 2103 (U.S. 2012).

²³¹ Respondents’ Petition for Rehearing, *Pliva, Inc. v. Mensing*, 2011 WL 2874547 1* (U.S. 2011); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

²³² See *Mensing*, 658 F.3d at 867.

from the market theory as a legitimate means to avoid conflict preemption, it would not have found compliance with both the state and federal law impossible.²³³

Likewise, the Sixth Circuit rejected the failure-to-withdraw argument.²³⁴ On appeal in *Smith v. Wyeth, Inc.*, the plaintiffs argued that the failure-to-withdraw theory was consistent with *Mensing* because no federal law prohibited generic manufacturers from independently suspending the sale of their drugs.²³⁵ The Sixth Circuit was not persuaded, and affirmed its grant of summary judgment on the issue of preemption.²³⁶

Courts have rejected the failure-to-withdraw argument because a “state law duty that would compel generic manufacturers to stop production of a drug that under federal law they have the authority to produce. . . would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug” could be sold and marketed throughout the United States.²³⁷ Thus, a state law that would permit a jury to reassess the risks and benefits of an FDA approved drug cannot coexist with the FDA’s drug approval authority. A failure-to-withdraw claim strikes at the very essence of the FDA’s power to determine what prescription drugs can be marketed in the United States.

Similarly, every other federal appellate court to consider a design defect claim against a generic manufacturer has rejected the failure-to-withdraw from the market theory in light of *Mensing*.²³⁸ The District Court for the Eastern District of Louisiana stated that the failure-to-withdraw from the market theory is nothing more than a “cleverly dress[ed] up failure to warn

²³³ *Id.*

²³⁴ *See Smith*, 657 F.3d at 423.

²³⁵ Appellants’ Supplemental Letter Brief, *PLIVA, Inc., v. Mensing, Smith v. Wyeth, Inc., Wilson v. PLIVA, Inc., Morris v. Wyeth, Inc.*, 2011 WL 3662688, 6 (2011); *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011) *cert. denied*, 132 S. Ct. 2103 (2012).

²³⁶ *See Smith*, 657 F.3d at 423.

²³⁷ *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011).

²³⁸ *See supra* note 158.

claim[] in a tempting but ultimately illegitimate guise.”²³⁹ The court explained that if state law could require a generic manufacturer to withdraw its drug from the market based on the unreasonable danger of the product, then it necessarily must also repudiate the labeling approved by the FDA.²⁴⁰ And since failure-to-warn claims against generic manufacturers are undisputedly preempted by *Mensing*,²⁴¹ so too must the failure-to-withdraw from the market theory.

Lastly, the failure-to-withdraw from the market theory would “render conflict preemption largely meaningless because it would make most conflicts between state and federal law illusory.”²⁴² A failure-to-withdraw claim could be made anytime the issue of impossibility preemption arises since a conflict between state and federal law would always be avoided by withdrawing from the regulated conduct altogether.²⁴³ Consequently, the Supreme Court recognizes that requiring drug manufacturers to withdraw their products from the market or face state law liability does not avoid the conflict between federal law and state tort law

²³⁹ *Aucoin v. Amneal Pharms., LLC*, CIV.A. 11-1275, 2012 WL 2990697, *8 (E.D. La. July 20, 2012) (“The logic would go something like this: a manufacturer has a duty to warn consumers of dangers; the drug labeling indicates some of its dangers, but the labeling is not enough; federal law disallows stronger labeling, so the only way to responsibly account for the danger is to take the drug off the market altogether. But if it is this logic that permits a withdrawal from the market claim to stand, that claim did not survive the Supreme Court’s reversal of the Eighth Circuit in *Mensing*. Such contentions cleverly dress up failure to warn claims in a tempting but ultimately illegitimate guise. If state law could *require* a generic drug manufacturer to wholly withdraw from the market based on the unreasonable danger of the product (which is all a successful failure to withdraw from the market claim could be), it *necessarily* must repudiate the label approved by the FDA.”); *See also* *Johnson v. Teva Pharms. USA, Inc.*, No. 10–0404, 2012 WL 1866839, at *5 (W.D.La. May 21, 2012); *Cooper v. Wyeth, Inc.*, No. 09–0929, 2012 WL 733846 (M.D.La. Mar. 6, 2012).

²⁴⁰ *Aucoin*, 2012 WL 2990697 at *8; Federal courts sitting in Louisiana are not alone in their conclusion that a failure-to-withdraw from the market argument does not overcome impossibility preemption. *See, e.g.*, *Eckhardt v. Qualitest Pharms., Inc.*, No. 11–0235, 2012 WL 1511817 (S.D.Tex. Apr. 30, 2012).

²⁴¹ *Mensing*, 131 S. Ct. at 2572.

²⁴² *Id.* at 2579.

²⁴³ *In re Darvocet, Darvon & Propoxyphene Products Liab. Litig.*, No. 2:11–MD–2226–DCR, 2012 WL 718618, at *3 (E.D. Ky. Mar. 5, 2012); *See also In re Fosamax (Alendronate Sodium) Products Liab. Litig. (No. II)*, No. 08–008 (GEB–LHG), 2011 WL 5903623, at *6 n. (D.N.J. Nov. 21, 2011) (“Plaintiffs insist that Generic Defendants could have simply removed alendronate sodium from the market. Whatever the merit of that contention, it is essentially a re-argument of *Mensing*.”).

obligations.²⁴⁴ Rather, it exacerbates that conflict by ensuring that state law requirements triumph over federal requirements, in direct conflict with the Supremacy Clause.

D. Implications of the Supreme Court's Decision

If the Supreme Court reverses *Bartlett* that will greatly reduce the liability generic drug manufacturers may face. After *Mensing*, all claims premised on a failure-to-warn theory were preempted,²⁴⁵ and if *Bartlett* is reversed, then design defect claims will also be preempted. This will, in effect, immunize generic manufacturers from the majority of state law product liability claims that a plaintiff may bring.

A system where generic manufacturers are not held accountable to consumers injured by their drugs is not a desirable situation.²⁴⁶ This leaves many consumers with a difficult dilemma. Does the consumer purchase the low cost generic drug, but then be without a remedy for resultant injuries, or does the consumer pay more for the brand-name drug so the manufacturer can be sued in the event of an injury?

In *Mensing*, the Supreme Court acknowledged the “unfortunate hand” the plaintiff was dealt by the federal regulations when her failure-to-warn claim was preempted.²⁴⁷ But at the same time, the Court explained that “it is not this Court’s task to decide whether the statutory scheme established by Congress is unusual or even bizarre.”²⁴⁸ Congress struck a careful balance between the public and private interests in passing the Hatch-Waxman Act. It is not the

²⁴⁴ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992).

²⁴⁵ *See Mensing*, 131 S. Ct. at 2567.

²⁴⁶ Indeed, U.S. Representative Henry A. Waxman wrote a letter requesting that the Commissioner of the FDA respond to the *Mensing* decision by “devising a system that both permits consumers injured by the use of a generic drug to seek a remedy in court and ensures that the labels of generic drugs are the same as those of their brand name counterparts.” Letter from Henry A. Waxman, Ranking Member, U.S. House Comm. on Energy & Commerce, to Margaret Hamburg, Comm’r, The Food & Drug Admin. (Apr. 11, 2012), *available at* <http://democrats.energycommerce.house.gov/index.phpPq=news/waxman-urges-fda-for-proper-revisions-in-light-of-supreme-court-ruling>.

²⁴⁷ *Id.*

²⁴⁸ *Id.* (citing *Cuomo v. Clearing House Assn., L.L.C.*, 557 US 519 (2009)).

role of the judiciary to second guess this judgment and recognize a state tort remedy that conflicts with federal law.

Congress entrusted the FDA with regulating the national market for prescription drugs, and the agency grants approval only if it determines that the drug is safe and effective for its intended use.²⁴⁹ It would then be inconsistent with the FDCA to allow a lay jury to independently assess the health risks and benefits of a FDA approved drug and second guess the FDA's safety determination. Such an ad-hoc reconsideration on a state-by-state and lawsuit-by-lawsuit basis would completely undermine the FDA's drug approval process.²⁵⁰

As the foregoing discussion demonstrates, the Supreme Court should reverse *Bartlett* and hold that design defect claims, just like failure-to-warn claims, are preempted when brought against generic manufacturers. It is not the role of the courts to recognize a state tort remedy that conflicts with federal law, no matter how unfortunate it may be for the plaintiff. As always, it is the duty of Congress and the FDA to change the laws and regulations governing prescription drugs if they see fit.²⁵¹

Conclusion

As the number of generic drugs on the market continues to rise,²⁵² issues involving generic drugs and preemption will continue to confront the courts. In addressing *Bartlett*, the Court should reason that a generic manufacturer's federal "ongoing duty of sameness" requirement is no different in the design context than it is in the labeling context. This "duty of

²⁴⁹ 21 U.S.C. §§ 355(d), (d)(1), (4) (2012).

²⁵⁰ *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324–26 (2008) (noting that such claims would disrupt FDCA's regulatory scheme because the jury inevitably focuses on the risks to the injured plaintiff while FDA's risk-benefit determination considers interests of all potential users, including "those who would suffer without [the product]").

²⁵¹ *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2582 (2011).

²⁵² FACTS AT A GLANCE, GENERIC PHARMACEUTICAL ASSOCIATION, <http://www.gphaonline.org/about-gpha/about-generics/facts> (last visited Nov. 1, 2012).

sameness” is even more pertinent in the design context, as the generic product must be the same as the brand-name drug.

In *Mensing*, the Supreme Court stressed that the Supremacy Clause should not be distorted “in order to create similar pre-emption across a dissimilar statutory scheme.”²⁵³ The converse is also true. The Supremacy Clause may not be distorted in order to create dissimilar preemption across a similar statutory scheme. Yet this is exactly what the First Circuit did in *Bartlett*.²⁵⁴ Faced with the same regulatory scheme at issue in *Mensing*, the First Circuit crafted a remedy for individuals harmed by generic drugs.²⁵⁵ In doing so, however, that court ignored the rationale of *Mensing*²⁵⁶ and ran roughshod over the statutory scheme carefully crafted by Congress. The decision of the Supreme Court to review the *Bartlett* decision presents the perfect opportunity for the Court to expand *Mensing*’s holding to non-failure-to-warn claims, ending the preemption debate.

²⁵³ *Mensing*, 131 S. Ct. at 2582.

²⁵⁴ See *Bartlett v. Mut. Pharm. Co., Inc.*, 678 F.3d 30 (1st Cir. 2012).

²⁵⁵ *Id.*

²⁵⁶ *Mensing*, 131 S. Ct. at 2575 (The rationale being that “generic drug manufacturers have an ongoing federal duty of ‘sameness’”).