Innovator Liability: Restoring Symmetrical Rights to Consumers of Generic Drugs

Stanford L Moore
TABLE OF CONTENTS

I. INTRODUCTION ................................................................. 3

II. REGULATION OF BRAND-NAME AND GENERIC DRUGS .......... 7
   A. Brand-Name Drugs ....................................................... 8
   B. Generic Drugs ......................................................... 9

III. ASYMMETRICAL PHARMACEUTICAL CUSTOMER RIGHTS ..... 10
   A. Consumers of Brand-Name Drugs Can State Viable Failure-
      to-Warn Claims ....................................................... 11
   B. Consumer of Generic Drugs Cannot State Viable Failure-to-
      Warn Claims ......................................................... 12
      1. The Law Shields GDMs From Liability ......................... 12
      2. The Majority of Jurisdictions Insulate BNMs ............... 17

IV. FAILURE-TO-WARN CLAIMS ARE NECESSARY ............... 18
   A. Redress .................................................................. 18
   B. Deterrence ................................................................ 19

V. INNOVATOR LIABILITY ..................................................... 21
   A. BNMs Owe a Duty to Consumers of Generic Drugs ........... 22
      1. Duty ..................................................................... 22
      2. Standard of Conduct ............................................... 23
   B. Counter Arguments .................................................... 26
      1. Duty ..................................................................... 26
      2. Common Law Post-Mensing Permits Innovator Liability .... 28
   C. Conte and Its Progeny .................................................. 31
      1. Conte v. Wyeth ....................................................... 31
      2. Kellogg v. Wyeth ................................................... 33
      3. Weeks v. Wyeth ..................................................... 34
   D. Courts Should Continue to Reevaluate Innovator Liability ... 35
      1. Sustained Development of New Drugs ......................... 36
      2. Innovator Liability Would not Prejudice the BNM .......... 37
      3. Uniformity of the Label ............................................ 37

VI. CONCLUSION ................................................................. 38
“[A] drug consumer’s right to compensation for inadequate warnings . . . turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic . . . leads to so many absurd consequences.”

I. INTRODUCTION

Although an overwhelming amount of research from 1989-1992 began to show that the drug Reglan and the generic version metoclopramide caused tardive dyskinesia, a severe side effect, it was not until two decades later that drug manufacturers issued a proper warning label. This warning was too late for Gladys Mensing. In September of 2005, following her continuous use of

---

2 Tardive dyskinesia is a permanent disfiguring neurological movement disorder. It causes uncontrollable, repetitive movements of the body such as lip smacking, grimacing, tongue protrusion, puckering and pursing of the lips, rapid eye movements or blinking, and rapid movements of the fingers, arms, legs, and trunk. [http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm142815.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm142815.htm) (last visited Mar. 15, 2013).
[http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm142815.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm142815.htm). In February 2009, after Mensing initiated her lawsuit, the Food and Drug Administration (“FDA”) warned against the long-term use of metoclopramide. The FDA is the federal agency charged with “protect[ing] the public health by ensuring that human . . . drugs are safe and effective.” 21 U.S.C. § 393(b)(2)(B). The FDA warned that research has linked frequent and long-term use to development of tardive dyskinesia.
4 Mensing v. PLIVA, Inc., 2008 WL 5707474 (C.A.8) opening brief. That warning was also insufficient because the “labels for Reglan and generic metoclopramide repeatedly assert that . . . tardive dyskinesia [is] quite rare. The “Clinical Pharmacology”
metoclopramide for four years, a neurologist diagnosed Mensing with tardive dyskinesia caused by her long-term use of metoclopramide.

Mensing sued the manufacturer, but because the pharmacist filled her prescription with a generic drug instead of a brand-name drug, the law did not allow her an opportunity to seek a remedy. In *PLIVA v. Mensing*, the Supreme Court held that federal law, specifically the Food, Drug, and Cosmetic Act (the “FDCA”), preempted Mensing’s state-tort-law failure-to-warn claim. If the section of the label stated: “[M]etoclopramide . . . may produce [movement disorder] symptoms, although these are comparatively rare (See WARNINGS).” Id. The “Warnings” section only stated that tardive dyskinesia “may develop in patients treated with metoclopramide.”

http://www.accessdata.fda.gov/drugsatfda_docs/label/2004/17854s047lbl.pdf @ 7. The label also included the words, “[b]oth the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase with the duration of treatment and the total cumulative dose.” Id. at 7.


6 Id.

7 PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2571 (2011) reh'g denied, 132 S. Ct. 55 (2011). The GDM has “another route, and that's what the government is telling us: That you could propose a revision of the label, and if you did that, then you would be home free. You would not be subject to the State suit.” If the generic-drug manufacturer (“GDM”) had strengthened the warning label, Mensing would not have sued. Mensing Oral Transcript 5:9, http://www.supremecourt.gov/oral_arguments/argument_transcripts/09-993.pdf (last visited Mar. 15, 2013).


9 “This Constitution, and the Laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land.” US Constitution 6th Amendment.

10 A manufacturer is liable for a failure-to-warn claim when its product-warning label is inadequate. However, the label does not have to disclose all apparent dangers.
federal law preempts state law, then the state law disappears. Accordingly, any wrongdoing on the part of the manufacturer that the preempted state law governed becomes irrelevant. Moreover, preemption removes the issue from the province of the jury.

If the pharmacist had filled Mensing’s prescription with the brand-name drug, then the law would not have limited her ability to seek a remedy.11 This decision affects not only Mensing and other consumers who take metoclopramide but also any user of any generic drug. Important among the many implications of Mensing is the fact that it denies a broad class of consumers a right to redress.12 Pharmacists fill approximately eighty percent of prescriptions with generic drugs.13 Furthermore, all states have laws that allow pharmacists to substitute a generic drug for a brand-name drug even if the physician prescribes the brand-name drug.14

---


Mensing insulates a GDM from future failure-to-warn claims. This decision creates a problem because state-tort-law claims incentivize drug manufacturers to act reasonably.\textsuperscript{15} Accordingly, if the law insulates a broad class of consumers from stating a viable claim against drug manufacturers, then it is a detriment to society. Pharmaceuticals (whether generic or brand-name) cause side effects, and complications from those side-effects are a leading cause of physical harm and death.\textsuperscript{16} In all jurisdictions, post-Mensing, a consumer of generic drugs cannot sue the GDM because the FDCA preempts their claim. This note argues that the courts should reevaluate innovator liability as a means to redress this unjust result.\textsuperscript{17}

Innovator liability allows consumers of generic drugs to state a viable negligence claim against the BNM by expanding the duty of the BNM to include consumers of the generic drug. It introduces a reasonableness element and maintains a uniform

---

\textsuperscript{15} [[[These suits complement, they're not at odds with, the Federal regime, because they give the manufacturers an incentive to come forward.” Mensing Oral Arg. Trans. 11:22, \url{http://www.supremecourt.gov/oral_arguments/argument_transcripts/09-993.pdf} (last visited Mar. 13, 2013).]]

\textsuperscript{16} As many as 106,000 deaths per year in America result from adverse effects of medication absent medical error in administration. See Barbara Starfield, Is US Health Really the Best in the World? 284 JAMA 483, 484 (2000).

\textsuperscript{17} “[E]ach person is to have an equal right to the most extensive basic liberty compatible with a similar liberty for others.” John Rawls, A Theory of Justice, Chapter 2, Section 11. This note advocates a state-common-law solution to the problem because a legislative one has less than a 1% chance of passing Congress, chiefly due to the power of the pharmaceuticals’ lobbyist.
warning label that must appear on the brand-name drug and all generic equivalents of a drug. Innovator liability would require a sufficient warning label for both the reference and the GDM’s equivalent drug. This solution plausible because the brand-name-drug manufacturer (“BNM”) creates the warning label on its drug (the “reference”) and the GDM must copy it exactly.\textsuperscript{18}

This note argues that the pharmacist’s selection of a generic rather than a brand-name drug should not affect the availability of remedies. Section II of this note provides the background information necessary to understand the note’s thesis. Section III explores the gap in liability that Mensing created. Section IV expands on the assertion made in the introduction that state-tort-law claims are important not only to provide redress to injured consumers but also to incentivize the manufacturer to act reasonably. Section V advances the proposed solution, innovator liability, and discusses why it will work well.\textsuperscript{19}

II. REGULATION OF BRAND-NAME AND GENERIC DRUGS

The use of all pharmaceuticals carries a risk.\textsuperscript{20} The FDA's mission is to reduce that risk to a tolerable level, resulting in a drug that is safe and effective.\textsuperscript{21} The FDA is the government agency that

\textsuperscript{19} Innovator liability is the concept that expands the duty of the BNM to include a GDM's consumers. The concept does not cause the BNM to be automatically liable; it only unlocks the door. The fact-finder holds the key to the door.
\textsuperscript{20} There are several types of drugs; the focus of the note is generic drugs. Each type is subject to its own body of regulations.
\textsuperscript{21} PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2574 (2011).
regulates the pharmaceuticals industry; the FDCA is the collective body of statutes that empowers the FDA to accomplish its mission. The FDA must approve any drug before a manufacturer may market it. There are different classes of drugs—brand name, generic, and over-the-counter drugs. Over-the-counter drugs are outside the scope of this note.

A. Brand-Name Drugs

A brand-name drug is a new drug that enjoys patent protection. The BNM proposes and maintains the warning label for a drug (both the reference and the generic) to the FDA. The FDA must approve that label based on evidence that the BNM provides relating to the drug’s safety and efficacy. The FDCA obligates the BNM to police any side effects of its drugs. Upon

---

22 Id.
23 Id.
24 If a manufacturer desires to introduce a new drug into the market place, the manufacturer must file either a new drug application or an abbreviated new drug application with the FDA. If the drug is new, the manufacturer must comply with the more stringent NDA. This application can be time consuming and costly. D. Beers, Generic and Innovator Drugs: A Guide to FDA Approval Requirements § 2.02[A] (7th ed.2008) (discussing the cost and how long it takes). Once a drug has undergone the NDA process, typically its generic equivalent may be eligible for a more relaxed application, the ANDA. The application of the BNM, the drug’s innovator, is contingent upon FDA approval.
25 A new drug is one that qualified experts have not yet recognized as safe and effective for its intended use. 21 USCS § 321(p)(1).
26 A patent, which can last up to 25 years from the date of the patent application, is a legal monopoly, which gives the manufacturer a time-limited right to exclude competitors from the market. http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm.
29 Id.
sufficient evidence, the BNM may strengthen the warning label without the consent of the FDA.\textsuperscript{30} The FDCA obliges the BNM to strengthen the warning label that a drug—both a brand-name drug and its generic equivalent—must use.\textsuperscript{31}

B. Generic Drugs

After a brand-name drug’s patent expires,\textsuperscript{32} a GDM may apply to the FDA to produce a generic drug;\textsuperscript{33} the generic drug must have the “same” warning label and active ingredients as its reference.\textsuperscript{34} However, unlike the BNM, the GDM is not obligated to strengthen its warning label; the FDCA only obligates it to report side effects periodically to the FDA.\textsuperscript{35} The FDA negotiates any necessary change to the warning label with the BNM.\textsuperscript{36} A GDM cannot change its label without permission from the FDA.\textsuperscript{37}

The Hatch-Waxman Act (“HW Act”) is an amendment to the FDCA that regulates generic drugs.\textsuperscript{38} The HW Act allowed GDMs

\begin{itemize}
\item \textsuperscript{30} \textit{Id.}
\item \textsuperscript{31} \textit{Id.}
\item \textsuperscript{32} Normally, a patent last 20 years. Martin A. Ramey, Conte v. Wyeth: Caveat Innovator and the Case for Perpetual Liability in Drug Labeling, 4 \textsc{Pitt. J. Envtl. Pub. Health} L. 73, 91 (2010). However, pharmaceutical patents may last for up to 25 years. The FDA publishes a list of drugs eligible for a GDM to produce. 21 C.F.R. 314.92(b).
\item \textsuperscript{33} \url{http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm}.
\item \textsuperscript{34} The drug achieves its intended therapeutic effect with active ingredients. Inactive ingredients in the generic drug may vary, but the HW Act requires a generic drug to have the same active ingredients, dosage form, strength, route of administration, and bioequivalence as its reference. 21 U.S.C 355(j)(2)(A)(ii), (iii), and (iv); 21 C.F.R. § 314.92(a)(1).
\item \textsuperscript{35} PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2571 (2011).
\item \textsuperscript{36} \textit{Id.}
\item \textsuperscript{37} \textit{Id.}
\item \textsuperscript{38} The HW Act established a new standard of approval. The original body of rules, the FDCA, required generic drugs to undergo the same testing as a brand-name drug.
\end{itemize}
to provide consumers with cheaper drugs by relieving them of the obligation to complete the expensive independent safety and efficacy testing that a BNM must complete. The HW Act allows a GDM to market its product after the FDA approves the application, and does not obligate a GDM to strengthen a drug’s warning label upon sufficient evidence. This duty is the obligation of the BNM.

After the HW Act, the generic drug business became a flourishing market, which continues to prosper today.

III. ASYMMETRICAL PHARMACEUTICAL CUSTOMER RIGHTS

Intuitively, consumers of generic drugs assume that they possess the same rights to redress as consumers of the reference. This assumption, however, is a fallacy. Sections A and B highlight the status quo of the law. Section A establishes that BNMs are accountable to consumers of their products. Section B establishes that GDMs are not accountable to consumers for their products. The

---


---

42 The generic must be the “same” as the reference drug. Id.
current law prevents consumers of generic drugs from suing either the GDM or the BNM.

A. Consumers of Brand-Name Drugs Can State Viable Failure-to-Warn Claims

The law does not limit the availability of remedies to a consumer of brand-name drugs. Before the Supreme Court decided Mensing, it held that consumers of brand-name drugs might state a viable claim against a BNM. In Levine v. Wyeth, a majority of the Supreme Court held that federal law, specifically the FDCA, does not preempt the consumer of a brand-name drug’s failure-to-warn claim against a BNM.43

In Supreme Court jurisprudence, the hint that a consumer in the future may not be able to state a viable failure-to-warn claim against a pharmaceutical manufacturer appeared in the dissent of

43 In Levine v. Wyeth, Diana Levine sought treatment from a hospital for a migraine headache. Levine v. Wyeth, 2006 VT 107, 183 Vt. 76, 82, 944 A.2d 179, 182 (2006) aff’d, 555 U.S. 555 (2009). During the hospital visit a staff member improperly administered Phenergan, a brand-name drug used to treat nausea, into Levine’s artery. Id. (The drug was supposed to go in the vein.) A generic drug is available. Id. The incorrect administration of Phenergan caused Levine to have a reaction that resulted in her forearm being amputated. Id. Levine sued Wyeth. Id. She alleged that Wyeth had inadequately labeled the drug. “Levine alleged that the labeling was defective because it failed to instruct clinicians to use the IV-drip method of intravenous administration instead of the higher risk IV-push method. More broadly, she alleged that Phenergan is not reasonably safe for intravenous administration because the foreseeable risks of gangrene and loss of limb are great in relation to the drug’s therapeutic benefits.” Wyeth v. Levine, 555 U.S. 555, 560 (2009). The FDA mandated that Phenergan’s label disclose, “INADVERTENT INTRA–ARTERIAL INJECTION CAN RESULT IN GANCRENE OF THE AFFECTED EXTREMITY.” Id. (noting that “[u]nfortunately, the physician’s assistant who treated respondent in this case disregarded Phenergan’s label and pushed the drug into the single spot on her arm that is most likely to cause an inadvertent intra-arterial injection.”) Id. After trial, the jury issued a verdict for Levine. Id. Wyeth unsuccessfully appealed to the Supreme Court, alleging that the FDCA preempted Levine’s state-tort-law failure-to-warn claim against a BNM. Levine v. Wyeth, 944 A.2d 179, 184 (2006) aff’d, 555 U.S. 555 (2009). The Court held that the FDCA did not preempt Levine’s failure-to-warn claim against the BNM.
The dissenters introduced their opinion with the maxim that tragic facts make bad law, and then avowed a discriminatory view—that the law should not allow juries to regulate warning labels for prescription drugs because the FDA is responsible for that task. It was the dissenter’s argument that the Court applied in PLIVA v. Mensing.

B. Consumer of Generic Drugs Cannot State Viable Failure-to-Warn Claims

1. The Law Shields GDMs From Liability

In PLIVA v. Mensing, the Court used preemption as a mechanism to remove the issue from the province of a jury. In a 5-4 decision split along political party lines, the Supreme Court insulated the GDM from liability. In 2001, Gladys Mensing's

45 In the dissenters’ view, it is irrelevant whether the patient took a brand-name or a generic drug; no patients should be able to bring a state-tort-law claim against any pharmaceuticals manufacturer. Wyeth v. Levine, 555 U.S. 555 (2009) (Justice Alito, with whom THE CHIEF JUSTICE and Justice SCALIA join, dissenting).
48 Id.
51 PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2581 (2011).
physician prescribed her Reglan, a brand-name drug that increases the motility of the digestive system. The pharmacist, however, filled her prescription with the generic form of Reglan, metoclopramide. Mensing took metoclopramide for several years and subsequently developed a side effect, tardive dyskinesia—a severe neurologic disorder. When Mensing took metoclopramide, the label did not warn against tardive dyskinesia, although there was mounting evidence that long-term use of the drug caused tardive dyskinesia.

Mensing sued the GDM, alleging that the GDM failed to provide an adequate warning label. During litigation, the GDM persuaded the trial court that the FDCA preempted Mensing’s failure-to-warn claim. Thus, Mensing could not state a viable failure-to-warn claim against the GDM. Subsequently, Mensing

---

52 Id.
53 Id.
54 Id.; See note 2.
55 Id. (29% of patients who took the drug for several years developed tardive dyskinesia); Shaffer, Butterfield, Pamer, & Mackey, Tardive Dyskinesia Risks and Metoclopramide Use Before and After U.S. Market Withdrawal of Cisapride, 44 J. Am. Pharmacists Assn. 661, 663 (2004) (noting 87 cases of metoclopramide-related tardive dyskinesia reported to the FDA’s adverse event reporting system by mid-2003).
56 “[T]ort law requires a drug manufacturer that is or should be aware of its product’s danger to label that product in a way that renders it reasonably safe.” PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2573 (2011).
57 Mensing v. Wyeth, Inc., 562 F. Supp. 2d 1056, 1066 (D. Minn. 2008) rev’d, 588 F.3d 603 (8th Cir. 2009) rev’d sub nom. PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (U.S. 2011) and opinion vacated in part, reinstated in part, 658 F.3d 867 (8th Cir. 2011). “Pliva’s Motion to Dismiss is GRANTED.”
appealed to the United States Court of Appeals; however, the Supreme Court concluded that the trial court was correct.

The Court found that it was impossible for the GDM to comply with federal and state law. State law imposed a duty on the GDM to strengthen the warning label. Federal law did not impose that duty. Moreover, a GDM cannot change its label without permission from the FDA; therefore, it is possible that a failure-to-warn claim would require the GDM to change the label when it could not do so.

The GDM argued that a preamble to the HW Act stated that given sufficient evidence that a stronger warning label is necessary, GDMs “should,” request that the FDA change the label not “shall,” or “must,” request that the FDA change the label. Therefore, the GDM did not believe it had an obligation to request that the FDA

---

58 Mensing v. Wyeth, Inc., 588 F.3d 603, 614 (8th Cir. 2009) rev’d sub nom. PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (U.S. 2011) and opinion vacated in part, reinstated in part, 658 F.3d 867 (8th Cir. 2011) “Mensing has stated a viable claim against the generic metoclopramide manufacturers.”
59 PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2572 (2011). “The question presented is whether federal drug regulations applicable to [GDMs] directly conflict with, and thus pre-empt, these state-law claims. We hold that they do.”
60 Id.
61 Id.
62 Id.
63 Id.
64 Id. at 2576; “If a [GDM] believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised” (emphasis added) U.S. Brief 20; 57 Fed.Reg. 17961, Mensing Oral Tr 19:12, http://www.supremecourt.gov/oral_arguments/argument_transcripts/09-993.pdf (last visited Mar. 13, 2013); PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2576 (2011); U.S. Brief 20; (“If a [GDM] believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised”) (emphasis added) 57 Fed.Reg. 17961.
change warning labels upon receipt of negative information. The Supreme Court concluded, “the only action the manufacturers could independently take—asking for the FDA’s help—is not a matter of state-law concern.” The GDM could have lobbied the FDA to strengthen the warning label; however, the Supreme Court did not understand the word “should” as compulsory because it was in a preamble to the HW Act that had not been through notice and rulemaking procedures.

The majority noted that this outcome “makes little sense,” and the dissent acknowledged that the “decision leads to so many absurd consequences.” Nevertheless, the majority concluded that Congress intended to deprive consumers of a remedy for successful failure-to-warn claims. Although legislative intent is not dispositive, Mensing contradicts the express intentions of the co-author of the HW Act, Henry Waxman. He stated that Congress

---

66 PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2581 (2011); Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341 (2001) (holding that the FDCA preempts state law that meddles in communication between the manufacture and the FDA.). The plaintiffs did not base their claims on failure to communicate with the FDA, and even if they had, the FDCA preempts claims based on failure to communicate with the FDA. Id. (holding that federal drug and medical device laws pre-empted a state tort-law claim based on failure to communicate properly with the FDA). The court reasoned that the fraud on the FDA claims conflicts with the police powers of the FDA, and “the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and the Administration uses this authority to achieve a delicate balance of statutory objectives that can be skewed by allowing state-law fraud-on-the-FDA claims.” Id.
69 Id.
70 Id.
intended state-law failure-to-warn claims to be viable against GDMs because failure-to-warn claims are consistent with the purpose of the HW Act. Moreover, examination of the legislative history does not indicate that any member of Congress intended to deny consumers the ability to seek relief for failure-to-warn claims.

In the Mensing decision, the majority was concerned that exposure to litigation would indirectly increase the price of generic drugs. The Court decided that the potential for an increase in drug prices would impede the Congressional purpose of the HW Act—to make low-cost safe drugs available to the public. The Court was also concerned that imposing a labeling requirement on the GDM would increase its administrative costs, which would also contradict the purpose of the HW Act.

The Supreme Court’s unclear rationale has exacerbated the problem because lower courts have relied on it to delete other claims against GDMs. GDMs have celebrated this result; however,

---

74 Id.
75 Id.
76 Id.
77 In Bartlett v. Mutual Pharmaceutical, 678 F.3d 30 (1st Cir. 2012) cert. granted, 133 S. Ct. 694 (2012), the GDM argues that the FDCA preempts defect design claims under Mensing. Preemption of defective design claims would only exacerbate the problem because it would reduce the number of viable theories a harmed victim may use to bring action against a GDM. Design defect claims based on negligence, however, fare differently. The BNM voluntarily created the design; thus, the BNM knows or should have known that GDMs would depend on that design to survive.
consumers are left devastated. The Supreme Court, upon issuance of a decision, created a problem: Consumers deserving redress for harm attributed to a generic drug are without an avenue to recovery. If the consumer had taken a brand-name drug, the law would not limit the pathway to remedies.

2. The Majority of Jurisdictions Insulate BNMs

This section discusses a route to remedies for consumers of generic drugs that some courts are beginning to reconsider. If a consumer receives a generic drug, even if her physician prescribed a brand-name drug, she cannot state any viable claims against a BNM in the vast majority of jurisdictions. Current law clings to the notion that a BNM does not owe any duty to a consumer of a generic drug, even though the BNM is responsible for the label on the generic drug. *Foster v. American Home Products* is the landmark case that established this principle that the majority accepts. The court in *Foster* concluded that the BNM did not have a duty to the users of another manufacturer's product; accordingly, the law prevents a consumer of a generic drug from stating a viable claim against the BNM.

---

78 See Dana Taschner, *Pliva Shields Big Pharma from Billions, Cuts Consumers’ Rights*, 49 SAN DIEGO L. REV. 879, 902 (2012) (noting “PLIVA was a big win for Big Pharma, but a huge loss for consumers”).
80 Id.
82 Id.
83 Id.
If a BNM fails to request an adequate warning label for its product or a generic equivalent, the law insulates it from liability. If a doctor prescribes a brand-name drug and the consumer takes the brand-name drug, the law does not limit the pathway for redress of harm. If, however, the pharmacist substitutes a generic drug, the law significantly limits a consumer’s pathway to redress. Next, the note discusses justifications for restoring symmetry to the pharmaceuticals liability regime.

IV. Failure-to-Warn Claims Are Necessary

Wyeth placed the decision as to whether the warning label on a drug is sufficient in the province of the jury.\textsuperscript{84} Mensing, however, removed the same issue from the province of the jury. This section discusses the implications of Mensing, and justifies placing the issue back in the province of the jury. The current state of the law is unacceptable because not only does it deny consumers redress, but it also raises consumer safety issues because it does not deter unreasonable conduct. Section A discusses the importance of providing an opportunity for redress for consumers of generic drugs, and Section B discusses the implications that flow from insulating manufactures from liability.

A. Redress

A consumer’s access to remedies is important because consumers who suffer harm from the use of mislabeled pharmaceutical products do not have the financial resources to recover.\textsuperscript{85} Drug consumers typically lack the knowledge and the information to make informed healthcare decisions, including choosing appropriate drugs.\textsuperscript{86}

B. Deterrence

Consumers value their right to sue because it provides assurances that GDMs will not neglect their welfare.\textsuperscript{87} Pre-\textit{Mensing}, no GDM had \textit{ever} lobbied the FDA for a stronger warning label.\textsuperscript{88} When, however, the parties filed briefs in \textit{Mensing}, GDMs inundated the FDA with requests to change warning labels on generic drugs.\textsuperscript{89} As this situation demonstrates, it is imperative to provide incentive for a manufacturer to act after it is aware of a problem with its drug.\textsuperscript{90}

Along with the desire to satisfy the market, tort law provides incentives and accountability for drug manufacturers to produce the

\textsuperscript{85} \textit{Escola v. Coca Cola Bottling Co.,} 24 Cal.2d 453, at 462 (1944) (Traynor, J., Concurring).


\textsuperscript{88} \textit{PLIVA, Inc. v. Mensing}, 131 S. Ct. 2567, 2577 (2011).


highest quality products and adequately label them. If the law prevents consumers of generic drugs, who represent the majority of pharmaceutical consumers, from seeking remedies, then only the minority of consumers—those who take brand-name drugs—may seek remedies. This status quo reduces manufacturers’ motivation to ensure safety for the whole.

Society benefits from a duplicative system of risk and harm rules in the pharmaceutical products liability niche. FDA regulation creates risk rules that anticipate and minimize harm; tort law complement the FDCA\(^{91}\) and creates much-needed harm rules to allow consumers to recover, incentivizing manufacturers to disclose risk.\(^{92}\) Some are concerned that shielding manufacturers from tort law incentives will only cause manufacturers to rest on their laurels.\(^{93}\)


“[GDMs] are basically given a free pass. [O]ften once a generic drug enters the market, the BNM will stop production, leaving no clear manufacturer liable for failure-to Warn claims. Any regulation that places a greater burden on the generic manufacturer would likely force generics to increase their prices, defeating the purpose of generic drugs. On the other hand, generic-drug manufacturers should not be given a free pass while victims injured as a result of inadequate labeling are denied all legal recourse.” Feeney, supra note 92, p 271.
Consumers may report problems to the FDA directly, and the FDA has the option to manipulate the behavior of a manufacturer. These mechanisms, however, are insufficient because the side effects of drugs are difficult to monitor, and the FDA has limited resources to conduct post-marketing drug evaluation.

No data exists to prove that FDA regulation is adequate without incentive from the law. Data, however, does exist (pre-\textit{Mensing}) for the contrary proposition— with incentive from the law and FDA regulations manufacturers have failed to provide adequate warnings. That data exists in the facts of many court cases. For example, there are approximately 3500 metoclopramide cases nationwide. The next section discusses how a consumer of generic drug may seek remedies, post-\textit{Mensing}, for harm.

\textbf{V. INNOVATOR LIABILITY}

\footnotesize{
\begin{itemize}
  \item \footnotesize{$^95$} See \textit{Wyeth}, 555 U.S., at 578, 129 S.Ct. 1187. At the time \textit{Mensing} was argued “there [were] over 1,600 requests for labeling revisions pending at the FDA now, 650 of them [have been] pending for more than 6 months.” \textit{Mensing} Oral arg tr. pg. 55:19, http://www.supremecourt.gov/oral_arguments/argument_transcripts/09-993.pdf (last visited Mar. 13, 2013). Almost all of the requests were from BNMs. \textit{id}. at 12:11. In 2009, after \textit{Mensing}, the FDA mandated a warning label change. http://www.cnn.com/2011/HEALTH/06/23/scotus.generic.drugs/index.html?iref=allsearch
  \item \footnotesize{$^96$} Absent any other change, if the number of “incidents” is “X” with incentive from the law, then it is far-fetched to argue that number of “incidents” would decrease absent that incentive.
  \item \footnotesize{$^98$} A consumer may sue a drug manufacturer alleging a failure-to-warn claim or negligent misrepresentation. A consumer must use negligence to advance her causes of action under the theory advocated in this note—innovator liability.
\end{itemize}
}
What is a lawyer to do with a generic consumer’s complaint post-\textit{Mensing}? This note advocates suing the BNM responsible for the label and arguing for innovator liability.\textsuperscript{99} Section A posits the core argument of the note that BNMs owe a duty to consumers of generic drugs to act reasonably. Section B surveys the arguments against innovator liability and concludes that they are unpersuasive. Section C analyzes the common law that has accepted innovator liability. Section D reasons that courts should continue to reevaluate innovator liability because it is the best solution to the problem \textit{Mensing} created.

A. BNMs Owe a Duty to Consumers of Generic Drugs

1. Duty

Innovator liability provides that a BNM owes a duty to produce a reasonable warning label to all consumers of a drug who reasonably rely on the warning label that a BNM broadcasts. The BNM knows that the GDM must use its label and should expect that the consumer will rely on the reasonableness of the label.\textsuperscript{100} In this instance, there is ‘such a relation [between BNM and a consumer of generic drugs] that [a consumer of a brand-name equivalent] has the


\textsuperscript{100} BNMs have made payments to GDMs for the GDM’s agreement not to enter the market with a generic alternative to a brand-name drug. Alternatively, BNMs have attempted to patent small changes in a brand-name drug to prevent the GDM from entering the market. See \textit{In re K-Dur Antitrust Litig.}, 686 F.3d 197 (3d Cir. N.J. 2012). Thus, BNMs have knowledge that GDMs will use their design and label.
right to rely for information upon the [BNM], and the [BNM] giving information owes a duty to give it with care.”101 Thus, even a consumer who only took the generic drug should be able to state a viable claim against the innovator, the BNM.

2. Standard of Conduct

Innovator liability provides the keys to the finder of fact to unlock a closed door. Acceptance of innovator liability does not automatically hold the BNM liable; it only expands the duty of the BNM. For a manufacturer to be at fault, the consumer must prove that the manufacturer owed her a duty to act reasonably, and that the breach of the standard of care owed to the consumer resulted in harm.102 Thus, the manufacturer may redeem itself by disproving any element.

a. Burden of Persuasion

A manufacturer with a duty to a consumer must conform to the legal standard of reasonable conduct in light of the apparent risk;103 the effort to warn must be reasonable under the circumstances.104 The consumer must prove that the BNM breached the standard of care, and the BNM may escape liability by persuading the finder of fact that it acted reasonably. In the case of a reasonable warning, the manufacturer should not incur liability.

102 Id. at 149.
104 Sterling Drug, Inc. v. Yarrow, 408 F.2d 978 (8th Cir. 1969).
For example, if the manufacturer acted reasonably, ensuring that an adequate warning was in place, then it should not be liable if the BNM increased the advisory warning to the strongest warning level possible, and the manufacturer had previously increased the warning two times. In this situation, reasonable warning was available to the physician, pharmacist, and the consumer.

b. Why It Is Important to Introduce Reasonableness

It is important to incorporate reasonableness from negligence because courts do not seem pleased with the results of strict liability in the pharmaceuticals industry. It is important to introduce reasonableness to the mix. Unlike strict liability, negligence is fault-based. A manufacturer may exculpate itself by showing that it was not negligent and thus, without fault. If the alleged manufacturer created an unreasonable risk of harm to another, the consumer may hold that manufacturer liable.

105 Id. Typical consumers base product liability claims against manufacturers upon strict liability. McEwen v. Ortho Pharma. Corp., 528 P.2d 522 (1974). Strict liability does not require the consumer to prove that the accused was at fault—only that the manufacturer produced the item in question. Id. “A manufacturer cannot be held liable [based on strict liability] unless and until the plaintiff proves that her injuries resulted from use of that manufacturer's product.” McEwen v. Ortho Pharma. Corp., 528 P.2d 522 (1974). Whether the manufacturer knew or should have known it was not acting reasonably is irrelevant. Id. Courts accepted the theory of strict liability, a non-fault based regime, and to get around the issue of privity, which stated that consumers who purchased products from retailers could not sue the manufacturer because it asserted the defense that the consumer did not have a contractual relationship with the manufacturer. Id. Some States have laws that create a presumption that a case concerning product liability is based on strict liability. Id. In this situation, the only manufacturer the consumer can sue is the one who made the product that caused the injury.


107 Id. at 149.
If the BNM has sufficient evidence that it should strengthen the warning label, but takes inadequate action, then a consumer should be able to state a viable claim against that manufacturer for a failure-to-warn claim. If a BNM knew or reasonably should have known about side effects that warranted strengthening the label, then the BNM should be subject to liability.\textsuperscript{108} For example, in Mensing, evidence that the drug caused a severe neurological disorder existed for several years before the lawsuit,\textsuperscript{109} but the GDM ignored that data and did not seek modification of the drug’s warning.\textsuperscript{110}

Allowing a court to hold a manufacturer liable for a failure-to-warn claim when it has acted reasonably by implementing the appropriate warning would not do anything except unnecessarily increase the cost of the drug. Allowing a multi-million dollar verdict against manufacturers is not efficient because it would only raise the price of the drug without any benefit. The manufacturer has no control over physicians’, pharmacists’, or consumers’ behavior.\textsuperscript{111} Innovator liability requires that the basis of the claim be negligence

\textsuperscript{108} A Product “manufactured by a third person is subject to liability . . . , if, although he is ignorant of the dangerous character or condition of the chattel, he could have discovered it by exercising reasonable care . . . .” \textit{RESTATEMENT (FIRST) OF TORTS} § 402 (1934).

\textsuperscript{109} \textit{McNeil v. Wyeth}, 462 F.3d 364, 370, n. 5 (C.A.5 2006); see also Shaffer, supra note 55, p 663 (noting 87 cases of metoclopramide-related tardive dyskinesia reported to the FDA’s adverse event reporting system by mid–2003).


\textsuperscript{111} Physicians are the only professionals allowed to prescribe drugs, and they receive warning labels. The law only allows pharmacist to dispense medicine. Physicians, however, continue to prescribe. Pharmacists continue to fill prescriptions that are contraindicated, and consumers continue to use drugs with reasonable warning labels.
not strict liability.\textsuperscript{112} If the BNM persuades the finder of fact that it was not responsible for the harm, then the consumer of generic drugs may not hold the BNM liable for the harm. The BNM may clear itself by defeating any element of negligence.

B. Counter Arguments

1. Duty

Ambivalence about innovator liability persists; opponents mainly contest the expansion of the BNM’s duty to include consumers of generic drugs. Generally, the manufacturer of a product does not owe a duty of care to a consumer who did not use its product.\textsuperscript{113} It is well-established law that the consumer of a generic drug may not sue the BNM and base her action on strict liability; however, because of public policy, the court may expand BNM’s duty to include customers of its competitor—the GDM. Courts have the authority to hold that a manufacturer owes a duty to a consumer of a competitor’s product.\textsuperscript{114} Including the BNM would not only reduce GDMs’ litigation cost but would also benefit society by allowing consumers access to potential remedies and incentivizing the BNM to maintain reasonable warnings.

\textit{a. Framing the Question}

\textsuperscript{112} Normally, consumers may choose any theory of liability to advance their cause of action against a manufacturer, whether it be strict liability or negligence based.

\textsuperscript{113} \textit{Carrier v. Riddell, Inc., 721 F.2d 867 (1st Cir. 1988)} (holding that a football helmet manufacturer did not owe a duty of care to a consumer who did not wear its helmet).

\textsuperscript{114} \textit{Wyeth, Inc. v. Weeks, 1101397, 2013 WL 135753 (Ala. Jan. 11, 2013).}
The precise duty question is whether the accused owed the consumer a standard of care at all.\textsuperscript{115} Importantly, what the manufacturer must do is a question of whether the standard of conduct is required to satisfy the duty, and not whether a duty exists.\textsuperscript{116} Generally, everyone (even a manufacturer) has a duty to exercise reasonable care to others, subject to some exceptions.\textsuperscript{117} The law fails to recognize a duty to rescue, for example,\textsuperscript{118} however, even the absence of a duty to rescue is subject to exceptions, most of which require a preexisting relationship.\textsuperscript{119}

\textit{b. Consumers of Generic Drugs Reasonably Rely on the Warning Label Produced by the BNM}

Consumers of generic drugs have a reasonable expectation that they will have the same rights as consumers of brand-name drugs. If a consumer reasonably relies on an actor, then courts have imputed an affirmative duty to act reasonably on the actor.\textsuperscript{120} If the BNM causes the harm by broadcasting an unreasonable label, consumers of generic drugs should be able to state viable claims against the BNM in order to determine the truth—whether the BNM

\textsuperscript{115} Henderson, supra note 106 at p 171.

\textsuperscript{116} Id.

\textsuperscript{117} For example, there is no duty to rescue others unless certain conditions exist.

\textsuperscript{118} \textit{RESTATEMENT (SECOND) OF TORTS} § 314.

\textsuperscript{119} \textit{RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM} § 40.

\textsuperscript{120} “[W]here the practice is known to the traveler upon the highway, and such traveler has been educated into reliance upon it, some positive duty must rest upon the railway with reference thereto.” See also Erie R. Co. v. Stewart, 40 F.2d 855, 856,857 (6th Cir. 1930) See \textit{Lacey v. United States}, 98 F. Supp. 219 (D. Mass. 1951) (holding that an actor who undertakes rescue operations owes a duty of care to the rescue); see also \textit{RESTATEMENT (SECOND) OF TORTS} § 323 (1965).
acted reasonably. The consumer should be able to sue the manufacturer responsible for labeling to determine whether it has acted unreasonably. If the BNM’s own negligence causes the risk of harm, it always owes a duty of care to the consumer. The relationship between BNM and GDM is a unique one. No other business must be a copycat in order to preserve its niche; nor is there any similar business relationship that the law relieves any other manufacturer of the obligation to seek an adequate warning label.

2. Common Law Post-Mensing Permits Innovator Liability

   a. Past Improper Analysis of Duty Warrants Reevaluation

   The courts that have rejected innovator liability have analyzed duty improperly; they construed duty to evaluate different

---

121 “[A]n actor ordinarily has a duty to exercise reasonable care when that actors’ conduct creates a risk of physical harm.” If an innkeeper, a landowner, or some other actor causes the harm, the law imputes a duty to rescue. RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 7(a) (proposed final draft no 1, 2005).

122 Id.

123 Id.

standards of care. This reasoning is in error because negligence is fact-sensitive, and the use of duty to measure the standard of care construes negligence as not fact sensitive. Duty is a question of whether the manufacturer is under any obligation. If a duty exists, it is always the same. Those courts have come to the incorrect conclusion, relying on assumptions and conclusions from previous decisions.

Courts have used duty in improper ways. Some courts have confused duty with the level of the standards of care owed. Other courts have confused duty with causation, holding that duty requires a close relationship between the act and the harm. Some courts have used duty as a basis to conclude that public policy exempts certain actors. Finally, courts have been analytically dishonest because of jury distrust. Those courts use duty to decide,

127 Id.
128 Rostron, supra note 90, p1124.
129 Henderson, supra note 106 at p 171.
130 “Many tort decisions exhibit an unfortunate tendency to confuse the concepts of duty and the standard of conduct . . . .” Coburn v. City of Tucson, 691 P.2d 1078, 1079 (1984). For example, a victim’s family cannot successfully bring a negligence claim when a car crashes through a wall of a restaurant and kills the consumer inside the restaurant. Albert v. Hsu, 602 So.2d 895 (Ala. 1992). The claim fails not because of a lack of duty to the restaurant consumer, but because the victim’s family cannot successfully show breach of that duty. Id. The restaurant owed a duty to the consumer that the restaurant was reasonably safe. Id. The victim’s family could not show breach of that duty. John C. P. Goldberg and Benjamin C. Zipursky, The Restatement (Third) and the Place of Duty in Negligence Law, 54 VAND. L. REV. 657, 698-723, (2001); Henderson, supra note 106 at p 171.
131 Henderson, supra note 106 at p 171; see also, Goldberg, supra note 130.
132 Id.; Henderson, supra note 106 at p 171.
as a matter of law, that only an unreasonable finder of fact would hold that the accused failed to meet the standard of care.\textsuperscript{133}

\textit{b. Foster & Mensing}

\textit{Foster v. American Home Products Corporation} is the landmark case that rejected innovator liability in 1994.\textsuperscript{134} \textit{Foster} held that a consumer of generic drugs could not hold a BNM liable because the BNM did not owe a duty to act reasonably to the consumers of another manufacturer’s product.\textsuperscript{135} \textit{Foster} placed a duty on the GDM for the reasonableness of its label; however, \textit{Mensing} clarified that this is not correct.\textsuperscript{136} \textit{Mensing} held that the BNM is the only party required to propose changes to the label for the generic and its reference.\textsuperscript{137} \textit{Mensing} clarified that the law does not require a GDM to lobby the FDA to strengthen the label. Pre-\textit{Mensing}, all consumers had access to remedies. \textit{Mensing} removed a large portion of those available remedies.\textsuperscript{138} Duty is a dynamic standard with roots in public policy; accordingly, public policy dictates the boundaries of a party’s duty.\textsuperscript{139} Courts may, through

\textsuperscript{133} \textit{Id.} see also, Goldberg, supra note 130.
\textsuperscript{134} Foster, 29 F.3d 165 (4th Cir. 1994).
\textsuperscript{135} \textit{Id.} at 168.
\textsuperscript{136} \textit{See Phelps v. Wyeth, Inc.}, 857 F. Supp. 2d 1114, 1130 (D. Or. 2011) Foster rejected the idea that the generic manufacturer was not responsible for the adequacy of its own warning label. \textit{Mensing} has abrogated the Foster court’s first determination.
\textsuperscript{138} After \textit{Mensing} consumer of generic drugs may no longer state viable failure to warn claims against GDM because of preemption.
common law, use public policy to create, expand, deny, or limit those boundaries.\textsuperscript{140} Here, public policy warrants expanding the boundaries of the BNM’s duty.

C. \textit{Conte} and Its Progeny

A minority of courts have accepted innovator liability arguments. In these cases, the consumers based their claims against the BNM in negligence rather than strict liability.\textsuperscript{141} In a watershed decision, \textit{Conte v. Wyeth} resuscitated innovator liability.\textsuperscript{142} The courts in \textit{Kellogg v. Wyeth} and \textit{Wyeth v. Weeks}\textsuperscript{143} subsequently relied on \textit{Conte}’s reasoning to advance the concept.\textsuperscript{144}

1. \textit{Conte v. Wyeth}\textsuperscript{145}

In \textit{Conte v. Wyeth}, Elizabeth Ann Conte took metoclopramide, the generic version of Reglan, for almost four years.\textsuperscript{146} Subsequently, Conte developed tardive dyskinesia.\textsuperscript{147} Although she only took the generic drug, she sued the GDM and BNM.\textsuperscript{148} She claimed that the BNM should have known that the

\textsuperscript{140} “In exceptional cases, when an articulated countervailing principle or policy warrants denying or limiting liability in a particular class of cases, a court may decide that the defendant has no duty or that the ordinary duty of reasonable care requires modification.” \textit{Restatement (Third) of Torts: Liability for Physical Harm § 7(b)} (proposed final draft no 1, 2005). For criticism of the Restatements approach, see W. Jonathan Cardi, \textit{Purging Foreseeability the New Vision of Duty and Judicial Power in the Proposed Restatement (Third) of Torts}, 58 \textit{Vand. L. Rev.} 739, 740 (2005).


\textsuperscript{142} Conte, 168 Cal. App. 4th 89 (2008).


\textsuperscript{144} Kellogg, 762 F. Supp. 2d 694 (D. Vt. 2010).

\textsuperscript{145} Conte, 168 Cal. App. 4th 89 (Cal. App. 1st Dist. 2008).

\textsuperscript{146} \textit{Id.} at 95. (between August 2000 and April 2004).

\textsuperscript{147} \textit{Id.} at 95.

\textsuperscript{148} \textit{Id.} at 95.
drug’s label substantially understated the risk of tardive dyskinesia. She based her claim in negligence, arguing that her doctors overexposed her to metoclopramide due to the BNM’s dissemination of false, misleading, and incomplete warnings about the drug's side effects. The BNM requested that the court dismiss the case because it did not owe a duty to Conte. The Court, however, disagreed.

Conte accepted innovator liability. Since the court disagreed with the reasoning of Foster, and it was outside the court’s jurisdiction, Conte traversed the holding of Foster. The court expanded the BNM’s duty to include the consumers of generic drugs because it was foreseeable that consumers and their doctors

149 Id. at 95.
150 Id. at 95.
151 Id. at 100-101.
152 The court noted that if Conte were to pursue a strict liability action, it would be defeated. Her action was in negligence. Id. at 101. “[F]ailure to warn in strict liability differs markedly from a failure-to-warn claim in the negligence context. Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons that fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer had known and warned. Strict liability is not concerned with the standard of due care or the reasonableness of a manufacturer's conduct. The rules of strict liability require a plaintiff to prove only that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Thus, in strict liability, as opposed to negligence, the reasonableness of the defendant's failure to warn is immaterial.” Id. at 101. “Stated another way, a reasonably prudent manufacturer might reasonably decide that the risk of harm was such as not to require a warning as, for example, if the manufacturer's own testing showed a result contrary to that of others in the scientific community. Such a manufacturer might escape liability under negligence principles. In contrast, under strict liability principles the manufacturer has no such leeway; the manufacturer is liable if it failed to give warning of dangers that were known to the scientific community at the time it manufactured or distributed the product.” Id. at 85.
153 Id. at 85.
154 Foster, 29 F.3d 165 (4th Cir. 1994) (“holding that innovator liability would "stretch the concept of foreseeability too far.").
would justifiably rely on information the BNM provided. Some of the court’s rationale depended on a state statute that authorized the pharmacist to substitute a generic drug when the physician prescribes a brand-name drug.

2. Kellogg v. Wyeth

In Kellogg v. Wyeth, Ethel Kellogg took metoclopramide for four years. Kellogg’s use of the generic drug also caused her to develop tardive dyskinesia. Kellogg sued the BNM and the GDM for negligent misrepresentation. The BNM agreed that it had a duty to provide Kellogg’s physicians an adequate warning, but not to provide one to Kellogg as the consumer. The BNM argued that

---

156 It is “inescapable that Wyeth, [which manufactured the brand-name product Reglan], knows or should know that a significant number of patients whose doctors rely on its product information for Reglan are likely to have generic metoclopramide prescribed or dispensed to them.” Kellogg, 762 F. Supp. 2d 694 (D. Vt. 2010).


158 Id.


160 Id.

161 Id. "Wyeth was, or should have been, aware that Reglan was prescribed routinely for long-term use," given testimony that its own market data showed that 84% of patients were using Reglan long-term. McNeil v. Wyeth, 462 F.3d 364, 369 (5th Cir. 2006).

Whereas a failure-to-warn claim deals with an omission, a negligent misrepresentation claim involves an affirmative false statement about a product. David G. Owen, PRODUCTS LIABILITY LAW (2d ed. 2008) § 3.2 at 117-23. The claim may stem from the product itself or from information about the product. Rostron, supra note 90, p1186. In order for a consumer to succeed, she must prove that a manufacturer had a duty to disclose. Nesbitt v. Frederick, 941 So.2d 950, 955 (Ala.2006). The disclosure must be a false representation made about a material fact on which the consumer relied that subsequently harmed the consumer as a proximate result. Fisher v. Comer Plantation, 772 So.2d 455, 463 (Ala.2000) (quoting Baker v. Bennett, 603 So.2d 928, 935 (Ala.1992)).

162 Kellogg, 762 F. Supp. 2d at 700 (D. Vt. 2010). Generally, any manufacturer of products must warn the consumer about side effects of the product. McCullock v. H.B. Fuller Co., 981 F.2d 656 (2d Cir. 1992). In pharmaceutical product liability, the learned intermediary doctrine is an exception to the general rule. Walls v. Alpharma USPD, Inc., 887 So.2d 881, 883 (Ala.2004). “Under the learned intermediary doctrine, a manufacturer's duty to warn is limited to an obligation to advise a prescribing physician of any potential dangers that may result from the use of its product.” Not all States
the court should dismiss it from the lawsuit since it did not
manufacture the product. The court, however, found that the
BNM owed a duty to Kellogg. In reliance on Conte, the court
concluded that it was foreseeable that a physician will prescribe a
drug in reasonable reliance upon information that the BNM
disseminates, and that the consumer will take the generic
equivalent. The court held that a BNM owes a duty to use
reasonable care to avoid causing injury to consumers of generic
drugs. The court concluded that it would not prejudice the BNM
to acknowledge this duty.

3. Weeks v. Wyeth

recognize this exception. See MacDonald v. Ortho Pharm. Corp., 394 Mass. 131, 475
N.E.2d 65 (1985) (holding that the warning must reach the patient). Since a consumer
may only purchase a pharmaceutical from a pharmacy after her physician has prescribed
it, the law views the physician as the intermediary between the manufacturer and
consumer. Ramey, supra note 32, p95-96. Disclosure to the intermediary satisfies the
manufacturer’s obligation to warn. Thus, the learned intermediary doctrine requires the
manufacturer of pharmaceuticals to warn physicians, not consumers. Id. Pharmaceutical
manufacturers use the learned intermediary doctrine as a defense. The consumer must
show that the manufacturer failed to warn the physician and that if the physician had
known about the warning, the physician would not have prescribed the medication. Id.

Kellogg, 762 F. Supp. 2d at 703 (D. Vt. 2010). If Kellogg’s claims against the BNM
had been in strict liability, they would not be viable. “To establish strict liability in a
products liability action, a plaintiff must show that the defendant’s product . . . caused
establish strict liability for an inadequate warning, a plaintiff must prove that the
inadequate warning made the product unreasonably dangerous and was the proximate
cause of the injury,” Webb, 692 A.2d at 347, “but is relieved of showing that the
defendant was negligent.” Id.

Kellogg, 762 F. Supp. 2d at 706 (D. Vt. 2010).

that Wyeth knows or should know that a significant number of patients whose
doctors rely on its product information for Reglan are likely to have generic
metoclopramide prescribed or dispensed to them.”), review denied, 2009 Cal. LEXIS 233
(2009).


“[T]here is no reason, under Vermont law, to limit Wyeth’s duty of care to
physicians by the pharmacist’s choice of a generic bioequivalent drug to fill the
physician’s prescription.” Id. at 708-709.

In *Weeks v. Wyeth*, Danny Weeks used generic metoclopramide over several years and suffered side effects. Weeks did not take the BNM’s product. Weeks, however, claimed that the BNM made misrepresentations to Weeks’ physician. The BNM argued that it had no duty to Weeks’ physician because Weeks only took a competitor’s generic product. The court had to decide whether the BNM owed a duty to Weeks’ physician and whether Weeks, as a third party, could bring a lawsuit for the breach of that duty. The court held that the BNM did owe a duty to Weeks and his physician.

D. Courts Should Continue to Reevaluate Innovator Liability

Scholars and courts have supported innovator liability. Others predict that innovator liability will expand post-*Mensing*.

Only pre-*Mensing* jurisprudence is preventing acceptance of

---

168 *Id.* at *1.
170 *Id.*
171 *Id.*
172 *Id.*
173 *Id.* at 15. “[I]f the warning to the learned intermediary is inadequate or misrepresents the risk, the manufacturer remains liable for the injuries sustained by the patient.” *Id.* “19 ‘[T]he patient must show that, but for the false representation made in the warning, the prescribing physician would not have prescribed the medication to his patient.””
175 Joe Hollingsworth, Robert S. Peck, Moderator: Henry N. Butler, *Emerging Civil Justice Issues*, 8 J.L. ECON. & POLY 167, 168 (2011) (noting “there are a number of jurisdictions that have rejected this approach, but they did so on the fact that there’s still a remedy against the GDM. Since that rationale no longer exists, we can imagine that this will be revisited in a number of states.”)
innovator liability. This section argues that public policy supports continued acceptance of innovator liability.

The *Kellogg* court noted that “broader public policy issues are worthy of debate.” The best solution is for the law to force the manufacturer to bear the risk of harm since it can best spread the cost to the public as a cost of doing business. Innovator liability is consistent with the purpose of the HW Act: to retain low-cost safe generic drugs. Innovator liability does not impose obligations that would raise the gross cost of pharmaceuticals to consumers.

1. Sustained Development of New Drugs

Some are worried about how increased liability relates to incentives to develop new drugs. The main public policy issue is whether extending the duty of the BNM to include the GDM’s consumers would decrease the number of new drugs, thus harming the public. Some GDMs and BNMs share the same balance sheet; they are part of the same parent corporation. BNMs have also made payments to GDMs as incentive for the GDM to delay production of a drug. Thus, the argument that innovator liability

---

178 Christopher M. Holman, *Unpredictability in Patent Law and Its Effect on Pharmaceutical Innovation*, 76 Mo. L. Rev. 645 (2011) (noting that “the major innovator pharmaceutical companies have experienced two pronounced and significant trends: a decreasing output of innovative new drugs and cutbacks in research and development (R&D) investment.”).
180 http://ftc.gov/opa/2013/01/mmarpt.shtm.
will decrease the incentive to bring new drugs to the market is not persuasive. The patent system supplies a huge incentive for a private manufacturer to bring a new drug to the market.\textsuperscript{181}

2. Innovator Liability Would not Prejudice the BNM

Some argue that innovator liability would impose a burden on a manufacturer that has not received any benefit.\textsuperscript{182} Congress, however, provided several benefits to the BNM in order to pass the HW Act. First, the BNM may receive up to a five-year patent extension, which gives the BNM five more years to market the brand-name drug exclusively.\textsuperscript{183} Secondly, some BNMs also have a GDM in their corporate family.\textsuperscript{184} Lastly, advertising on the part of the GDM may benefit the BNM and vice versa.

3. Uniformity of the Label

Innovator liability is the best solution because it maintains a uniform warning label for pharmaceuticals. The current system for

\textsuperscript{181} “The poster child for the \textit{financial} model of patents is the pharmaceutical industry and its development of synthetic chemical drugs. It is at the interface of organic chemistry and private pharmaceutical research that the \textit{financial} conceptualization of patents works best.” Academic Medicine: December 2002 - Volume 77 - Issue 12, Part 2 - p 1315-1328, \textit{Special Theme Articles Human Gene Patents}, Goldstein, Jorge A. PhD, JD; Golod, Elina JD.

\textsuperscript{182} A recent court case held that “an agreement by a manufacturer of a generic drug that, in return for a payment by the patent holder, agrees to drop its challenge to the patent and refrain from entering the market for a specified period of time” is prima facie evidence of an unreasonable restraint of trade. In re K-Dur Antitrust Litigation, 3rd Cir., No. 10-2077, (Jul. 16, 2012).

\textsuperscript{183} “In exchange for relieving [GDM] of providing clinical data, FDA would now extend the period of market exclusivity for pioneer manufacturers.” Ramey, \textit{supra} note 32, p 90.

\textsuperscript{184} “[In 2007, Americans spent more than $227 billion on prescription drugs,” and “in 1994, Americans spent only $19.6 billion on prescription drugs.” Ramey, \textit{supra} note 32, p92.
warning consumers about a drug's side effects is flawed. The biggest problem with the system is the lack of distribution to doctors and the failure of doctors to act on the warnings. Another problem is under-reporting of adverse drug events.

It is important to have a uniform label. Negligence is the better theory of liability with which to advance the thesis of this note because innovator liability maintains a uniform drug label. The FDCA holds only the BNM responsible for the label because it does not want different versions of the label for the same drug. Innovator liability would be in line with this goal, while a statutory amendment may create issues if the GDM is responsible for one label, and the BNM is responsible for another. Only the pharmacist knows which generic version the consumer receives. Thus, the physician is not in a position to consider the side effects of a specific drug.

VI. CONCLUSION

Arguments against innovator liability are not persuasive after Mensing. To prevent extinction of state-tort-law claims,
innovator liability should be adopted. The goal of this note is to provide an alternative that balances the underlying concern in *Mensing* with consumers’ right to recovery. Expanding the duty of the BNM would accomplish this goal under a negligence-based theory. Others have proposed other solutions that are not ideal. If the state courts embraced innovator liability, it would create avenues of potential redress for consumers of generic drugs without overturning *Mensing* or requiring a statutory amendment to the FDCA. Legislation imputing an obligation on a GDM to lobby the FDA for stronger warning labels is one option, but there is little likelihood that Congress will enact it.

---

190 This note only advocates innovator liability, that a generic drug consumer may state a viable claim against a BNM. This note does not propose that a BNM should always be liable for a GDM’s mistakes or vice versa. Under innovator liability, a fact-finder may only find the BNM liable after the burden of persuasion is satisfied for each element of the victim’s claim.

191 Caitlin Sawyer, *Duty of “Sameness?” Bartlett Preserves Generic Drug Consumers’ Design Defect Claims*, 54 B.C.L. REV. E-SUPPLEMENT 1, 12 (2013) (Congress should enact a limited compensatory damages remedy to provide injured generic drug consumers with a means to obtain compensation.). The FDA is considering changing its regulatory scheme, obligating the GDM to strengthen its label upon sufficient evidence, which would moot *Mensing*. FDA considers changes to generic drug labeling rules [February 21, 2013](http://www.lexology.com/library/detail.aspx?g=e177881b-c723-4c69-b3a3-63daf208deaa). Sarah C. Duncan, *Allocating Liability for Deficient Warnings on Generic Drugs: A Prescription for Change*, 13 VAND. J. ENT. & TECH. L. 185, 191 (2010) (a victim’s trust fund to provide compensation to those who are injured because of an inadequately labeled generic drug); Leonard H. Glantz & George J. Annas, *Impossible? Outlawing State Safety Laws for Generic Drugs*, 365:8 N. ENG. J. MED. 681, 683 (2011) (bolstering FDA efforts to developing stronger post-market surveillance procedures); Feeney, supra note 92, p 272 (“for Congress to establish a cause of action against [GDM] if the generic manufacturer fails to provide information to the FDA when the generic manufacturer should know that its product has an inadequate warning label”); Wesley E. Weeks, supra note 137, 1259 (brand-name drug manufacturers should be liable for the harm caused by their generic counterparts because the [BNMs] have a duty to generic patients.”)


193 [http://www.govtrack.us/congress/bills/112/s2295](http://www.govtrack.us/congress/bills/112/s2295) (noting it has only a 1% chance of being passed).
There is no requirement for a GDM to request label changes from the FDA when it is aware of side effects, and the majority of courts insulate the BNM. This gap in regulation allows the BNM and the GDM to act unreasonably. Since generic drugs dominate the market, the law should close this loophole to assure public health and safety. This note advocates innovator liability as a working theory of liability. Innovator liability would restore consumer rights and pharmaceutical manufacturers’ incentive to maximize consumer safety. Because all consumers should have equal rights to redress of harm, the courts should expand the duty of the BNM to include consumers who take only the generic drug. The BNM is responsible for the warning label. The law does not require any other manufacturer to be a copycat in order to survive. Including the BNM as a necessary party provides incentive to keep warning labels current even though its product may occupy the minority position in the market place.