regulatory changes. Plaintiff attorneys have also met limited success in attempting to circumvent, reframe or distinguish the holdings in Mensing and Bartlett. However, as long as regulatory change is stagnant, expect plaintiff attorneys to continue to try and poke holes in holdings in Mensing and Bartlett with limited success in narrow circumstances.

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Recent research indicates that the current cost of generic medications in the United States is the highest in history.[1] Many patients are no longer able to afford life saving medications that were once affordable only five years ago.[2] Concurrent to the rising prices of generic drugs, pharmaceutical companies have lauded preemption as a necessary and viable solution to combat the increasing prices.[3] Two recent Supreme Court decisions, *PLIVA, Inc. v. Mensing*[4] and *Mutual Pharmaceutical Co. v. Bartlett*,[5] have agreed with this logic, and have attempted to pervert the Hatch-Waxman Act, and its corresponding ANDA approval process to shield generic drug manufacturers from liability. Not only has this immunity done nothing to combat the price of drugs, but it has also decreased incentives for generic manufacturers from engaging in thorough pre-market testing and studies, putting consumers of generic drugs at an increased risk of injury.[6]

This paper proceeds in six parts. Part I provides background of

for generic drugs. Part II explores the preemption analysis of generic drug claims made in three recent Supreme Court decisions. Part III explores in-depth the damaging effects that these decisions have on the safety of consumers, and the long-term vitality of the generic drug industry. Having established that preemption of generic drug claims is undesirable, Part IV identifies recent attempts by the FDA to introduce regulatory changes that eliminate preemption of generic drugs. Part V explores cutting edge strategies that have been used by plaintiff lawyers to circumvent, reframe and

will proceed to clinical testing, and only one will eventually be approved by the [18] The NDA process is an extremely expensive and time-consuming process, costing upwards of a billion dollars and up to ten years to complete.[19]

c. "ANDA" Approval Process

In 1984, Congress introduced the Hatch-Waxman Act, which introduced

the FDA.[20] Recognizing a need for cheaper, more available drugs, Congress intended the ANDA process to be a less demanding standard for drugs that are similar to previously approved brand-name drugs.[21] Under the ANDA approval process, a generic manufacturer need only show bioequivalence between a NDA approved drug and the ANDA drug it seeks to have approved.[22] identical to the [23] Any dissimilarity between the two labels will result in the FDA denying a submitted ANDA.[24] A generic manufacturer is also required to timely update its label to reflect any new changes made by the brand-name counterpart.[25] Courts have dubbed these stringent

of generic drugs contend that it is impossible to comply with both this federal
rug reasonably safe
since a generic drug is required to remain the same as its brand-name counterpart.[28] Although a conflict of duties seems to suggest that preemption is appropriate, the Courts have disagreed over the extent to which the FDCA preempts state law claims.[29] In their decisions, courts have wrestled over the importance of affordability and accessibility of medication balanced against the potential harms to consumers of those generic products.[30] There have been three Supreme Court decisions within the past five years that have attempted to demarcate the precise preemptive scope of the Hatch-Watchman Act.

a. Wyeth v. Levine

Wyeth v. Levine was the first Supreme Court case that addressed the
ion drug
claims.[31] The plaintiff in *Wyeth*

Mensing was the first to address preemption in the generic drug context.[37] *Mensing* involved failure-to-warn claim against a generic manufacturer of metoclopramide, a drug designed to assist the digestive system.[38] After taking metoclopramide, the plaintiff developed severe and irreversible neurological disorders.[39] Although studies surfaced early on that the brand-name compound caused neurological damage in almost one-third of its users, it was years before the manufacturer of the brand name product was forced to make significant changes to its warning label.[40] By then, the plaintiff had ingested the generic equivalent and been severely injured.[41] The generic manufacturer of metoclopramide argued for preemption, arguing that they were barred by federal law from making any unilateral changes to the label of metoclopramide.[42] The Supreme Court agreed, reasoning it was not possible for the generic drug manufacturer to fulfill state tort law requirements and a federal law that forbade generic drug manufacturers from having a label different than the brand-name manufacturer.[43]

c. Mutual Pharmaceutical Co. v. Bartlett

Most recently, in *Mutual Pharmaceutical Co. v Bartlett*, the Supreme Court finally addressed preemption within the context of design defect claims

remedial action required to avoid liability under New Hampshire state law.[48] Relying heavily upon the decision in *Mensing*, The Supreme Court held that s product is on the positive side of the balancing inquiry is preempted by the federal [49]

III. IMPLICATIONS OF *MENSING* AND *BARTLETT*

Following the decisions of *Wyeth*, *Mensing* and *Bartlett*, plaintiffs injured by generic drugs are essentially barred from all areas of redress.

and argue that decreased costs will be subsequently passed on to the consumer in the form of lower drug prices.[61] However, shielding generic drugs from state tort law liability runs the risk of ultimately hurting, rather than helping the generic drug industry in the long run. Doctors, concerned

generic drugs less and may avoid generic substitutions.[62] Doctors may also have less altruistic concerns, especially as it relates to increased liability for themselves. For example, a patient injured by a generic drug who has not

doctor for partial compensation in the form a of a medical malpractice lawsuit.[63] Doctors, who have virtually unchecked powers to prevent generic substitutions, may increasingly refuse to prescribe generic drugs in order to avoid future liability.[64]

Pharmacies, concerned for many of the same reasons, will refrain from filling prescriptions with a generic substitute.[65] Consumers become more educated about the potential risks and lack of legal remedies for generic drugs will request brand-name drugs.[66] States, concerned over the lack of generic manufacturer accountability, and preemption of its own state defect standards, may begin to implement laws that discourage generic substitution.[67] While the long-term impacts of the *Mensing* and *Bartlett* decisions have yet to be felt in full force, we should expect many of these changes if generic manufacturers continue to be shielded from liability.

IV. LEGISLATIVE EFFORTS

Given the huge ramifications of *Mensing* and *Bartlett*, there has been a tremendous effort to introduce regulatory action that minimizes the impact of the decisions. In November 2013, the FDA introduced a proposed rule that would enable generic drug manufactures to unilaterally update their labels, irrespective of whether the revised labeling differs from its brand-name

61. *See generally* Steve Yahn, *Generic Drug Manufacturers May Face Increased Premiums and Higher Risk Management Costs Due to a Proposed FDA Rule*, RISK & INS., (Feb. 19, 2015), http://www.riskandinsurance.com/rule-change/ (finding erosion of the rule will lead to claim expenses and potential judgments).

62. Marie Boyd, *Unequal Protection under the Law: Why FDA Should Use Negotiated Rulemaking to Reform the Regulation of Generic Drugs*, 35 CARDOZO L. REV. 1525, 1577 (2014).

63.

counterpart.[68] The updated labeling will be submit

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manufacturer to implement a revised label while it submits the changes to the FDA.[69] The generic manufacturer is also required to notify its brand-name counterpart of its intention to change its label and the reasons behind the change.[70] In a supplemental report, the FDA lists the social costs associated with the new rule as minimal, only $4,237 to $25,852 annually.[71]

a. Criticism of the "CBE-O" Proposal

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with sharp criticism by Republican members of Congress. These] directly with the statute, th nd imposing [72] In

February 2013, a consulting group estimated that increased liability as a result of the new rule would lead to increased costs to generic drug manufacturers at $4 billion, or 1.16 per prescription.[73] These studies into their analysis the increased costs associated with higher exposer to liability.[74]

b. Criticism of the "CBE-O" Proposal Is Unwarranted

it is well known that the FDA has historically refrained from considering as a dispositive factor in its decisions costs associated with increased civil

68. Jennifer M. Thomas, *FDA Proposes a Rule that Would Undercut Generic Drug Preemption*, FDA L. BLOG (Nov. 12, 2013), http://www.fdalawblog.net.

69. *Id.*

70. *Id.*

71. ALEX BRILL, S PROPOSED GENERIC DRUG LABELING RULE: AN ECONOMIC ASSESSMENT, MATRIX GLOBAL ADVISORS 3 (Feb. 5, 2014), http://www.gphaonline.org/media/cms/Economic_Impact_Study_FDA_Labeling_Rule_-_MGA.pdf.

72. Generic Drug Labeling Policy (Jan. 22, 2014), http://www.help.senate.gov/chair/newsroom/press/alexander-leads-inquiry-into-fdas-proposed-change-to-generic-drug-labeling-policy.

73. BRILL, *supra* note 71, at 10.

74. *Id.* at 8.

Bartlett have impressed upon the courts a strong directive to preempt any product liability claims made against a generic manufacturer.[81] Second, as long as generic manufacturers continue to market drugs and regulatory change is stagnant, plaintiff attorneys will continue to try and poke holes in the *Mensing* and *Bartlett* decisions.[82] Although no strategy has proven exceptionally successful, three have proven to be marginally useful for litigants.

a. Failure-to-Update

The most well known plaintiff strategy in the wake of *Bartlett* and *Mensing* relates to failure to timely update labeling to match the labeling of the brand manufacturer.[83] While a generic manufacturer is not allowed to unilaterally change their label or drug composition per *Mensing*, it is still required to update their label to match a brand name manufacturer if the brand name manufacturer has made any changes to its label.[84] Plaintiffs have seized onto this requirement, and many state courts have proven to be sympathetic towards plaintiffs asserting failure-to-update claims. Most recently, the Appellate Division in New Jersey in *In Re Reglan Litigation* held that a -to- [85] There are also multiple petitions for writ of certiorari that are pending before the U.S. Supreme Court on this issue.[86]

While failure-to-update claims have seen some success in state courts, litigators and scholars alike are dubious regarding the future success and

2015]