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Generic Drugs & Federal Preemption

Generic Drug Manufacturer Liability Post-*Mensing*

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I. Introduction and Scope

Over 75% of Americans prescribed to medication take a generic form of its brand-name counterpart drug.[1] In 1984, Congress passed legislation allowing for expedited FDA approval of generic prescription medication. The purpose of this legislation, commonly known as the "Hatch-Waxman" Amendments, was to provide the American public with affordable medication by allowing generic manufacturers to bypass expensive clinical testing procedures and normal processes[2] required by brand-name manufacturers upon introducing new drugs to the market. The focus of this article is on the liability of generic drug manufacturers, against whom consumers have brought suit under failure-to-warn and design defect strict liability claims in the United States.

In 2011, the U.S. Supreme Court ruled that generic manufacturers could not be held liable for "failure-to-warn" cases brought by consumers because any state law tort duty owed to consumers was preempted by federal law.[3] Since this decision, most courts have interpreted this decision as precluding liability for design defect claims as well. The First Circuit has recently taken the polar opposite approach and ruled that generic drug manufacturers may be held liable under state law for design-defect claims, despite the fact that they cannot unilaterally change the composition of their drugs to deviate from their brand-name counterparts. The U.S. Supreme Court has granted certiorari and will decide this issue in the summer of 2013. I predict that the high Court will reverse the First Circuit's judgment and find federal preemption present in that case.

This liability issue has far-reaching effects and may impact state governmental programs and generic drug substitution laws, pending the outcome of the upcoming

decision by the U.S. Supreme Court. As a potential solution to this issue, some have suggested[4] the adoption of new legislation holding brand-name manufacturers liable when consumers are injured by their generic manufacturer competitors' drugs. This theory, commonly known as "innovator liability," undermines congressional intent and will likely never be enacted. The perceived unfair outcomes for certain consumers injured by generic drugs is significantly outweighed by public policy supporting the widespread availability and interstate commerce of generic prescription medication for consumers. The fact remains that the utility of affordable generic drugs for American consumers significantly outweighs the relatively few injuries caused by these drugs. Because the healthcare industry is vital to societal welfare, innovation in the pharmaceutical industry must continue to thrive, and it cannot be stifled by unfairly holding generic drug manufacturers strictly liable for injuries caused by their FDA-approved products.

Strict products liability is a term of art. It primarily describes liability that is, unlike negligence, not contingent upon one's behavior or conduct. The traditional rule for prescribing strict liability can be found in Restatement (Second) of Torts § 402A (1965), which states in part, "one who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property…" under certain circumstances.[5] Such liability is extended if both the seller is engaged in the business of selling such a product, and it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.[6]

More recently drafted, the Restatement (Third) of Torts §2 states that a product can be defective in its manufacture, design, or warnings.[7] In the "warning" context, a product "is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe."[8]

Recently, much litigation has revolved around the adequacy of product warnings. All FDA-approved pharmaceutical drugs contain warning labels on their packaging and/or bottles. Recently, consumers have sued generic drug manufacturers with design defect claims, in which the parties have argued over the role of "inadequate warnings" in this context. Indeed, this is a central source of disagreement in the *Bartlett*[9] decision, discussed *infra*. The scope of this paper, therefore, focuses on this disagreement, and whether there is enough of a distinction between design defect and failure-to-warn claims to allow the First Circuit's decision to stand in the face of *PLIVA, Inc. v. Mensing.*[10] Because brand-name manufacturers and generic drug manufacturers have different duties under federal law, consumers injured by these drugs have different avenues of relief, depending upon which form of a drug he or she takes (i.e. brand or generic). Specifically, in the "failure-to-warn" context, consumers injured by *generic* drugs will have no recourse, due to preemption problems. Judge Geoffrey W. Crawford,[11] among others, is troubled that such an important question may lie in the arbitrary distinction of which form of a drug

one takes. This result seems more disconcerting due to the fact that many consumers lack a meaningful choice as to what drug he or she is initially prescribed and ultimately takes.

Several people have weighed in and submitted amicus curiae briefs supporting one party or the other. Henry Waxman, a principal sponsor of the Hatch-Waxman Amendments, supported the respondent and argued a lack of preemption under *Mensing*. The United States, however, supported the petitioner and agreed that design defect claims fall within the ambit of *Mensing* and are preempted in these situations. Both parties recognize the fact that the generic manufacturer in *Bartlett* had no authority to change either its labeling or the chemical composition of its drug, which caused injuries to the respondent. The Supreme Court, therefore, must decide when and whether generic drug manufacturers will be able to evade liability under the preemption shield established in *Mensing*. Its upcoming decision will have far-reaching impact on the states and governmental programs. The Food and Drug Administration (FDA) is responsible for approving both brand-name and generic medication, and its regulatory authority is also affected by the outcome of the High Court's upcoming decision. In a country where almost 80% of people prescribed to medication take generics, this issue is highly relevant and important for the future of pharmaceutical development and innovation.

II. The Hatch-Waxman Amendments and *PLIVA, Inc. v. Mensing* [12]

In 1984, in response to high-priced brand-name drugs and a lack of generic alternatives, Congress passed the Drug Price Competition and Patent Term Restoration Act.[13] A primary purpose of the act was to "make available more low cost generic drugs by establishing a generic drug approval procedure."[14] Before 1984, branded drugs often

obtained monopoly status because of the difficulty and expense required for other companies to perform safety testing and other clinical trials before securing approval for generic substitutes. By 1984, the process to submit a new drug application ("NDA") was seen as a reason for "serious anti-competitive effects" in the pharmaceutical industry.[15]

This act has commonly become known as the "Hatch-Waxman Amendments." The Act created a new approval process for generic drug manufacturers to bring their products to the market. Specifically, it created an Abbreviated New Drug Application ("ANDA"), which prescribed a shorter approval process for generic drug manufacturers to introduce new products to the market. Unlike brand-name drug manufacturers who can gain FDA approval only through a normal New Drug Application ("NDA"), generic drug manufacturers no longer need to conduct certain clinical safety tests normally required as part of an NDA.[16] Further, the ANDA process requires that the new generic drug is "bio-equivalent"[17] to that of its brand-name counterpart.[18] For example, in October 2012, Perrigo R&D Company successfully used the ANDA process to gain FDA approval of a drug called "Nicotine Polacrilex Lozenge," a generic form of the popular "Nicorette Mini Lozenge" approved years prior via the normal NDA process.[19] The ANDA process provides generic drug manufacturers with expedited FDA approval, and it results in more generics being available to consumers in a shorter amount of time.

As part of the ANDA process, generic drug manufacturers are required to include the identical warning label as its listed bio-equivalent brand-name drug.[20] For instance, in the example above, the ANDA process required Perrigo R&D to provide its "Nicotine Polacrilex Lozenge" with a label identical to the one found on the brand-name "Nicorette

Mini Lozenge." Therefore, generic drug manufacturers cannot gain FDA approval through the ANDA process if they unilaterally decide to change its drug's warning label in any way. Nor may generic drug manufacturers send "Dear Doctor Letters" to physicians under the Hatch-Waxman Amendments. "Dear Doctor Letters" have been widely defined as correspondence "required by the FDA when a drug company advertises a drug with incomplete or misleading information about its efficacy or safety."[21] Because the FDA has interpreted these "letters" as constituting promotional labeling, generic drug manufacturers cannot convey this information to physicians.[22] The inability of generic drug manufacturers to send this information to physicians can conflict with many states' tort laws on a drug manufacturer's continuing duty to warn of post-sale risks inherent in its drugs.

Thus, the duties of brand-name and generic drug manufacturers differ in an important respect: brand-name manufacturers seeking FDA approval must have accurate and adequate warning labels for its drugs, while generic manufacturers need only ensure its warning label is identical to its brand-name counterpart.[23] In 2011, the U.S. Supreme Court confronted this situation in its landmark decision: *PLIVA, Inc. v. Mensing*.[24]

In 2001, Gladys Mensing was prescribed Reglan, a brand-name drug commonly used to treat digestive tract problems, such as gastroparesis.[25] Her pharmacist filled her prescription with a generic form of Reglan, which she proceeded to take for several years. She alleged that the long-term use of this generic drug caused her to develop tardive dyskinesia,[26] and that the generic manufacturer should be held liable under Minnesota tort law for providing inadequate warnings.[27]

The generic manufacturer did not dispute that, taking the allegations as true, state law required it to use a safer warning label.[28] Instead, it argued that the FDA regulations and federal statutes required it to use identical warnings as its brand-name counterpart, Reglan. This requirement, according to the manufacturer, rendered it impossible to comply with its state law duty, which required it to provide a safer warning label on its product. The Court of Appeals for the Fifth Circuit rejected the manufacturer's arguments and held that federal law did not preempt Mensing's claims.[29] In 2010, the United States Supreme Court granted certiorari.[30]

The U.S. Supreme Court addressed two main arguments advanced by Mensing. First, Mensing pointed to the FDA's "changes-being-effected" (CBE) regulation[31] to argue that the manufacturers should have changed its label without waiting for FDA approval. However, although the CBE regulation allows *brand-name* manufacturers to change its label under these circumstances, the FDA has interpreted the CBE process in a way that prohibits *generic* drugs' warning labels from being unilaterally changed unless it is done to match its brand-name drug counterpart. Therefore, the Supreme Court deferred to the FDA's interpretation and rejected Mensing's claim. Next, Mensing argued that the generic manufacturers should have informed physicians of new warnings associated with this drug through "Dear Doctor" letters. The FDA has interpreted Dear Doctor letters to constitute "labeling" and has reasoned that such new information would be inconsistent with the brand-name drug's already-approved labeling. Such a difference, therefore, could "inaccurately imply a therapeutic difference between the brand and generic drugs and

could be impermissibly misleading."[32] The U.S. Supreme Court deferred to this interpretation and rejected Mensing's claims.

The Court addressed a third issue related to an alleged duty of generic manufacturers to propose stronger warning labels to the FDA if "there is reasonable evidence of an association of a serious hazard with a drug."[33] According to the FDA, generic drug manufacturers must ask the FDA to develop stronger warning labels for a drug if they become aware of new safety issues related to the drug.[34] Because the Court found federal preemption present, it left this issue unresolved. The court noted in dicta that the claims at issue would be preempted even assuming such a duty existed.[35]

The Court then held that federal conflict preemption existed, rendering it impossible for the generic drug manufacturer to comply with both state and federal law.[36] Specifically, state law required the manufacturer to provide a safer label for its drug, but federal law mandated that its label stay identical to its brand-name counterpart. The Court then addressed Mensing's argument that the manufacturers cannot satisfy the burden of showing "impossibility" because they never tried to initiate the process that eventually could have resulted in the FDA issuing a safer warning label.[37] Despite calling the argument "fair," the Court rejected the argument.[38] Accepting this argument, the Court explained, would render conflict preemption meaningless. Further, the *non obstante* provision[39] of the Supremacy Clause suggests that when the ordinary meaning of federal law prevents a private party from complying with both state and federal law, preemption is established. Therefore, despite Mensing's claim, the analysis leaves no room for speculation about the FDA's ability to assist the generic manufacturers' compliance with

state law. Instead, the court explained, "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 preemption purposes."[40]

III. Jurisdictions cannot agree on *Mensing*'s Reach

As noted above, the Restatement (Second) of Torts §402A imposes liability for selling "any product in a defective condition unreasonably dangerous to the user or consumer…". The Restatement (Third) of Torts: Products Liability § 6, cmt. *f*, at 156 (1998) notes that courts "traditionally have refused to review the reasonableness of the designs of prescription drugs." However, in *Bartlett v. Mutual Pharmaceutical Co., Inc.*[41], the First Circuit interpreted New Hampshire law to allow it to exercise such review. From the events initially giving rise to this litigation, to the time of the First Circuit's decision, the State of New Hampshire followed §402A.[42]

In 2004, Karen Bartlett's physician prescribed her sulindac (under the brand name Clinoril) for shoulder pain. Her pharmacist, however, filled her prescription[43] with a generic form of sulindac, manufactured by Mutual Pharmaceutical Co., Inc. ("Mutual"). According to the court, sulindac rarely can cause Stevens Johnson Syndrome[44] and toxic epidermal necrolysis[45] ("SJS/TEN"). Within a few months, Bartlett developed TEN. As a result, 60-65% of her entire body's outer skin level had either deteriorated, turned into an open wound, or burned off completely. She suffered drastic injuries including severe burns, twelve eye surgeries, disfigurement, partial blindness and other injuries which resulted in

her inability to read, drive, work, eat normally, engage in sexual relations, or perform aerobic activities.[46]

Bartlett sued Mutual in New Hampshire state court, under negligence and product liability claims, including a design defect claim.[47] When Mutual removed the case to federal court, the district court dismissed all claims except for the design defect claim. Bartlett's theory of design defect was that sulindac's risks outweighed its benefits, rendering it unreasonably dangerous to consumers.[48] After a two-week trial, a jury found for Bartlett and awarded her $21.06 million in compensatory damages.

Mutual appealed and argued, inter alia, that the district court misapplied New Hampshire law on design defect claims and that such claims involving generic drugs are preempted under federal law. Before reaching the preemption issue, the Court noted in dicta that Mutual could have avoided liability by proving that sulindac "was highly useful and had an adequate safety warning."[49] Specifically, the court observed that the petitioner might be able to avoid liability by raising Restatement (Second) of Torts (1965), § 402A, comment k as an affirmative defense.[50] Without explanation, Mutual abandoned this "comment k" defense before trial. As a result, the adequacy of sulindac's warning was no longer a trial issue.

The Court held that Bartlett's design-defect claim was not preempted by federal law, thereby declining to extend *Mensing*'s liability shield to include Bartlett's design-defect claim. Mutual argued that just as a generic manufacturer cannot unilaterally change its labeling, it cannot alter the composition of its drug, either.[51] Arguably, therefore, *Mensing*'s

"policy of encouraging generics by preempting state tort claims should extend to design defect as well as claims based on inadequate warnings."[52]

The court rejected Mutual's argument and distinguished *Mensing*, explaining, "while the generic maker has no choice as to label, the decision to make the drug and market it in New Hampshire is wholly its own."[53] The court then admitted its holding was inconsistent with the rationale in *Mensing*, since a generic manufacturer can avoid defective warning lawsuits as well as design defect lawsuits by simply not manufacturing the drug. Finally, the court concluded that it would be up to the U.S. Supreme Court to decide whether to extend *Mensing*'s rule to design-defect claims. On November 30, 2012, the U.S. Supreme Court granted certiorari.

Courts in other jurisdictions have disagreed with the 1st Circuit and have held that generic drug manufacturers are shielded from liability, under *Mensing*, in design defect claims. For instance, the U.S. District Court for the District of Vermont recently held that the "federal duty of sameness"[54] applies to the design or composition of the drug as well as to its labeling.[55] The *Lyman* court thus rejected the plaintiff's claims that the generic manufacturer should have designed or manufactured the drug differently.[56] Similarly, the U.S. District Court for the Eastern District of New York held plaintiffs' state law claims of design defect related to generic drugs were preempted under *Mensing*.[57] In that consolidated action, 134 plaintiffs sued certain generic drug manufacturers of the drug pamidronate, a generic for its brand-name counterpart "Aredia."[58] After *Mensing* was decided, however, 124 plaintiffs voluntarily dismissed their claims, and only a handful remained. Defendants moved to dismiss the remaining claims, including design defect,

failure to warn, and negligence. After ruling the failure-to-warn claims preempted by *Mensing*, the Court ruled the design defect claims preempted as well. Citing *Mensing*, the Court emphasized that a generic drug is "designed to be a copy of a reference listed drug (typically a brand-name drug)" and it must be "identical in active ingredients, safety, and efficacy."[59] Therefore, according to the court, federal law also preempts state laws imposing a duty on generic drug manufacturers to change a drug's design.[60] At least one circuit court has followed suit and disagreed with the *Bartlett* court in this regard.[61]

Recently, the U.S. District Court for the Eastern District of Kentucky heard similar arguments from plaintiffs that *Mensing* did not apply to their negligence and design-defect claims against generic manufacturers.[62] In *In re Darvocet*, *et al.*, the plaintiffs alleged that they suffered injuries as a result of ingesting propoxyphene, a generic pain medication with brand-name counterparts called Darvon and Darvocet. The plaintiffs claimed that the generic manufacturers knew their product was unreasonably dangerous and "should have withdrawn it from the market."[63] However, the Court rejected this "failure to withdraw" assertion by the plaintiffs. It reasoned that although the withdrawal of its product would avoid preemption conflicts, it would render the concept of preemption meaningless. Further, this would be an "oversimplified solution" applicable any time the issue of impossibility preemption arises. The court, therefore, took the opposite approach from the *Bartlett* court, which had reasoned that the decision to make the drug and market it in New Hampshire was wholly the defendant's choice.[64]

All other circuit courts that have considered whether state law design-defect claims survive post-*Mensing* have concluded them to have been preempted.[65]

IV. Certiorari Granted in *Bartlett*

As noted above, the U.S. Supreme Court granted certiorari in *Bartlett v. Mutual Pharmaceutical Co., Inc.* on November 30, 2012. On March 19, 2013, the Supreme Court heard oral arguments. The high Court will decide whether the 1st Circuit erred in failing to find conflict preemption present in the design defect claims against the generic manufacturers. Its decision will clarify the scope of generic drug manufacturer liability under state tort law for design-defect claims.

V. The U.S. Supreme Court will likely reverse the First Circuit.

I predict the U.S. Supreme Court will reverse the 1st Circuit's decision in *Bartlett v. Mutual Pharmaceutical Co., Inc*.[66] My prediction is based upon errors in the First Circuit's rationale, reasoning from *Mensing*, and congressional intent underlying the Hatch-Waxman Amendments.

The *Bartlett* court conceded that generic drug manufacturers cannot alter the biological composition of its drugs or deviate from its referenced brand-name counterpart.[67] Yet it rejected the rationale in *Mensing*, which encouraged the use of generic drugs by preempting state tort claims. After refusing to extend *Mensing's* rationale to design-defect claims, the First Circuit failed to establish any distinction between failure-to-warn and design-defect claims with respect to the assessment of preemption. Instead, the court reasoned that Mutual could have avoided preemption in the following way: "It certainly can choose not to make the drug at all."[68] Further, the court admitted such an argument created tension with *Mensing's* rationale, which impliedly rejected this argument because the generic manufacturers in *Mensing* likewise could have chosen "not to market

the drug at all."[69] Indeed, before the U.S. Supreme Court granted certiorari in *Mensing v. Wyeth,*[70] the Eighth Circuit had previously accepted a similar argument:

> *"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. Instead, they are alleged to have placed a drug with inadequate labeling on the market and profited from its sales. If Mensing's injuries resulted from their failure to take steps to warn their customers sufficiently of the risks from taking their drugs, they may be held liable."*[71]

Yet, in *Mensing,* the Supreme Court reversed the Eighth Circuit and ruled that these claims were preempted by federal law. This "failure to withdraw" or "stop-selling" argument is a radical approach. It imposes liability on manufacturers precisely *because* they complied with federal law from which they cannot deviate. As Mutual's brief points out, "If the Supremacy Clause does anything, it forecloses this radical approach: Because every manufacturer can "choose" to stop making any product, no federal requirement could generate a direct preemptive conflict in a stop-selling world."[72] Therefore, the Supreme Court has already rejected the reasoning advanced by the First Circuit, which erred when it rejected the U.S. Supreme Court's rationale in *Mensing* and opened the possibility (and arguably, the probability) that its decision will be reversed.

The Hatch-Waxman Amendments require identical warning labels for generics and their approved brand-name counterparts, as well as identical biological composition (i.e., identical design). Specifically, the generic drug must have the same active ingredients, strength, route of administration, and other traits as its referenced brand-name equivalent.[73] The ANDA process requires a generic drug's labeling to mirror its brand-name counterpart because it is inherently based upon the brand-name drug. As such, Mutual

argues in its brief: “Hatch-Waxman requires the generic labeling be materially identical to branded labeling *precisely because* generic design must be materially identical to branded design.”[74] Either deviation, therefore, from the brand-name drug’s labeling *or design* results in the violation of federal law by a generic manufacturer.

One of the primary reasons Congress passed the Hatch-Waxman amendments was to introduce generic drugs to market through a quick, safe and efficient process by requiring “sameness” in all material respects to already-approved FDA brand-name drugs. “It is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs quickly and cheaply to the public.”[75] The effect of the First Circuit’s approach guts the congressional intent in passing the Hatch-Waxman Amendments. It does not make sense to require generic drug manufacturers to comply with federal regulations only to impose liability later *because* they complied with those regulations. However, the First Circuit’s approach effectively punishes manufacturers who fully comply with this federal law to sell generic drugs in interstate commerce. This clear inconsistency with congressional intent underlying Hatch-Waxman stands out in the rationale provided in *Bartlett*.

Finally, the First Circuit mentioned the Supreme Court might base its decision upon sympathy.[76] But sympathy has no room in a preemption analysis in general, much less in the prescription drug context. Instead, where the substantive state-law requirement embodied by a given tort claim conflicts with a contrary federal requirement, the ordinary operation of the Supremacy Clause prevents the state from enforcing its conflicting demand; were it otherwise, federal law would no longer be “the supreme Law of the

Land."[77] Further, it is not enough to overrule precedent in *Mensing*, in which the Supreme Court applied the Supremacy Clause to support its finding of federal preemption.

VI. A Judge's Perspective - *Wyeth v. Levine*[78]

Judge Geoffrey W. Crawford[79] currently presides on the Superior Court[80] of Vermont in Chittenden County.[81] Judge Crawford previously presided on the Superior Court of Vermont in Washington County and decided what eventually became a widely-cited, landmark decision which was appealed up to the U.S. Supreme Court. During an interview with Judge Crawford on March 6, 2013, he noted his excitement when he first heard the Supreme Court granted certiorari in this case after the Supreme Court of Vermont affirmed his initial decision.

In March 2004, Judge Geoffrey Crawford decided *Levine v. Wyeth*,[82] after a jury trial in which a brand-name drug manufacturer was held strictly liable under state tort law for inadequate warnings associated with its drug, "Phenergan."[83] In *Wyeth*, plaintiff Diana Levine was given Phenergan for nausea associated with a migraine. Because the first dose of the antihistamine did not provide relief, a second dose was given to Levine by way of an "IV-push" method.[84] When the drug entered Levine's artery, she developed gangrene and had to have her right arm amputated.[85]

Levine sued the drug manufacturer under negligence and strict liability theories, including a failure-to-warn claim whereby she alleged that the labeling was defective because it failed to instruct doctors to use the "IV-drip"[86] method instead of the IV-push method of administration, which posed a higher risk of the possibility of developing

gangrene. Wyeth argued, inter alia, that the failure-to-warn claims were preempted by federal law. The court rejected Wyeth's preemption argument and determined there was no conflict between state and federal law because FDA regulations "permit strengthened warnings without FDA approval on an interim basis and the record contained evidence of at least 20 reports of amputations similar to Levine's since the 1960's."[87] A five-day jury trial rendered a plaintiff's verdict, and judgment was entered accordingly.[88]

After the Vermont Supreme Court affirmed judgment,[89] the U.S. Supreme Court granted certiorari[90] to determine whether the FDA's labeling requirements preempted state law failure-to-warn claims. The Court affirmed the lower courts and held that federal law did not preempt Levine's claim that the labeling contained inadequate warnings about the IV-push method of administration.[91] The Court rejected Wyeth's claim that it was impossible for it to comply with both the state-law duties underlying Levine's claims and its federal labeling duties.[92] Specifically, the Court explained, Wyeth could have unilaterally strengthened its warning label pursuant to the "changes-being-effected (CBE) regulation, which provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may change the label upon the filing of a supplemental application with the FDA, and it need not wait for FDA approval to do so.[93] The CBE regulation allows a manufacturer to change its label "to reflect newly acquired information."[94] The court pointed to the FDA's explanation in its notice of the final rule, that "newly acquired information" is not limited to new data, but also encompasses new analyses of previously

submitted data.[95] Levine presented evidence at trial of at least twenty other incidents in which a Phenergan injection resulted in gangrene and an amputation.[96] The court concluded that Wyeth could have analyzed this accumulating data and added a stronger warning about IV-push administration of its drug, pursuant to the CBE regulation.[97]

Additionally, the court emphasized Wyeth's incorrect suggestion that the FDA bears primary responsibility for drug labeling.[98] It explained that many amendments to FDA regulations emphasized a central premise of federal drug regulation that "the manufacturer bears responsibility for the content of its label at all times.[99]

Wyeth dealt with the liability of a brand-name drug manufacturer. The CBE regulation applies only to brand-name drug manufacturers, not generic manufacturers. A central argument revolved around the CBE regulation and a *brand-name* manufacturer's authority to change its label pursuant to that regulation. However, had Levine taken a *generic* form of Phenergan and suffered the same injury, a different result would likely have occurred. Specifically, the court would likely have stated that because generic drug manufacturers do not have authority to change its labeling, the CBE regulation would have been irrelevant to the court's analysis. Consequently, Levine could have suffered the same injury but had no recourse against a generic manufacturer. *Mensing*, decided two years later, would confirm such a result. Presumably then, two consumers who take bio-equivalent drugs and develop the same side effects may have different avenues for relief. The consumer who took the brand-name drug may be able to recover for injuries due to inadequate warnings, but not the one who took the generic equivalent. This result presents the question: Is there *any* avenue for relief for those injured by generic drugs? In response

to the perceived unfairness of this situation, Judge Crawford seemed troubled that such an important liability question is based upon the arbitrary distinction of which form of a drug a patient took. The result seems especially troubling when one considers the fact that some states require pharmacies to substitute brand-name drugs with generics, depending on information supplied by the prescribing physician. Consequently, some consumers will not have the choice of which form of a drug they are prescribed. The effect of a *Bartlett* affirmation on these generic substitution laws is further explored, *infra*.

VII. Bartlett, Henry Waxman and the United States weigh in

In her brief, respondent Bartlett maintained the position that Mutual could comply with both the district court judgment and federal law. After citing New Hampshire's adoption[100]of the Restatement (Second) of Torts § 402A, Bartlett emphasized the statute's compensatory, rather than regulatory, purpose.[101] Specifically, New Hampshire law imposes no duty on manufacturers to re-design their products; rather, it compensates injured consumers. Therefore, Bartlett argued, Mutual cannot prove that compliance with federal and state law is impossible because New Hampshire law requires it to change to design of its generic drug whereas federal law prohibits it. Instead, Bartlett emphasized that New Hampshire law is well settled that a damages judgment based upon strict products liability does not require a manufacturer to alter its product.**[102]**

Henry Waxman[103] and Senator Tom Harkin[104] submitted a brief emphasizing that the decision about whether and how to compensate those injured by products (including drugs) has been left to the states. Hence they argued, "in the absence of compelling evidence that Congress sought to alter that tradition, this Court should not reach out to do

so."[105] The main thrust of their argument was that neither the text nor the purpose of the FDCA or the Hatch-Waxman Amendments requires preemption of state-law design defect claims brought by injured patients against drug manufacturers. The FDCA, as a consumer protection statute, was enacted "to bolster consumer protection against harmful products."[106] In enacting the FDCA, Congress declined to create an express federal remedy for those injured by ineffective or unsafe pharmaceutical drugs. Even in 1976, when Congress enacted express preemption provisions[107] for other FDA-related products (including foods, medical devices, and cosmetics), it never enacted such a provision for prescription drugs.

The Waxman brief then compared over-the-counter (OTC) medication with prescription drugs, with respect to express preemption provisions. Congress enacted an express preemption provision for OTC medication in 1997, but explicitly stated that states' products liability laws would not be affected by the new provision.[108] Waxman compared OTC medication to prescription drugs and explained that the same NDA process used for new prescription drugs "applies to new OTC drugs that are not covered by a monograph[109]."[110] Both types of drugs meet FDA specifications based on the FDA's weighing of risks and benefits. While OTC medication manufacturers must follow FDA specifications for acceptable ingredients, doses, and labeling, brand-name drug manufacturers must abide by the FDA regulations set forth in the NDA process.

Waxman's focus on the OTC provision noted above, which explicitly removes product liability suits from the scope of an express preemption provision, reflects Congress's understanding that "those suits pose no obstacle to the purpose of federal

regulation of OTC drugs."[111] Therefore, argued Waxman, Congress has "made plain that state product liability law should coexist with federal approval of such drugs."[112]

Also, Waxman suggested the idea that Congress's policy of promoting the sale of generics to consumers by creating the ANDA process implies a policy of eliminating legal constraints that help protect consumers against unsafe drugs by offering remedies such as damages.[113] Further, the objectives of the Hatch-Waxman Amendments are being reached by clear data evidencing generic drugs' high market share in recent years. For instance, approximately 80% of all prescriptions are now filled with prescription drugs.[114]

Finally, Waxman emphasized the basic inquiry into preemption should be one "into whether the ordinary meanings of state and federal law conflict."[115] Congress has not preempted state damages actions in the realm of prescription drugs even though it is well aware of its authority to do so. This decision, whether to preempt state-law claims, was "for decades left to Congress" and "properly remains with Congress."[116]

The United States filed an amicus curiae brief supporting petitioner, Mutual Pharmaceutical, Inc. and disagreeing with Mr. Waxman's views. In its brief (hereinafter "US Brief"), the United States maintained the position that *Mensing*'s holding that the FDCA preempts state law failure-to-warn claims against generic drug manufacturers controls this case. The US Brief focused on, inter alia, Congress's requirement that drug safety determinations be made on the basis of sound scientific judgments, by an "expert" federal agency.[117] According to the US Brief, allowing pure design defect claims against generic drug manufacturers undermines Congress's purpose of "ensuring that expert, science-based judgments are made by the FDA."[118] Indeed, the data upon which Bartlett relied at

trial came directly from the FDA. Specifically, the FDA knew of data concerning the relative safety risk of sulindac, evidenced by its efforts to conduct a comprehensive review of the risks and benefits of all NSAIDs. In the end, the FDA decided against pulling sulindac from the market.

Respondent's claim, argued the US Brief, is preempted under *Mensing* because under New Hampshire law, "the presence and efficacy of a warning to avoid an unreasonable risk of harm" constitutes part of the determination of whether a product is deemed "unreasonably dangerous."[119] Therefore, the state law duty to provide an adequate warning is necessarily included in the overall duty to design a non-defective product. Consequently, any state law that demands different or stronger labels must conflict with federal law which prohibits generic drug manufacturers from unilaterally changing its drug warning labels. Thus, even though a proper warning does not insulate a design defect claim, it is still relevant to the overall determination of its level of dangerousness.

The United States addressed the 1st Circuit's reasoning for not finding preemption because Mutual could have stopped selling and marketing its drug in New Hampshire. The problem with this reasoning, argued the US Brief, is that it cannot be reconciled with *Mensing*'s holding. The *Mensing* court concluded that it was impossible for the manufacturer to comply with both state and federal law. Thus, the Supreme Court's reasoning presupposed that the generic form of the drug would continue to stay on the market when it analyzed the preemption issue. It logically follows that such a

presupposition impliedly ignored the 1st Circuit's rationale that Mutual could have stopped selling its product in the state.

VIII. Oral Arguments - March 19, 2013

Jay P. Lefkowitz, counsel for petitioner, argued on behalf of Mutual that the respondent was trying to "carve out a distinction between strict liability and negligence claims."[120] The respondent makes this argument, he stated, despite admitting that the petitioner's "hands are tied" with respect to its ability to change either its warnings or the design (i.e., chemical composition) of its drug. "We have a case here that is directly controlled by *Mensing*, because the warning was critical to the design defect case."[121] Justice Kagan seemed to agree with Lefkowitz, as she later confirmed the prevalence of discussions about warnings during the trial. She noted, "the plaintiff really spent a large portion of their case trying to show...that the warning was inadequate."[122] Justice Breyer also commented on this prevalence.[123]

Anthony A. Yang argued on behalf of the United States, as amicus curiae, supporting petitioner Mutual. In the view of the United States, "the obligation to change the labeling to make it safer and therefore escape liability under design-defect law in New Hampshire falls within the Court's decision in *PLIVA, Inc. v. Mensing*."[124] Justice Kagan noted that Yang's argument suggested that there was an obligation to, rather than permission from, the Federal government to engage in the type of interstate commerce at issue. If an obligation to the government exists, noted Justice Kagan, and it's impossible to comply with both state and federal law, "there's a conflict and yes, there's an impossibility

defense."[125] However, Justice Kagan then asked, "but if there's no obligation, if all there is is permission from the Federal Government, where do you get the impossibility from?"[126] Yang emphasized that the FDA was an expert agency and that when the State is imposing an obligation based on a safety standard, then "that is in fact second-guessing the FDA…".[127] "And so what we are trying to do here is preserve the FDA's role, not have juries second-guess on a case-by-case basis imposing different safety obligations on manufacturers, when Congress has established a regime for the FDA to control this."[128]

Finally, Mr. Yang emphasized the basic argument of petitioner Mutual: that design defect claims should be preempted under *Mensing*. "When we're talking about a drug's formulation, the manufacturer [of a generic drug] cannot change it... that's what brings this within the ambit of...*Mensing*."[129]

David C. Frederick, counsel for respondent, tried to explain the duty that New Hampshire imposed on drug manufacturers: "All New Hampshire is imposing here is a duty to pay compensation if your unreasonably dangerous product harms a patient."[130] He further explained, "This case...was tried as a design case only, and the State law duty made very clear there was no duty to change the design of the drug...and so therefore, under *Mensing*, there can't be impossibility…".[131] In response to Justice Kagan's comment that the plaintiff spent a lot of time discussing inadequate warnings, Mr. Frederick argued that up until the day before trial the case was litigated "with a comment k defense, which allows as an affirmative defense for the defendant to say if the drug is unavoidably unsafe and it has an adequate warning…" he has complete immunity from the suit. Because the defendant abandoned this defense before trial, Bartlett's counsel argued, the judge

instructed the jury that "the only role the warning actually played was whether it could lessen the risk to patients who took the drug…". Justice Breyer noted his difficulty in seeing a difference between this "lessening" of the risk and "adequacy" in general: "Now, you can call that diminishing or you could call it adequacy. Call it what you want, but that seems to me to come to the same thing and is different from saying, no label in the universe would say it."[132] Even Justice Kennedy inquired about the correlation between warning adequacy and design defect claims.[133]

Although the theme of oral arguments revolved around the role of inadequate warnings in design defect claims, one potential issue came up during Mr. Frederick's argument on behalf of the respondent. Mr. Frederick argued that a New Hampshire jury has the power to conduct, based upon evidence provided at trial, a risk/benefit analysis of a certain drug. Arguably, Justice Scalia's responsive comments[134] share the same concern as the petitioner: the respondent's argument, if accepted, effectively allows a jury to second-guess an expert federal agency in conducting extensive cost/benefit analyses for new and beneficial pharmaceutical drugs.

IX. An Affirmation of *Bartlett* Could Impact States' Generic Substitution Laws

Currently, state laws differ in allowing pharmacists to fill prescriptions with the generic-equivalent of brand-name drugs. Certain states, like Delaware, *allow* a pharmacy to substitute generics unless the doctor expressly requires the brand-name drug to be filled.[135] Other states, including Vermont, *require* pharmacies to substitute generics for brand-name prescriptions if there is no preference or mandate indicated by the prescribing physician.[136] The prices of generic drugs impact pharmacies, because pharmacies

generally receive larger mark-ups for new generic drugs when compared to brand-name.[137]

If the U.S. Supreme Court refuses to reverse *Bartlett*, then states like Vermont, Washington,[138] and New York[139] (all of which require pharmacies to use generics absent an indication from the prescribing physician) could potentially see a rise in prices because of design defects in generic drugs if pharmacies then cost-shift this loss of mark-up profit down to the consumer. In the alternative, states may decide to alter their respective rules on pharmacy substitutions to reflect potentially rising costs of generic drugs. For instance, states may be less inclined to require pharmacies to use generic drugs over brand-name. Such a result runs contrary to the primary purpose underlying the Hatch-Waxman Amendments in quickly providing consumers with affordable generic medication. Therefore, the upcoming Supreme Court decision will potentially have far-reaching effects among the States in the generic-substitution context.

X. Impacts on Governmental Programs

According to the Generic Pharmaceutical Association (GPhA), "approximately 65% of all drugs dispensed through Medicaid are generic costing on average 60% less per prescription than then corresponding brand and saving the Medicaid program tens of billions of dollars each year."[140] The GPhA argues that states can save money in their Medicaid programs by using generics rather than brand-name drugs. With rising Medicaid costs and an unstable economy in general, the United States should actively work to maintain Medicaid costs through the use of generics over brand-name. A reversal of *Bartlett* will further this purpose by avoiding cost-shifting from generic drug manufacturers

down the chain to the ultimate consumer. If generic drug manufacturers are found liable under design-defect claims, even if they fully complied with FDA regulations, they will arguably increase their prices to offset the risk of future litigation. Such a result begs the question: How is this different from a manufacturer paying a judgment and then attempting to recoup its losses by raising prices? An affirmation of *Bartlett* would present a real fear that those harmed most by the increased price of generic drugs are the very same people whom generics were meant to help: the consumers.

Medicare has many prescription drug plans that include lists of covered prescriptions drugs called "formularies."[141] Medicare drug plans tend to categorize drugs into tiers, and drugs in each tier have different costs. For example, a common drug plan may cover most generic prescription drugs in its first tier plan. Medicare beneficiaries pay the lowest co-payment in this tier. As the tier levels increase, the amount of drug coverage increases to encompass more preferred brand-name drugs and other unique medication that is unavailable in generic form. The *Bartlett* decision has the potential to reach the Medicare arena as well, because if generic drug prices increase to offset the risk of liability, then these Medicare beneficiary co-payments may also increase to reflect these rising costs. Subsequently, these programs may require more funding from the U.S. Government to adequately cover prescription drugs its beneficiaries need. More funding could potentially come from cutbacks, higher taxes, or other sources. The current state of the United States economy does not welcome any of these measures. Ultimately, the result for both governmental programs is the same: consumers would end up paying more money for "affordable" generic drugs.

XI. The Ball Lands in Congress' Court, but will Congress shoot?

If the U.S. Supreme Court reverses *Bartlett*, Congress may be prompted to step in and propose legislation to address the perceived unfairness to injured plaintiffs like Gladys Mensing and Karen Bartlett. One proposed theory involves holding brand-name manufacturers liable for harm caused by their generic counterparts, in what is commonly known as "innovator liability." Specifically, innovator liability refers to failure-to-warn liability imposed on brand-name manufacturers when a consumer is injured by a generic form of the drug. Proponents of this view argue that because of brand-name manufacturers' ability to change its warning labels, they have a duty to provide adequate warnings to users of its generic counterparts. Further, this theory posits that such inadequate warnings are the proximate cause of failure-to-warn injuries resulting from the use of generics.[142] Presumably then, this theory would extend to design-defect claims arising against generic drug manufacturers. People like Karen Bartlett, who take generic medication, would have potential recourse against the generic drug's brand-name counterpart for both failure-to-warn and design-defect claims.

The innovator liability theory should not be adopted by Congress post-*Mensing*. First, a primary purpose of the Hatch-Waxman Amendments was to efficiently introduce affordable generics to the market. This process was made possible through the ANDA process, discussed *supra*, which *prohibits* generic manufacturers from unilaterally changing warning labels for its drugs. The innovator liability theory conflicts with a core congressional purpose in enacting the Hatch Waxman Amendments: to quickly provide *affordable* generic drugs to the American consumer. Furthermore, innovator liability could

pose a threat to competition (and thus, low prices) because brand-name manufacturers may feel the need to protect themselves by withdrawing their products from the market after their patents inevitably expire. Once this happens, the innovator liability theory fails: there is no longer a brand-name manufacturer to hold accountable for injuries resulting from generic drugs. The Hatch-Waxman Amendments already provides brand-name manufacturers the ability to strengthen their warnings in response to newly-discovered reactions and injuries, through the CBE process. Therefore, innovator liability may seem fair to few, but it has no basis in the law, and it conflicts with congressional intent in providing consumers with access to affordable medication.

Finally, the theory of holding brand-name manufacturers liable for injuries resulting from the use of generics is inherently and conceptually unfair. A brand-name manufacturer should not have to compensate an injured person who took a generic form of the manufacturer's drug, because the brand-name manufacturer didn't manufacture the drug; its competitor did. Its generic competitor manufactured, marketed, and sold the drug which lands in the consumer's hand. The brand-name manufacturer has no real presence in this transaction. Although the generic competitor's drug was based upon a brand-name counterpart, it nonetheless retains its own identity (as does its manufacturer). Courts and others have recognized this notion of unfairness.[143]

Alternatively, Congress may decide not to step in at all. Indeed, Congress enacted Hatch-Waxman for the very purpose of providing generic drug manufacturers with an express lane for FDA approval. By restricting generic manufacturers' ability to change warning labels for its drugs, the FDA implicitly rejected the theory of innovator liability. The

fact that some individuals are injured by certain chemicals present in modern prescription drugs cannot be cured through legislation. Indeed, it cannot be cured at all. There is no such thing as a *100% safe* pharmaceutical drug. Consequently, the prescription drug industry requires constant innovation, research, and experimentation for the benefit of the welfare of society. Only through these methods can we hope to achieve our common goal of improving societal welfare and curing deadly diseases. Theories and methods to cripple this innovation, such as innovator liability, should be discouraged.

XII. Conclusion

The U.S. Supreme Court should issue its opinion in the summer of 2013. I predict the Court will reverse the decision of the First Circuit in *Bartlett*. The issue of generic drug manufacturer liability will continue to remain a significant issue in the pharmaceutical arena, especially in light of current economic conditions. States will likely see changes in prices for generic drugs if the First Circuit is affirmed. Also, governmental programs such as Medicare and Medicaid would likely see price increases to reflect a cost-shift from generic drug manufacturers. Many people, including Judge Crawford, find this issue relevant and in desperate need of clarity by the United States Supreme Court.

Although Congress could potentially adopt new legislation to clarify the issue of design defect claims and preemption in this context, it may decline to do so. The future of pharmaceuticals in the realm of products liability remains unclear, but the likely consequence of an affirmation of *Bartlett* remains as a widely-held belief: spreading the cost down to consumers is inevitable; consumers will pay higher prices for generic drugs.

[1] *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2584 (Sotomayor, J., dissenting) (citing OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, U.S. DEP'T. OF HEALTH & HUMAN SERVS., ASPE ISSUE BRIEF: EXPANDING THE USE OF GENERIC DRUGS 2 (2010)).

[2] Normal processes refer to the required process for brand-name drug manufacturers seeking FDA approval of newly-manufactured drugs. Before a manufacturer may submit an NDA, it generally must conduct clinical trials to test the drug's safety and efficacy. 21 U.S.C. §355(i); 21 C.F.R. 312.20-312.21.

[3] See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

[4] *See* "Picking up the Tab for your Competitors: Innovator Liability After *PLIVA, Inc. v. Mensing*," 19 Geo. Mason L. Rev. 1257 (2012).

[5] Restatement (Second) of Torts § 402A (1965).

[6] *Id*.

[7] Restatement (Third) of Torts §2.

[8] Restatement (Third) of Torts §2(c).

[9] *Bartlett v. Mutual Pharmaceutical Co., Inc.*, 678 F.3d 30 (1st Cir. 2012).

[10] 131 S. Ct. 2567 (2011).

[11] Judge Geoffrey W. Crawford is currently a state-court judge in the State of Vermont, and was interviewed for this article on March 6, 2013 by the author.

[12] *See supra*, note 3.

[13] *See* 21 U.S.C. § 355.

[14] H.R. Rep. No. 98-857, pt. 1, at 14 (1984).

[15] H.R. Rep. No. 98-857, pt. 2, at 4 (1984).

[16] *See* 21 U.S.C. § 355(i). Before a manufacturer may submit an NDA, it generally must conduct clinical trials to test the drug's safety and efficacy. 21 U.S.C. §355(i); 21 C.F.R. 312.20-312.21. The clinical trial process is designed to elicit reliable and comprehensive scientific evidence regarding the drug's safety and efficacy. Only then may a brand-name manufacturer submit an NDA, along with extensive information regarding its clinical trials and tests.

[17] Two drugs are considered bio-equivalent if there is "no significant difference in the rate and extent to which the active ingredient...becomes available at the site of action when administered at the same molar dose under similar conditions." 21 C.F.R. § 320.1(e).

[18] 21 U.S.C. §355(j)(2)(A)(iv).

[19] *See* "First-Time Generic Drug Approvals - October 2012" (http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/ucm334158.htm) (last accessed March 29, 2013).

[20] 21 C.F.R. § 314.94 (1993).

[21] Segen's Medical Dictionary. 2011. Farlex, Inc.

[22] See *Mensing*, 131 S. Ct. at 2576.

[23] *Id*. at 2574.

[24] *Id*. at 2567.

[25] Gastroparesis, also called delayed gastric emptying, is a disorder that slows or stops the movement of food from the stomach to the small intestine. The disorder reduces the stomach's ability to empty its contents.

[26] Dyskinesia refers to the involuntary nature of muscular movements or the difficulty in performing voluntary muscular movement. Tardive means a condition has the tendency to appear late. Tardive dyskinesia can appear similar to other types of disorders, most notably Tourette's syndrome. "Tardive Dyskinesia" *at* http://www.tardivedyskinesia.com (last modified January 3, 2012).

[27] *Id*. at 2573 (explaining that under Minnesota law, where the manufacturer of a product has actual or constructive knowledge of danger to users, the...manufacturer has a duty to give warning of such dangers).

[28] *Mensing*, 131 S. Ct. at 2574.

[29] *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 614 (5th Cir. 2009).

[30] *Mut. Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 694, 184 L. Ed. 2d 496 (2012).

[31] The changes-being-effected (CBE) regulation provides in part, that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may change the label upon the filing of a supplemental application with the FDA, and it need not wait for FDA approval to do so. *See* 21 U.S.C. § 255; 21 CFR § 314.70(c)(6)(iii)(A), (C).

[32] *Mensing*, 131 S. Ct. at 2576.

[33] *Id*. (citing 21 CFR § 201.57(e)).

[34] *Id*.

[35] *Id*.

[36] *Id*. at 2577 (citing *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 ("We have held that state and federal law conflict where it is impossible for a private party to comply with both state and federal requirements.")).

[37] *Id*. at 2579.

[38] *Id*.

[39] The Court is referring to the phrase "any state law to the Contrary notwithstanding" in the Supremacy Clause.

[40] *Id*. at 2580-81.

[41] 678 F.3d 30 (1st Cir. 2012).

[42] Restatement (Second) of Torts § 402A (1965).

[43] Bartlett's pharmacist filled her prescription with a generic, pursuant to New Hampshire Law. *See* N.H. Rev. Stat. Ann. § 318:47-d (2003) (allowing generic substitution).

[44] Stevens-Johnson Syndrome, Mayocinic.com. (Stevens-Johnson syndrome is a rare, serious disorder in which your skin and mucous membranes react severely to a medication or infection. Often, Stevens-Johnson syndrome begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters, eventually causing the top layer of your skin to die and shed). http://www.mayoclinic.com/health/stevens-johnson-syndrome/DS00940 (last visited Apr. 4, 2013).

[45] Toxic epidermal necrolysis, Uptodate.com. (Toxic epidermal necrolysis (TEN), or Lyell's syndrome, involves sloughing of greater than 30 percent of the body surface area). http://www.uptodate.com/contents/stevens-johnson-syndrome-and-toxic-epidermal-necrolysis-clinical-manifestations-pathogenesis-and-diagnosis (Last visited Apr. 5, 2013).

[46] *Bartlett*, 678 F.3d 30 at 43.

[47] A product's design is "unreasonably dangerous" and thus defective under New Hampshire law, regardless of the possibility of a safer design, if "the magnitude of the danger outweighs the utility of the product" in light of the "usefulness and desirability of the product to the public as a whole" and "the presence and efficacy of a warning to avoid an unreasonable risk of harm." *Vautour v. Body Master Sports Indus., Inc.*, 784 A.2d 1178, 1182 (N.H. 2001).

[48] *Bartlett*, 678 F.3d 30 at 34.

[49] *Id.* at 36.

[50] "There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs"…"Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous"... "It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." Restatement (Second) of Torts § 402A, cmt. k. (1965).

[51] *Bartlett*, 678 F.3d 30 at 37.

[52] *Id*. at 37.

[53] *Id*. at 38.

[54] See *Mensing*, 131 S. Ct. at 2575 ("The 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.").

[55] See *Lyman v. Pfizer, Inc.*, No. 2:09 cv 262, 2012 WL 368675, at 4 (D.Vt. Feb. 3, 2012).

[56] *Id*. at 4.

[57] See *In re Pamidronate Products Liability Litigation*, 842 F.Supp.2d 479, 484 (2012).

[58] Pamidronate is the generic equivalent of Aredia. Pamidronate, Drugs.com, http://www.drugs.com/mtm/pamidronate.html (last visited Feb. 20, 2013).

[59] *Mensing*, 131 S. Ct. at 2574 n. 2.

[60] *In re Pamidronate Products Liability Litigation*, 842 F.Supp.2d 479, 484 (E.D.N.Y. 2012).

[61] See *Smith v. Wyeth, Inc.*, 657 F.3d 867 (6th Cir. 2011) (finding preemption despite plaintiffs' post-*Mensing* "stop selling"/failure to withdraw arguments).

[62] See *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 2012 WL 718618, at 2 (E.D. Ky. Mar. 5, 2012).

[63] *Id*.

[64] *Bartlett*, 678 F.3d 30 at 37.

[65] See *Smith v. Wyeth, Inci*, 657 F.3d 420 (6th Cir. 2011); *Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir. 2011). See also, *Gaeta v. Perrigo Pharms. Co.*, 469 Fed. App'x 556 (9th Cir. 2012) ("The Supreme Court having vacated our prior opinion for further consideration in light of PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), see L. Perrigo Co. v. Gaeta, 132 S. Ct. 497 (2011), we now affirm the district court's grant of summary judgment in favor of Perrigo Pharmaceuticals Company.").

[66] *Bartlett*, 678 F.3d 30 at 38.

[67] *Id*. at 37.

[68] *Id*.

[69] See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

[70] See *Mensing v. Wyeth, Inc.,* 588 F.3d 603, 611 (8th Cir. 2009).

[71] *Id.* at 611.

[72] Pet. Brief 3.

[73] 21 U.S.C. § 355(j)(2)(A)(i)-(iv).

[74] Pet. Brief 32.

[75] *Mensing*, 131 S. Ct. at 2582.

[76] See *Bartlett*, 678 F.3d 30 at 38 ("Bartlett having lost her warning claim by the mere chance of her drug store's selection of a generic, the Supreme Court might be less ready to deprive Bartlett of her remaining avenue of relief.").

[77] U.S. CONST. art. VI, cl. 2.

[78] See *Wyeth v. Levine*, 555 U.S. 555 (2009).

[79] Judge Geoffrey W. Crawford is currently a state-court judge in the State of Vermont, and was interviewed for this article on March 6, 2013 by the author.

[80] The Superior Court of Vermont is a state trial court.

[81] "Currently" means as of April 18, 2013.

[82] 2004 WL 5452938 (Vt. Super. 2004).

[83] *Id*.

[84] *See* 2004 WL at 1. The IV-push method is a method of drug administration whereby the drug is injected directly into the vein.

[85] *Id*.

[86] The IV-drip method administers a drug by having the drug mixed in a saline solution, which slowly enters a patient's vein through a catheter.

[87] See *Wyeth v. Levine*, 555 U.S. 555, 562-63 (2009).

[88] *Id*.

[89] 183 Vt. 76, 84, 944 A.2d 179, 184 (2006).

[90] 552 U.S. 1161 (2008).

[91] See *Wyeth v. Levine*, 555 U.S. 555 (2009).

[92] *Id*. at 573.

[93] *See* 21 U.S.C. § 255; 21 CFR § 314.70(c)(6)(iii)(A), (C).

[94] *See* 73 Fed.Reg. 49603, 49609 (2008).

[95] 555 U.S., at 569.

[96] *Id*.

[97] *Id*. at 570.

[98] *Id*.

[99] *Id*. at 570-71.

[100] Red. Br. 18 (citing *Kelleher v. Marvin Lumber & Cedar Co.*, 891 A.2d 477, 492 (N.H. 2005)).

[101] Red. Br. 19.

[102] Red. Br. 18.

[103] Representative Henry Waxman has served in the House of Representatives since 1974. He was one of the two principal sponsors of the Drug Price and Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). Waxman has also presided over legislative hearings concerning preemption under the FDCA.

[104] Senator Harkin was a member in the House of Representatives starting in 1975, and he became a US senator in 1985. He is currently (as of March 20, 2013) a member of the Senate Appropriations Committee and serves in a subcommittee with jurisdiction over FDA funding.

[105] Brief for Sen. Tom Harkin and Rep. Henry Waxman as Amici Curiae, p. 19, *Mut. Pharm. Co., v. Bartlett*, 133 S. Ct. 694 (2012).

[106] See *Kordel v. United States*, 335 U.S. 345, 349 (1948).

[107] *See* 21 U.S.C. § 343-1(a), 360k(a), 379.

[108] *See* 21 U.S.C. § 379r(e) (“No Effect on State Product Liability law - Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability of any State.”).

[109] An OTC drug monograph is similar to a "recipe book" covering acceptable ingredients, doses, formulations, and labeling.

[110] Brief for Sen. Tom Harkin and Rep. Henry Waxman as Amici Curiae, p. 6, *Mut. Pharm. Co., v. Bartlett*, 133 S. Ct. 694 (2012). *See also* FDA, *Drug Applications for Over-the-Counter Drugs* (Oct. 18, 2012).

[111] Brief for Sen. Tom Harkin and Rep. Henry Waxman as Amici Curiae, p. 7, *Mut. Pharm. Co., v. Bartlett*, 133 S. Ct. 694 (2012).

[112] *Id*.

[113] *Id*. at 12.

[114] *See* IMS Inst. for Healthcare Informatics, *The Use of Medicines in the United StatesL Review of 2011* at 26 (2012).

[115] Brief for Sen. Tom Harkin and Rep. Henry Waxman as Amici Curiae, p. 15, *Mut. Pharm. Co., v. Bartlett*, 133 S. Ct. 694 (2012) (citing *Wyeth*, 555 U.S. at 588 (Thomas, J., concurring)).

[116] *Id*.

[117] Brief for the United States as Amici Curiae, p. 13, *Mut. Pharm. Co., v. Bartlett*, 133 S. Ct. 694 (2012).

[118] *Id*.

[119] See *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1182.

[120] Transcript of Oral Argument at 17, *Mut. Pharm. Co., v. Bartlett*, 133 S. Ct. 694 (2012) (No. 12-142).

[121] *Id*. at 6-7.

[122] *Id*. at 33.

[123] *Id*. at 35 (“Because everything in the...complaint that I’ve read so far seems to talk about the adequacy of warnings, not that there is no warning in the universe could possibly have made a difference.”).

[124] *Id*. at 21.

[125] *Id*. at 22.

[126] *Id*.

[127] *Id*. at 23.

[128] *Id*.

[129] *Id*. at 24.

[130] *Id*. at 46.

[131] *Id*. at 48.

[132] *Id*. at 36.

[133] *Id*. at 39 ("Do you want me to write down in this case, from my understanding, that under New Hampshire law, strict liability is determined quite without reference to the adequacy of warning?").

[134] *Id*. at 28 (Justice Scalia responds to Mr. Frederick's assertion that the jury decides this type of cost/benefit analysis, "That's wonderful...twelve tried and men...and true decide for the whole State what the...cost/benefit analysis is for a very novel drug that unquestionably has some deleterious effects, but also can save some lives...and the jury's going to decide that?").

[135] *See* 24 Del. C. § 2549.

[136] *See* 18 V.S.A. § 4605(a) (requiring pharmacists to select the lowest-priced "equivalent" drug as defined in the most recent edition of the U.S. Department of Health and Human Services' publication "Approved Drug Products with Therapeutic Equivalence").

[137] ASPE Issue Brief: "Expanding the Use of Generic Drugs." (December 1, 2010) at 8.

[138] *See* RCW 69.41.120.

[139] *See* Article 137, Pharmacy § 6810(6)(a) (Requiring generic substitution "unless the prescriber writes d a w in such box in the prescriber's own handwriting or, in the case of electronic prescriptions, inserts an electronic direction to dispense the drug as written, the prescriber's signature or electronic signature shall designate approval of substitution by a pharmacist of a drug product").

[140] GPhA: "Medicaid: GPhA Position." http://www.gphaonline.org/issues/medicaid# (Last visited Feb. 12, 2013).

[141] Medicare Glossary. Medicare.gov - http://www.medicare.gov/glossary/f.html (Last viewed Feb. 10, 2013).

[142] *See generally*, "Picking up the Tab for your Competitors: Innovator Liability After *PLIVA, Inc. v. Mensing*," 19 Geo. Mason L. Rev. 1257 (2012).

[143] See e.g., *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994) ("This would be especially unfair when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising.); *See also*, Sarah C. Duncan, Note, *Allocating Liability for Deficient Warnings on Generic Drugs: A Prescription for Change*, 13 Vand. J. Ent. & Tech. L. 185, 209 (2010).