

Implications of the Supreme Court's Decision in PLIVA, Inc. v. Mensing: Why Generic and Brand-Name Pharmaceuticals Must Be Treated Equally Under the Federal Food, Drug, and Cosmetic Act

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**IMPLICATIONS OF THE SUPREME COURT'S
DECISION IN *PLIVA, INC. V. MENSING*: WHY
GENERIC AND BRAND-NAME PHARMACEUTICALS
MUST BE TREATED EQUALLY UNDER THE FEDERAL
FOOD, DRUG, AND COSMETIC ACT**

Courtney A. Markey*

I. INTRODUCTION

Traditionally, medical patients overwhelmingly have had to rely on their doctors to give them all the information they needed to make certain decisions about their health. Unless one was a doctor, medical student, or pharmacist it usually was much more difficult to obtain information about prescription drugs and certain over-the-counter medications in the past than it is today. However, we have progressed as a society from times of doctors making house calls to an era in which mass marketing of medical products and communication about medical information spans the globe. Nowadays, we have the luxury of the internet to disseminate and obtain medical information, including the risks certain prescription drugs may pose to their users.

Nevertheless, patients should not be forced to figure out on their own the potential problems with prescription drugs they take. Although newspapers, magazines, television, Google, and WebMD supplement information patients may receive from their doctors, patients should not have to rely on these other sources for warning information about pharmaceutical prescription drugs. Companies that manufacture prescription drugs should have a duty to inform patients about the risks of ingesting those substances.

Notification to consumers of risks presented by prescription

drugs is instrumental in ensuring the utmost safety of consumers who take them. *Wyeth v. Levine*¹ and *PLIVA, Inc. v. Mensing*² are two relatively recent landmark Supreme Court cases involving pharmaceutical companies' alleged failure to provide adequate warnings on prescription drugs. Although their fact patterns are extremely similar, the cases produced very different results. In *Wyeth*, the Court found that a brand-name prescription drug manufacturer, Wyeth, was able to comply with state and federal laws simultaneously and that, therefore, the federal Food, Drug, and Cosmetic Act (FDCA) did not statutorily preempt the plaintiff's failure-to-adequately-warn claims.³ In *Mensing*, however, the Court held that a generic prescription drug manufacturer, PLIVA, was not able to comply with both state and federal regulations, and that the FDCA statutorily preempted the plaintiffs' failure-to-adequately-warn claims.⁴

These contrasting results have now created obstacles for ordinary Americans involved in prescription drug litigation. To help explain how they have done so, this paper discusses and analyzes the Supreme Court's decision in *Wyeth* and the Court's analysis in *Mensing* of the FDCA. This paper not only concludes that the Court's analysis of the FDCA in *Mensing* is incorrect, but also alternatively finds that the Court's interpretation of the FDCA in *Mensing* results in the FDCA violating the Equal Protection component of the 5th Amendment's Due Process clause because of the FDCA's irrational different treatment of generic and brand-name prescription drugs. Particularly, this paper explains how the Court's interpretation of the FDCA in these two cases creates problems for many Americans who are

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1. *Wyeth v. Levine*, 555 U.S. 555 (2009).
2. *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011).
3. *Wyeth*, 555 U.S. at 555.
4. *Mensing*, 131 S.Ct. at 2581.

harméd by prescription drugs that fail to adequately warn. Persons who are most affected by the *Mensing* decision may not have access to mass communication such as the internet and television. Many poor individuals do not have these luxuries, so there may be no way that they would have access to the kind of medical information that some of us take for granted. Even if a doctor prescribes a prescription drug to a patient, there is no guarantee that the patient will be able to find out the relevant information about the drug on his or her own via today's communication.

Because generic and brand-name prescription drugs are substantively equivalent, this paper ultimately concludes that the Equal Protection component of the Fifth Amendment Due Process clause requires that generic and brand-name pharmaceuticals be treated the same way under the FDCA. Further, it recommends the introduction of congressional legislation to remedy the implications of the *Mensing* decision.

Section II provides a brief overview of the similarities and differences between generic and brand-name prescription drugs. Section III then discusses the legal implications of such similarities and differences in the context of the Supreme Court's *Wyeth v. Levine* and *PLIVA, Inc. v. Mensing* decisions. Section IV discusses the Court's reasoning in *Mensing* along with the specific problems its holding presents. Subpart A of Section IV explores issues with off-market brand-name prescription drugs, while Subpart B of Section IV discusses the practice of prescribing brand-name pharmaceuticals but dispensing generics. Subpart C of Section IV discusses the particular problem of denial of equal protection by the FDCA as a result of the *Mensing* decision's federal statutory preemption of failure-to-warn claims regarding generic drugs. Section V then explains how the interpretation of the FDCA by the *Mensing* decision disproportionately affects women, minorities, and the elderly in Subheadings A, B, and C, respectively. These disproportionate effects result in the FDCA violating the Equal Protection component of the Due Process clause of the Fifth Amendment of

the U.S. Constitution. Section VI identifies certain state appellate courts which are more and less favorable to such demographic groups in cases involving tort claims against prescription drug manufacturers. Section VII explores alternative causes of action besides failure-to-adequately-warn claims that can be used by consumers injured by a prescription drug. Finally, Section VIII examines how new legislation amending the FDCA can overcome the equal protection violation in the FDCA created by the *Mensing* decision.

II. OVERVIEW OF BRAND NAME AND GENERIC PHARMACEUTICALS

The issue of cost is probably the most obvious difference that comes to mind when examining brand-name and generic prescription drugs. Almost everyone knows that brand-name or “designer” drugs are almost always more expensive than generics, but they may not know much more about these two types of drugs beyond this fact. Most people in the United States probably have, at one time or another, been prescribed a drug from a physician and filled the prescription at a local pharmacy. Sometimes a person may check to see if they were dispensed the brand-name or the generic equivalent, but most of the time they likely trust that the drug dispensed to them will do its intended job regardless of whether it’s a designer brand-name drug or a generic.

The Drug Price Competition and Patent Term Restoration Act of 1984⁵, more commonly referred to as the Hatch-Waxman Act of 1984, revolutionized the way we as a society consume prescription drugs. After pharmaceutical manufacturers that initially create new prescription drugs have their patents on those drugs expire, the Hatch-Waxman Act allows pharmaceutical manufacturers other than the original parent

5. Gerald J. Mossinghoff, *Striking the Right Balance Between Innovation and Drug Price Competition – Understanding the Hatch-Waxman Act*, 54 FOOD & DRUG L.J. 187, 188 (1999).

company – generic manufacturers – to produce the same drug at a much lower cost.⁶

The Hatch-Waxman Act has enabled more Americans to get the pharmaceuticals they need at affordable prices. In fact, the average cost of a generic drug is about 80 to 85 percent lower than the same drug in its brand-name form.⁷ Before the Hatch-Waxman Act, only about 19 percent of pharmaceutical drugs sold in the U.S. were generic.⁸ Today, about 75 percent of all prescriptions in the U.S. are filled with generic drugs; this number increases to 90 percent when the generic drug is available.⁹ The Hatch-Waxman Act has also resulted in a boon for the generic pharmaceutical industry because generic manufacturers have been able to piggyback on the labors of the brand-name manufacturers and reap similar financial rewards.

Both brand-name and generic prescription drugs must be approved by the Food & Drug Administration (FDA) under the FDCA.¹⁰ In order for a generic prescription drug to be approved by the FDA, it has to be exactly the same effect-wise under the FDA's regulations.¹¹ The FDA can approve a generic drug that is "bioequivalent" to the brand-name drug; this means that there is an "absence of a significant difference in the availability of the active ingredient at the site of drug action."¹²

Generic and brand-name prescription drugs share many

6. Linda Park, *The Generic Pharmaceutical Industry*, REG. SCI. J., <http://regulatory.usc.edu/Articles/GenericPharmaceuticalIndustry.pdf> (last visited Sep. 30, 2013).

7. The U.S. Food and Drug Admin., *Facts About Generic Drugs*, DRUGS (Sept. 19, 2012), <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm>.

8. CONG. BUDGET OFFICE, *HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY*, 27 (1998), <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/6xx/doc655/pharm.pdf>.

9. Erwin Chemerinsky, *A Devastating Decision*, TRIAL, Sept. 2011, at 54.

10. 21 U.S.C. § 355 (2006).

11. Aaron S. Kesselheim et al, *Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease*, JAMA, 2008, <http://jama.ama-assn.org/content/300/21/2514.full>.

12. *Id.* at 2514.

similarities in their substantive composition. Besides the fact that the active ingredients in these drugs must function the same way in each person's body to get FDA approval, there are still some differences between the two types of drugs that are worth noting. According to the Journal of American Medicine, "[g]eneric drugs are chemically equivalent to their brand-name counterparts in terms of active ingredients but may differ in peripheral features, such as pill color or shape, inert binders and fillers, and the specific manufacturing process."¹³ Other differences may include other superficial traits like taste and packaging.¹⁴ Often times, there are also different inactive ingredients in generics that may alter the way that a person's bloodstream absorbs them.¹⁵

According to the FDA's guidelines, "Generics can produce blood levels as much as 20 percent below or 25 percent above that of the original drug and still be considered 'bioequivalent.'"¹⁶ Because such variances exist, generic manufacturers must prove to the FDA

that their product is manufactured in accordance with good manufacturing practices (GMPs), and is as pure and stable as the brand-name product. Additionally, the generic needs to meet pharmacokinetic parameters in the body, which means it must dissolve (in a beaker) at the same rate and to the same extent as the original. This process ensures that the two products are bioequivalent because if product A and product B dissolve in a virtually identical manner, then they should behave the same in the body.¹⁷

While the FDA makes sure that generics reach the market without any significant divergences from their brand-name

13. *Id.*

14. Erik Mogalian & Paul Myrdal, *What's the Difference Between Brand-Name and Generic Prescription Drugs?*, SCI. AM., Dec. 13, 2004, <http://www.scientificamerican.com/article.cfm?id=whats-the-difference-betw-2004-12-13>.

15. Melinda Beck, *Inexact Copies: How Generics Differ from Brand Names*, WALL ST. J., Apr. 22, 2008, at D1.

16. *Id.*

17. Mogalian, *supra* note 14.

counterparts, there still remains a major important difference between generics and brand-names. Most people may not know about it, but it affects us all: the Supreme Court's decision in *PLIVA, Inc. v. Mensing*. This decision precludes the filing of a lawsuit against a generic drug manufacturer under a failure-to-adequately-warn claim.

III. WYETH V. LEVINE AND PLIVA, INC. V. MENSING

In 2009, the Supreme Court decided *Wyeth v. Levine*.¹⁸ In *Wyeth*, the plaintiff, Levine, was injected with Phenergan, a brand-name anti-nausea drug, through the IV-push method, directly into her vein.¹⁹ Phenergan was found to have entered Levine's artery, which led to her developing gangrene, and as a result, she unfortunately had to have her forearm amputated.²⁰ Levine thereafter sued Wyeth, the brand-name manufacturer of Phenergan, for failing to adequately warn about the serious risks involved with injecting Phenergan via the IV-push method.²¹ In this decision, the Court held that a person's claim against the manufacturer of a brand-name prescription drug—alleging that the manufacturer failed to adequately warn both the patient and her doctor of a brand-name prescription drug's harmful effects—is not preempted by federal law, and that a brand-name prescription drug manufacturer could be held liable for damages under such a claim.²²

A central premise of federal drug regulation is that a pharmaceutical manufacturer is always fully responsible for the contents of its label, so the manufacturer is thus the party who must ensure that its labels and warnings are adequate while its corresponding drug continues to be sold.²³ In addition, a manufacturer of a brand-name prescription drug is required to

18. *Wyeth v. Levine*, 555 U.S. 555, 570 (2009).

19. *Id.* at 555.

20. *Id.*

21. *Id.*

22. *Id.* at 581.

23. *Id.* at 570-71.

revise its label “to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug.”²⁴ According to Justice Stevens, who authored the Court’s majority opinion in *Wyeth*, allowing liability of such manufacturers aligns with and furthers the goal of manufacturers’ disclosure of harmful effects of their drugs to consumers and doctors, thereby better protecting them.²⁵

In general, a pharmaceutical manufacturer must obtain FDA approval of any changes in a particular prescription drug’s label.²⁶ However, via the “changes being effected” (CBE) regulation, the FDA also lets a manufacturer of a brand-name prescription drug change its label even before the new label becomes approved.²⁷ The way the CBE regulation works is that

if a manufacturer is changing a label to ‘add or strengthen a contraindication, warning, precaution, or adverse reaction’ or to ‘add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product,’ it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval.²⁸

Wyeth argued that it could not have changed its label unilaterally because the FDCA prohibits misbranding.²⁹ However, as Justice Stevens noted in his opinion, Wyeth could have changed its warning label legally because the FDCA “does not provide that a drug is misbranded simply because the manufacturer has altered an FDA-approved label.”³⁰ The FDCA’s misbranding provision instead “focuses on the substance of the label and, among other things, proscribes labels that fail to include ‘adequate warnings.’”³¹ In other words, the

24. *Id.* at 571 (quoting 21 C.F.R. § 201.80(e) (2013)).

25. Erwin Chemerinsky, *Closing the Courthouse Doors*, 14 GREEN BAG 2D 375, 380 (Oct. 2010).

26. *Wyeth*, 555 U.S. at 568.

27. *Id.* (quoting 21 C.F.R. § 314.70(c)(6) (2013)).

28. *Id.* (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2013)).

29. *Id.* at 570.

30. *Id.*

31. *Id.*; *See also* 21 U.S.C. § 352(f) (2006).

FDCA seeks to ensure that a label accurately informs people about the drug even if it means erring on the side of caution. According to the Court in *Wyeth*, because Wyeth, a manufacturer of brand-name prescription drugs, could have used the CBE regulation mechanism while complying with the FDCA, it therefore could have complied with both state and federal law.³²

Furthermore, the Court correctly concluded that Wyeth, as the responsible party, should have changed its warning and had the ability to do so. Because there was no clear evidence that the FDA would have rejected approval of the warning label change in *Wyeth*, the Court reasoned that it was not “impossible for [the manufacturer] to comply with both federal and state requirements,”³³ and properly held that the plaintiff’s state common law failure-to-adequately-warn claim was not preempted by federal law.³⁴

The Court also used Congress’s intent to support its holding in the *Wyeth* case. According to Justice Stevens, “[I]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA’s 70-year history.”³⁵ He further noted that Congress enacted an express preemption provision for failure-to-adequately-warn claims involving medical devices in 1976, but that it has not done the same for prescription drugs, emphasizing that: “Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.”³⁶ Justice Stevens concluded that Congress’ silence on this issue, along with its awareness of the frequency of state tort litigation, “is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety

32. *Wyeth*, 555 U.S. at 581.

33. *Id.* at 571.

34. *Id.* at 581.

35. *Id.* at 574.

36. *Id.* at 574-5 (2009) (quoting *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008)).

and effectiveness" and that the manufacturer must look out for the safety of its own products.³⁷ Given that Congress' intent is paramount when interpreting legislation, the Court correctly used this inference to conclude that the plaintiff's state law claims were not preempted by federal law.³⁸

Since the *Wyeth* decision, consumers could have confidence that a remedy in law existed for any undisclosed harms that befell them from their brand-name prescription drugs. However, that confidence in the case of generic prescription drugs changed in June 2011 once the Supreme Court decided *PLIVA, Inc. v. Mensing*.

In *Mensing*, the plaintiffs were prescribed the brand-name drug Reglan to treat their digestive tract disorders in 2001 and 2002.³⁹ Their pharmacies instead dispensed to them the generic form of Reglan – metoclopramide – which was manufactured by PLIVA, Inc.⁴⁰ After taking metoclopramide for years, the plaintiffs developed tardive dyskinesia, a severe neurological disorder consisting of involuntary repetitive movements, which is often irreversible.⁴¹

The manufacturer of Reglan changed the drug's warnings several times over the course of a number of years to include the possibility of tardive dyskinesia as a side effect. In 1985, the warning label cautioned that "'tardive dyskinesia . . . may develop in patients treated with metoclopramide,' and the drug's package insert added that '[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended.'"⁴² In 2004, the manufacturer added to its warnings that Reglan should not be used for more than 12 weeks because of the

37. *Id.* at 575.

38. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

39. *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567, 2573 (2011).

40. *Id.*

41. The Nat'l Insts. of Neurological Disorders and Stroke, *NINDS Tardive Dyskinesia Information Page*, NAT'L INSTS. OF HEALTH (Oct. 4, 2011), <http://www.ninds.nih.gov/disorders/tardive/tardive.htm>.

42. *Mensing*, 131 S.Ct. at 2572 (quoting PHYSICIAN'S DESK REFERENCE 1635-6 (41st ed. 1987)).

disorder.⁴³ In 2009, the FDA ordered its strongest warning, the “black box warning,” on Reglan, stating that treatment with the drug can cause tardive dyskinesia and that “[t]reatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases.”⁴⁴

However, in 2001-2002 when the plaintiffs first began taking metoclopramide, the label still carried the 1985 warning that patients who took the drug “may develop” tardive dyskinesia and that treatment with the drug had not been evaluated and could not have been recommended for longer than twelve weeks.⁴⁵ The plaintiffs had been taking metoclopramide for several years when they sued PLIVA, and they argued that there existed a great deal of evidence that tardive dyskinesia was a major risk of metoclopramide, but that its label did not indicate such a correspondingly serious threat at the time.⁴⁶

Although state law in the plaintiffs’ respective states required prescription drug manufacturers to adequately warn of their drugs’ dangers, federal law, according to the Court in *Mensing*, did not require a manufacturer of a generic prescription drug to upgrade the warnings in the drug’s FDA-approved label to reflect new information about the drug’s dangers.⁴⁷ Even though the *Wyeth* decision in effect means that federal law does not preempt state failure-to-adequately-warn claims involving a brand-name prescription drug, the Court concluded in *Mensing* that the *Wyeth* decision only applied to brand-name pharmaceutical manufacturers, not generic ones, and that *Wyeth* therefore was not controlling.⁴⁸

In *Mensing*, the Court supported its holding by reasoning that it was impossible for the generic drug manufacturer to change its warning label on its own without the FDA’s assistance and that it could not have used the CBE process for

43. *Id.*

44. *Id.* at 2573 (quoting PHYSICIAN’S DESK REFERENCE 2902 (35th ed. 2011)).

45. *Id.* at 2572.

46. *Id.* at 2573.

47. *Id.* at 2577-78.

48. *Id.* at 2581.

the generic drug.⁴⁹ Specifically, the Court stated that “federal law would permit the [generic] [m]anufacturers to comply with the state labeling requirements if, and only if, the FDA and the brand-name manufacturer changed the brand-name label to do so.”⁵⁰ In *Mensing*, even though the plaintiffs had been given the generic drug, the corresponding brand-name manufacturer of the drug had not changed the label, so the Court concluded that the generic manufacturer could not change the label either.⁵¹

The Supreme Court also based the *Mensing* decision on its interpretation of the U.S. Constitution’s Supremacy Clause, which states 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.”⁵² Reasoning that federal law is supreme over state law – even if the state law made the drug safer because of stricter warning label requirements – the Court found that federal statutory preemption of failure-to-adequately-warn claims involving a generic prescription drug was thus final. With all due respect to the Court, there exist many problems with the Court’s reasoning and decision in *Mensing* which the following section explores.

IV. PROBLEMS WITH THE *MENSING* DECISION

Justice Thomas wrote the opinion of the Court in *Mensing*, even though he concurred in the judgment in *Wyeth*. Unfortunately, Justice Thomas gives no clear indication why he changed his stance on the subject of pharmaceutical drug preemption in *Mensing*, nor does he adequately explain why there should even be a difference between the ways the FDCA treats generic and brand-name prescription drugs. The following paragraphs examine the Court’s reasoning in *Mensing*, explain why the reasoning is erroneous, and articulate how the Court could have reached a different, better result.

49. See *infra* Part IV (full discussion of the *Mensing* reasoning).

50. *Mensing*, 131 S.Ct. at 2578.

51. *Id.* at 2575.

52. U.S. CONST., art. VI, cl. 2.

The FDA requires that generic pharmaceutical manufacturers must always have the same warning labels as their brand-name counterparts.⁵³ In *Mensing*, the Court deferred to the FDA's interpretation of the CBE regulation, which is that generic manufacturers may only change a drug's label "to match an updated brand-name label or to follow the FDA's instructions," and ultimately concluded that a generic pharmaceutical manufacturer may not change its warning label, even via the CBE process.⁵⁴ The main difference between the *Wyeth* decision and the *Mensing* decision, then, is the fact that it was possible for a brand-name manufacturer (Wyeth) to unilaterally comply with state and federal law by using the CBE process, but that it was not possible for a generic manufacturer (PLIVA) to do so because of the generic manufacturer's need to rely on the label of the corresponding brand-name drug.⁵⁵ The Court consequently reasoned that because it was impossible for a generic drug manufacturer to comply with both federal and state law, federal law therefore statutorily preempted the plaintiffs' failure-to-adequately-warn claims in *Mensing*.⁵⁶

Similarly, the Court in *Mensing* held that PLIVA, the generic manufacturer, would not have been allowed by FDA regulations to send a "Dear Doctor" letter to physicians with new warning information.⁵⁷ The FDA asserted that "if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'"⁵⁸ Consequently, the Court in *Mensing* deferred to the FDA's stance on this issue as well, and used it to support its ultimate conclusion.

Even though PLIVA, as a generic manufacturer, apparently could not have used either the CBE process or the "Dear Doctor"

53. *Mensing*, 131 S.Ct. at 2575.

54. *Id.*

55. *Id.* at 2571.

56. *Id.* at 2576.

57. *Id.* at 2581.

58. *Id.* at 2576.

letter to notify consumers or their doctors of a proposed updated metoclopramide label, PLIVA still was required to propose a stronger warning label to the FDA if it believed the drug warranted it.⁵⁹ The FDA mandates that “[g]eneric drug manufacturers that become aware of safety problems *must* ask the agency to work toward strengthening the label that applies to both the generic and brand-name equivalent drug.”⁶⁰ Furthermore, “[i]f a [generic drug manufacturer] believes new safety information should be added to a product’s labeling, it should contact [the] FDA, and [the] FDA will determine whether the labeling for the generic and listed drugs should be revised.”⁶¹ Nevertheless, PLIVA never notified the FDA that it believed a stronger warning was required for metoclopramide or asked the FDA to strengthen the label that applied to both the brand-name and the generic drug.⁶²

Through contacting the FDA about the need for a change in the metoclopramide label this way, PLIVA may have been able to comply with both federal and state law. Nevertheless, the Court in *Mensing* rejected this theory as a basis for permitting the plaintiff Mensing’s failure-to-adequately-warn claim. Instead, the Court stated that it was impossible for PLIVA to abide by both state and federal regulations⁶³ because the generic manufacturer would have violated federal law if it had independently changed its labels to satisfy its state-law duty.⁶⁴ Thus, the Court found in *Mensing* that even if the generic manufacturer had attached a safer label to its metoclopramide, it still would have been in violation of federal law because the label would have been different from the corresponding brand-name drug Reglan’s label.⁶⁵

The Court’s reasoning here is problematic, however,

59. *Id.*

60. *Id.* (emphasis added).

61. *Id.* at 2577.

62. *Id.* at 2578.

63. *Id.* at 2577.

64. *Id.* at 2578.

65. *Id.* at 2570.

because the Court fails to acknowledge that PLIVA could have complied with federal and state law in this situation. *Wyeth* provides that, absent any clear evidence that the FDA would have rejected the proposed label changes, the Court will not conclude impossibility in complying with federal and state regulations.⁶⁶ Unfortunately, the Court in *Mensing* defies this principle by inventing a new preemption rule,⁶⁷ according to Justice Sotomayor, when it states “[t]he question for ‘impossibility’ is whether the private party could *independently* do under federal law what state law requires of it.”⁶⁸ Because a generic manufacturer, such as PLIVA, is dependent on the FDA for approval before it may change its warning labels, the Court then held that it would have been impossible for a generic manufacturer to comply with both state and federal law “independently” without the FDA’s intervention.⁶⁹ However, as Justice Sotomayor points out, the test of a generic drug manufacturer’s “independence” of action

has no basis in our precedents. The majority cites only *Wyeth* in support of its test. As discussed above, however, *Wyeth* does not stand for the proposition that it is impossible to comply with both federal and state law whenever federal agency approval is required. To the contrary, label changes by brand-name manufacturers such as *Wyeth* are subject to FDA review and acceptance. . . . And, even if *Wyeth* could be characterized as turning on the fact that the brand-name manufacturer could change its label unilaterally, the possibility of unilateral action was, at most, a sufficient condition for rejecting the impossibility defense in that case. *Wyeth* did not hold that unilateral action is a necessary condition in every case.⁷⁰

As Justice Sotomayor states, this new principle that requires a drug manufacturer’s ability to act “independently” from the FDA before a failure-to-adequately warn claim can be allowed

66. *Wyeth*, 555 U.S. at 571.

67. *Mensing*, 131 S. Ct. at 2589.

68. *Id.* (Sotomayor, J., dissenting) (emphasis added).

69. *Id.*

70. *Id.* at 2589-90.

under the FDCA is unprecedented. Thus, the only way the Court may arrive at its result is by improperly creating this new standard “out of thin air” for generic drug manufacturers.⁷¹ Furthermore, this new standard directly contradicts common sense that taking action to make patients safer – such as improving a warning label—would be a violation of federal law.

The most significant problem with the *Mensing* decision is that the Court should have required the defendant generic drug manufacturer to prove that the FDA would not have approved the label change in order to find the impossibility that led the Court to find federal statutory preemption of the claims. As the Court in *Wyeth* states, “[i]mpossibility pre-emption is a demanding defense,” and the Court’s decision in that case turned on the defendant’s failure to demonstrate impossibility of simultaneously following federal and state law.⁷² In *Mensing* though, the Court did not require the defendant to prove that the FDA would not have approved a change in the generic’s label which would have provided for impossibility in following both federal and state law. Instead, it simply decided that because the defendant was dependent on the FDA for label approval, the fact that it could not “independently” fulfill its state duties was enough to satisfy impossibility.⁷³ However, this is problematic because without proving that the FDA would have rejected the label change, there only exists a mere “possibility” that state and federal law would have been at odds.⁷⁴ As Justice Sotomayor states in her dissent in *Mensing*,

had the [m]anufacturers invoked the available mechanism for initiating label changes, they may well have been able to change their labels in sufficient time to warn respondents. Having failed to do so, the [m]anufacturers cannot sustain their burden . . . to demonstrate that it was impossible for them to comply with both federal and state law. At most, they have demonstrated only a ‘hypothetical or potential

71. *Id.* at 2582.

72. *Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

73. *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567, 2581-2 (2011).

74. *Id.* at 2582.

conflict.⁷⁵

Even though PLIVA failed to invoke the mechanism for changing metoclopramide's warning label, PLIVA nevertheless prevailed – being shielded from the plaintiffs' claims without even meeting its burden of proof.

The Court also uses the “non obstante” provision of the Supremacy Clause, “any [state law] to the [c]ontrary notwithstanding,” to support its holding.⁷⁶ The Court reasons in *Mensing* that this clause suggests that “federal law should be understood to impliedly repeal conflicting state law” and that “courts should not strain to find ways to reconcile federal law with seemingly conflicting state law.”⁷⁷ However, this reasoning contradicts the long-held idea that federal statutory preemption of state law is not to be assumed unless there is a clear indication that Congress intends preemption.⁷⁸ Given that there is no such indication in the FDCA, as it was explained in *Wyeth*,⁷⁹ the Court should not have used the “non obstante” clause in *Mensing* to support preemption of the plaintiffs' claims.

If *Mensing* has correctly interpreted the FDCA as regulating brand-name and generic prescription drugs differently with respect to how changes in warnings and labels on prescription drugs can be made, then, as Section VIII of this paper discusses in more detail, the FDCA violates the Equal Protection component of the Fifth Amendment's Due Process clause because this difference is irrational.⁸⁰ As discussed in more detail in subpart C *infra*, the Supreme Court presumes that Congress does not intend a federal statute it enacts to have absurd results⁸¹, but the interpretation of the FDCA in *Mensing* results in absurd and irrational differences in how the FDCA

75. *Id.* at 2587-88 (quoting *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982)).

76. *Id.* at 2579.

77. *Id.* at 2580.

78. *Wyeth v. Levine*, 555 U.S. 555, 574 (2009).

79. *Id.* at 574-75.

80. *See infra* Part IV.C.

81. *Mensing*, 131 S.Ct. at 2582.

regulates warnings and labels of brand-name and generic drugs. The Supreme Court also presumes that Congress does not intend to enact a statute that violates the United States Constitution. So, the Court usually interprets a federal statute in a manner that avoids the statute violating the Constitution unless it is clear that Congress intended such an interpretation.⁸² The Court in *Mensing* should have applied this principle to infer that Congress did not mean to discriminate between generic and brand-name prescription drugs in the FDCA to the detriment of the public, which is how the Court construes Congress's intent in *Mensing*.⁸³ This paper discusses this topic further in section VIII.

With this general overview of the holding and reasoning in *Mensing* as background, the next three subsections explore some of the specific problematic implications of the *Mensing* decision. The first of the three addresses how the removal of brand-name pharmaceuticals from the market impacts consumers, the next discusses how a consumer may wind up taking a generic drug even though the consumer's physician has prescribed the brand-name drug, and the last examines equal protection problems presented by *Mensing's* application of federal statutory preemption of state tort law.

A. BRAND NAMES OFF THE MARKET

One major problem with the holding in *Mensing* is that certain brand-name drugs may be off the market now. According to a recent article discussing the *Mensing* decision, "[a]bout a third of generic drugs have no brand-name competitors."⁸⁴ This situation presents a variety of implications. One is that the corresponding generic drug still in the market

82. See *Solid Waste Agency of N. Cook Cnty v. U.S. Army Corps of Engineers*, 531 U.S. 159, 160 (2001).

83. John F. Manning, *The Absurdity Doctrine*, 116 HARV. L. REV. 2387, 2432 (2003).

84. Bill Mears, *High Court Sides with Generic Drug Makers in Narrow Ruling*, CNN (Jun. 23, 2011, 6:04 PM), <http://www.cnn.com/2011/HEALTH/06/23/scotus.generic.drugs/index.html>.

would be a patient's only option. Another implication is that, as a result of the *Mensing* decision, there would be no way that a generic manufacturer would be able, on its own, to amend its warning for the increased safety of its consumers because of its need to rely on the warning label of a brand-name-manufactured drug that no longer even exists.

Even if a brand-name prescription drug leaves the market after its patent expires, and all that is left is on the market is the generic equivalent, it is significant that the generic manufacturer would still have no duty to provide additional warnings about newly-discovered risks of the drug. This means that consumers potentially could be adversely affected by the drug in ways that are not warned about in the drug's label – even though there is still a real possibility that harmful effects of the drug have been found – but consumers would have no legal recourse. Under *Mensing*, bringing a failure-to-adequately-warn claim would be impossible for those patients injured by a generic drug, since the generic manufacturer would have no way to change its label, given that the brand-name no longer exists. The generic manufacturer would be prevented from ever being sued for failure to provide adequate warnings because the FDCA prohibits it from making any unilateral changes to its warnings that may be helpful to its consumers. This seems to contradict common sense and generates an absurd result.

Furthermore, the practice of requiring a generic to follow a brand name warning label could discourage generic manufacturers from making known the harmful effects of the generic drug. There certainly exist positive reasons for the requirement of total label similarity, such as the disclosure of actual viable harms and reassuring the consumer that the drugs are the same. On the other hand, if a generic manufacturer discovers harm about its particular drug, but the brand name manufacturer does not, federal law does not require the generic manufacturer to change its warning label. This disparity may in fact encourage the generic manufacturer to stay silent and refrain from speaking up when it discovers a problem presented

by the drug.⁸⁵

In this same vein, a manufacturer of a brand-name pharmaceutical drug may use federal law as a good reason to conduct its own studies regarding the harms its drug causes. As Steven Rotman notes in his article on epidemiology and pharmaceutical litigation, “when pharmaceutical companies sponsor case-control studies to investigate whether their drug causes a disease or injury, they often do so under pressure from the FDA and usually design the studies to be marginal on power. By doing this, they save money and, more important, are more likely to miss detecting a result associating their drug with the disease. . .”⁸⁶

Likewise, in weak studies, “if there is a result that associates a drug with a disease, defendants will be able to argue that the results are not statistically significant or that the numbers are small or ‘fragile.’”⁸⁷ In other words, by setting up their own studies, pharmaceutical companies can defend themselves either way to demonstrate their drug’s weak correlation with harm.

Justice Sotomayor makes a number of compelling arguments regarding some of these problems in her dissent in *Mensing*. She points out that in *Wyeth*, the Court recognized that “manufacturers have superior access to information about their drugs, especially in the post marketing phase as new risks emerge,”⁸⁸ and that therefore “[f]ederal law thus obliges drug manufacturers – both brand-name and generic – to monitor the safety of their products.”⁸⁹ This view makes more sense as it properly holds accountable those manufacturers who fail to warn about drug harm or who otherwise equivocate. After all, our justice system was designed to do exactly that, and the court should retain such an avenue for recourse.

85. *Mensing*, 131 S.Ct. at at 2592.

86. Steven Rotman, *Don't Know Much About Epidemiology?*, TRIAL, Sept. 2007, at 33-34.

87. *Id.*

88. *Wyeth v. Levine*, 555 U.S. 555, 578-79. (2009).

89. *Mensing*, 131 S.Ct. at 2584.

B. TAKING GENERICS WITHOUT KNOWLEDGE

Another significant problem caused by *Mensing* is that patients can be given generic prescription drugs without their knowledge. Similar to what happened to the plaintiffs in *Mensing*, doctors may prescribe brand-name drugs, but the pharmacist may simply switch the brand-name for a generic prescription. This practice is commonplace, and is even compulsory in some states.⁹⁰ Often times, a patient may not even know or realize that the drug he or she has been given is in fact a generic.

As noted above in the summary of the *Mensing* decision, generic manufacturers are allowed to abide by state warning labeling requirements to change the warning information only if the FDA has approved the corresponding brand-name warning change.⁹¹ A doctor may prescribe a brand-name prescription drug to a patient, but if that brand-name drug is no longer on the market, the pharmacy will automatically fill the prescription with the generic drug.⁹² However, as stated in Section A of this paper, if that generic drug manufacturer has found harmful effects of the drug, it still cannot change its warning label because of its need to rely on the brand-name manufacturer which no longer exists. Thus, if no worrisome information about the drug makes its way home with the consumer because the generic manufacturer is unable to change its warning label, the consumer would have no reason to think that the very drug he or she is ingesting is unsafe, even though it may be. Justice Sotomayor remarks on this result in her dissent in *Mensing*: “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.”⁹³ She goes further to note

90. *Id.* at 2583.

91. *Id.* at 2578.

92. *Id.* at 2583.

93. *Id.*

that even the majority of the Court acknowledges that such an outcome “makes little sense.”⁹⁴

C. *FEDERAL STATUTORY PREEMPTION OF STATE TORT LAW AND EQUAL PROTECTION*

It is well known that congressional intent does matter when courts interpret a federal statute. According to the Supreme Court, “[t]he purpose of Congress is the ultimate touchstone’ in every pre-emption case.”⁹⁵ In *Wyeth*, the Supreme Court confirmed this view, noting that “‘all evidence of Congress’ purposes’ in enacting and amending the FDCA pointed against [federal] preemption.”⁹⁶ Moreover, the FDCA—which is a linchpin in the decisions in *Wyeth* and *Mensing*—lacks an express preemption provision.⁹⁷ Even if it did contain one, “where the text of a preemption clause is open to more than one plausible reading, courts ordinarily ‘accept the reading that disfavors pre-emption.’”⁹⁸

When deciding a case, the Supreme Court is supposed to keep in mind that Congress does not intend absurd results from its legislation.⁹⁹ However, when the Court applied preemption the way it did in *Mensing*, it directly and effectively gave rise to an absurd result: allowing brand name consumers to sue for failure to adequately warn, but preventing generic consumers from doing so, regardless of the fact that the drugs are substantively equivalent. In Justice Sotomayor’s dissent, she appropriately addressed this issue. She reasoned that

‘If Congress had intended to deprive injured parties of [this] long available form of compensation, it surely

94. *Id.*

95. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)).

96. Louis M. Bograd, *W(h)ither Preemption?*, *TRIAL*, Nov. 2009, at 26 (quoting *Wyeth*, 555 U.S. at 574).

97. *Id.* at 24.

98. *Altria Group, Inc. v. Good*, 555 U.S. 70, 101 (2008) (quoting *Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005)).

99. Manning, *supra* note 83, at 2388, 2409.

would have expressed that intent more clearly...’ Given the long-standing existence of product liability actions, including for failure to warn, ‘[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct...’ In concluding that Congress silently immunized generic manufacturers from all failure-to-warn claims, the majority disregards our previous hesitance to infer congressional intent to effect such a sweeping change in traditional state-law remedies.¹⁰⁰

Even though the dissent in *Mensing* recognized that “the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress,” the Court allowed federal preemption without it being the *clear and manifest* purpose of Congress.¹⁰¹ As Dean Erwin Chemerinsky succinctly states, “there is no indication whatsoever that Congress meant to preempt tort liability for generic drugs in the exact same situations in which failure-to-warn suits can be brought against their brand-name equivalents.”¹⁰²

According to the Due Process clause of the Fifth Amendment, “[n]o person shall . . . be deprived of life, liberty, or property without due process of law.”¹⁰³ The Due Process clause impliedly includes equal protection of the laws and provides against unjustifiable discrimination in federal laws.¹⁰⁴ Additionally, the rational basis test is the usual standard by which laws are measured in an equal protection challenge¹⁰⁵ When this test – which ensures that a federal statute is rationally related to the purposes it serves – is applied in *Mensing*, one must conclude that the FDCA, as interpreted by *Wyeth* and *Mensing*, violates equal protection.

100. *Mensing*, 131 S.Ct. at 2592.

101. *Id.* at 2586 (Sotomayor, J., dissenting) (alteration in original) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

102. Chemerinsky, *supra* note 9, at 56.

103. U.S. CONST. amend. V.

104. *United States v. Thoresen*, 428 F.2d 654, 658 (9th Cir. 1970).

105. *U.S. v. Carolene Products Co.*, 304 U.S. 152 (1938).

A court conducting a rational basis review first looks at how the government has defined the group that is burdened by the law.¹⁰⁶ Next, it looks at the goal that is seeking to be achieved by the law.¹⁰⁷ Finally, it should ensure that there is a sufficient nexus between the end result and the means to arrive at the end.¹⁰⁸ Rational basis review presumes that a challenged statute is valid, and puts the burden on the plaintiff to prove that it is impermissibly discriminatory.¹⁰⁹

When one examines federal statutory preemption of generic but not brand-name pharmaceutical failure-to-warn claims, the group burdened by the *Mensing* Court's interpretation of the FDCA is quite clearly generic pharmaceutical consumers. The goal seeking to be achieved by the distinction between brand-name and generics is unclear, so the rational basis test is not satisfied because of such uncertainty as to the reason for the distinction. Therefore, there is no valid reason to distinguish between generics and brand-names in federal preemption failure-to-warn claims, and doing so would produce an absurd result, which Congress could not have intended.

Through this analysis, it is apparent how the Supreme Court has effectively denied equal protection of the laws to generic prescription consumers. Generics and brand-names are essentially the same and are recognized as such, so there is no rational basis to treat them any differently in litigation. Because brand-name and generic drugs are interchangeable by doctors, pharmacists, the FDA, and consumers alike, and because they are substantively the same as each other effect-wise on the body, there is no reason for them to be distinguished from each other under the FDCA. Nevertheless, the *Mensing* decision interprets the FDCA as regulating brand-name and generic prescription drugs in a different manner, thus violating equal protection.

106. GEOFFREY R. STONE ET AL, CONSTITUTIONAL LAW 489 (6th ed. 2009).

107. *Id.*

108. *Id.*

109. *Id.*

V. GROUPS MOST NEGATIVELY AFFECTED BY *MENSING*

Even though the *Mensing* decision affects the overwhelming majority of Americans who take any prescription drug, it will hit hardest those persons who have little autonomy in the choice between brand-name and generic drugs. Included in this group are persons with low income, those with little or no insurance coverage, and the poverty-stricken. Three subgroups with such little autonomy who are disproportionately harmed by the *Mensing* decision are women, minorities, and the elderly.

A. WOMEN

Various research studies have demonstrated that women may be more likely to be harmed by pharmaceutical drugs than men.¹¹⁰ This fact would suggest, then, that women will also be more disproportionately affected by the *Mensing* decision than their male counterparts.

The biological and anatomical differences between the sexes sometimes affect the way pharmaceuticals metabolize in men's and women's bodies. In the liver, where most prescription drugs are metabolized by the body, certain drugs are cleared faster by men, and others are cleared faster by women.¹¹¹ Differences in sex affect even those drugs that happen to be "within the same pharmacological class and drugs with the same structures."¹¹²

Because there can be such varied reactions to pharmaceuticals in men and women, it is important to note that women have not always been the primary focus of drug studies. Until very recently, women have been underrepresented in drug trials. The General Accounting Office's report, "Women in

110. OFFIE P. SOLDIN ET AL., *SEX DIFFERENCES IN DRUG DISPOSITION 2* (Stelvio M. Bandiera eds., 2011), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3051160/pdf/JBB2011-187103.pdf>.

111. THERESA M. WIZEMANN & MARY-LOU PARDUE, *EXPLORING THE BIOLOGICAL CONTRIBUTIONS TO HUMAN HEALTH: DOES SEX MATTER?* 125 (2001).

112. *Id.*

Clinical Drug Trials," notes that as recently as 1992, the FDA had failed to adequately ensure that women were being represented in medical drug studies and that sex differences were being sufficiently studied in pharmaceutical drug trials.¹¹³

Limited attention to the specific ways women's bodies handle some types of pharmaceuticals may be one reason why adverse reactions and other harms tend to be more prevalent in women than men. Although the monitoring of this issue has improved over the past two decades, some doctors and scientists continue to express concern over the degree of analysis regarding women's reactions to such drugs, and they suggest that more research should be conducted on the topic.¹¹⁴

If drug studies have historically examined mainly men and lacked sufficient attention to women, as the GAO report suggests, then it is no wonder that women have a higher rate of adverse reactions to prescription drugs. In fact, female patients have 1.5 to 1.7 times greater risk than male patients of suffering an adverse reaction to their prescription drugs.¹¹⁵ Catherine White, an Associate Professor of Pharmaceutical and Biomedical Sciences at the University of Georgia, summarizes the issue well: "Since 'sex/gender clearly influences the pharmacokinetics of some drugs, it should also be expected to play a significant role in the incidence and severity of drug interactions.'" ¹¹⁶ Because the effects of prescription drugs on women in particular fail to be fully comprehended, it is likely that discord between women and their prescriptions will persist as long as this is the case, making women more likely to be harmed by prescription drugs and to file claims against pharmaceutical companies.

Unique to women are some of the bodily changes they undergo in life. Women obviously have different reproductive

113. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-01-754, WOMEN'S HEALTH: WOMEN SUFFICIENTLY REPRESENTED IN NEW DRUG TESTING, BUT FDA OVERSIGHT NEEDS IMPROVEMENT (2001).

114. *Id.*

115. Colleen Fuller, *Women and Adverse Drug Reactions Reporting in the Canadian Context*, WOMEN & HEALTH PROT., Oct. 2002, at 20.

116. *Id.*

functions than men; menstruation at puberty signals the beginning of a woman's ability to get pregnant, and menopause signals the end of it. For a number of decades, these particular stages in females' lives have often meant pharmaceutical drug regimens. During years when menstruation still takes place, women will often take oral contraceptives or employ other means of pharmaceutical birth control to prevent pregnancy, limit the size of their families, or for other health reasons. According to a 2002 government survey, about eight in ten women between ages fifteen and forty-four have taken a prescription birth control pill at some point in their lives.¹¹⁷ Such widespread use of the pill and other forms of contraception can only mean that most women will eventually take some kind of prescription drug.

Lawsuits involving prescription contraceptives happen relatively frequently nowadays and direct marketing of such prescription drugs to consumers is a growing problem. In 2005, the pharmaceutical manufacturing industry spent over \$4.23 billion on direct-to-consumer advertising while total spending on drug promotion was more than \$29 billion.¹¹⁸

In one particular contraceptive lawsuit, *Perez v. Wyeth*, plaintiffs brought suit against the manufacturer of Norplant, a contraceptive device that is implanted in a woman's upper arm which may prevent pregnancy for up to five years.¹¹⁹ In this Supreme Court of New Jersey case, plaintiffs complained that Wyeth's widespread marketing campaign of Norplant was aimed directly at women and that its marketing practices failed to disclose any sort of complications that could arise from the removal of the device¹²⁰ In its decision, the Court held that the "learned intermediary rule," which typically discharges any

117. Rita Rubin, *The Pill: 50 Years of Birth Control Changed Women's Lives*, USA TODAY, May 7-9, 2010 at 2A.

118. Heather Harrell, *Direct-to-Consumer Advertising of Prescription Pharmaceuticals, The Learned Intermediary Doctrine, and Fiduciary Duties*, 8 IND. HEALTH L. REV. 71, 71 (2011).

119. *Perez v. Wyeth Laboratories Inc.*, 734 A.2d 1245, 1247 (N.J. 1999).

120. *Id.* at 1248

manufacturer's duty to warn users directly when it supplies information on harmful effects to users' doctors, does not apply to marketing campaigns like Norplant's when it advertises directly to patients.¹²¹ The Court stated that when a manufacturer follows such a practice, it still has a duty to warn the consumer since it is marketing the product directly to the consumer.¹²²

Once women begin menopause they may use hormone therapy or other drugs to prevent or limit certain effects of menopause and osteoporosis. According to the GAO report, "[w]omen metabolize some drugs differently if they are pregnant, lactating, pre- or postmenopausal, menstruating, or using oral contraceptives or hormone replacements. Women's generally smaller body weight compared to men can result in higher levels of drug concentration in the bloodstream."¹²³ Men do not have to go through either of these processes; they cannot get pregnant and their bones do not lose calcium at the same rate as women's. Accordingly, there is nothing exactly comparable that happens to men that may involve such long-term prescription drug use.

Women also experience certain disorders at a higher rate than men, and therefore may take prescription drugs to remedy those disorders more often. Depression is one such example. Serotonin, one of the body's natural chemicals that creates feelings of happiness, may help explain some of the discrepancy: its synthesis rates have been found to be 52 percent higher in male subjects than female subjects.¹²⁴ According to the researchers, "this marked difference in rates of serotonin synthesis could contribute to the higher incidence in women of major unipolar depression."¹²⁵ The greater prevalence of depression in women may consequently lead them to take even

121. *Id.* at 1257; RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1997).

122. *Id.* at 1246, 1263.

123. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 113, at 7.

124. WIZEMANN, *supra* note 111, at 130.

125. *Id.*

more prescription drugs to treat the depression, thus increasing women's risk of being harmed by pharmaceuticals and initiating such lawsuits.

Opponents of this paper's thesis may argue that just because women have a higher risk of adverse reaction to prescription drugs does not necessarily mean that women therefore take prescription drugs more often than men. However, this higher risk faced by women does mean that women may have a problem with a prescription drug more often than men and that they, rather than men, may be disproportionately affected, making the likelihood higher that they will bring suit against a pharmaceutical company.

Other sociological factors may play into women's higher likelihood of taking generic instead of brand-name prescriptions. Women tend to be children's primary caregivers, and single mothers, especially, may be the sole caregivers for their children. Many single mothers also tend to be on the lower end of the economic spectrum, represent a majority of the poor, and hold lower education levels and lower incomes.¹²⁶ In fact, it was estimated that during the years 1969 through 1979, women between the ages of twenty-five and seventy-five, at a rate of 20 percent to 35 percent, had experienced or would experience poverty at some point in their lives.¹²⁷ Because of the need to take care of both themselves and their children without supplemental income, single mothers may experience more strain on their purse strings than men, thus causing them to choose generic over brand-name prescription drugs out of necessity.

All of these various factors contribute to women's increased risk of pharmaceutical harm and similarly make them more likely to take generic prescription drugs. As a result, women as a group are largely directly disadvantaged by the *Mensing* decision.

126. David R. Williams & Chiquita Collins, *U.S. Socioeconomic and Racial Differences in Health: Patterns and Explanations*, 21 ANN. REV. SOC. 349, 357 (1995).

127. *Id.* at 355.

B. MINORITIES

There are a variety of circumstances that have contributed to the general ill state of health of minority groups in the U.S. Such circumstances may then lead them to take more prescription drugs – particularly generics – thus making them more greatly affected by the *Mensing* decision. Unequal treatment of minority groups within many spheres of society has sometimes led to further discrimination, and although efforts are being made to lessen such discrimination, more still needs to be done to bring their health up to an adequate level. The prolonged impact of racism and the ethnic or racial discrepancies in the quality of medical care are especially important factors to consider when examining the reasons for the poor health of members of minority groups.¹²⁸ The *Mensing* decision is likely to cause further setbacks for these populations by removing one of the necessary remedial options of suing for damages caused by use of generic prescription drugs.

Historically, race and ethnicity have often been bases for different treatment both socially and medically in the U.S. Language and cultural barriers have also played a part, as has racism, unfortunately. Sometimes this spills over into the realm of medical care: “[w]hen providers fail to take social and cultural factors into account, they may resort to stereotyping, which affects their behavior and decision-making. In the worst cases, this may lead to biased or discriminatory treatment of patients based on their race/ethnicity, culture, language proficiency, or social status.”¹²⁹

In general, members of minority groups in the U.S. tend to be poorer than members of the white majority. While the poverty rate for white Americans stands at about 11 percent, that number increases to 29 percent for Hispanics and 33 percent

128. Joseph R. Betancourt et al, *Defining Cultural Competence: A Practical Framework for Addressing Racial/Ethnic Disparities in Health and Health Care*, 118 PUB. HEALTH REP. 293, 294 (2003).

129. *Id.* at 297.

for African-Americans.¹³⁰ As a result, members of these minority groups also tend to have a much lower level of education than their Caucasian counterparts. This fact then leads minorities to hold lower wage jobs than the majority of the population, which sometimes include more dangerous jobs with higher rates of occupational hazards.¹³¹ Such bleak work and financial circumstances tend to make minority groups more socioeconomically disadvantaged, thus leaving them less able to afford prescription drugs that they may need. When they can afford pharmaceuticals, they are thus more likely to choose a cost-saving generic drug.

Furthermore, minorities tend to be underrepresented when it comes to health insurance, thus leaving them to pay the bulk, if not all, of their health-related costs. One study mentions that Latinos comprise just 13 percent of the U.S. population, yet they account for 25 percent of all Americans without any health insurance at all.¹³²

Research has shown that minority ethnic groups in the U.S. also suffer disproportionately from certain medical conditions, including heart disease, cancer, diabetes, and asthma.¹³³ For all of these diseases prescription medications are commonplace, yet minorities are less able to afford them than are whites. This fact would then suggest that when a minority person can afford prescriptions, that person is more likely to take a generic than brand-name because of the lower cost.

Minority groups also tend to have more health problems because, in general, they tend to get less exercise, have less healthy diets, and live in worse environments.¹³⁴ Education and improved awareness about food and nutrients have led to improved eating habits in low-income families,¹³⁵ but the cost of

130. David R. Williams & Chiquita Collins, *U.S. Socioeconomic and Racial Differences in Health: Patterns and Explanation*, 21 ANN. REV. SOC. 349, 363 (1995).

131. See Betancourt et al, *supra* note 128, at 294.

132. *Id.*

133. *Id.*

134. *Id.* at 118.

135. Helen Afrasiabi, *Education Helps Low-Income Families Make Better Health*

healthier foods still tends to be prohibitive for many minority individuals.

All of these factors have roots in minority groups' poor financial situation and low socioeconomic status. According to Thomas LaVeist, Director of the Center for Health Disparities Solutions at Johns Hopkins's Bloomberg School of Public Health, "When people are living in a similar type of environment and they behave similarly, they tend to have similar health outcomes."¹³⁶ A different study conducted by the U.S. Department of Housing and Urban Development (HUD) examined the relationship between the types of neighborhoods where people lived and their physical and mental health. HUD found that those persons who lived in neighborhoods in which 40 percent or more residents lived in poverty improved their health significantly when they were able to move out of those neighborhoods and into more affluent ones.¹³⁷

When lack of health insurance and high rates of disease are combined, such as is the case with many minority persons, the result inevitably may lead to an inability to afford necessary prescription medications. Because such minority groups "currently experiencing poorer health status are expected to grow as a proportion of the total U.S. population," there will be an even higher percentage of Americans with less ability to afford brand-name drugs, forcing them to choose generic, if any at all.¹³⁸ Thus, the *Mensing* decision disproportionately affects these minority groups, affording them no legal recourse for harmful generic prescription drugs in the form of failure-to-adequately-warn claims.

Choices, Advocates Say, CAL. HEALTH REP. (Nov. 8, 2011), <http://www.healthycal.org/archives/6278>.

136. Andrea K. Walker, *Where You Live Can Help Determine Your Health*, *Studies Say*, THE BALTIMORE SUN (Nov. 18, 2011), http://articles.baltimoresun.com/2011-11-18/health/bs-hs-health-neighborhood-disparities-20111114_1_health-outcomes-health-status-health-disparities-solutions.

137. *Id.*

138. Betancourt et al, *supra* note 128, at 299.

C. *THE ELDERLY*

When a person ages, health problems certainly arise more frequently, and the older one gets, the likelihood of needing prescription drugs for health reasons skyrockets. Although the elderly represent just 12 percent of the U.S. population, they comprise 30 percent of all prescription medication users.¹³⁹ Additionally, about 86 percent of senior citizens take prescription drugs every year, and spend on average about \$1,000 per person for such drugs.¹⁴⁰

Furthermore, the elderly are a group that overwhelmingly uses prescription drugs particularly to treat chronic illnesses.¹⁴¹ Such illnesses often require a lifetime of treatment.¹⁴² Additionally, the top four categories of drugs that the elderly consume are those that are frequently identified with health issues that arise later in life: cardiac drugs (for coronary heart disease), cardiovascular drugs (to reduce blood pressure), diuretics (to treat heart failure), and psychotherapeutic drugs (to treat dementia).¹⁴³

The elderly's high rate of consumption of prescription drugs likely means that they will be more disproportionately affected by pharmaceutical drugs that harm. With statistics like those above, it is only natural that the elderly therefore will be more greatly affected by the *Mensing* decision. Consequently, the fact that about a third of seniors on Medicare do not have prescription drug coverage¹⁴⁴ allows one to infer that those seniors will more likely use generic rather than brand-name pharmaceuticals to reduce cost.

Critics might say that those seniors who take generic drugs

139. Gerda G. Fillenbaum et al, *Prescription and Nonprescription Drug Use among Black and White Community-Residing Elderly*, 83 AM. J. PUB. HEALTH, 1577, 1577 (1993).

140. Mark McClellan, *Medicare Reform: Fundamental Problems, Incremental Steps*, 14 J. ECON. PERSP., 21, 34 (2000).

141. *Id.*

142. *Id.*

143. *Id.*

144. *See id.* at 35.

do not have the money or resources to sue generic manufacturers anyway. Those critics would be mistaken though, because “lack of drug insurance in Medicare is not strongly correlated with income . . . More than half of uninsured beneficiaries have incomes above 1.5 times the poverty level.”¹⁴⁵ Furthermore, as stated previously, 90 percent of consumers use generic rather than brand-name prescription drugs when generics are available.¹⁴⁶ This means that there are plenty of well-to-do consumers who take generic drugs who are capable of filing tort suits involving failure-to-adequately-warn claims.

VI. JURISDICTIONS THAT MAY BE BETTER OR WORSE FOR THESE DEMOGRAPHIC GROUPS

In state court lawsuits, certain jurisdictions tend to be more sympathetic to the plight of plaintiffs when it comes to claims against pharmaceutical manufacturers, and others tend to side with the defendants. In West Virginia, for example, the learned intermediary doctrine does not excuse prescription drug manufacturers from their duty to warn consumers of risks of their products,¹⁴⁷ which is a very positive approach for plaintiffs harmed by pharmaceuticals. Similarly, New Jersey's Supreme Court also has held that the role of the doctor does not break the chain of causation for a manufacturer's failure to adequately warn the users of the drug.¹⁴⁸ Also, Pennsylvania courts have held that state law failure-to-warn claims involving prescription drugs are not preempted by federal law.¹⁴⁹ It would seem that plaintiffs in these states would have a better chance of recovery and compensation when bringing claims involving generic drugs.

In Illinois, however, the courts seem to be fervently

145. *Id.*

146. Chemerinsky, *supra* note 9, at 54.

147. *See* State ex rel Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 906, 910-11 (W. Va. 2007).

148. *See* Perez v. Wyeth Laboratories, 734 A.2d 1245, 1260 (N.J. 1999).

149. Knipe v. SmithKline Beecham, 583 F.Supp.2d 553, 581, 591 (E.D. Pa. 2008).

opposed to holding drug manufacturers directly accountable for harm their pharmaceuticals cause. One such Illinois case dealt with injuries caused by the Yaz/Yasmin brand of birth control pill, which is one of the most recent types of oral contraceptives known to produce dangerous side effects.¹⁵⁰ In that same case, the judge held that the plaintiff had no viable claims against either the manufacturer or the pharmacy that dispensed the drug to her.¹⁵¹

VII. ALTERNATIVE CAUSES OF ACTION

Because failure-to-adequately-warn claims for generic prescription drugs have now been held by the Supreme Court to be preempted by federal law, it is necessary to analyze other possible causes of action that could be used by a person harmed by a generic drug.

If failure-to-warn claims fail in litigation because of federal statutory preemption, then one useful cause of action still available to affected consumers may be misrepresentation. In the Supreme Court case *Altria Group, Inc. v. Good*, plaintiffs brought misrepresentation claims about “light” cigarettes; it was this misrepresentation which affirmatively induced plaintiffs to buy them.¹⁵² The Court concluded that these misrepresentation claims were not preempted by federal law and upheld them based upon a general common law duty not to deceive.¹⁵³

Even more recently, and perhaps more relevantly, the Alabama Supreme Court ruled in early 2013 that brand-name pharmaceutical companies may be liable for misrepresentation of a drug’s risk, even if the injured patients who bring suit against them were treated with the generic version of the drug.¹⁵⁴ In *Wyeth, Inc. v. Weeks*, the plaintiff was treated with the

150. *See In re Yasminv. Bayer Corp.*, 692 F.Supp.2d 1025, 1035, 1037 (S.D. Ill. 2010).

151. *Id.*

152. *Altria Group, Inc. v. Good*, 555 U.S. 70, 73-74 (2008).

153. Bograd, *supra* note 96, at 24.

154. Steven M. Sellers, *Plaintiff Can Sue Brand-Name Drugmaker for Injury Caused*

drug metoclopramide, the generic version of Reglan, and, just as in the *Mensing* case, subsequently developed tardive dyskinesia.¹⁵⁵ Justice Michael Bolin reasoned that brand-name manufacturers “could reasonably foresee that a physician prescribing a brand-name drug (or a generic drug) to a patient would rely on the warning drafted by the brand-name manufacturer even if the patient ultimately consumed the generic version,” so they should thus be held responsible.¹⁵⁶ Justice Bolin went on to note that many insurance plans encourage use of generic drugs regardless of whether a doctor prescribes a brand-name or generic drug, and that brand-name drug manufacturers should be held liable for misrepresentations by generic manufacturers because the generics merely replicate the same misrepresentation of information drafted by the brand-names.¹⁵⁷ This decision may give hope to injured consumers contemplating lawsuits against drug manufacturers. Furthermore, if misrepresentation is not the chosen claim of action, the Alabama decision could perhaps even encourage injured potential plaintiffs to sue brand-name manufacturers on a failure-to-warn claim even if those same plaintiffs were injured by the generic version of the drug in question.

Another cause of action consumers may use is a strict products liability design defect theory.¹⁵⁸ If a product is “dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics,” a product is then “unreasonably dangerous” and a court could thereby properly find a design defect in the product.¹⁵⁹ Some jurisdictions balance the risk of harm against

by Generic, TRIAL, Feb. 7, 2013 (online update).

155. *Wyeth, Inc. v. Weeks*, 2013 WL 135753 (Ala. Jan. 11 2013).

156. *Sellers*, *supra* note 155.

157. *Id.*

158. *Bartlett v. Mut. Pharm. Co., Inc.*, 678 F.3d 30, 34 (1st Cir. 2012)(deciding that the FDCA did not preempt an injured plaintiff’s design defect claims), *overruled by* *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

159. RESTATEMENT (SECOND) OF TORTS § 402A cmt. I at 352 (1965).

the usefulness of the product to determine if a design defect exists, under what is known as the “risk-utility” test, and others require showing a reasonable alternative design that would have eliminated the particular risk to the plaintiff.¹⁶⁰ Therefore, if a plaintiff has been harmed by a particular drug, he or she may recover damages if he or she is able to demonstrate that the drug meets one of these three tests in a corresponding jurisdiction.

In *Forster v. R.J. Reynolds*, the plaintiffs sued a tobacco company under a strict liability claim for unsafe design of cigarettes.¹⁶¹ Because it was in a jurisdiction that used the risk-utility test, the Supreme Court of Minnesota used the test to agree with the plaintiffs’ claim, subsequently ruling that strict liability for the design defect of the cigarettes was not preempted by federal law.¹⁶² *Forster* thus suggests that strict products liability claims for design defects may be another way for consumers harmed by generic pharmaceutical drugs to address their injuries in court, as long as the claim passes the particular design defect test that its jurisdiction uses.

Just because pharmaceutical companies may be protected from suits for failing to adequately warn does not necessarily mean that they have fulfilled all their duties to consumers. Individuals harmed by prescription drugs should look for other ways to address their injuries. Dean Chemerinsky also notes the possibility of “alternative litigation theories.”¹⁶³ Through this concept, plaintiffs would sue parties other than generic drug manufacturers, possibly including a patient’s own doctors, pharmacists, and pharmacies. This could prove useful, for instance, if it could be found that pharmacies dispensed generic pharmaceuticals when they were in fact directed to dispense brand-names. Alternatively, a patient could sue his or her doctor (instead of the manufacturer) for failure to inform of particular harms created by prescriptions.

160. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) (1998).

161. *Forster v. R.J. Reynolds Tobacco Co.*, 437 N.W.2d 655, 656-57 (Minn. 1989).

162. *Id.* at 661.

163. Chemerinsky, *supra* note 9, at 56.

VIII. HOW LEGISLATION CAN HELP

Cases like *Mensing* involving harms caused by a generic drug are sure to surface again despite the difficulties facing plaintiffs. Because the Supreme Court will not likely overturn *Mensing* any time soon, the best solution for this problem is for Congress to amend the FDCA so that *Mensing* would be overturned.

It is logical that prescription drugs that are the same in effectiveness and substance should be treated the same way in court. Congress should amend the FDCA so that claims involving generic prescription drugs will always be treated the same as brand name drugs. This way, the *Wyeth* decision would apply to claims involving both kinds of drugs, the way it should have been applied in *Mensing*. The author of this paper recommends that Congress amend the FDCA with very clear and unambiguous language, specifically stating that these drugs be treated exactly the same in litigation so that this kind of problem does not arise again in the future.

IX. CONCLUSION

Critics of this paper may argue that generic manufacturers should not be allowed to be sued because they do not participate in the creation of the original drug, and that, therefore they are not the ones who are really responsible for harms caused by generics. However, this argument misses the point; generic manufacturers are just as capable of discovering harms caused by their drugs, such that they should still be liable if they hide harmful information or fail to disclose it. It may be true that brand-name manufacturers hold more culpability because they first produced a particular drug, but they often eventually exit the market, leaving generics as the consumers' only option. When this happens, generic manufacturers must take responsibility for being the sole provider or one of just a few providers of a particular drug. Otherwise, it fosters a climate of blamelessness, irresponsibility, and finger-pointing, helping

neither consumers nor manufacturers.

Even though *PLIVA, Inc. v. Mensing* has demonstrated the Court's ability to rule illogically, remedies fortunately still exist to ameliorate the situation. Our judicial and political systems are complementary, and, as previously noted, our legislatures may act to correct decisions like *Mensing*. During a time in our nation's history when health care is a very relevant and important topic, Congress should take notice of the *Mensing* decision and overturn it for all our sakes by passing a bill that would amend the FDCA so that generic and brand-name prescription pharmaceuticals are regulated in the same manner.

