MUTUAL PHARMACEUTICAL CO. V. BARTLETT: A NEED FOR “EXPLICIT” CONGRESSIONAL ACTION AND STATE TORT LAW REFORM

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Mutual Pharmaceutical Co. v. Bartlett: A Need for “Explicit” Congressional Action and State Tort Law Reform
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“A life threatening skin disorder characterized by a blistering and peeling of the skin…caused by a drug reaction.”¹ A condition causing “skin to peel in sheets, leaving large, raw areas exposed.”² This is Karen Bartlett’s affliction – acute toxic epidermal necrolysis³ – an affliction for which the Supreme Court foreclosed any damage recovery based on the doctrine of impossibility preemption.⁴

Introduction

In December 2004, Karen Bartlett received a prescription for Clinoril, a Federal Food and Drug Administration (“FDA”) approved non-steroidal anti-inflammatory pain reliever for shoulder pain.⁵ When Ms. Bartlett filled her prescription, her pharmacist dispensed an FDA approved, generic form of the drug.⁶ As a result of taking that drug, Ms. Bartlett developed a debilitating condition referred to as acute toxic epidermal necrolysis⁷ affecting over sixty to sixty-five percent her skin’s surface.⁸ She suffered devastating injuries including skin deterioration and open wounds that required she be placed into a medically induced coma.⁹ Ultimately, the condition left Ms. Bartlett severely disfigured, physically disabled, and nearly blind.¹⁰

Mutual Pharmaceutical Company, despite having knowledge that its drug could cause “severe skin reactions” and “[f]atalities,” did not refer to or warn of these known side effects on

² Id.
⁴ See id. at 2480.
⁵ Id. at 2472.
⁶ Id.
⁸ Mutual Pharm. Co., 133 S. Ct. at 2472.
⁹ Id.
¹⁰ Id.
the drug’s label.\textsuperscript{11} Under New Hampshire law, Ms. Bartlett filed a tort suit to recover damages for her personal injuries.\textsuperscript{12} Her suit, however, exposed a disturbing flaw in current products liability jurisprudence as it relates to generic prescription drug manufacturers. Pursuant to statutory strict liability, most prescription drug manufacturers can fulfill their statutory duties either by changing the drug’s design or label.\textsuperscript{13} However, the FDA prohibits generic drug manufacturers, like Mutual Pharmaceutical Company, from changing a drug’s design.\textsuperscript{14} Therefore, compliance with state tort law, like New Hampshire’s, ordinarily would require changing the drug’s labeling.\textsuperscript{15} However, as discussed below,\textsuperscript{16} because federal labeling regulations prevent generic drugs manufacturers from unilaterally changing their drug labels, Ms. Bartlett’s state law claims were preempted.\textsuperscript{17} She was left with no remedy.\textsuperscript{18}

This article will address the Supreme Court’s preemption jurisprudence in the prescription drug industry and will assess both the Court’s recent decision in \textit{Mutual Pharmaceutical Company v. Bartlett}\textsuperscript{19} and the FDA’s recent proposal to amend federal regulations in this area. Part I(a) of this article will provide an overview of relevant statistics related to filling prescriptions, and Part I(b) will explain the background to and the current state of the law as it pertains to the prescription drug industry, as well as the FDA’s current regulations of prescription drug labeling. Part II(a) of this article briefly will outline the Supreme Court’s preemption jurisprudence, differentiating between express and implied preemption doctrines and explaining certain interpretations of those doctrines as applied to the

\textsuperscript{11} \textit{Mutual Pharm. Co.}, 133 S. Ct. at 2472.
\textsuperscript{12} \textit{Id}.
\textsuperscript{13} \textit{Id} at 2479.
\textsuperscript{14} See 21 C.F.R. § 314.70(b)(2)(i); \textit{Mutual Pharm. Co.}, 133 S. Ct. at 2468 (noting that once approved, manufacturers are prohibited from changing drugs’ active ingredients or specifications).
\textsuperscript{15} \textit{Mutual Pharm. Co.}, 133 S. Ct. at 2474.
\textsuperscript{16} See infra Part II(b).
\textsuperscript{17} \textit{Mutual Pharm. Co.}, 133 S. Ct. at 2480.
\textsuperscript{18} \textit{Id}.
\textsuperscript{19} See generally \textit{id} at 2466 (preempting state law design defect claims against a generic drug manufacturer).
prescription drug industry. Part II(b) of this article will discuss the policy considerations and legislative intent behind federal prescription drug regulations in the United States. Part II(c) of this article will summarize the application of the preemption doctrines to two landmark cases leading up to the Bartlett decision: Wyeth v. Levine\(^{20}\) and PLIVA, Inc. v. Mensing.\(^{21}\) Part III of this article will explain the factual and procedural background to the Supreme Court’s opinion in Bartlett, and Part IV will analyze and compare the Court’s reasoning in Bartlett to its prior preemption jurisprudence, as well as discuss the legislative intent behind federal prescription drug regulations. In addition, this Part will identify the differing duties between brand name and generic drug manufacturers, and will discuss the logic of the “stop-selling” rationale,\(^{22}\) which the Court improperly rejected in the PLIVA and Bartlett decisions. Part V of this article will summarize the FDA’s recently proposed rule intending to resolve the problems described in Part IV. Specifically, Parts V(a) and (b) will compare and contrast the advantages and drawbacks of the FDA’s proposal, concluding that it does not adequately address the problems described infra. Finally, Part VI of this article will propose a more appropriate, alternative solution to the problems described in Part IV, and address potential counterarguments. Specifically, Part VI attempts to resolve the disparity between brand name and generic prescription drug manufacturers’ duties with respect to labeling regulations by suggesting: (1) an express non-preemption provision at the federal level and (2) placing a cap on recovery of non-economic damages for state tort law claims lodged against generic prescription drug manufacturers.


\(^{21}\) See generally PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011) (preempting state law failure to warn claims against a generic drug manufacturer).

\(^{22}\) See Bartlett v. Mutual Pharm. Co., 678 F.3d 30, 37 (1st Cir. 2012), rev’d 133 S. Ct. 2466 (2013) (explaining the “stop-selling” rationale as the theory that a manufacturer can comply with both federal and state regulations by withdrawing their product from the market).
Part I:

(a) Statistical Overview of the Prescription Drug Industry

A brief statistical review of the prescription drug industry provides some insight into the number of consumers who face the same preemption peril that befell Ms. Bartlett.

Over the last decade, instances of adverse drug reactions have nearly tripled. Between 2003 and 2011, FDA reports of patient outcomes from adverse events increased from 34,948 deaths to 98,518 deaths, and reports of serious outcomes, including hospitalizations, increased from 176,256 to 573,111. This number of consumer injuries is daunting. Of course, all drugs have risks, and the physician and patient must balance the risks and benefits of any drug when deciding a course of treatment. That decision necessarily includes choosing between prescribing a brand name drug versus a generic drug. However, it remains unclear whether consumers actually have a real choice between filling their prescriptions with brand name drugs versus generic drugs. This is due to the price disparity between brand name and generic drugs, as well as the fact that many health insurance providers do not provide comparable coverage of brand name drugs when a generic is available. Therefore, consumer choice is arguably limited to the point of inexistence.

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24 Id.
Recent studies evidence this disturbing phenomenon. In 2011, pharmacies across the United States filled nearly 4 billion prescriptions for brand name and generic drugs.\textsuperscript{27} According to one study, “[s]ince 2004, one out of every 10 dollars expended on health care in the United States has been for prescription drugs.”\textsuperscript{28} In 2005, those expenditures reached $790 per capita.\textsuperscript{29}

At the same time, as compared to other countries, Americans are the most likely to leave prescriptions unfilled or skipped.\textsuperscript{30} Why? Because of cost.\textsuperscript{31} The Centers for Disease Control reported in a recent study, that “one out of every five Americans has asked their doctor to prescribe a cheaper medication in order to lower their prescription costs.”\textsuperscript{32} Generic drugs do provide a lower-cost alternative to brand name drugs, costing 30-80\% less than their brand name counterparts do,\textsuperscript{33} and doctors may suggest the use of generics to offset prescription drug costs.\textsuperscript{34} The FDA has reported that nearly “8 in 10 prescriptions…are for generic drugs[,]” and it expects generic drug use to grow as brand name drug patents expire through 2015.\textsuperscript{35} Ironically, however, most consumers perceive brand name drugs to be safer than generic drugs,\textsuperscript{36} and therefore would

\begin{footnotesize}
\begin{enumerate}
\item \textsuperscript{27} Sovey, Chris, \textit{United States Tops 4 Billion Annual Prescriptions: Is our Health Improving?} \textit{HEALTHY CONSUMER} (Oct. 5, 2012), http://www.healthyconsumer.com/911/united-states-tops-4-billion-annual-prescriptions-is-our-health-improving/ (last visited Jan. 2, 2014)
\item \textsuperscript{29} Id. at 2.
\item \textsuperscript{30} Morgan & Kennedy, \textit{supra} note 28, at 4.
\item \textsuperscript{31} Id.
\item \textsuperscript{34} Id.
\item \textsuperscript{36} U.S. Dep’t of Health & Human Servs., \textit{Expanding the Use of Generic Drugs} 8 (Dec. 1, 2010), http://aspe.hhs.gov/sp/reports/2010/genericdrugs/ib.pdf.
\end{enumerate}
\end{footnotesize}
opt to fill their prescriptions with brand name, not generic, drugs.37 Thus, based on the foregoing statistics, it appears that consumers opt not to fill their prescriptions with brand name drugs due to the cost differential.38

In addition to this seeming lack of consumer choice, consumers who fill prescriptions with generic drugs may, like Ms. Bartlett, unintentionally and unknowingly waive the state tort liability of generic drug manufacturers.39 In addition to prescribing physicians, pharmacists and insurance companies also promote filling prescriptions with generic drugs.40 Yet unbeknownst to most – if not all – consumers, accepting a generic drug may waive potential tort liability for injuries or adverse effects of taking the generic drug.41 This potential waiver arises from a trilogy of Supreme Court cases holding brand name drug manufacturers liable in tort for state law claims, but preempting the same or similar claims against generic drug manufacturers.42 More specifically, in 2011 the Supreme Court determined that “brand name and generic drug manufacturers have different federal drug labeling duties.”43 That difference is significant in that it suggests a foreclosure of state tort actions against generic drug manufacturers;44 specifically as to causes of action based in strict liability, including failure to warn and design defect.45 In other

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37 Steele, supra note 26, at 462.
38 See generally Morgan & Kennedy, supra note 28, at 4.
41 See generally Mutual Pharm. Co., 133 S. Ct. 2466.
43 PLIVA, Inc., 131 S. Ct. at 2574.
44 See Mutual Pharm. Co., 133 S. Ct. at 2480 (foreclosing plaintiff’s recovery for personal injuries arising out of design defect claims brought against a generic drug manufacturer); PLIVA, Inc., 131 S. Ct. at 2577-78 (foreclosing plaintiff’s recovery for personal injuries arising out of failure to warn claims brought against a generic drug manufacturer).
45 See Mutual Pharm. Co., 133 S. Ct. at 2480; PLIVA, Inc., 131 S. Ct. at 2577-78.
words, taking generic drugs may preclude consumers from establishing a prima facie tort claim against generic manufacturers because of preemption.\textsuperscript{46}

Attempting to create parity between brand name and generic drug manufacturers in terms of labeling duties, the FDA recently announced a proposed amendment to its regulations.\textsuperscript{47} However, that proposal will not adequately resolve the risk of waiver born by consumers taking generic prescription drugs.

\textbf{(b) Background to and Current State of the Law Related to the FDA’s Regulation of Prescription Drug Labeling}

As previously noted, consumers face severe financial burdens in purchasing prescription drugs,\textsuperscript{48} and healthcare affordability is a major concern in today’s society.\textsuperscript{49} Indeed, as early as 1984, this was a concern. Congress responded to this concern by passing the Hatch-Waxman Amendments,\textsuperscript{50} which aimed to increase the availability of low cost generic drugs.\textsuperscript{51} More specifically, those Amendments allowed generic drug manufacturers to gain FDA approval by showing equivalence to a reference-listed drug already approved by the FDA.\textsuperscript{52} This process, the “Abbreviated New Drug Application” ("ANDA"), requires far less stringent procedures\textsuperscript{53} than an application for a novel drug ("NDA").\textsuperscript{54} As a result, the Amendments succeeded in providing

\textsuperscript{46} See, e.g., Mutual Pharm. Co., 133 S. Ct. 2466; PLIVA, Inc., 131 S. Ct. 2567; Wyeth, 555 U.S. 555.
\textsuperscript{47} See infra Part V.
\textsuperscript{48} See supra Part I(a).
\textsuperscript{51} Steele, supra note 26, at 447.
\textsuperscript{53} An abbreviated application for a new drug requires, generally: “(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug,” and “(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug.” 21 U.S.C. § 355(j)(2)(A) (West 2013). Additionally, the ANDA application requires that the “labeling…proposed for the drug product must be the same as the labeling approved for the reference listed drug.” 21 C.F.R. § 314.94(a)(8)(iv) (West 2013).
\textsuperscript{54} An application to market a novel drug requires, among other things: “(A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list
manufacturers with the ability to develop generic drugs at a lower cost, because they excuse
generic drug manufacturers from having to duplicate clinical trials already performed on the
brand name drug.\footnote{PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2574 (2011).} Therefore, to obtain FDA approval, federal regulations only require generic
drugs to be the chemical equivalent and bioequivalent of the brand name drug, and to have the
same label as the brand name drug.\footnote{21 U.S.C. § 355(j) (West 2013).}

The FDA also imposes monitoring and reporting requirements on drug manufacturers,
both of NDA and ANDA drugs.\footnote{21 U.S.C. § 355(j) (West 2013).} Thus, brand name and generic drug manufacturers must
adhere to almost identical post-market duties.\footnote{Steele, supra note 2, at 455.} However, of major concern, the Amendments –
and the corresponding FDA regulations – continue to prohibit generic manufacturers from
making unilateral changes to their drug labels,\footnote{See 21 U.S.C. §§ 314.94(a)(8)(ii), 314.150(b)(10).} even changes intended to \textit{enhance} consumer
safety.\footnote{6 The prohibition on unilaterally altering a drug’s label exists even though drug manufacturers are required to
develop written procedures to survey, receive, evaluate, and report adverse drug reactions to the FDA. \textit{See} 21
C.F.R. §§ 314 and 601, at 8 (Proposed Rule 2013), \textit{available at}
https://www.federalregister.gov/articles/2013/11/13/2013-26799/supplemental-applications-proposing-labeling-
changes-for-approved-drugs-and-biological-products.} As discussed in detail herein,\footnote{Infra Part III-IV.} the result of these restrictions has been a finding by the
United States Supreme Court that federal FDA regulations preempt certain state tort causes of
action asserting liability against generic drug manufacturers.\footnote{See Mutual Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2480 (2013) (foreclosing plaintiff’s recovery for personal
injuries arising out of design defect claims brought against a generic drug manufacturer); PLIVA v. Mensing, 131 S.
Ct. 2567, 2577-78 (2011) (foreclosing plaintiff’s recovery for personal injuries arising out of failure to warn claims
brought against a generic drug manufacturer).} Those include state tort claims
requiring the manufacturer to change its drug composition or label in order to increase safety or
warnings. The threat of immunizing generic drug manufacturers from liability for consumer injuries establishes a need for state tort reform in the prescription drug industry.

Opponents of proposed state law tort reform suggest that exposing generic drug manufacturers to liability to the same extent as brand name manufacturers would undermine the purpose of the Hatch-Waxman Amendments. Specifically, opponents argue that state tort exposure would subject drug manufacturers to more lawsuits thereby increasing prescription drug costs. Furthering this argument, state tort judgments arising out of these claims can be in the tens of millions of dollars, including crippling non-economic damage awards. To alleviate this concern, Congress should limit manufacturer’s liability by placing a cap on recovery of non-economic damages for tort causes of action. Doing so would preserve the low cost purpose of the Hatch-Waxman Amendments while still protecting the interests of consumers and providing an ongoing incentive for manufacturers to increase the safety and effectiveness of their drugs.

Part II

(a) Preemption

The Supremacy Clause of the United States Constitution establishes that federal law “shall be the supreme Law of the Land…any Thing in the Constitution of Laws of any State to the Contrary notwithstanding.” As such, federal laws will preempt conflicting state laws.

63 See Mutual Pharm. Co., 133 S. Ct. at 2480 (foreclosing plaintiff’s recovery for personal injuries arising out of design defect claims brought against a generic drug manufacturer); PLIVA, Inc., 131 S. Ct. at 2577-78 (foreclosing plaintiff’s recovery for personal injuries arising out of failure to warn claims brought against a generic drug manufacturer).
64 The Advisory Board Co., FDA proposal would expose generic drugmakers to lawsuits (Nov. 12, 2013 7:00 a.m.), http://www.advisory.com/Daily-Briefing/2013/11/12/FDA-proposal-would-expose-generic-drugmakers-to-lawsuits.
65 Id.
67 A reasonable cap might be $500,000.00 adjusted annually for inflation. See, e.g., Cal. Civ. Code § 3333.2(b) (West 2013) (capping non-economic damage recovery in medical malpractice suits to $250,000).
68 U.S. CONST. art. VI, cl. 2.
69 See Gibbons v. Ogden, 22 U.S. 1 (1824).
Both express and implied forms of preemption arise from this Constitutional provision.\(^70\) In determining preemption, the Court considers the purpose of Congress and the assumption that “the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”\(^71\) A presumption against preemption must inform the Court’s inquiry into Congressional intent.\(^72\) This presumption exists because an irreconcilable conflict between state and federal law eliminates any need to inquire into the Congressional intent at all.\(^73\) Rather, in such a case, the Court may infer that Congress intended the federal law to displace conflicting state law.\(^74\)

Nonetheless, preemption can arise in several distinct situations. Express preemption arises when Congress explicitly states its intent to preempt state law in a federal statute.\(^75\) Comparatively, implied preemption can arise pursuant to three scenarios. First, where Congress has legislated in a particular field such that the legislation creates a reasonable inference “that Congress left no room for the states to supplement [the legislation],” federal law impliedly preempts state law i.e. “field preemption.”\(^76\) Second, where state law undermines or creates an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, federal law impliedly preempts state law i.e. “obstacle conflict preemption.”\(^77\) Third, where it is


\(^{73}\) Id. at 2485.

\(^{74}\) Id.


“impossible for a private party to comply with both state and federal requirements” 78 i.e. “impossibility conflict preemption.”

The Court’s analyses in the cases discussed herein hinge on impossibility preemption. As noted above, impossibility preemption requires a direct conflict between two mutually incompatible legal requirements. 79 However, as discussed in detail below, 80 the Court in the cases discussed herein erred in holding that federal law preempted state law under the impossibility preemption doctrine, because “courts may not automatically assume that Congress intended for state law to give way[]” to federal regulations. 81 Rather, the Court should have conducted a careful inquiry, informed by the presumption against preemption, into the Congressional intent. 82 In the context of prescription drug labeling regulations, Congress’ intent is ascertained easily from the legislative history of the Federal Food, Drug, and Cosmetic Act (“FDCA”).

(b) The Legislative History of the Federal Food, Drug, and Cosmetic Act

Congress enacted the Federal Food, Drug, and Cosmetic Act in the 1930s due to increased concerns about, among other things, unsafe drugs. 83 The bill’s first version included a federal cause of action for damages for injured consumers. 84 However, prior to the law’s enactment, Congress deleted this federal cause of action provision, deeming it unnecessary in light of common law claims available under state law. 85 Between 1933 and 2007, Congress

79 Mutual Pharm. Co., 133 S. Ct. at 2487 (Sotomayor, J., dissenting).
80 Infra Part IV.
81 Mutual Pharm. Co., 133 S. Ct. at 2486 (Sotomayor, J., dissenting).
82 Id.
84 Id. at 574 n.7.
85 See id.
amended the FDCA numerous times.86 A 1962 amendment required manufacturers to show that
their drugs were both safe and effective for use under conditions prescribed, recommended, or
suggested in the proposed labeling before distribution.87 A 2007 amendment gave the FDA
statutory authority to require a manufacturer to change its label based on newly acquired safety
information, but left manufacturers primarily responsible for contents of their labels.88 At the
same time, however, Congress “took care to preserve state law”89 and specifically refused to
enact an express preemption provision for prescription drugs as recently as 1976.90 Accordingly,
one may assume that Congress intended to allow states to pass laws that “establish[ed] greater
safety than the minimum safety achieved by a federal regulation intended to provide a floor.”91

The FDCA’s history suggests that, to date, Congress has opted not to create a federal
cause of action precisely because of its belief that state tort law would afford injured consumers a
remedy.92 Historically, “federal drug law and state common-law liability have long been
understood to operate in tandem to promote consumer safety.”93 Specifically, federal law was
intended to “supplement[] the protection for consumers already provided by state regulation and
common-law liability.”94 The recent Supreme Court decisions preempting state tort law claims
against generic drug manufacturers undermine this Congressional intent of establishing a floor,
not a ceiling, for drug manufacturer liability.95 Prior to the Court’s finding these causes of action
preempted under the “impossibility preemption” theory, tort suits helped fill the gaps in federal

https://www.federalregister.gov/articles/2013/11/13/2013-26799/supplemental-applications-proposing-labeling-
changes-for-approved-drugs-and-biological-products.; See also Wyeth, 555 U.S. at 570-71.
87 See Wyeth, 555 U.S. at 567.
88 See id. at 570-71.
89 Id. at 567.
90 Id.
92 See Wyeth, 555 U.S. at 574-75 and n. 7.
94 Wyeth, 555 U.S. at 566.
95 Id. at 575 (citing 71 Fed. R. 3922, 3934-35 (2006) (declaring that “the FDCA established “both a ‘floor’ and a
‘ceiling,’’ so that “FDA approval of labeling…preempts conflicting or contrary State law.”)).
regulation by serving as catalysts for identifying previously unknown drug dangers.\textsuperscript{96} Now, however, the Supreme Court’s preemption jurisprudence in this area threatens to erode consumer safety and protection related to use of generic prescription drugs. Already, state tort claims requiring certain elements of proof have left consumers with no remedy against generic drug manufacturers.\textsuperscript{97}

(c) Preemption, as Applied, in \textit{Wyeth v. Levine} and \textit{PLIVA, Inc. v. Mensing}

In the years immediately preceding its decision in \textit{Mutual Pharmaceutical Co. v. Bartlett},\textsuperscript{98} the Supreme Court twice applied impossibility preemption in the context of prescription drugs.\textsuperscript{99} Each of those cases analyzed whether impossibility preemption defeated a state law failure to warn claim.\textsuperscript{100} In \textit{Wyeth v. Levine}, impossibility preemption did not defeat the state law claim,\textsuperscript{101} while in \textit{PLIVA, Inc. v. Mensing}, it did.\textsuperscript{102} The distinguishing factor between these two cases is simply that one claim – in \textit{Wyeth v. Levine} – was brought against a brand name drug manufacturer while the other – in \textit{PLIVA, Inc. v. Mensing} – was brought against a generic manufacturer.

In 2009, in \textit{Wyeth}, the Court held a brand name drug manufacturer liable to an injured consumer under a state law failure to warn cause of action.\textsuperscript{103} More specifically, the Court stated that the defendant, Wyeth, failed to demonstrate impossibility preemption because the “changes

\textsuperscript{96} See \textit{Mutual Pharm. Co.}, 133 S. Ct. at 2485 (Sotomayor, J., dissenting) (citing \textit{Bates v. Dow Agrosciences, LLC}, 544 U.S. 431, 451 (2005)).
\textsuperscript{97} See generally \textit{Mutual Pharm. Co.}, 133 S. Ct. 2466; \textit{PLIVA, Inc. v. Mensing}, 131 S. Ct. 2567 (2011).
\textsuperscript{98} See generally \textit{Mutual Pharm. Co.}, 133 S. Ct. 2466.
\textsuperscript{99} See \textit{PLIVA, Inc.}, 131 S. Ct. at 2581 (applying a preemption analysis to failure to warn claims against a generic drug manufacturer); \textit{Wyeth v. Levine}, 555 U.S. 555, 573 (2009) (applying a preemption analysis to failure to warn claims against a brand name drug manufacturer).
\textsuperscript{100} See \textit{PLIVA, Inc.}, 131 S. Ct. at 2581 (preempting failure to warn claims against a generic drug manufacturer); \textit{Wyeth}, 555 U.S. at 573 (declining to preempt failure to warn claims against a brand name drug manufacturer).
\textsuperscript{101} \textit{Wyeth}, 555 U.S. at 573.
\textsuperscript{102} \textit{PLIVA, Inc.}, 131 S. Ct. at 2581.
\textsuperscript{103} See generally \textit{Wyeth}, 555 U.S. 555.
being effected\textsuperscript{104} regulation in the FDCA permitted the brand name manufacturer unilaterally to strengthen its warnings. Thus, showing the FDA’s approval of the label was not sufficient to establish that the FDA would have prohibited a change to the label.\textsuperscript{105}

Comparatively, in 2011, the \textit{PLIVA} Court deemed a generic drug manufacturer not liable under a state law failure to warn cause of action.\textsuperscript{106} The \textit{PLIVA} Court stated that plaintiffs’ failure to warn state tort claims were preempted under the doctrine of impossibility preemption because the state law imposed a duty on the generic drug manufacturers to take actions that federal law barred them from taking.\textsuperscript{107} The Court reasoned, in part, that its impossibility preemption jurisprudence has held that the “stop-selling” rationale\textsuperscript{108} does not defeat impossibility.\textsuperscript{109}

As a result, leading up to the \textit{Bartlett} case, the Supreme Court’s interpretation of the FDCA imposed different federal drug labeling duties and liabilities on brand name and generic drug manufacturers.\textsuperscript{110} While a brand name drug manufacturer remained liable in tort for the accuracy and adequacy of its label, generic drug manufacturers immunized because their only responsibility was ensuring the warning labels of their drugs matched the brand name label.\textsuperscript{111}

\textsuperscript{104}“Changes being effected” are supplemental labeling change applications based on newly acquired information about an approved drug, which is to be implemented upon receipt by the FDA. See 21 C.F.R. \textsection\textsection 314 and 601, at 9 (Proposed Rule 2013), available at https://www.federalregister.gov/articles/2013/11/13/2013-26799/supplemental-applications-proposing-labeling-changes-for-approved-drugs-and-biological-products. See also infra Part V(a).

\textsuperscript{105}\textit{Wyeth}, 555 U.S. at 573.

\textsuperscript{106} See generally \textit{PLIVA, Inc.}, 131 S. Ct. 2567 (emphasis added).

\textsuperscript{107} \textit{PLIVA, Inc.}, 131 S. Ct. at 2581.

\textsuperscript{108} See \textit{Bartlett v. Mutual Pharm. Co.}, 678 F.3d 30, 37 (1st Cir. 2012), \textit{rev’d} 133 S. Ct. 2466 (2013) (explaining the “stop-selling” rationale as the theory that a manufacturer can comply with both federal and state regulations by withdrawing their product from the market).

\textsuperscript{109} \textit{Mutual Pharm. Co. v. Bartlett}, 131 S. Ct. 2466, 2477 (2013). However, as argued \textit{infra} in Part IV, the Court has improperly foreclosed the “stop-selling” rationale in the prescription drug industry.

\textsuperscript{110} \textit{PLIVA, Inc.}, 131 S. Ct. at 2574.

\textsuperscript{111} Id.
Part III: Mutual Pharm. Co. v. Bartlett

Statement of Case

In December of 2004, Plaintiff Karen Bartlett was prescribed a brand name prescription, Clinoril, which contained an FDA approved nonsteroidal anti-inflammatory pain reliever called “sulindac,” for shoulder pain. Bartlett’s pharmacist filled the prescription with an FDA approved generic form of the drug, manufactured by Defendant Mutual Pharmaceutical. In a small number of patients, certain classifications of prescription drugs, including sulindac, can cause toxic epidermal necrolysis and Stevens-Johnson syndrome, both of which are hypersensitivity skin reactions. However, when Ms. Bartlett was prescribed the drug, its label did not refer to either of these conditions, nor warn that it could cause “severe skin reactions” and/or “[f]atalities.” Ms. Bartlett subsequently developed acute toxic epidermal necrolysis affecting sixty to sixty-five percent of the surface of her skin. She suffered from skin deterioration and open wounds requiring her, among other things, to be placed in a medically induced coma. Ultimately, Ms. Bartlett was left severely disfigured, with numerous physical disabilities, and nearly blind. Subsequent to Ms. Bartlett’s suffering from this condition, the FDA reviewed Clinoril and recommended changes to its labeling to include a more explicit warning against toxic epidermal necrolysis, the precise condition from which Ms. Bartlett suffered.

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112 Mutual Pharm. Co., 133 S. Ct. at 2472.
113 Id.
114 These conditions are hypersensitivity skin reactions characterized by necrosis of the skin and mucous membranes. Id. at 2471-72.
115 Id.
116 Id. at 2472.
117 Id.
118 Id.
119 Id.
120 Id.
In attempting to recover from her serious and debilitating injuries, Ms. Bartlett filed a state law design-defect claim against the manufacturer of her generic prescription drug, Mutual Pharmaceutical.\(^{121}\) Ms. Bartlett filed suit pursuant to New Hampshire’s strict liability tort law, which states, in relevant 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” even though he “has exercised all possible care in the preparation and sale of the product.\(^{122}\)

The duty imposed on prescription drug manufacturers in accordance with this law could have been satisfied either by changing the drug’s design or by changing its label.\(^{123}\) However, as noted above, the FDA prohibits generic drug manufacturers like Mutual Pharmaceutical from changing a drug’s design.\(^{124}\) Therefore, compliance with state tort law like New Hampshire’s would require changing the drug’s labeling.\(^{125}\)

**Procedural History**

At the trial court level, in denying defendant’s motion for summary judgment, the District Court of New Hampshire specifically found that, “Mutual…had not been monitoring the medical literature for information about Sulindac’s safety risks [because] Mutual believed that the manufacturer of Clinoril, the brand-name version of the drug, was responsible for such monitoring.”\(^{126}\) As such, the case proceeded to trial, at the conclusion of which, a jury awarded Ms. Bartlett over $21 million in damages on her design-defect claim.\(^{127}\) The Court of Appeals affirmed, ruling that neither the FDCA nor the FDA’s regulations preempted the design-defect

\(^{121}\) *Mutual Pharm. Co.*, 133 S. Ct. at 2466.

\(^{122}\) *Id.* (citing RESTATEMENT OF TORTS (Second) § 402A, at 347-48).

\(^{123}\) *Id.* at 2474.

\(^{124}\) See 21 C.F.R. § 314.70(b)(2)(i); *Mutual Pharm. Co.*, 133 S. Ct. at 2468 (noting that once approved, manufacturers are prohibited from changing drugs’ active ingredients or specifications).

\(^{125}\) *Mutual Pharm. Co.*, 133 S. Ct. at 2474.


\(^{127}\) *Mutual Pharm. Co.*, 133 S. Ct. at 2472.
cause of action. This ruling relied in part on the “stop-selling” rationale, because generic drug manufacturers could comply with both federal and state laws by choosing not to make the drug at all. However, on appeal, the Supreme Court rejected this “stop-selling” rationale. Reasoning that preemption jurisprudence presumes that seeking to comply with federal and state law obligations does not require cessation altogether to avoid liability, the Supreme Court that held “it was impossible for Mutual to comply with both its state-law duty to strengthen the warnings on sulidac’s label and its federal-law duty not to alter sulindac’s label. Accordingly, the state law is pre-empted.” More generally, the Court held that state law tort claims which impose “a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling” would be deemed in conflict with federal law, thus prohibiting the unilateral alteration of drug composition and labeling.

Part IV: Analysis

(a) Consumers need an alternative to preemption of state law tort causes of action against generic drug manufacturers.

As noted, generic drug manufacturers dispense over seventy-five percent of all prescription drugs in the United States. Substitution laws, which authorize or require pharmacists to substitute a biosimilar – i.e. generic – prescription under certain conditions, may be contributing to this trend.

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128 Mutual Pharm. Co., 133 S. Ct. at 2477.
129 See Bartlett, 678 F.3d at 37 (explaining the “stop-selling” rationale as the theory that a manufacturer can comply with both federal and state regulations by withdrawing their product from the market).
130 Mutual Pharm. Co., 133 S. Ct. at 2477.
131 Id.
132 Id.
133 Id. at 2473.
134 Id. at 2479.
Currently, all states have generic substitution laws that at least permit, but may also require, generic substitution in certain circumstances.\(^\text{137}\) In those states with permissive substitution laws – including California – selection often is made pursuant to the pharmacist’s discretion.\(^\text{138}\) Although the laws require pharmacists to inform patients of substitutions,\(^\text{139}\) consumers’ actual ability to reject the substitution is illusory. This is because, pursuant to the laws, substitutions must either be the same cost to the consumer as the brand name drug or less expensive than the brand name drug.\(^\text{140}\) In addition, many health insurance providers do not provide comparable coverage of brand name drugs when a substitute is available.\(^\text{141}\) As a result, among those prescription drugs that now have a generic substitute available, ninety-nine percent of prescriptions are filled with generic substitutes.\(^\text{142}\) With this volume of generic drugs on the market, immunizing generic drug manufacturers by preempting state law tort causes of action is unconscionable. It undermines the legislative purpose of consumer safety by effectively eliminating substantial remedies for personal injuries suffered by consumers of generic drugs.

The prescription drug market’s uniqueness, as well as the extensive federal oversight in this industry, necessitates state legislation directed at imposing duties on generic drug manufacturers that align with or supplement the federal labeling regulations. In \textit{Bartlett}, the Supreme Court invited Congress to resolve the difficult preemption questions in the prescription drug industry.\(^\text{143}\)


\(^{138}\) \textit{E.g.}, S.B. 598(3-4), 2013 Leg., Assembly Health Comm. (Ca. 2013).

\(^{139}\) \textit{E.g.}, \textit{id.} at 598(6).

\(^{140}\) \textit{E.g.}, \textit{id.} at 598(4).

\(^{141}\) \textit{See generally} Steele, \textit{supra} note 26, at 462.


In considering whether to adopt an express preemption provision, the legislature should consider consumer protection, including the need to preserve remedial causes of action against generic prescription drug manufacturers, as well as the need for incentivizing innovation, research, and development in the prescription drug industry. In addition to a federal non-preemption clause, state law causes of action in tort against prescription drug manufacturers, should be revised to include a cap on recovery of non-economic damages.

(b) Bartlett was wrongly decided because the Supreme Court’s application of impossibility preemption improperly left Ms. Bartlett with no remedy.

The Supreme Court repeatedly has cautioned against construing federal statutes in such a way as would leave consumers without a remedy. However, that is precisely the result of the Bartlett decision. An innocent consumer who, by no choice of her own, suffered devastating injuries from a generic substitute prescription drug was left with no remedy. The Court primarily relied upon PLIVA to reach this conclusion. However, the PLIVA decision arose out of a failure to warn claim, not a strict liability design-defect claim, and its application to the Bartlett case, therefore, was erroneous.

The Bartlett Majority found plaintiff’s claim preempted under the impossibility doctrine, despite no finding of “conflicting affirmative legal obligations such that state law ‘require[s] the doing of an act which is unlawful under’ federal law.” Rather, in Bartlett, New Hampshire’s design-defect claim creates an incentive for manufacturers to change their products, including labels, to avoid tort liability. However, merely providing an incentive by imposing strict liability on manufacturers for defective drug design does not equate with the manufacturer being

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144 Mutual Pharm. Co., 133 S. Ct. at 2483-84.
145 See generally id. at 2466.
146 See generally id.
147 PLIVA, Inc., 131 S. Ct. 2567.
148 Mutual Pharm. Co., 133 S. Ct. at 2486 (Sotomayor, J., dissenting).
149 Id.
“actually required by state law to take…action.”\textsuperscript{150} Where state law requires no action other than to compensate consumers who suffer injury from an unreasonably dangerous drug, it cannot follow that such a law is preempted by impossibility preemption.\textsuperscript{151}

Critics have argued that impossibility preemption is beneficial in that it insulates drug manufacturers from liability caused by a physician’s negligence.\textsuperscript{152} Still further, that “upstream player[s] should never be held accountable for the mistakes of downstream players.”\textsuperscript{153} Rather, that liability should fall on the negligent physician, not the drug manufacturer.\textsuperscript{154} However, this argument misses the point. Courts should not construe federal regulations of drug labeling to limit consumer’s remedies, nor to leave them with no remedy whatsoever.\textsuperscript{155} Further, pursuant to the Federal Rules of Evidence, a plaintiff or attorney may bring a cause of action so long as they have a good faith belief that the claim is “warranted by existing law or by a non-frivolous argument for extending, modifying, or reversing existing law or for establishing new law.”\textsuperscript{156} The Rules do not prohibit the joinder of multiple parties or claims, and would not foreclose a lawsuit both under a negligence theory against the physician and under a strict liability theory against the drug manufacturer.\textsuperscript{157} As such, the drug manufacturer may file a cross-claim or third-party complaint against the negligent physician for contribution or indemnification.\textsuperscript{158} This alternative would more appropriately resolve any liability concern while preserving consumers’ potential remedies.

\textsuperscript{150} \textit{Mutual Pharm. Co.}, 133 S. Ct. at 2489 (Sotomayor, J., dissenting).
\textsuperscript{151} \textit{Id}.
\textsuperscript{152} Lisa M. Mottes, Comment, \textit{The Need for Federal Preemption of State Tort Claims in the Context of “New Drugs” and Premarket-Approved Medical Devices}, 41 SETON HALL L. REV. 723, 754 (2011).
\textsuperscript{153} \textit{Id.} at 758 (citing Richard A. Epstein, \textit{The Case for Field Preemption of State Laws in Drug Cases}, 103 NW. U. L. REV. 463, 471 (2009)).
\textsuperscript{154} Mottes, \textit{supra} note 152 at 759.
\textsuperscript{155} \textit{See generally Mutual Pharm. Co.}, 133 S. Ct. 2466 (Sotomayor, J., dissenting) (citations omitted).
\textsuperscript{156} \textit{Fed. R. Civ. P.} 11(c) (West 2013).
(c) Bartlett was wrongly decided because the Supreme Court should not have rejected the “stop-selling” rationale in the prescription drug industry.

Additionally, the Supreme Court’s must reexamine its broader application of impossibility preemption to generic prescription drug manufacturers. Under the circumstances presented in Mutual Pharmaceutical Co. v. Bartlett, a state tort suit against a generic drug manufacturer, the Supreme Court erroneously rejects the “stop-selling” rationale, which the First Circuit Court of Appeals relied upon in upholding the jury verdict in favor of Ms. Bartlett. The “stop-selling” rationale argues that the generic drug manufacturer can “choose not to make the drug at all[.]” Additionally, the Court of Appeals suggests that the FDCA may permit states to instruct generic manufacturers to remove their product from the market “if risk-benefit analysis weights against the drug, despite what the Supreme Court made of similar arguments in the labeling context.” As such the Court of Appeals properly concluded that the decision for a generic drug manufacturer to make and market its drug is wholly its own, and plaintiffs like Ms. Bartlett ought not be deprived of warning claims “by the mere chance of [their] drug store’s selection of a generic.”

In the prescription drug industry, the intent and purpose of federal regulation under the FDCA is to enhance consumer safety and protection in the manufacture and distribution of prescription drugs, both brand name and generic, while reducing consumer cost. Allowing generic drugs that are known to have hazardous side effects, regardless of how rare, to remain on the market while immunizing the manufacturers from liability is contrary to Congressional

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160 See Bartlett v. Mutual Pharm. Co., 678 F.3d 30, 37-38 (1st Cir. 2012), rev’d 133 S. Ct. 2466 (2013) (holding state law tort claim for design defect against a generic manufacturer not impossibility preempted and declining to extend PLIVA to design defect claims).
161 Id. at 37.
162 Id.
163 Id. at 38.
164 See Wyeth v. Levine, 555 U.S. 555, 574 (2009) (reasoning that state tort suits provide motivation for manufacturers to produce safe and effective drugs and provide adequate warnings).
intent. Specifically, it exposes consumers to an even greater risk of harm because there is no incentive or obligation for generic manufacturers to continue research or testing on the safety and effectiveness of the drugs they manufacture. Therefore, to accomplish Congress’ goals of consumer safety and prescription drug affordability, generic drug manufacturers must be held accountable to the same extent as brand name manufacturers if they choose to produce and distribute hazardous drugs. As applied to the prescription drug industry, the “stop-selling” rationale defeats impossibility preemption.

**Part V:**

(a) **The FDA’s proposed labeling changes**

The FDA has recognized the diminishing importance of requiring the same product labeling on brand name and generic prescription drugs. Indeed, that duty of sameness now conflicts with the need for generic drug manufacturers to be independently responsible for ensuring the accuracy and currency of its label. Accordingly, on November 13, 2013, the FDA released a proposal to amend its regulations to revise and clarify prescription drug labeling procedures. The amendment would create a new exception for generic drug labeling which allows generic drugs to have their labels temporarily to be inconsistent with the brand name drug label. This exception would arise out of safety-related concerns to allow the label to include stronger warnings about adverse side effects and reactions. More specifically, the amendment intends to allow generic drug manufacturers to distribute revised labeling on a temporary basis

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166 Id.
167 Id. at 8.
168 Id. at 6.
169 Id.
upon submission of a “changes being effected”\textsuperscript{170} (CBE-0) supplement, thus creating equivalent labeling standards between brand name and generic drugs.\textsuperscript{171} The proposed rule also intends to establish a dedicated Web page where the FDA would post information regarding any labeling changes pursuant to the CBE-0 supplement.\textsuperscript{172}

(b) The FDA’s proposed rule adequately addresses the problem of deficient labeling of prescription drugs.

Some concerns arise where the FDA permits the distribution of the same drug with a different label.\textsuperscript{173} For example, generic drug companies previously have argued that modifying the current labeling regulations “would create a chaotic situation in which several different labels exist[] for the same drug.”\textsuperscript{174} However, the generic drug companies are those that the proposed rule could adversely affect. Therefore, this argument lacks merit because it is merely self-serving and intended to diminish – even eliminate – generic drug manufacturers’ accountability for their products. Regardless, the proposed rule has already accounted for this by stating that it merely allows for temporary differences between the brand name drug label and the generic drug label.\textsuperscript{175} Other safeguards, including the proposed comprehensive website containing updated labeling information and warnings, may also help alleviate generic drug companies’ concern

\textsuperscript{170} “Changes being effected” are supplemental labeling change applications based on newly acquired information about an approved drug, which is to be implemented upon receipt by the FDA. See 21 C.F.R. §§ 314 and 601, at 9 (Proposed Rule 2013), available at https://www.federalregister.gov/articles/2013/11/13/2013-26799/supplemental-applications-proposing-labeling-changes-for-approved-drugs-and-biological-products. CBE-0 supplements may include the following labeling changes: to add or strength a contraindication, warning, precaution, or adverse reaction, to add or strengthen a statement about drug abuse, dependence, psychological effect, or over-dosage, to add or strengthen an instruction about dosage and administration intended to increase safe usage, to delete false, misleading, or unsupported indications for use or claims for effectiveness, or any other change requiring a supplemental submission and approval. \textit{Id.} at 9-10.

\textsuperscript{171} \textit{Id.} at 1.

\textsuperscript{172} \textit{Id.}

\textsuperscript{173} See generally \textit{id.} at 35.


about having different labels on the same drug. Still further, the FDA has determined that the 
public health benefit of allowing all drug manufacturers independently to update their labeling to 
reflect safety issues outweighs any such concerns.176

The proposed rule provides the important public health benefit of improving 
communication of important drug safety information to physicians and the public.177 The FDA 
anticipates that “[t]his proposal will help ensure that health care professionals and consumers 
have access to the latest safety information for the medications they use.”178 In addition, it 
would reduce the time in which generic drug manufacturers make safety-related changes to their 
drug labels.

(c) The FDA’s proposed rule fails to address adequately the problem of immunizing 
generic drug manufacturers from state tort liability.

Despite the foregoing, the proposed rule fails to address the problem of immunizing 
generic drug manufacturers from state law tort claims. First, it is unlikely that the FDA can 
manage any of the additional burden that the proposed rule intends to place on it. Specifically, 
the FDA “estimates the net annual social costs [of the proposed rule] to be between $4,237 and 
$25,852” to review CBE-0 supplements.179 However, the agency already is overextended.180 As 
recently as 2008, the FDA faced inadequacies, which threatened to prevent it from fulfilling its 
mission181 without substantial and sustained additional appropriations.182 Further, according to 
the Institute of Medicine, the FDA “lacks the resources needed to accomplish its…mission

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https://www.federalregister.gov/articles/2013/11/13/2013-26799/supplemental-applications-proposing-labeling- 
changes-for-approved-drugs-and-biological-products.
177 Id. at 39.
178 U.S. Food and Drug Admin., FDA takes action to speed safety information updates on generic drugs (Nov. 8, 
https://www.federalregister.gov/articles/2013/11/13/2013-26799/supplemental-applications-proposing-labeling- 
changes-for-approved-drugs-and-biological-products.
180 See generally, Mottes, supra note 152, at 751.
181 The mission of the FDA is to protect the public and ensure safety and efficacy. Id.
182 Mottes, supra note 152, at 751.
today, let alone to position itself for an increasingly challenging future.\textsuperscript{183} Based on these authorities, placing any additional burden on the FDA to oversee CBE-0 applications should be avoided.\textsuperscript{184}

Second, the proposed rule states that, if adopted, the regulatory change “\textit{may} eliminate the preemption of certain failure-to-warn claims with respect to generic drugs.”\textsuperscript{185} However, this speculative language fails to resolve the issue of immunizing generic drug manufacturers from state tort liability for consumer injuries. Rather, it would require courts to conduct fact-intensive assessments in state law tort claims to determine whether federal law, in fact, preempts the plaintiff’s claim. Additionally, it fails to provide any standard for courts uniformly to apply preemption. How is a plaintiff, an attorney, or even a trial judge supposed to know whether a consumer’s allegations constitute a viable cause of action against a generic drug manufacturer? To avoid continued speculation, the rule should contain an express non-preemption provision related to state law tort claims against prescription drug manufacturers, both brand name and generic.

Michael Johnson, counsel for plaintiff Gladys Mensing in \textit{PLIVA, Inc. v. Mensing}, appropriately comments that “[i]t is a first step toward acknowledging that there is a problem with the current system. It doesn’t make sense to have one set of rules for the name brand and another set of rules for the generics.”\textsuperscript{186}

\textsuperscript{183} Mottes, \textit{supra} note 152, at 751.
\textsuperscript{184} The proposed solution of adding a non-express preemption clause and capping non-economic damages contained in this article would not place any additional burden on the FDA.
\textsuperscript{186} Thomas, \textit{supra} note 174.
(d) The FDA should include a cap on non-economic damage recovery for claims against generic drug manufacturers

In order to meet the legislative goals of maintaining low cost prescriptions, the FDA should include a cap on non-economic damages arising out of tort claims against generic drug manufacturers. This effectively would preserve a remedy for consumers who suffer injuries resulting from inadequate warnings and design defects. The legislative may look to California’s Medical Injury Compensation Reform Act of 1975 (‘MICRA’).\textsuperscript{187} The purpose of MICRA is “to reduce the cost of medical malpractice litigation, and thereby restrain the increase in medical malpractice insurance premiums.”\textsuperscript{188} Here, the goal of placing a similar cap on recovery of non-economic damages for claims against generic drug manufacturers would also reduce litigation costs and help to restrain rising prescription drug costs.\textsuperscript{189}

However, the legislature should revisit and adjust the non-economic damages cap periodically to account for inflation. According to one group of experts in health law and empirical legal research:\textsuperscript{190}

[A] dollar value should…represent a societal judgment about what constitutes reasonable but not excessive compensation for noneconomic loss. That judgment is made at a particular point in time; however, the value of dollars decreases over time. If the social-valuation judgment is to have any enduring meaning, the cap should at least be adjusted annually for inflation in order to maintain its real value.\textsuperscript{191}

\begin{footnotesize}
\textsuperscript{187} MICRA is a statutory limitation on noneconomic losses in actions for injury against health care providers arising out of negligence. \textit{CAL. CIV. CODE} § 3333.2 (West 2013). Specifically, the statute states, in relevant part: “In no action shall the amount of damages for noneconomic losses exceed two hundred fifty thousand dollars ($250,000).” \textit{Id.} at § 3333.2(b).

\textsuperscript{188} Fein v. Permanente Medical Group, 695 P.2d 665 (Cal. 1985).

\textsuperscript{189} See infra Part VI for a more in depth discussion of the benefits of this proposed limitation on non-economic damages.


\textsuperscript{191} \textit{Id.} at 64.
\end{footnotesize}
The MICRA cap is not adjusted for inflation.\textsuperscript{192} That $250,000 cap, “adjusted annually by the Consumer Price Index[,]” would now exceed $1,052,250.\textsuperscript{193} To avoid a similar inequity for a non-economic damages cap in the prescription drug industry, the legislature should include a provision in the regulation to revisit and revise the cap on an annual basis to account for inflation.\textsuperscript{194}

**Part VI: Conclusion**

The *Bartlett* Court’s reasoning “has the ‘perverse effect’ of granting broad immunity ‘to an entire industry that, in the judgment of Congress, needed more stringent regulation.'”\textsuperscript{195} This immunity applies squarely to generic prescription drug manufacturers. Consumer choice in the prescriptions drug industry has been and continues to be narrowed due to the price disparity between brand name and generic drugs as well as insurance coverage of brand name compared to generic drugs. The continued growth of generic drug usage\textsuperscript{196} demands Congressional action to further the intent of the FDA and to protect consumers. Resolving the disparity between brand name and generic prescription drug manufacturers’ duties with respect drug labeling would be best accomplished by: (1) an express non-preemption provision at the federal level and (2) a cap on recovery of non-economic damages on state tort law claims against generic prescription drug manufacturers.

For example, a new statute might read as follows:

**General Rule:**

(a) Nothing in these regulations should be construed to preempt, expressly or impliedly, more restrictive state or local regulations or requirements

\textsuperscript{192} Studdert, supra note 190, at 63-64.

\textsuperscript{193} See, e.g., id. at 64 (citing The Inflation Calculator, http://www.westegg.com/inflation/ (last visiting Feb. 5 2011).\textsuperscript{194} See infra Part VI for a sample provision in proposed legislation.


\textsuperscript{196} See Steele, supra note 26, at 460-62.
governing generic drug manufacturers or other abbreviated new drug application holders, as that term is defined in C.F.R. § 355(j); and

(b) In no action for personal injuries against prescriptions drug manufacturers or other abbreviated new drug application holders, as that term is defined in C.F.R. § 355(j), shall the amount of damages for non-economic losses exceed five hundred thousand dollars ($500,000).

(i) Five hundred thousand dollars ($500,000) should be calculated as the present value at the time the cause of action arises. Present value means the adjusted value based on inflation since the date of enactment of this rule.

Combined with the language of the FDA’s Proposed Rule, an express non-preemption clause will effectively preserve consumer remedies against generic drug manufacturers. Specifically, such a clause will extend the holding of Wyeth v. Levine to all prescription drug manufacturers, brand name and generic.

Like opponents to MICRA, brand name drug manufacturers might attempt to attack the validity of such a statute under the Equal Protection Clause of the United States Constitution. Such a claim arises where the government burdens or benefits certain persons or entities and declines to burden or benefit other persons or entities which are similarly situated. Arguably, under this statute, generic drug manufacturers or ANDA holders may receive the benefit of a limitation on liability while brand name drug manufacturers remain liable to the fullest extent. However, such a distinction must only pass rational basis review requiring a legitimate

198 See CAL. CIV. CODE § 3333.2(b) (West 2013).
199 Wyeth v. Levine, 555 U.S. 555, 573 (2009) (holding brand name manufacturer liable in tort for consumer injuries because it could rely on the FDA “changes being effected” provision to preemptively strengthen its warning label).
200 U.S. CONST. amend. XIV, § 1.
government interest and that a rational person would think the law or policy, in some way, furthers that conceivable legitimate interest. In the prescription drug industry, a major thrust of the generic drug market is to encourage production of lower cost prescriptions. As such, opponents must concede that lower prescription drug costs is a legitimate government interest and that, like in the context of medical malpractice claims, it is rational to believe such a law or policy furthers that legitimate interest.

Alternatively, opponents may argue that such a statute will increase the number of lawsuits filed. However, this argument arguably is without merit. In the past, Congress has passed legislation containing fee-shifting provisions and/or attorney fee provisions aimed at creating an incentive to file more claims. Comparatively, the FDA’s proposed legislation discussed herein does not contain an attorney’s fees provision. Therefore, there is no additional incentive to file more claims against generic drug manufacturers. Still further, the applicable court rules continue to restrict the claims filed to non-frivolous ones. An express non-preemption clause also effectively holds plaintiffs to a higher burden in proving claims for strict liability, thus adding an additional disincentive to filing additional claims against generic drug manufacturers. Finally, adopting an express non-preemption clause furthers the legislative

See Hoffman v. U.S., 767 F.2d 1431 (9th Cir. 1985) (holding MICRA passed rational basis review because there was a legitimate government interest in reducing malpractice insurance premiums and it was reasonable that limiting noneconomic damages would achieve that legitimate interest).

See id.

See Fein v. Permanente Medical Group, 695 P.2d 665 (Cal. 1985) (holding that the MICRA limitation on liability responded to a legitimate purpose of responding to insurance crisis and did not violate equal protection); Flores v. Natividad Medical Center, 192 Cal. App. 3d 1106 (1987) (holding that MICRA does not violate equal protection guarantees).


See e.g., 42 U.S.C. § 1988; CAL. WELF & INST. CODE §§ 15657 and 15657.5 (West 2013).

See CAL. CIV. CODE § 3333.2 (West 2013).

See, e.g., FED. R. CIV. PROC. 11(c) (West 2013).

E.g., RESTATEMENT (SECOND) OF TORTS § 402A (1965) (requiring the sale of products in defective conditions unreasonably dangers to consumers or property to be liable for physical harm caused by a design defect).
intent of having state tort law supplement federal regulations on prescriptions drugs to enhance consumer safety. Overall, the legislation proposed herein intends to hold generic prescription drug manufacturers accountable while counterbalancing any potential appeal of filing additional, or non-meritorious, lawsuits with disincentives to allay opponents’ concerns.

For the foregoing reasons, FDA should revise its proposed rule to include the statutory provisions suggested herein. Doing so would eliminate the disparity that has arisen between duties imposed on brand name drug manufacturers as compared to generic drug manufacturers and continue to hold generic drug manufacturers accountable for the drugs they market.