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PLIVA, INC. v. MENSING AFTERMATH:
INFORMED CONSENT LAWSUITS A
POTENTIAL SOLUTION FOR SOME
GENERIC DRUG CONSUMERS INJURED
BY INADEQUATE WARNING LABELING

*Deena K. Herndon-Remy**

The Supreme Court's 2011 ruling in *PLIVA, Inc. v. Mensing* left generic drug consumers without a cause of action for injuries resulting from generic manufacturers' inadequate warning labeling.¹ The Court held that federal law preempts the state-law failure-to-warn claims.² The Court, while recognizing that this ruling creates an undesirable result for generic drug consumers, is waiting for the FDA or Congress to resolve the issue.³ This issue, however, may not be resolved in the near future.⁴ Perhaps informed consent lawsuits can provide relief to some of these injured generic drug consumers. The viability of these lawsuits will depend on the jurisdiction in which the consumer is able to file suit.

This issue affects most drug consumers in the United States because "75 percent of all prescription drugs dispensed in this country" are generic drugs.⁵ Additionally, this issue arises from a typical daily scenario: a patient visits his or her physician, the physician writes a prescription for a drug, and the patient fills his or her prescription at a pharmacy. Although the consumer's transaction with the physician or pharmacist may seem insignificant to the consumer, the transaction can prove to be costly be-

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¹ See generally *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

² *Id.* at 2581. (A state-law failure-to-warn claim is based in tort law and alleges that a manufacturer has failed to provide an adequate warning label for a product); *Id.* at 2572.

³ *Id.* at 2582.

⁴ See generally *id.* at 2582 (Part III specifically discusses this issue).

⁵ *Id.* at 2583.

cause the consumer may have waived his or her right to sue and to receive compensation if injured from inadequate warning labeling.

Currently, no one informs generic drug consumers that they are waiving their right to sue and ability to receive compensation if injured by inadequate warning labeling on generic drugs. Meanwhile, physicians and pharmacists receive financial incentives to prescribe and dispense generic drugs.⁶ Since “the consumer is unlikely to realize the legal consequences of purchasing generic drugs,”⁷ perhaps those who prescribe, dispense, and pay for the drugs—physicians, pharmacists, and medical insurance companies—can be held responsible. The most viable lawsuits are likely those 1) against physicians in jurisdictions where the physician’s duty is measured by the patient’s viewpoint; or 2) against pharmacists who are able to choose whether a prescription is filled by a brand-name or generic drug.

This paper discusses the *Mensing* case; the issue that *Mensing*’s ruling has created for generic drug consumers, and the viability of informed consent lawsuits against physicians, pharmacists, and medical insurance companies to provide compensation to an injured generic drug consumer who lost his or her right to sue and to receive compensation under state-law failure-to-warn claims.

I. *PLIVA, INC. V. MENSING*

A. *Facts: Consumers Injured by Generic Drug Use*

Mensing involved two consolidated state lawsuits against generic drug manufacturers for a failure to warn consumers.⁸ The generic drug manufacturers in these cases were not brand-name manufacturers producing generic drugs.⁹ In both cases, the plaintiffs received generic metoclopramide from their pharmacists.¹⁰ Physicians typically prescribe metoclopramide to treat digestive

⁶ U.S. Dep’t. of Health and Human Servs., *ASPE Issue Brief: Expanding the Use of Generic Drugs* 7-8, 2010, available at <http://aspe.hhs.gov/sp/reports/2010/genericdrugs/ib.pdf>; Vanessa Fuhrmans, *Doctors Paid to Prescribe Generic Drugs*, THE WALL STREET JOURNAL, Jan. 24, 2008, available at <http://online.wsj.com/news/articles/SB120114138064112219>.

⁷ 8 Okla. Prac., Product Liability Law § 6:7 (2012 ed.).

⁸ *Mensing*, 131 S. Ct. at 2572.

⁹ *See id.* at 2589.

¹⁰ *Id.* at 2573.

tract problems;¹¹ however, long-term use can result in tardive dyskinesia, a severe neurological disorder.¹²

The plaintiffs in both cases took the generic medicine for several years and developed tardive dyskinesia.¹³ Both plaintiffs sued the generic drug manufacturers for inadequate labeling because, although the labels warned of the risk of acquiring tardive dyskinesia, evidence proved that the risk was a far greater percentage than that listed on the label.¹⁴ The Court of Appeals for both cases held that the plaintiffs' claims were not preempted, even though the manufacturers argued the impossibility for them to simultaneously comply with both the federal and state law requirements.¹⁵

*B. Majority Opinion: State-Law Failure-to-Warn Claims
Preempted*

The Court's majority in *Mensing*¹⁶ held that the federal law preempted state-law claims for inadequate labeling by generic drug manufacturers because it was impossible for the manufacturers to simultaneously comply with both state and federal labeling requirements.¹⁷ In both cases, the state law duties required drug manufacturers to label their products in a way that enabled them to be used in a reasonably safe way when the manufacturer was aware, or should have been aware, of a product's risks of danger.¹⁸ Under federal law, labeling requirements are different for brand-name and generic drug manufacturers.¹⁹ The Hatch-Waxman Amendments, also known as the Drug Price Competition and Patent Term Restoration Act of 1984, allow generic drugs to be developed less expensively than brand-name drugs. Generic drugs can be marketed without performing significant research and development when it is shown that it is equivalent

¹¹ *Id.* at 2572.

¹² *Id.*

¹³ *Id.* at 2573.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ Section III-B-2 of the opinion is not discussed because it did not receive majority acceptance and is not precedential.

¹⁷ See *Mensing*, 131 S. Ct. at 2577-78, 2581. Preemption is a constitutional law principle (derived from the Supremacy Clause) that the federal law can supersede or supplant any inconsistent state law or regulation. Black's Law Dictionary (9th ed. 2009).

¹⁸ *Id.* at 2573.

¹⁹ *Id.* at 2574.

to the brand-name drug.²⁰ This equivalence includes ensuring that the generic drug's warning labeling exactly matches the brand-name drug's labeling.²¹

The parties in *Mensing* disagreed over the generic drug manufacturers' duties under the FDA's regulations.²² The generic drug manufacturers argued that it was impossible for them to comply with the state-law requirements of changing their labels when the FDA regulations required their labels to match the brand-name manufacturers' labels.²³ The plaintiffs argued that the generic drug manufacturers had options available to them, including the FDA's changes-being-effective (CBE) process²⁴ and "Dear Doctor" letters²⁵ that would have allowed them to comply with both the federal and state requirements.²⁶

The FDA argued that the generic drug manufacturer could not change its label under the CBE process to comply with state law because the label would have been unilaterally changed, and thus violating federal regulations requiring generic labels to be identical to the brand-name labels.²⁷ Also, the FDA interpreted Dear Doctor letters as labeling that would have been inconsistent with the drug's approved brand-name labeling.²⁸ The Court gave deference to the FDA's interpretation of its own rules and, thus, agreed with the generic drug manufacturers' argument.²⁹

²⁰ *Id.* (Summarizing the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301–99f.); *Greater Access to Generic Drugs: New FDA Initiatives to Improve the Drug Review Process and Reduce Legal Loopholes*, FDA (Mar. 14, 2013, 2:30 PM), available at www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm; *See also Abbreviated New Drug Application (ANDA): Generics*, FDA (Mar. 14, 2013, 2:32 PM), available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/> (explaining the abbreviated application process for generic drugs created by the Hatch-Waxman Act).

²¹ *Mensing*, 131 S. Ct. at 2574.

²² *Id.*

²³ *See id.* at 2586.

²⁴ *Id.* at 2575. The CBE process allows manufacturers to, among other things, strengthen its warnings without the FDA's prior approval. *Id.* at 2575 (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2006)).

²⁵ *See id.* at 2576.

²⁶ *Id.* at 2574.

²⁷ *Id.* at 2575.

²⁸ *Id.* at 2576.

²⁹ The Court determined that "the FDA's views are 'controlling unless plainly erroneous or inconsistent with the regulation[s]' or there is any other

The Court held that when a party cannot satisfy its state duties without the federal government's permission or assistance, in this case the FDA, the party cannot independently satisfy those state duties.³⁰ The Court reasoned that accepting the plaintiffs' argument would make conflict preemption meaningless.³¹ The Court stated that federal law is the "Supreme Law of the Land," even without an express statement by Congress.³² The Court further reasoned that even if the generic drug manufacturers had requested help from the FDA, they would not have fulfilled the state requirements because "it demanded a safer label; it did not instruct the [m]anufacturers to communicate with the FDA about the possibility of a safer label."³³ The Court opined that asking the FDA for help "is not a state-law concern."³⁴ The Court stated its interpretation of the test used in *Levine*: "[t]he question for 'impossibility' is whether the private party could *independently* do under federal law what state law requires of it."³⁵ In *Levine*, decided in 2009, the Court held that state-law failure-to-warn claims against a drug manufacturer were not preempted by federal law.³⁶ The Court then discussed how *Levine* is not contrary to its decision because Wyeth is a brand-name drug manufacturer and this case involved generic drug manufacturers.³⁷

The Court concluded that by acknowledging "the unfortunate hand that federal drug regulation has dealt [these plaintiffs] and others similarly situated,"³⁸ "Congress and the FDA retain the authority to change the law and regulations if they so desire."³⁹

reason to doubt that they reflect the FDA's fair and considered judgment." *Id.* at 2575 (quoting *Auer v. Robbins*, 519 U.S. 452, 462 (1997)).

³⁰ *Id.* at 2581.

³¹ *See id.* at 2578.

³² *Id.* at 2579. "The Supremacy Clause establishes that federal law 'shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.'" *Id.* at 2577 (quoting U.S. CONST., art. VI, cl. 2).

³³ *Id.* at 2578.

³⁴ *Id.* at 2581.

³⁵ *Id.* at 2578 (emphasis added). *See also* *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187 (2009).

³⁶ *Levine*, 555 U.S. at 581, 1204.

³⁷ *Mensing*, 131 S. Ct. at 2581.

³⁸ *Id.*

³⁹ *Id.* at 2582.

C. Dissenting Opinion: Injured Generic Drug Consumers Unable to Obtain Compensation; Generic Drug Manufacturers Should Not Have Complete Immunity From Failure-to-Warn Lawsuits

The dissenting opinion rejected the conclusion that generic drug manufacturers are categorically immune from failure-to-warn lawsuits under state tort law. Instead, the dissent believed that generic drug manufacturers should not be immune when the manufacturer did not even attempt to comply with state law through available mechanisms.⁴⁰ The dissenters highlighted the importance of Congress' intent 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."⁴¹ The dissenters reasoned that "the states have traditionally regulated health and safety matters,"⁴² and "Congress has not expressly preempted state-law tort actions against prescription drug manufacturers, whether brand-name or generic."⁴³

The dissenters further argued that preemption is an affirmative defense, which demands that the defendant prove impossibility.⁴⁴ The dissenters reasoned that the generic drug manufacturers did not meet their burden of proving impossibility because the mere possibility of impossibility is not enough.⁴⁵ The generic drug manufacturers "only [proved] that they *might* have been unable to comply with both federal law and their state law duties to warn."⁴⁶

The dissent also argued that *Mensing* was not distinguishable from *Levine* because *Mensing* involved a generic manufacturer rather than a brand-name manufacturer. Rather, *Mensing* was similar to *Levine* because both cases involved manufacturers that had options available for them to attempt to comply with state law.⁴⁷ "As in [*Levine*], [the dissenters] would require the [m]anufacturers to show that the FDA would not have approved a proposed label change."⁴⁸

The dissenters also argued that the majority invented a

⁴⁰ *Id.* at 2589.

⁴¹ *Id.* at 2586 (citing *Levine*, 555 U.S. at 565).

⁴² *Levine*, 555 U.S. at 485.

⁴³ *Mensing*, 131 S. Ct. at 2586.

⁴⁴ *Id.* at 2587.

⁴⁵ *Id.* at 2581, 2587.

⁴⁶ *Id.* at 2582.

⁴⁷ *Id.* at 2588.

⁴⁸ *Id.*

new preemption rule not based on existing precedent.⁴⁹ “[*Levine*] did not hold that unilateral action is a necessary condition in every case.”⁵⁰

The dissenters predicted that the “majority’s preemption analysis [would strip] generic drug consumers of compensation when they are injured by inadequate warnings.”⁵¹ The dissenters also predicted that by preempting state tort suits, drug manufacturers would no longer be incentivized to uncover unknown drug hazards and disclose safety risks promptly.⁵²

The dissenters further argued that the majority’s “decision [undid] the core principle of the Hatch Waxman’s Amendments” of sameness between brand-name and generic drugs.⁵³ They believed that drawing a distinction between these could result in reduced consumer demand, ethical dilemmas for physicians, and less support from states for generic drug use.⁵⁴ The dissenters argued that these consequences would not further the Hatch-Waxman Amendment’s goal of increasing generic drug consumption.⁵⁵

II. WHY THE MAJORITY OPINION GOT IT RIGHT, EVEN THOUGH IT CREATED AN ISSUE FOR GENERIC DRUG CONSUMERS

In *Mensing*, the Court confronted an issue that it did not have the power to solve.⁵⁶ While the dissenters’ arguments are persuasive, the Court’s decision was right because either Congress or the FDA has proper authority to address this issue. -If the Court would have allowed the plaintiff’s claim against generic drug manufacturers to move forward, then it would have undermined the purpose of the Hatch-Waxman Amendments.⁵⁷

In 2009, “the [Supreme] Court resolved an unsettled question . . . by holding [in *Wyeth v. Levine*] that state-law claims for

⁴⁹ *Id.* at 2589.

⁵⁰ *Mensing*, 131 S. Ct. at 2590.

⁵¹ *Mensing*, 131 S. Ct. at 2592.

⁵² *Id.* (quoting *Levine* 555 U.S. at 579).

⁵³ *Mensing*, 131 S. Ct. at 2593.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.* at 2581-82.

⁵⁷ See *Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments)*, FDA (Aug. 1, 2013), <http://www.fda.gov/newsevents/testimony/ucm115033.htm>.

failure to warn were not preempted by FDA regulations.”⁵⁸ Similar to the plaintiffs in *Mensing*, *Levine* involved a patient that had sued a drug manufacturer for inadequate labeling under state tort law.⁵⁹ In *Mensing*, the court could have interpreted *Levine*’s holding to apply to both brand-name and generic drug manufacturers, leaving cases involving state-law claims for failure to warn predictably preempted.⁶⁰ Instead, the Court interpreted the holding in *Levine* narrowly. This created an issue for generic drug consumers because the types of injuries in these cases are no longer controlled by *Levine*, and thus, are preempted by federal law per *Mensing*.⁶¹

The dissenters in *Mensing* argued that the majority’s ruling conflicted with the Hatch-Waxman Amendments because it drew a distinction between brand-name and generic drugs. In fact, the Hatch-Waxman Amendments already had drawn a distinction, unrelated to the generic drug’s equivalence with the brand-name drug—generic drug manufacturers can market their drugs at lower prices than their brand-name competitors because they do not have the same research and development costs.⁶² The Hatch-Waxman Act, allows generic drug companies to bring their products to market without repeating the expensive clinical trials that brand-name manufacturers have already performed.⁶³ Therefore, the upfront research is more burdensome for a brand-name drug versus a generic drug. The Hatch-Waxman requirement of “sameness” only applies to qualities of the drugs themselves: “A generic drug is identical-or *bioequivalent*-to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.”⁶⁴ The ruling in *Mensing* does not affect the qualities of the drugs themselves.

The Court’s ruling was not contrary to the Hatch-Waxman Amendments because its policy goals were not bur-

⁵⁸ Product Liability Law, *supra* note 7.

⁵⁹ *Levine*, 555 U.S. at 558-62.

⁶⁰ Product Liability Law, *supra* note 7.

⁶¹ *Id.*

⁶² *Greater Access to Generic Drugs*, *supra* note 20.

⁶³ *Id.*

⁶⁴ *Generic Drugs: Questions and Answers*, FDA (Mar. 14, 2013, 3:05 PM), www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (emphasis added). See also, *Understanding Generic Drugs*, FDA (March 14, 2013, 3:07 PM), <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/default.htm>.

dened. The Hatch-Waxman Amendments were intended to balance two important public policy goals. First, Congress wanted to ensure that brand-name (also known as innovator) drug manufacturers would have meaningful patent protection and a period of marketing exclusivity to enable them to recoup their investments in the development of valuable new drugs. Second, Congress sought to ensure that, once the statutory patent protection and marketing exclusivity for these new drugs . . . expired, consumers would benefit from the rapid availability of lower priced generic versions of innovator drugs.⁶⁵

Conversely, the dissenting opinion stated that if the majority had held that federal law did not preempt state tort lawsuits for failure to warn, then it would be contrary to the purpose of the Hatch-Waxman Amendments, which keep generic drugs at a low price. The majority's ruling protects generic drug manufacturers from incurring the costs of lawsuits and passing these costs to their customers. If these costs were passed to customers, then this would negatively affect health care costs. It is widely acknowledged that "[g]eneric drugs play a key role in making health care more affordable."⁶⁶

The *Mensing* dissenters' concern—that generic drug consumers would not have a claim for inadequate warning labeling—has become a reality: “As a result of today’s decision, whether a consumer harmed by inadequate warnings can obtain relief turns solely on the happenstance of whether her pharmacist filled her prescription with a brand-name or generic drug.”⁶⁷ Since the Court’s ruling, some lower courts have applied its holding broadly, leaving generic drug manufacturers categorically immune from failure-to-warn lawsuits and denying relief to generic drug consumers that have been injured due to inadequate warning labels.⁶⁸ Because of the harsh result of *Mensing*’s ruling, some low-

⁶⁵ *Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments)*, *supra* note 57.

⁶⁶ See also *Greater Access to Generic Drugs*, *supra* note 21; Generic Competition and Drug Prices, FDA (Mar. 14, 2013, 3:33 PM), <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.

⁶⁷ *Greater Access to Generic Drugs*, *supra* note 20.

⁶⁸ *Mensing*, 131 U.S. at 2583.

⁶⁹ See, e.g., *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177 (5th Cir. 2012); *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011); *Frazier v. Mylan Inc.*, No. 1:11-CV-03037-MHS, 2012 WL 6641626 (N.D. Ga. Dec. 18, 2012); *In re Accutane Products Liab.*, MDL 1626, 2012 WL 3194952 (M.D. Fla. Aug. 7, 2012).

er courts have decided to wait for Congress or the FDA to address the issue and have applied the rule more narrowly by refusing to extend *Mensing's* holding and reasoning to areas beyond failure-to-warn claims, including defective design, even when *Mensing's* reasoning is directly on point.⁶⁹

While the majority's opinion reached the correct result, an issue still exists for injured generic drug consumers, they are left without a remedy until either Congress or the FDA acts to resolve the issue.

III. IT IS UNCLEAR WHEN THE ISSUE WILL BE RESOLVED BY CONGRESS OR THE FDA

As the majority in *Mensing* correctly states, Congress or the FDA must resolve this issue.⁷⁰ To date, Congress has attempted to take action, but the FDA has not; therefore, it is unknown when consumers can expect this issue to be resolved.

On April 18, 2012, the Democrats introduced companion bills in the House and Senate, titled the Patient Safety and Generic Labeling Improvement Act.⁷¹ This Act could overrule the Supreme Court's *Mensing* decision, and allow generic drug manufacturers to update their warning labels independently of the brand-name drug warning labels.⁷² However, both of these bills have stalled. The House referred their bill to a committee, which subsequently referred the bill to a subcommittee, but the House has taken no action since April 20, 2012.⁷³ The Senate also re-

⁶⁹ *Bartlett v. Mutual Pharm. Co., Inc.*, 678 F.3d 30 (1st Cir. 2012). *Bartlett* has been granted certiorari by the Supreme Court, and the Court is scheduled to hear arguments on March 19, 2013. *Mutual Pharmaceutical Co. v. Bartlett*, SCOTUSBLOG (Mar. 17, 2013, 6:27 PM), <http://www.scotusblog.com/case-files/cases/mutual-pharmaceutical-co-v-bartlett/>.

⁷⁰ *Mensing*, 131 S. Ct. at 2582-83.

⁷¹ *Id.*

⁷² Katie Thomas, Bills Seek to Change Rule on Generic Drug Labels, N.Y. TIMES (April 18, 2012), available at http://www.nytimes.com/2012/04/19/health/bills-seek-to-change-rule-on-generic-drug-label.html?_r=0. See also Press Release, Leahy, Franken, Bingaman, Whitehouse, Brown, Coons, Blumenthal Introduce Bill To Protect Consumers Using Generic Drugs (Apr. 18, 2012), available at <http://www.leahy.senate.gov/press/leahy-franken-bingaman-whitehouse-brown-coons-blumenthal-introduce-bill-to-protect-consumers-using-generic-drugs>.

⁷³ Patient Safety and Drug Labeling Improvement Act, H.R. 4384, 112th Cong. (2013), available at <http://www.gpo.gov/fdsys/pkg/BILLS-112hr4384ih/pdf/BILLS-112hr4384ih.pdf>.⁷³

ferred their bill to a committee, but the Senate has taken no action since April 18, 2012.⁷⁴

Some have petitioned the FDA to change their labeling requirements so that *Mensing's* ruling no longer applies.⁷⁵ The FDA has stated that it needs more time to make a decision, and has not taken any action to date.⁷⁶ It is unclear whether the FDA will change its procedures because this may create problems of accuracy between brand-name and generic drug labels.⁷⁷ Also, the FDA believes “generic drugs are important options that allow greater access to health care for all Americans” and those that are “approved by [the] FDA have the same high quality, strength, purity and stability as brand-name drugs.”⁷⁸ The FDA supports initiatives to improve access to generic drugs by continuously attempting to improve and streamline its review process so generic drugs can reach consumers quickly.⁷⁹ Because of its support of generic drugs, if the FDA does decide to take action, its decisions likely: (1) will not cause distrust in generic drug consumers and (2) will ensure that consumers continue to purchase generic drugs.

Because neither Congress nor the FDA has taken any substantial action to resolve the issue created by *Mensing*, it is likely that those who have been injured by inadequate labeling will look for other avenues for relief.

IV. INFORMED CONSENT LAWSUITS COULD PROVIDE RELIEF TO SOME INJURED GENERIC DRUG CONSUMERS

A loss of the right to sue for inadequate warnings will likely lead injured consumers to find alternative responsible parties from whom they can receive compensation. One possibility is through informed consent lawsuits. Injured consumers in these cases could attempt to sue physicians, pharmacists, or medical in-

⁷⁴ Patient Safety and Drug Labeling Improvement Act, S. 2295, 112 Cong. (2013) available at <http://www.gpo.gov/fdsys/pkg/BILLS-112s2295is/pdf/BILLS-112s2295is.pdf>.

⁷⁵ Citizen Petition from Public Citizen to FDA (Aug. 29, 2011) available at <http://www.citizen.org/documents/Citizen-Petition-8-26.pdf>.

⁷⁶ Thomas, *supra* note 72. Generic drug manufacturers and the FDA disagree over whether there is a duty for generic drug manufacturers to propose changes to their warning labels to the FDA if they think the changes are needed. *Mensing*, 131 S. Ct. at 2576–77.

⁷⁷ See *Abbreviated New Drug Application*, *supra* note 20.

⁷⁸ *Understanding Generic Drugs*, *supra* note 64.

⁷⁹ *Greater Access to Generic Drugs*, *supra* note 20.

surance companies for failing to inform them that consumers lack the ability to sue generic medication manufacturers. Alternatively, consumers could attempt to sue physicians, pharmacists, or medical insurance companies for waiving the consumer's right to sue. Arguably, these consumers are not receiving enough information to provide true informed consent when they take generic drugs instead of brand-name drugs. The viability of these lawsuits will likely depend on the jurisdiction in which the consumer can file suit.

Informed consent refers to the rules of law that guide health care providers when interacting with patients; informed consent also promotes a patient's right to choose medical treatment.⁸⁰ Functions of informed consent include avoiding fraud or duress, fostering rational decision-making by the patient, and involving the public generally in medicine.⁸¹ Plaintiffs could potentially argue informed consent is hindered when health care providers do not inform patients of their loss of the right to sue generic drug manufacturers. To avoid fraud and duress, a patient should be notified that, "a disclosure of any appropriate alternative might be advantageous."⁸² Thus, when a health care provider recommends a generic drug to a patient because it costs less than the brand-name drug, he or she should also disclose that the lower cost comes with another price—loss of the right to sue and to receive compensation in case of injury by inadequate warning labeling—so that the patient can fairly determine the amount of risk he or she is willing to take.

In terms of rational decision-making, potential plaintiffs could argue that patients are not making rational decisions when choosing to take generic drugs because they are not fully informed of the consequences of their actions. The more information patients receive, the more rational their decisions will likely be. By not informing patients of the consequences of taking generic drugs, physicians risk an increase in distrust from the public, which could fester and result in consumers preferring brand-name drugs over their cost-efficient generic counterparts.

Under negligence, a plaintiff may recover for lack of informed consent by establishing the elements of: duty, breach, cau-

⁸⁰ JESSICA W. BERG ET AL., *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* 3 (2d ed. 2001).

⁸¹ Alexander Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 370-71 (1974).

⁸² *Id.*

sation, and harm.⁸³ A duty to inform patients has typically been placed on health care providers, including physicians,⁸⁴ surgeons,⁸⁵ dentists,⁸⁶ and chiropractors.⁸⁷ A breach occurs when a health care provider fails to disclose a risk to a patient for which he or she has a duty to disclose. Harm occurs when the undisclosed risk transpires and harms the patient, and causation involves proving that the treatment was a proximate cause of the patient's injury. A plaintiff's biggest hurdle in an informed consent case against a health care provider would likely be proving that the provider had a duty to inform the patient about their ability to sue generic drug manufacturers. Proving duty would be difficult because duty is not always measured from the patient's standpoint and a duty may not yet exist for some healthcare providers.

A. *Lawsuits Against Physicians*

Some jurisdictions measure a physician's duty from the physician's viewpoint, "measuring the duty to disclose by the standard of the reasonable medical practitioner similarly situated" (also called *professional standard*).⁸⁸ In these jurisdictions, expert testimony would be required to prove the proper standard,⁸⁹ and because physicians do not typically warn their patients of their loss of the right to sue by using generic drugs, the informed consent argument for physicians would likely fail in this type of jurisdiction.

However, in jurisdictions where the physician's duty is measured from the patient's viewpoint, it is possible to make a case for lack of informed consent in cases where a patient is in-

⁸³ Berg, *supra* note 80, at 133.

⁸⁴ See, e.g., *Jandre v. Wisconsin Injured Patients & Families Comp. Fund*, 813 N.W.2d 627 (Wis. 2012) (holding that physician had a duty to inform patient of an alternative, non-invasive treatment).

⁸⁵ See, e.g., *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972) (holding surgeon had a duty to inform patient of one percent chance of paralysis); *Mathies v. Mastromonaco*, 733 A.2d 456 (N.J. 1999) (holding surgeon had a duty to inform patient even though procedure was non-invasive).

⁸⁶ See, e.g., *Foote v. Rajadhyax*, 268 A.D.2d 745 (N.Y. 2000) (showing that a dentist can be held liable for lack of informed consent).

⁸⁷ See, e.g., *Hannemann v. Boyson*, 698 N.W.2d 714 (Wis. 2005) (holding that a chiropractor has the same duty of informed consent as a physician); *Bronneke v. Rutherford*, 89 P.3d 40 (Nev. 2004) (holding that a patient-oriented standard of informed consent applied to chiropractors).

⁸⁸ Barry R. Furrow et al., *HEALTH LAW* 240 (6th ed. 2009).

⁸⁹ Berg, *supra* note 80, at 47.

jured by a generic drugs' inadequate labeling.⁹⁰ Generally, the plaintiff will need to prove the following elements: (1) the physician failed to disclose the risk according to the reasonably prudent patient standard; (2) the undisclosed risk occurred and harmed the patient; (3) a reasonable person in the patient's position would have rejected the treatment if the risk was known; and (4) the treatment was a proximate cause of the patient's injury.⁹¹

There are several advantages to suing a physician in a jurisdiction where the physician's duty is measured from the patient's viewpoint. First, the burden of proof is easier to satisfy because a fact finder can determine what a reasonable person would have found material to make his or her decision without having any technical expertise.⁹² This allows the fact finder to make his or her own decision without being influenced by a medical expert's opinion. Second, because the fact finder must make a determination regarding what a reasonable person would do, "previous jury verdicts are not binding precedent. In every case, the jury is required to determine what would have been reasonable disclosure, taking into account all the facts and circumstances of the particular case."⁹³ This allows the patient a more flexible outcome, rather than being limited to what has been decided in similar cases. Third, "the patient-oriented standard imposes upon physicians more substantial obligations than the professional standard."⁹⁴ The physician's duty is not protected by agreement as to what similar physicians would have done, but is from the perspective of a reasonable patient whose material concerns are debatable.⁹⁵

The seminal case, *Canterbury v. Spence*, provides persuasive authority in jurisdictions measured from the patient's viewpoint.⁹⁶ According to *Canterbury*, the physician's duty is measured by what conduct would have been reasonable under the circumstances according to the patient's need to know material risks.⁹⁷ "[A] risk is . . . material when a reasonable person, in what

⁹⁰ See Wash. Rev. Code Ann. § 7.70.050 (West 2012).

⁹¹ *Howard v. Univ. of Med. & Dentistry of New Jersey*, 800 A.2d 73, 79 (N.J. 2002) (citing *Teilhaver v. Greene*, 727 A.2d 518 (N.J. App. Div. 1999)).

⁹² *Furrow*, *supra* note 88, at 241 (citing *Pederson v. Vahidy*, 552 A.2d 419 (Conn. 1989)).

⁹³ *Berg*, *supra* note 80, at 49.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ See *Canterbury*, 464 F.2d at 772.

⁹⁷ *Id.* at 785-87.

the physician knows or should know to be the patient's position, would be likely to attach significance to the risk . . . in deciding whether or not to forego the proposed therapy."⁹⁸ "There is no bright line separating the significant from the insignificant."⁹⁹ Potential plaintiffs could be argued that, from a reasonable person's standpoint, not having compensation available for an injury resulting from generic drug usage is a material risk because a reasonable person would otherwise not have decided to use the generic drug.

Every state allows physicians to specify that a brand-name drug must be dispensed when writing prescriptions.¹⁰⁰ Thus, physicians arguably have the control to decide what types of medications are dispensed to patients. In some states, physicians are forced to choose when writing a prescription whether a brand-name drug must be dispensed or if substitution is permitted.¹⁰¹ In these states, it may be difficult for a physician to blame another, such as a pharmacist, for waiving a patient's right to sue when the physician had the power to ensure that a brand-name drug was dispensed.

According to *Canterbury*, there are only two exceptions to the general rule of disclosure: (1) "when the patient is unconscious or otherwise incapable of consenting and harm from a failure to treat is imminent and outweighs any harm threatened by the proposed treatment;" and (2) when "communication of the risk information would present a threat to the patient's well-being."¹⁰² In most situations, these exceptions will not apply to cases involving lack of informed consent for generic drugs.

According to *Canterbury*, causality is determined objectively: in terms of what a prudent person in the patient's position would have decided if suitably informed of all perils bearing significance. If adequate disclosure could reasonably be expected to have caused that person to decline the treatment because of the revelation of the kind of risk or danger that resulted in harm, causation is shown.¹⁰³ A plaintiff could argue that a prudent person in the patient's position would have found the risk of waiving his or her right to sue and to receive compensation for injuries

⁹⁸ *Id.* at 787.

⁹⁹ *Id.* at 788.

¹⁰⁰ ASPE Issue Brief, *supra* note 6, at 7, 14-19.

¹⁰¹ *See, e.g.*, ALA. CODE §34-23-8(1) (West 2013); MO. REV. STAT §338.056(1) (West 2012).

¹⁰² *Canterbury*, 464 F.2d at 788-89.

¹⁰³ *Id.* at 790-91.

material to his or her decision to receive generic versus brand-name drug treatment.

According to *Canterbury*, when claiming inadequate disclosure of risk information by a physician, the patient has the burden of proving the essential elements of the cause of action.¹⁰⁴ The burden of going forward with evidence pertaining to a privilege not to disclose, however, rests upon the physician “because any evidence bearing on the privilege is usually in the hands of the physician alone.”¹⁰⁵ This is an additional advantage to the plaintiff because a privilege not to disclose may be difficult to prove in these cases when based on the patient’s viewpoint.

“Risk is not limited to medical- or health-related risk . . . since patients exercise choice in the wider context of their perceptions, values, and intentions.”¹⁰⁶ For example, physicians consider patients’ insurance coverage and other funding options available to patients when recommending treatment options.¹⁰⁷ Courts could find that “the foreseeable impact of treatment options on patients’ income and economic circumstances is material to their choice.”¹⁰⁸ Likewise, courts could also find that an inability to receive compensation for injury is material.

Informed consent is a broad concept: to be sure, questions about the validity of a patient’s consent to a procedure typically arise when the patient alleges that the physician failed to disclose medical risks, as in malpractice cases, and not when the patient alleges that the physician had a personal interest . . . The concept of informed consent, however, is broad enough to encompass the latter.¹⁰⁹

Canterbury is not the only case in which a court has determined that a non-health related risk was essential for a physician to disclose to obtain adequate informed consent. In *Moore*, the court held that a physician’s personal interest, whether re-

¹⁰⁴ *Id.* at 791.

¹⁰⁵ *Id.*

¹⁰⁶ B.M. Dickens and R.J. Cook, “Dimensions of Informed Consent to Treatment,” 85 INT’L J. OF GYNECOLOGY AND OBSTETRICS 309, 311 (2004).

¹⁰⁷ *Id.* at 312.

¹⁰⁸ *Id.* at 311.

¹⁰⁹ *Moore v. Regents of Univ. of Cal.*, 793 P.2d 479, 483 (Cal. 1990) (holding that a patient had a cause of action for lack of informed consent when a physician did not disclose his personal interest in the patient’s removed bodily tissue). See also *Goldberg v. Boone*, 912 A.2d 698 (Md. 2006) (stating that considerations other than risks, benefits, collateral effects, and alternatives may need to be discussed and resolved for physicians to obtain adequate informed consent).

search or economic, was an important factor for a physician to disclose to appropriately obtain informed consent. Likewise, courts have held that a patient's quality of life and self-consciousness can be required in certain situations.¹¹⁰ Cases like these leave the door open for courts to require additional informed consent disclosures, such as the loss of right to sue and to receive compensation for injury.

Because informed consent is a broad concept and physicians are sometimes required to take into consideration factors other than health-related risks, informed consent is a viable cause of action for patients to bring in jurisdictions where a physician's duty is measured from the patient's standpoint. Additionally, modern patient-centered informed consent justifies the disclosure of more information.¹¹¹

B. Lawsuits Against Pharmacists

Like physicians, pharmacists can be defined as health care providers and may be held liable for lack of informed consent.¹¹² However, it may be difficult to argue that a pharmacist has a duty to warn a consumer regarding a specific prescription written by a physician due to the possibility of interference in the physician-patient relationship. It may be easier to argue that a pharmacist has a duty to warn when a physician does not specify a certain medication and the pharmacist dispenses a generic drug instead of a brand-name drug at his or her discretion.

State laws control pharmacies' regulations for dispensing generic drugs, which allows for variation from state to state.¹¹³ Some states require pharmacists to substitute brand-name drugs with generic drugs, unless the physician specifies that the brand-name drug be dispensed.¹¹⁴ Some of these states also allow the

¹¹⁰ See *Matthies v. Mastromonaco*, 733 A.2d 456 (N.J. 1999); *Mannina v. Borland*, 869 So. 2d 946 (La. Ct. App. 2004).

¹¹¹ Marc D. Ginsberg, *Informed Consent: No Longer Just What the Doctor Ordered? The "Contributions" of Medical Associations and Courts to A More Patient Friendly Doctrine*, 15 MICH. ST. U. J. MED. & L. 17, 69 (2010).

¹¹² See, e.g., *McKee v. Am. Home Products, Corp.*, 782 P.2d 1045, 1048, 1054 (Wash. 1989); *Bryant v. HCA Health Servs. of N. Tenn., Inc.*, 15 S.W.3d 804, 809 (Tenn. 2000).

¹¹³ ASPE Issue Brief, *supra* note 6, at 7. See also RICHARD R. ABOOD, PHARMACY PRACTICE AND THE LAW 147-148 (7th ed. 2012).

¹¹⁴ ASPE Issue Brief, *supra* note 6 at 7, 14-19. See, e.g., FLA. STAT. §465.025(2) (West 2012); HAW. REV. STAT. ANN. §328-92(a), (b) (West 2012); KY. REV. STAT. ANN. §217.822(1), (3) (West 2012); ME. REV. STAT. tit. 32, §13781 (West 2012); MD. CODE ANN. HEALTH-GEN. §15-118(a)(1) (West 2012);

consumer to refuse a substituted generic drug and request a brand-name drug.¹¹⁵ Other states allow, but do not require, pharmacists to substitute brand-name drugs with generic drugs if the physician does not specify otherwise.¹¹⁶ However, some of these states require the pharmacist to obtain permission from the consumer prior to substitution.¹¹⁷

In states where pharmacists are required to substitute generic drugs when possible, an argument for lack of informed consent is likely to fail because pharmacists do not have control over what drugs they dispense. This is especially true in jurisdictions where the consumer has the right to refuse substitution and can control what medication is dispensed. However, in states where pharmacists have the ability to substitute generic drugs, but are not required to do so, an argument that the pharmacist has waived the consumer's right by choosing to dispense a generic versus a brand-name drug is stronger. However, this is not the case in states that require the pharmacist to obtain permission from consumers to substitute because the consumer is in control of what drug is dispensed. In these states, while waiver of informed consent is not a viable argument, lack of informed consent could be because the pharmacist recommended substitution without disclosing the consequences of the consumer's decision. It

MINN. STAT. §151.21(3) (West 2013); NEV. REV. STAT. §639.2583(1) (West 2011); 35 PA. STAT. ANN. §960.3(a) (West 2012); TENN. CODE ANN. §53-10-205(a) (West 2012); VT. STAT. ANN. tit. 18, §4605(a) (West 2012); W. VA. CODE ANN. §30-5-12b(b) (West 2012).

¹¹⁵ See, e.g., FLA. STAT. §465.025(2) (West 2012); HAW. REV. STAT. ANN. §328-92(a) (West 2012); MINN. STAT. §151.21(3) (West 2013); NEV. REV. STAT. §639.2583(1) (West 2011); 35 PA. STAT. ANN. §960.3(a) (West 2012); TENN. CODE ANN. §53-10-205(d) (West 2012); VT. STAT. ANN. tit. 18, §4605(a) (West 2012); W. VA. CODE ANN. §30-5-12b(n) (West 2012).

¹¹⁶ ASPE Issue Brief, *supra* note 6 at 7, 14-19. See, e.g., ALASKA STAT. §08.80.295(a) (West 2013); ARIZ. REV. STAT. ANN. §32-1963.01(A) (West 2012); ARK. CODE ANN. §17-92-503(b) (West 2013); CAL. BUS. & PROF. CODE § 4073 (West 2012); CONN. GEN. STAT. §20-619(b), (c) (West 2013); GA. CODE ANN. §26-4-81(a), (g) (West 2012); MICH. COMP. LAWS §333.17755(1), (3) (West 2012); MISS. CODE ANN. §73-21-117 (West 2012); MONT. CODE ANN. §37-7-505 (West 2013); NEB. REV. STAT. §71-5403(1) (West 2012); N.H. REV. STAT. ANN. §146-B:2(I), (II) (West 2013); N.M. STAT. ANN. §26-3-3(C) (West 2012); N.D. CENT. CODE §19-02.1-14.1(3) (West 2011); OHIO REV. CODE ANN. §4729.38(A) (West 2012); OR. REV. STAT. §689.515(2) (West 2012); TEX. OCC. CODE ANN. §562.008(b) (West 2011); UTAH CODE ANN. §58-17b-605(1) (West 2012); VA. CODE ANN. §54.1-3408.03(A) (West 2012); WYO. STAT. ANN. §33-24-148(b) (West 2012).

¹¹⁷ See, e.g., ALASKA STAT. §08.80.295(a) (West 2013); UTAH CODE ANN. §58-17b-605(1) (West 2012).

could be argued that when the pharmacist obtains permission from the consumer to substitute, that it would not take much more for the pharmacist to warn of the risk of loss of right to sue and to receive compensation for injury at this time.

However, courts have been hesitant to “interject the pharmacist into the physician-patient relationship,” believing that the duty to warn should remain with physicians.¹¹⁸ Also, there is a fear that this could negatively affect the relationship between physicians and pharmacists.¹¹⁹ However, these courts’ concerns are typically related only to health care and not to concerns outside of health care, such as the loss of the right to sue and to receive compensation.¹²⁰

Because disclosing to consumers that they lose their right to sue for injury if they take generic drugs is not likely to interfere with the physician-patient relationship, it could be argued that it is appropriate to place this duty on the pharmacist, especially when the pharmacist is the person responsible for dispensing the drug to the consumer and the physician may not have control over the actual drug that ultimately reaches his or her patient.

C. Lawsuits Against Medical Insurance Companies

Lawsuits against medical insurance companies would likely be difficult because they have neither previously been held liable for informed consent nor been labeled as a typical health care provider. Despite these obstacles, an argument could be made that they should be held liable for lack of informed consent because they have some control over what drugs consumers ultimately purchase and use.

Generic drugs are typically cheaper for consumers than brand-name drugs because they are placed on the cheapest tiers of insurance plans, where brand drugs typically are not placed.¹²¹ Medical insurance companies increase the cost of certain drugs by

¹¹⁸ *McKee*, 782 P.2d at 1051.

¹¹⁹ *Id.* at 1053.

¹²⁰ *See, e.g.,* *Leesley v. West*, 518 N.E.2d 758 (Ill. App. 1988) (showing court concerned with pharmacist disclosing a drug’s side effects to consumer); *Adkins v. Mong*, 425 N.W.2d 151 (Mich. App. 1988) (showing court concerned with pharmacist identifying consumer’s drug addiction); *W. KEETON ET AL., PROSSER AND KEETON ON TORTS* § 96 at 688 (5th ed. 1984).

¹²¹ Ernst R. Berndt and Joseph P. Newhouse, *Pricing and Reimbursement in U.S. Pharmaceutical Markets*, Faculty Research Working Paper Series 10 (2010). *See also* *What Drug Plans Cover*, MEDICARE.GOV (Mar. 17, 2013, 7:56 PM), <https://www.medicare.gov/part-d/coverage/part-d-coverage.html>.

placing them in higher tiers in order to incentivize consumers to not purchase the drugs.¹²²

When a consumer fills a prescription, does he or she really have a choice as to what prescription he or she buys? Brand-name drug pricing and insurance plans may make this impossible, even when the consumer has a choice.¹²³ “[I]n many cases, consumers will have no ability to preserve their state-law right to recover for injuries caused by inadequate warnings” because, for economic reasons, they may be forced to purchase generic drugs.¹²⁴ It could be argued that because insurance companies typically set their prices for brand-name drugs higher than generic drugs, consumers are forced to buy the cheaper drugs because they cannot afford to purchase the more expensive drugs, especially brand-name drugs, without financial help from insurance companies, which would likely be lacking. “Rising prescription drug costs remain a major challenge for consumers.”¹²⁵ Most likely, this will affect people above the age of 65, because they generally consume more drugs than those under age 65.¹²⁶

Also, there are medications that medical insurance companies will not cover under insurance plans, making the costs too high to purchase them without insurance coverage and forcing the consumer to purchase alternatives to the drug that are covered.¹²⁷ It could be argued that this is a situation where the consumer is forced to purchase cheaper drugs using his or her medical insurance.

Since medical insurance companies’ payment and reimbursement plans often disfavor brand-name drugs, they could potentially be held liable for waiving their insured customers’ right to sue and to compensation for injuries resulting from generic drugs’ inadequate warning labeling

¹²² Ernst R. Berndt and Joseph P. Newhouse, *Pricing and Reimbursement in U.S. Pharmaceutical Markets*, Faculty Research Working Paper Series 11 (2010).

¹²³ *Mensing*, 131 S. Ct. at 2592; ASPE Issue Brief, *supra* note 6, at 11.

¹²⁴ *Mensing*, 131 S. Ct. at 2592.

¹²⁵ Greater Access to Generic Drugs, *supra* note 20. See also Katie Thomas, *Brand-Name Drug Prices Rise Sharply, Report Says*, NY TIMES (Nov. 28, 2012), http://www.nytimes.com/2012/11/29/business/cost-of-brand-name-prescription-medicines-soaring.html?_r=0.

¹²⁶ Ernst R. Berndt and Joseph P. Newhouse, *Pricing and Reimbursement in U.S. Pharmaceutical Markets*, Faculty Research Working Paper Series 36 (2010).

¹²⁷ *Drug Plan Coverage Rules*, MEDICARE.GOV (Mar. 17, 2013, 7:56 PM), <https://www.medicare.gov/part-d/coverage/rules/drug-plan-coverage-rules.html>.

V. CONCLUSION

The decision in *Mensing* leaves injured generic drug consumers unable to receive compensation from generic drug manufacturers when they are injured by inadequate warning labels. Congress or the FDA needs to resolve this issue; however, it is unclear when this will occur. Because consumers are unable to sue generic drug manufacturers in failure-to-warn lawsuits, those injured may find relief from lawsuits based on lack of informed consent against physicians, pharmacists, or medical insurance companies. The most viable lawsuits are likely those (1) against physicians in jurisdictions where the physician's duty is measured by the patient's viewpoint; and (2) against pharmacists who are able to choose whether a prescription is filled by a brand-name or generic drug.