

***PLIVA* Shields Big Pharma from Billions, Cuts Consumers' Rights**

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I. INTRODUCTION

A multi-billion-dollar industry,¹ consistently rated among the most profitable in the world,² was handed a controversial victory by the Supreme Court in June 2011—a ruling that puts almost every American family at risk. The industry is the generic-pharmaceutical industry and the court ruling is *PLIVA, Inc. v. Mensing*, which lets generic manufacturers off the hook for legal liability when their products cause harm.³ The average consumer may not know it, but as of last June, generics and name-brand drugs differ significantly, not in their chemical make-up, but in the legal protections consumers have if something goes wrong. Patients who choose generics—or who have them chosen by their insurance company, pharmacist, or doctor—unknowingly give up their ability to sue under state law.

To illustrate: two patients walk into a pharmacy and get prescriptions filled for the same ailment. One buys a brand-name drug, the other a generic. Both medicines have identical ingredients, provide the same health benefit, and have labels that match word for word. Unfortunately, both patients suffer devastating harm because the labels fail to disclose known serious side effects. Thanks to *PLIVA*, one patient can seek legal remedy to recover expensive costs. The other cannot.

Generics have been promoted by government policy over the last three decades as a way to improve the health of Americans by reducing the costs of prescription drugs. Indeed, when a generic is available today, consumers will buy it 90% of the time.⁴ Overall, more than 75% of all drugs sold in the United States are now generic.⁵ In a twist of fate, however, the very success of generics now poses a threat: millions of Americans suddenly find themselves at huge financial risk should something go terribly wrong because of their prescription medicine. Buying a generic drug now carries a steep downside. It was not supposed to be like this.

1. Zacks Equity Research, *Pharmaceutical Industry Outlook - March 2011*, ZACKS INVESTMENT RES. (Mar. 2, 2011), <http://www.zacks.com/commentary/17173/Pharmaceutical+Industry+Outlook> (“According to IMS Health, the global pharmaceutical industry should record growth of 5–7% in 2011 representing sales of approximately \$880 billion.”).

2. Major Pharma ranks twentieth out of the 215 top industry profit margin ranks. *Industry Summary*, YAHOO! FIN. (Aug. 21, 2012), http://biz.yahoo.com/p/sum_qpmd.html.

3. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577–82 (2011).

4. See OFFICE OF SCI. & DATA POLICY, U.S. DEP’T OF HEALTH & HUMAN SERVS., ASPE ISSUE BRIEF: EXPANDING THE USE OF GENERIC DRUGS 3–4 (2010) [hereinafter EXPANDING THE USE OF GENERIC DRUGS] (citing ALAN SHEPPARD, *GENERIC MEDICINES: ESSENTIAL CONTRIBUTORS TO THE LONG-TERM HEALTH OF SOCIETY* 3 (2010), available at http://www.imshealth.com/imshealth/Global/Content/Document/Market_Measurement_TL/Generic_Medicines_GA.pdf).

5. *Id.* at 2.

It has been almost thirty years since Congress streamlined the drug approval process in an effort to bring generic drugs to market quickly after the brand-name patents expired.⁶ The goal was to give consumers the same health benefits at a much lower cost. With regulatory relief and increased competition, generics became wildly successful. The generic-pharmaceutical industry, consumers, the health care industry, and taxpayers all benefited. *PLIVA*, however, now casts a frightening shadow over the financial savings of generics. The economic benefits of generics may now be outweighed by the legal risks, at least for those unfortunate consumers who are harmed by generic prescription drugs.

The controversial five-to-four decision that overturned two circuit court cases⁷ puts millions in jeopardy. Now that seven out of every ten drugs sold is a generic, *PLIVA* effectively means that seven out of ten consumers lack legal remedy. Moreover, the immunity granted by the ruling could increase the number of patients who actually suffer harm because now generic-pharmaceutical companies have no incentive to police themselves and the highly profitable products they sell.

How did we create such an unfair predicament (even the majority opinion called it “bizarre”⁸) and what should be done to protect millions of consumers? This Article takes a look at the growth of the multi-billion-dollar pharmaceutical industry and its unprecedented clout; how *PLIVA* was decided and why the decision was wrong; what the implications are for consumers and other stakeholders; and what solutions might remedy a controversial decision that radically alters the legal landscape of one of the most profitable and powerful industries in the world.

6. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, §§ 101–103, 98 Stat. 1585, 1585–97 (codified as amended at 21 U.S.C. § 355 (2006)).

7. See *PLIVA*, 131 S. Ct. at 2572–73.

8. *Id.* at 2582 (quoting *Cuomo v. Clearing House Ass’n*, 129 S. Ct. 2710, 2733 (2009) (Thomas, J., concurring in part and dissenting in part)).

II. THE GENERIC-PHARMACEUTICAL INDUSTRY AND ITS EVOLUTION VIA LEGISLATION AND MARKET FORCES

Although many factors have played a role in the generic drug industry's rapid growth—the lack of innovation in brand-name prescription drugs and the increasing costs to produce those drugs,⁹ coupled with the intense pressure to control health care costs¹⁰—the most important force driving the generic market has been legislative efforts by both the federal government and the states.¹¹

In 1984, landmark legislation brought generic drug manufacturing to the forefront of the pharmaceutical industry.¹² The Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, changed the approval process for generics.¹³ The purpose behind Congress's enactment of Hatch-Waxman was “to make available more low cost generic drugs by establishing a generic drug approval procedure” distinct from the procedure for brand-name drugs.¹⁴ The amendments provide that generic drug manufacturers only need to show that a generic drug and its brand-name equivalent are the same in almost all respects.¹⁵ Hatch-Waxman does not require generic drug makers to prove a product's safety and efficacy independently, which brand-name drug manufacturers must do.¹⁶ As a result, generic manufacturers can bring drugs to market for a much lower cost and in a much shorter time.

9. Clifford Mintz, *Why Generic Drug Companies Will Dominate Future Pharmaceutical Markets*, BIOJOBLOG (Feb. 1, 2010), <http://www.biojobblog.net/2010/02/01/why-generic-drug-companies-will-dominate-future-pharmaceutical-markets/>. Mintz asked, “[I]s it any wonder why Pfizer is thinking about entering the generic-pharmaceutical business and that Western drug companies are shedding scientists and sales people in the US and Europe and growing the sizes of their R&D and sales force staffs in Asia, Eastern Europe and Latin America?” *Id.*

10. Doris de Guzman, *On a High: Generic Drug Sales Continue To Climb*, ICIS (Feb. 10, 2010, 12:00 AM), <http://www.icis.com/Articles/2010/02/15/9333169/generic-drugs-sales-continue-to-climb.html>.

11. This Article also recognizes, however, that market forces and federal and state legislation go hand in hand—legislation on generic drugs has been made to address the market forces plaguing the drug industry, such as increasing health care costs. Thus, market forces and legislation both affect the generic market.

12. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 (2006); 35 U.S.C. §§ 156, 271 (2006)).

13. *Id.*

14. H.R. REP. NO. 98-857, at 14 (1984).

15. The generic manufacturer must show that the generic drug has the same active ingredients as the brand-name drug, that the manner of administration, dosage form, and strength of the generic drug are the same as the brand-name drug, and that the generic drug is “bioequivalent” to the brand-name drug. 21 U.S.C. § 355(j)(2)(A)(ii)–(iv).

16. *See id.* § 355(b)(1), (d); *Wyeth v. Levine*, 555 U.S. 555, 567 (2009).

States have also enacted legislation to promote the growth of generic pharmaceuticals.¹⁷ Almost all states authorize pharmacists to substitute generic drugs for brand-name drugs when filling prescriptions, for example.¹⁸ Moreover, both state and federal insurance plans—as well as private ones—promote the use of generic drugs over brand-name drugs.¹⁹

Combined with other market forces, these government policies fueled phenomenal growth in generics. In 1984, generic sales made up less than 19% of all pharmaceuticals sold in the United States.²⁰ That rate steadily grew to reach 75% in 2009, about a four-fold increase over twenty-five years.²¹ Generic drug manufacturers sold an estimated \$66 billion worth of generic drugs in the United States that year.²² Globally, from 2008 to 2009, generic prescription drug sales climbed by 7.7%, compared to 5.7% growth in the overall global pharmaceutical industry.²³ Today, 90% of prescriptions for brand-name drugs are being filled by their generic equivalent if there is one.²⁴

Pharmaceutical drug manufacturing is consistently rated one of the largest and most profitable industries in the world, making hundreds of billions of dollars annually.²⁵ For example, in January 2011, several of the world's largest pharmaceutical companies reported multi-billion-

17. See EXPANDING THE USE OF GENERIC DRUGS, *supra* note 4, at 7.

18. Thomas P. Christensen et al., *Drug Product Selection: Legal Issues*, 41 J. AM. PHARMACEUTICAL ASS'N 868, 869 (2001). In some states, legislation permits generic drug substitution but only under certain circumstances. EXPANDING THE USE OF GENERIC DRUGS, *supra* note 4, at 7. Other states permit generic drug substitution but do not make generic substitution a requirement. *Id.* Others only permit it if there is patient consent. *Id.*

19. See CONG. BUDGET OFFICE, EFFECTS OF USING GENERIC DRUGS ON MEDICARE'S PRESCRIPTION DRUG SPENDING 9 box 1 (2010), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/118xx/doc11838/09-15-prescriptiondrugs.pdf>; JEFFREY S. CROWLEY ET AL., KAISER COMM'N ON MEDICAID AND THE UNINSURED, STATE MEDICAID OUTPATIENT PRESCRIPTION DRUG POLICIES: FINDINGS FROM A NATIONAL SURVEY, 2005 UPDATE 10 (2005), available at <http://www.kff.org/medicaid/upload/state-medicaid-outpatient-prescription-drug-policies-findings-from-a-national-survey-2005-update-report.pdf>.

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

21. EXPANDING THE USE OF GENERIC DRUGS, *supra* note 4, at 2.

22. Brief for Marc T. Law et al. as Amici Curiae in Support of Respondents at 15, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (No. 09-993).

23. Guzman, *supra* note 10.

24. EXPANDING THE USE OF GENERIC DRUGS, *supra* note 4, at 3–4 (citing SHEPPARD, *supra* note 4, at 3).

25. See Zacks Equity Research, *supra* note 1.

dollar fourth quarter revenues.²⁶ AstraZeneca PLC reported revenues of \$8.62 billion, Eli Lilly & Co. reported revenues of \$6.19 billion, Bristol Myers Squibb Co. reported \$5.11 billion, and Novartis reported \$14.2 billion.²⁷ Analysts predict that market growth in the pharmaceutical industry will continue at an annual rate of 4%–7% through 2013, and that the size of the global pharmaceutical market will exceed \$975 billion, with the U.S. market, the largest, driving much of that growth.²⁸

The generic drug market is predicted to be the main sector to lead this anticipated growth.²⁹ Not only are the current generic drug market trends predicted to continue, but industry analysts also report that over the course of the next five years, the generic drug market is positioned to incur rapid expansion due to the fact that “patents on many blockbuster drugs [are set to] expire”:

This year, for example, generic drug manufacturers will be able to make and sell drugs whose patents expire in 2011. These drugs had annual sales of \$15.3 billion under patent in 2010, and will be new markets for generic manufacturers. Next year, the market value of drugs entering the generics market will double; drugs losing patent protection in 2012 accounted for \$33.2 billion in sales last year. In the US alone, drugs with a combined \$133 [billion] in annual sales will enter the generics market from 2011 to 2016.³⁰

In the past year, seven of the world’s twenty most popular drugs became available in generic form.³¹ The cholesterol drug Lipitor, used by 4.3 million Americans, went generic in November 2011, and the blood thinner Plavix, used by 1.4 million, in May 2012.³² By 2016, many other common drugs such as Lexapro, Avandia, Lunesta, and Singulair, having roughly \$255 billion in global sales, will also be available in generic form.³³ It is estimated that “[m]ore than \$100 billion in annual brand-name drug sales will be at risk for generic competition from 2011 to 2015 . . . [which is] about one-third of the annual spending on all prescription drugs in the U.S.”³⁴ As a result of this anticipated surge in

26. *Pharmaceutical Earnings Roundup: AZN, BMY, LLY, NVS, DYNAMIC DIVIDEND* (Jan. 27, 2011), <http://dynamicdividend.com/pharmaceutical-earnings-roundup-azn-bmy-lly-nvs/>.

27. *Id.*

28. Mintz, *supra* note 9.

29. See Steven M. Rogé, *Hi-Tech Pharmacal: Bright Future in Generic Drugs*, SEEKING ALPHA (June 28, 2011), <http://seekingalpha.com/article/276949-hi-tech-pharmacal-bright-future-in-generic-drugs>.

30. *Id.*

31. Ben Tracy, *Popular Medications Are Going on the Cheap*, CBS NEWS (July 25, 2011, 6:51 PM), http://www.cbsnews.com/2100-18563_162-20083186.html.

32. *Id.*

33. *Id.*

34. Bruce Japsen, *Big Savings Ahead as Patents Expire*, CHI. TRIB., May 5, 2011, available at 2011 WLNR 8736772.

generics, “[p]harmacies and health insurance plans are expected to step up marketing and education to get consumers to use generics.”³⁵

Generic-pharmaceutical corporations are now setting their sights on also taking over emerging international markets, such as China, India, Brazil, and Eastern European countries.³⁶ In emerging markets, the potential for growth is higher and competition is smaller than in existing markets.³⁷ Moreover, consumers in these emerging markets are concerned about brands, more so than in the existing markets, and generic-pharmaceutical companies can sell their generics as “brands,” or rather, branded generics.³⁸ In May 2009, U.S.-based corporation Pfizer, the largest pharmaceutical company in the world, announced its growing relationships with the India-based firm Aurobindo, and Indian injectable generics specialist Claris Lifesciences.³⁹ In 2010, Pfizer became involved in a bidding war against Teva Pharmaceutical Industries—a defendant in *PLIVA*, in fact—for the acquisition of German-based Ratiopharm, which as of 2009 held 3% of the global generics market.⁴⁰

So, what does this all mean and how does it relate to *PLIVA*? The answer: profits, losses and liability, and power. The pharmaceutical industry is one of the most profitable in the world, with the generic drug market as the current and predicted future industry leader.⁴¹ Profits and losses of pharmaceutical corporations are riding on the continued success of the generics market.⁴² Market analyses show that in the upcoming decade the generic market is predicted to increase by an exponential margin, as brand-name patents are set to expire,⁴³ and furthermore, that generic pharmaceuticals are moving into emerging markets with expectations of

35. *Id.*

36. Guzman, *supra* note 10. Although many of these pharmaceutical corporations are part of the global market for international generic sales, they are also now looking for markets previously closed to generic activity. *Id.*

37. Clay Boswell, *Pharma Enters Emerging Markets via Generics*, ICIS (Oct. 7, 2009, 9:00 AM), <http://www.icis.com/Articles/2009/10/12/9253207/pharma-enters-emerging-markets-via-generics.html>.

38. *Id.*

39. *See Pfizer Ties Up with Aurobindo, Claris*, FIN. EXPRESS (May 21, 2009, 12:59 AM), <http://www.financialexpress.com/news/pfizer-ties-up-with-aurobindo-claris/463100/0>. In fact, “Pfizer acquired the rights to market 55 solid oral dose products and five sterile injectable products in more than 70 emerging markets through its May 2009 deal with Aurobindo.” Boswell, *supra* note 37.

40. Guzman, *supra* note 10.

41. *See supra* notes 25–29 and accompanying text.

42. *See supra* note 29 and accompanying text.

43. *See supra* note 30 and accompanying text.

gain and continued profitability.⁴⁴ The stakes are high. Unfavorable lawsuits against these corporations could have substantial financial costs—potentially hundreds of millions of dollars per plaintiff. The *PLIVA* victory was a huge win for the generic-pharmaceutical industry because now these highly profitable corporations are insulated from state tort liability and potential stigma if they sell drugs without adequate warnings and patients suffer as a result.

III. *PLIVA*'S LEGAL LANDSCAPE

A. *The PLIVA Decision: Shielding Generic Drug Manufacturers from State Tort Law Liability*

On June 23, 2011, the Supreme Court held in *PLIVA* that federal statutes and Food and Drug Administration (FDA) regulations preempted state tort claims by requiring that generic prescription drugs have the same safety and efficacy labeling as brand-name prescription drugs.⁴⁵ In reversing the rulings of both the Fifth and Eighth Circuits, which found that preemption did not exist,⁴⁶ the Court reasoned that federal law and state law requirements for generic drug labeling were in conflict such that it was impossible for generic drug manufacturers to comply with both federal and state law.⁴⁷ In essence, the Court introduced “a critical distinction between brand-name and generic drugs.”⁴⁸ The federal statutes and regulations that apply to generic prescription drug manufacturers differ from those applicable to brand-name prescription drug manufacturers, which leads to different preemption results.⁴⁹ In effect, the Court created a divide between consumers exercising their right to access the courts because “[c]onsumers of brand-name drugs can sue manufacturers for inadequate warnings; consumers of generic drugs cannot.”⁵⁰

The *PLIVA* decision arose out of two separate suits filed in the Fifth and Eighth Circuits.⁵¹ In the early 2000s, plaintiffs Julie Demahy and Gladys Mensing were prescribed Reglan and both received the drug's

44. See *supra* notes 36–37 and accompanying text.

45. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 (2011).

46. See *id.* at 2582; see also *Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010), *rev'd sub nom. PLIVA*, 131 S. Ct. 2567; *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611–12 (8th Cir. 2009), *rev'd sub nom. PLIVA*, 131 S. Ct. 2567. Although not joined in the case, the Ninth Circuit dealt with a similar situation, finding for plaintiffs on the basis of no preemption. See *Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225, 1230, 1234 (9th Cir. 2011), *vacated by L. Perrigo Co. v. Gaeta*, 132 S. Ct. 497 (2011).

47. See *PLIVA*, 131 S. Ct. at 2580–81.

48. *Id.* at 2593 (Sotomayor, J., dissenting).

49. See *id.*

50. *Id.*

51. *Id.* at 2573 (majority opinion).

generic equivalent, metoclopramide, from their pharmacists.⁵² After taking the generic drug for a number of years, both plaintiffs developed tardive dyskinesia, a severe neurological disorder.⁵³ There was existing evidence that long-term use of metoclopramide can lead to tardive dyskinesia—studies had shown that up to 29% of patients who have taken the drug for several years develop tardive dyskinesia.⁵⁴ As a result, the warning labels for the generic drug had been “strengthened and clarified several times” over the course of several decades.⁵⁵ The plaintiffs, who sued under state tort law,⁵⁶ alleged that they had suffered damages due to their long-term use of metoclopramide, which led to their tardive dyskinesia.⁵⁷ The plaintiffs asserted that the manufacturers

52. See *Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010), *rev'd sub nom. PLIVA*, 131 S. Ct. 2567; *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 605 (8th Cir. 2009), *rev'd sub nom. PLIVA*, 131 S. Ct. 2567.

53. See *Wyeth*, 588 F.3d at 605; see also *Actavis*, 593 F.3d at 430.

54. *PLIVA*, 131 S. Ct. at 2572 (citing *McNeil v. Wyeth*, 462 F.3d 364, 370 n.5 (5th Cir. 2006); and Douglas Shaffer, *Tardive Dyskinesia Risks and Metoclopramide Use Before and After U.S. Market Withdrawal of Cisapride*, 44 J. AM. PHARMACISTS ASS'N 661, 663 (2004) (noting that eighty-seven cases of metoclopramide-related tardive dyskinesia were reported to the FDA's adverse event reporting system by mid-2003)).

55. *Id.* at 2572.

In 1985, the label was modified to warn 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.” In 2004, the brand-name Reglan manufacturer requested, and the FDA approved, a label change to add that “[t]herapy should not exceed 12 weeks in duration.” And in 2009, the FDA ordered a black box warning—its strongest—which states: “Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases.”

Id. at 2572–73 (citations omitted).

56. See *id.* at 2573. In the relevant states, tort law requires that a drug manufacturer that is or should be aware of its product's danger to label that product in such a way as to make the product reasonably safe. Minnesota law requires that “where the manufacturer . . . of a product has actual or constructive knowledge of danger to users, the . . . manufacturer has a duty to give warning of such dangers.” *Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 788 (Minn. 1977). Similarly, Louisiana law states that “a manufacturer's duty to warn includes a duty to provide adequate instructions for safe use of a product.” *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 269–70 (5th Cir. 2002); see also LA. REV. STAT. ANN. § 9:2800.57 (2009) (categorizing a product as unreasonably dangerous if a product may cause damage and an adequate warning is not provided). In both states, the manufacturer has the duty to warn. See *Marks v. OHMEDA, Inc.*, 871 So. 2d 1148, 1155 (La. Ct. App. 2004); *Gray v. Badger Mining Corp.*, 676 N.W.2d 268, 274 (Minn. 2004).

57. *Actavis*, 593 F.3d at 430; *Wyeth*, 588 F.3d at 604.

of metoclopramide were liable for their damages because the manufacturers of the generic drug knew or should have known of the high risk of the condition's occurrence and knew or should have known that their labels were inadequate to warn of that risk.⁵⁸ The Supreme Court noted that the parties did not dispute the fact that if plaintiffs' allegations were true, "state law required the Manufacturers to use a different, safer label."⁵⁹ The manufacturers defended by arguing that federal statutes and FDA regulations required them to use the same labels as their brand-name equivalents, meaning that it was impossible for the manufacturers to simultaneously comply with federal law and any state tort law duty requiring the strengthening of their labels—therefore, they could not be held liable.⁶⁰ At issue was "whether, and to what extent, generic manufacturers may change their labels *after* initial FDA approval."⁶¹

In a five-to-four decision, the Supreme Court ruled that generic manufacturers were not liable because in accordance with the FDA's interpretation of its regulations, the generic manufacturers had only the power to maintain their drug labels as the same as their brand-name equivalents, and thus could not change their labels to make them in accordance with state law without violating federal law.⁶² In determining whether the manufacturers could have taken steps to warn consumers, namely, to have tried the FDA's change-being-effected (CBE) process or to have sent "Dear Doctor" letters, the Court stated:

The FDA, however, tells us that it interprets its regulations to require that the warning labels of a brand-name drug and its generic copy must always be the same The FDA's views are "controlling unless plainly erroneous or inconsistent with the regulation[s]"

. . . .

We defer to the FDA's interpretation of its CBE and generic labeling regulations. Although *Mensing* and *Demahy* offer other ways to interpret the

58. *Actavis*, 593 F.3d at 430; *Wyeth*, 588 F.3d at 605.

59. *PLIVA*, 131 S. Ct. at 2574.

60. *Actavis*, 593 F.3d at 430; *Wyeth*, 588 F.3d at 605. Originally, federal law required that any manufacturer of drugs applying for FDA approval, both brand and generic, prove that its drug was safe and effective and that the proposed label was accurate and adequate. *See, e.g.*, 21 U.S.C. § 355(b)(1)(A), (d) (2000) (current version at 21 U.S.C. § 355 (2006 & Supp. IV 2011)); *Wyeth v. Levine*, 555 U.S. 555, 567 (2009). However, since Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, the law has permitted generic drug manufacturers to gain approval by showing that the generic drug is equivalent to a brand-name drug that was already FDA approved. *See* Pub. L. No. 98-417, §§ 101–103, 98 Stat. 1585, 1585–97 (codified as amended at 21 U.S.C. § 355(j) (2006)). The generic manufacturer only needs to show that the safety and efficacy of its proposed labeling "is the same as the labeling approved for the [brand-name] drug." 21 U.S.C. § 355(j)(2)(A)(v); *see also id.* § 355(j)(4)(G).

61. *PLIVA*, 131 S. Ct. at 2574.

62. *See id.* at 2577–78.

regulations . . . we do not find the agency’s interpretation “plainly erroneous or inconsistent with the regulation.” . . .

. . . .

As with the CBE regulation, we defer to the FDA. . . . Accordingly, we conclude that federal law did not permit the Manufactures to issue additional warnings through Dear Doctor letters.⁶³

Because the Court, following the FDA’s interpretation, found that there were no means by which manufacturers could have improved their warning labels without violating federal law, it held that there was federal implied preemption based on impossibility: “It was not lawful under federal law for the Manufacturers to do what state law required of them.”⁶⁴ Furthermore, relying again on the FDA’s interpretation,⁶⁵ the Court reasoned that federal law likely “required the Manufacturers to ask for FDA assistance in convincing the brand-name manufacturer to adopt a stronger label, so that all corresponding generic drug manufacturers could do so as well.”⁶⁶ The Court noted that “even if [the manufacturers] had fulfilled their federal duty to ask for FDA assistance, they would not have satisfied the requirements of state law.”⁶⁷

The Court also rejected the plaintiffs’ argument that the manufacturers failed to show impossibility based on the fact that the manufacturers did not attempt to seek a change with the FDA, which if the FDA approved, would have allowed them improve their label in satisfaction of state law while still satisfying federal law.⁶⁸ The Court held that “[t]he question for ‘impossibility’ is whether the private party could *independently* do under federal law what state law requires of it”⁶⁹ because to hold otherwise “would render conflict pre-emption largely meaningless”⁷⁰ and because the Supremacy Clause is a *non obstante* provision, meaning that the federal law in the case “impliedly repeal[ed the] conflicting state law” at

63. *Id.* at 2574–76 (citations omitted).

64. *Id.* at 2577.

65. The Court noted that “[a]ccording to the FDA, the Manufacturers could have proposed—indeed, were required to propose—stronger warning labels to the agency if they believed such warnings were needed.” *Id.* at 2576. The Court did not, however, resolve whether such a duty did in fact exist because the Court determined that preemption was dispositive. *Id.*

66. *Id.* at 2577.

67. *Id.* at 2577–78.

68. *Id.* at 2578–79.

69. *Id.* at 2579 (emphasis added) (citing *Wyeth v. Levine*, 555 U.S. 555, 573 (2009)).

70. *Id.*

issue.⁷¹ In so reasoning, the Court essentially determined that impossibility occurs when approval by the FDA is a prerequisite to changing a drug's label.⁷²

B. *PLIVA Was Wrongly Decided; Its Flawed and Illogical Reasoning*

As summarized above, the *PLIVA* decision involved a legal analysis of the preemption doctrine, essentially turning on whether there was implied preemption based on impossibility because there was clearly no express preemption.⁷³ However, in this analysis, the Court gave great deference to the FDA's opinion, and as a result left out much of the Court's own interpretational analysis on whether there were any means available for manufacturers to make label changes.⁷⁴ The Court did, however, discuss several other theories in support of its impossibility holding—it argued against the plaintiffs' impossibility theory, considered the argument of *reductio ad absurdum*, discussed the potential to render the impossibility doctrine meaningless, and declared the Supremacy Clause to be a *non obstante* provision, thereby supporting federal preemption.⁷⁵

However, upon a closer look at the Court's analysis of each of these theories, it is evident that the analysis is both flawed and illogical. This subpart will discuss each of the majority's arguments to show how they fail, and Part V will later discuss the possible reasons for why the Court decided *PLIVA* the way it did.

1. *There Was No Express Preemption*

The majority and the dissent agreed on one thing—there was no express preemption of state law.⁷⁶ Two longstanding principles of preemption analysis support their conclusion. First, “the purpose of Congress is the ultimate touchstone in every pre-emption case,”⁷⁷ and second,

71. *Id.* at 2580. The Court determined for the first time in *PLIVA* that the Supremacy Clause is to be read as a *non obstante* provision. *See infra* Part III.B.3.

72. The Court appeared to rely on the distinction in federal law that requires generic manufacturers to get prior approval from the FDA, whereas the brand-name manufacturers do not need the same prior approval. *See PLIVA*, 131 S. Ct. at 2580–81 (citing *Wyeth*, 555 U.S. at 572–73).

73. *See supra* Part III.A.

74. *See PLIVA*, 131 S. Ct. at 2580–81.

75. *Id.* at 2577–80.

76. *Id.* at 2577 n.5. The majority noted “[t]he Hatch-Waxman Amendments contain no provision expressly pre-empting state tort claims. Nor do they contain any saving clause to expressly preserve state tort claims.” *Id.* (citations omitted).

77. *Wyeth*, 555 U.S. at 565 (internal quotation marks omitted) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

“[I]n all pre-emption cases, . . . particularly in those in which Congress has ‘legislated . . . in a field which the States have traditionally occupied,’ . . . ‘[the analysis begins with] 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.’”⁷⁸

States have traditionally regulated the fields of health and safety.⁷⁹ Within both of these fields, the states have created extensive systems for tort litigation against drug manufacturers.⁸⁰ And not once has Congress expressly preempted state law tort actions against either brand or generic-prescription drug manufacturers despite Congress’s “certain awareness of the prevalence of state tort litigation” against these manufacturers.⁸¹ In fact, when Congress amended the Federal Food, Drug, and Cosmetic Act (FDCA) in 1962, it specifically ensured the preservation of state law.⁸² The amendments state:

Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.⁸³

Logically, it would follow then that Congress amended the FDCA with the intention of retaining state tort remedies as a complement to federal consumer protection.⁸⁴ Moreover, given the fact that Congress did not make any express preemption for generic prescription drugs in the Hatch-Waxman Amendments when it had made express preemption for medical devices in 1976, it is more likely that Congress did not intend express preemption for generics.⁸⁵ Thus it is clear that Congress did not

78. *Id.* (third and fourth alterations in original) (quoting *Lohr*, 518 U.S. at 485).

79. *See id.* at 566.

80. The state laws at issue in *PLIVA* are a good example of such regulation. 131 S. Ct. at 2573.

81. *Wyeth*, 555 U.S. at 575.

82. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 87-781, § 202, 76 Stat. 781, 793 (1962); *see also Wyeth*, 555 U.S. at 567.

83. FDCA § 202.

84. Both the Constitution and its principles support this conclusion; maintaining the states’ traditional role in providing for the safety and health of their inhabitants when there is no direct conflict between state and federal law is a touchstone of preemption analysis. *See, e.g., Wyeth*, 555 U.S. at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

85. *Compare* Medical Device Amendments of 1976, Pub. L. No. 94-295, § 521, 90 Stat. 539, 574 (clearly stating that the new federal law respecting medical devices preempts state law), *with Wyeth*, 555 U.S. at 575 (“[Congress’s] silence on the

intend and clearly did not act with any clear and manifest purpose that the federal law on safety labeling preempt state law on ensuring drug safety and effectiveness.

2. *There Really Was No Implied Preemption*

There also was no implied preemption based on impossibility. Given the relevant law and facts in *PLIVA*, it is difficult to see how the majority found otherwise. First, implied preemption of state law based on the defense of impossibility “is a demanding defense,”⁸⁶ and the defendant seeking to set aside the state law on impossibility grounds bears this heavy burden.⁸⁷ Second, impossibility only occurs when federal and state law conflict—when “it is impossible for a private party to comply with both state and federal law.”⁸⁸ In order to show a conflict, the defendant must show that “compliance with both federal and state [law] is a physical impossibility.”⁸⁹ Showing “[t]he existence of a hypothetical or potential conflict is insufficient.”⁹⁰ As such, the showing of a *possibility* that impossibility exists does not meet the defendant’s burden.

However, the defendants in *PLIVA* only demonstrated “a hypothetical or potential conflict.”⁹¹ The defendant manufacturers argued, and the Court agreed, that because federal law prohibited them from changing their labels unilaterally, it was impossible for them to provide additional warnings.⁹² However, the manufacturers “could have asked the FDA to initiate a label change” and “[i]f the FDA agreed that a label change was required, it could have asked, and indeed pressured, the brand-name manufacturer to change its label, triggering a corresponding change to the Manufacturers’ generic labels.”⁹³ If the manufacturers had initiated

[prescription drugs] issue . . . is powerful evidence that [it] did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.”)

86. *Wyeth*, 555 U.S. at 573.

87. *See id.*; *see also* *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 255 (1984).

88. *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372 (2000). There is also a conflict when state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Id.* at 373 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) (internal quotation marks omitted). However, only the former mode of conflict was at issue in *PLIVA*. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577–78 (2011).

89. *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963); *see Wyeth*, 555 U.S. at 573 (concluding that *Wyeth* failed to demonstrate this standard).

90. *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982); *see also* *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 110 (1992) (Kennedy, J., concurring in part and concurring in the judgment) (quoting *Rice*, 458 U.S. at 659).

91. *PLIVA*, 131 S. Ct. at 2587 (Sotomayor, J., dissenting) (quoting *Rice*, 458 U.S. at 659) (internal quotation marks omitted).

92. *Id.*

93. *Id.*

such FDA action, it would have been possible then for them to comply with both federal and state law. Thus, without even trying to comply with state law by seeking help from the FDA, it is difficult to see how it was impossible for the generic manufacturers to comply with both federal and state law. This situation only gave rise to a potential conflict, as an actual conflict would only arise if the FDA denied the manufacturers' request for FDA action. Thus in reality, the manufacturers were not faced with the impossibility required by law—physical impossibility.

Yet, in a cursory fashion and with resort to inventive and novel theories, the majority found otherwise.⁹⁴ The Court appeared to invent a new preemption rule based on *Wyeth v. Levine*: “The question for ‘impossibility’ is whether the private party could *independently* do under federal law what state law requires of it.”⁹⁵ Essentially, the Court conditioned the impossibility analysis in *PLIVA* on whether a defendant could independently make a label change. The majority relied primarily on the differentiation between the so-called unilateral power that a brand-name manufacturer has to change its labels, as noted in *Wyeth*, and the lack of a similar power for generic manufacturers.⁹⁶ The majority reasoned that because generic manufacturers cannot change their labels of their own accord, unlike name-brand manufacturers, it was impossible for them to independently comply with both federal and state law.⁹⁷

However, no Supreme Court precedent ever supported any such rule. In fact, as the dissent discussed, even if *Wyeth* were to be considered as support for this rule, *Wyeth* did not hold that “it is impossible to comply with both federal and state law whenever federal agency approval is required.”⁹⁸ On the contrary, the *Wyeth* decision recognized that although prior approval by the FDA of label changes by brand-name manufacturers is not necessary,⁹⁹ the changes are still subject to FDA approval.¹⁰⁰ Furthermore,

94. *Id.* at 2577–78 (majority opinion).

95. *Id.* at 2579 (emphasis added) (citing *Wyeth v. Levine*, 555 U.S. 555, 573 (2009)).

96. *Id.* at 2589–90 (Sotomayor, J., dissenting).

97. *Id.* at 2577–78 (majority opinion).

98. *Id.* at 2589 (Sotomayor, J., dissenting).

99. *See id.* at 2574 (majority opinion); *Wyeth*, 555 U.S. at 570–71; 21 C.F.R. § 314.70(c)(6) (2011).

100. *See PLIVA*, 131 S. Ct. at 2588 (Sotomayor, J., dissenting); *Wyeth*, 555 U.S. at 568–71; 21 C.F.R. § 314.70(c)(6). As the dissent in *PLIVA* noted:

Just like the brand-name manufacturer in *Wyeth*, the Manufacturers had available to them a mechanism for attempting to comply with their state-law

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.¹⁰¹

The majority failed to address these facts.¹⁰² As such, in reality, the power of brand-name drug manufacturers to change their labels is not as independent as the majority makes it out to be—their power is akin to the power vested in generic drug manufacturers, who must also get approval from the FDA. Being so, the unilateral power of brand-name drugs to act without prior approval is not a compelling factor in the preemption analysis. Thus, the majority’s reasoning and finding of impossibility based on the grounds that brand-name manufacturers can independently change their labels is flawed. As in *Wyeth*, where FDA acceptance was the final step in changing label warnings for brand-name drug manufacturers, unless the generic manufacturers “show that the FDA would not have approved a proposed label change,”¹⁰³ there is no impossibility.¹⁰⁴ This reasoning comports with the notion of physical impossibility—actual rejection of the proposed change by the FDA would physically prevent generic manufacturers from complying with state law.

In sum, the majority’s reasoning here fails; because the Court created a rule that is itself flawed, illogical, and without support, there really is no adequate basis for the majority’s finding of implied preemption under the traditional impossibility analysis.

3. *And of the Court’s Other Theories, None Offer Strong Support*

Most likely due to the fact that the Court recognized its impossibility theory for preemption was flawed, it turned to several other theories to support its decision, including that *reductio ad absurdum* for the argument that the generic manufacturers could ask the FDA to initiate change, that deciding otherwise would make the impossibility analysis

duty to warn. Federal law thus “accommodated” the Manufacturers’ state-law duties. It was not necessarily impossible for the Manufacturers to comply with both federal and state law because, had they approached the FDA, the FDA may well have agreed that a label change was necessary.

131 S. Ct. at 2588 (Sotomayor, J., dissenting) (citations omitted).

101. *Id.* at 2589–90.

102. *Id.* at 2590.

103. *Id.* at 2588.

104. The dissent notes that impossibility could arise under these facts “[i]f a generic-manufacturer defendant proposed a label change to the FDA but the FDA rejected the proposal” *Id.*

illusory, and that the Supremacy Clause is a *non obstante* provision.¹⁰⁵ However, each of these theories is as equally flawed as the majority's main analysis and offers no strong support for *PLIVA*.

First, the majority turned to a *reductio ad absurdum* argument, arguing that the plaintiffs' premise that there was no conflict because the manufacturers could seek approval from the FDA was invalid because this conclusion would be akin to finding no conflict because the FDA could rewrite its legislation or Congress might amend the Hatch-Waxman Amendments—both of which the majority found to be absurd.¹⁰⁶ However, as the dissent notes, the majority's reasoning on *reductio ad absurdum* grounds is incorrect.¹⁰⁷ As Justice Sotomayor put it, “[c]onflict analysis necessarily turns on existing law,”¹⁰⁸ and as such, the use of *reductio ad absurdum* with examples of nonexistent law is flawed. “It thus would be ridiculous to conclude that federal and state law do not conflict on the ground that the defendant could have asked a federal agency or Congress to change the law.”¹⁰⁹ As such, the majority's use of *reductio ad absurdum* to support its analysis is illogical and offers the decision no valid support.

Second, the majority resorted to arguing that any other holding aside from finding implied preemption would make the doctrine of conflict preemption “illusory” and “meaningless.”¹¹⁰ However, had the Court ruled that there was no implied preemption in the case, there could still be a finding of preemption based on impossibility for future cases. For instance, if the generic manufacturers were to ask the FDA to initiate a change in the brand-name—and thus generic—labels and the FDA were to refuse to take action, it would be impossible to comply with federal and state labeling laws. Therefore, had the Court held that there was no implied preemption in *PLIVA*, such a holding would not render the doctrine of conflict preemption either “illusory” or “meaningless.” Furthermore, conflict preemption can also be found even when no impossibility is found when state law “stands as an obstacle to the

105. *See id.* at 2577–80 (majority opinion).

106. *Id.* at 2579.

107. *Id.* at 2590 (Sotomayor, J., dissenting) (“None of the rationales that [the majority] offers, however, makes any sense.”).

108. *Id.*

109. *Id.*

110. *Id.* at 2579 (majority opinion).

accomplishment and execution of the full purposes and objectives of Congress.”¹¹¹ The majority’s analysis failed to consider these options.

And finally, the *PLIVA* Court then determined that the Framers intended that the Supremacy Clause be a *non obstante* provision, departing from decades of precedent to find that generic drug manufacturers would be shielded from liability on the grounds of preemption.¹¹² In so holding, the majority “read[] the Supremacy Clause to operate as a provision instructing courts ‘not to apply the general presumption against implied repeals’” of state law,¹¹³ which no other Court had done before. For years, Supreme Court jurisprudence maintained that the police powers of the states were inviolable, and only when Congress acts with “the clear and manifest purpose” of superseding state law can it be considered superseded.¹¹⁴ This doctrine, focusing on Congress’s purpose, ensures that the courts find the true purpose of Congress in preemption cases.¹¹⁵ To discern Congress’s true purpose, the court must primarily look to

the language of the pre-emption statute and the “statutory framework” surrounding it. Also relevant . . . is the “structure and purpose of the statute as a whole,” . . . as revealed not only in the text, but through the reviewing court’s reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law.¹¹⁶

However, in *PLIVA*, the majority avoided assessing the true purpose of Congress, presumably because had it done so, the Court could have

111. *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) (internal quotation marks omitted); *see, e.g., Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 886 (2000) (Stevens, J., dissenting) (arguing that the state tort law for which the petitioners argued was preempted because it was inconsistent with Congress’s objective); *Barnett Bank of Marion Cnty., N. A. v. Nelson*, 517 U.S. 25, 31 (1996) (finding impossibility where a state ban on certain banking activities stood as an obstacle to the purpose of a federal statute); *Hines*, 312 U.S. at 67 (determining whether Pennsylvania state law was a direct obstacle that impeded Congress’s intent for the conflicting federal law).

112. *PLIVA*, 131 S. Ct. at 2580.

113. *Id.* at 2591 (Sotomayor, J., dissenting) (citations omitted).

114. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *see also Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in the judgment) (adopting same language for preemption). Moreover, this presumption is applied in all cases where Congress has expressly or impliedly dealt with preemption. *See Wyeth v. Levine*, 555 U.S. 555, 566 n.3 (2009).

115. *Retail Clerks Int’l Ass’n, Local 1625 v. Schermerhorn*, 375 U.S. 96, 103 (1963) (“The purpose of Congress is the ultimate touchstone [in every preemption case].”); *see also Cipollone v. Liggett Grp.*, 505 U.S. 504, 516 (1992) (quoting same language); *Gade*, 505 U.S. at 96 (quoting same); *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978) (quoting same).

116. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996) (citations omitted) (quoting *Gade*, 505 U.S. at 98; and *id.* at 111 (Kennedy, J., concurring in part and concurring in the judgment)).

found no way to justify its holding. For instance, it clearly failed to consider how Congress intended the law to affect business, consumers, and the law, most likely because Congress would have never intended that the law make consumers' ability to exercise their right to seek justice for drug-related harm contingent on whether they were prescribed generic or brand-name drugs. Thus, rather than engaging in the proper clear and manifest purpose analysis to find the real purpose of Congress, the Court instead held that the "courts [are] to 'look no further than the ordinary meaning of federal law.'"¹¹⁷

The Court's unprecedented change of law on preemption assessment had no basis in prior law. The Court should have conducted the proper clear and manifest purpose analysis and as such, the decision is faulty. Moreover, because the use of the *non obstante* argument under the law and facts of *PLIVA* really only appears to be a means for the Court to justify its position on preemption, there is no valid basis for supporting the majority's finding of preemption on these grounds.

Upon a deeper analysis of the majority's opinion, it is clear each of its arguments is flawed or illogical. The ruling calls into question whether the Court may have based its decision not on the law but rather on its ideological underpinnings. In likely so doing, the Court harmed consumers in a great way—the Court took away their right to seek redress against generic manufacturers for injuries caused as a result of their drugs. Parts IV and V will cover this discussion further.

IV. *PLIVA*'S EFFECT: DEVASTATION FOR CONSUMERS BUT A BIG WIN FOR BIG PHARMA

The majority's "pre-emption analysis strips generic-drug consumers of compensation when they are injured by inadequate warnings."¹¹⁸ In one brief opinion, the Court essentially determined that "Congress silently immunized generic manufacturers from all failure-to-warn claims."¹¹⁹ In so doing, the Court ignored the Supreme Court's general historical reluctance to "infer congressional intent to effect such a sweeping change in traditional state-law remedies."¹²⁰ Now, after *PLIVA*, "a drug consumer's right to compensation for inadequate warnings . . . turns on

117. *PLIVA*, 131 S. Ct at 2591 (Sotomayor, J., dissenting).

118. *Id.* at 2592.

119. *Id.*

120. *Id.*

the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic.”¹²¹ Moreover, as the dissent noted:

In some States, pharmacists must dispense generic drugs absent instruction to the contrary from a consumer’s physician. Even when consumers can request brand-name drugs, the price of the brand-name drug or the consumers’ insurance plans may make it impossible to do so. As a result, in many cases, consumers will have no ability to preserve their state-law right to recover for injuries caused by inadequate warnings.¹²²

In an age when name-brand drugs that have a generic equivalent are filled by the generic 90% of the time,¹²³ the *PLIVA* decision has created devastating consequences for the vast majority of prescription drug consumers.

Patients who suffer injuries caused by prescription drugs can be left with physical impairment.¹²⁴ Some patients may be left unable to work to support their families. They may be burdened with medical expenses such as doctor visits, treatments, surgery, counseling, and further medications. For example, in one recent case, the child of an Iraq war soldier was born with severe birth defects because his mother was prescribed medication to alleviate the stress she suffered while her husband was away at war. The child required extensive surgery, causing extreme hardship for the child and the family. However, because the medication received was generic, the family is now prohibited from pursuing a claim under state law against the manufacturer for its failure to warn of the risk of a possible birth defect.¹²⁵ The results of *PLIVA* are unjust for those Americans who may be or have already been harmed by the side effects of generic prescription drugs.

Furthermore, *PLIVA* “eliminates the traditional state-law incentives for generic manufacturers to monitor and disclose safety risks” due to the market forces in the pharmaceutical industry driving monitoring and disclosing actors out of the market.¹²⁶ Generally, when a generic drug and its brand-name equivalent are on the market concurrently, the brand-name drug manufacturer has the incentive to investigate and find safety risks for both the brand-name and generic drug.¹²⁷ However, market analyses show that once a generic drug enters the market, the

121. *Id.*

122. *Id.*

123. EXPANDING THE USE OF GENERIC DRUGS, *supra* note 4, at 3–4 (citing SHEPPARD, *supra* note 4, at 3).

124. For example, the plaintiffs in *PLIVA* developed tardive dyskinesia, a severe neurological disorder. 131 S. Ct. at 2572–73.

125. For confidentiality purposes, the parties involved in this case will not be identified.

126. *Id.* at 2592 (Sotomayor, J., dissenting).

127. *Id.* at 2592–93.

pharmaceutical manufacturer of the brand-name drug equivalent will often take its product off the market.¹²⁸ As a result of the *PLIVA* decision, no party will be liable for inadequate warning claims, as there will be no brand-name manufacturers on the market and generic manufacturers, free from liability, have no incentive—or even legal authority—to monitor and disclose newfound risks.¹²⁹ Because the brand-name manufacturers often leave the market, their generic drug equivalents that remain on the market lack the additional drug safety check originally provided by the now absent brand-name drug manufacturers.¹³⁰

Although the *PLIVA* decision deals a devastating blow to consumers, it marks a huge victory for the pharmaceutical industry. Now, generic-pharmaceutical corporations are insulated from litigation regarding and liability for state law failure-to-warn claims. Litigating these cases can cost multiple billions per year. For instance, from 2009 to 2010, eight drug safety cases regarding selling drugs with possible side effects were settled for approximately \$8.6 billion.¹³¹ AstraZeneca announced in August 2010 that it had spent approximately \$656 million to defend itself in numerous cases involving the drug Seroquel alone.¹³² In recent years, the growth of class action suits by groups claiming harm from nondisclosure of full drug safety information has cost pharmaceutical companies millions to settle, plus revenue loss due to product recalls.¹³³

128. *Id.* at 2593.

129. *See id.*

130. *See id.*

131. *Rising Costs of Litigation in Pharmaceuticals Industry*, KPMG ISSUES MONITOR, June 2011, at 1, 3, available at http://www.kpmg.com/CH/en/Library/Articles-Publications/Documents/Sectors/pub_20110601_issues-monitor_EN.pdf. Eight cases regarding selling drugs for unapproved uses were settled for \$4.9 billion. *Id.* These figures do not even include the settlement costs to Big Pharma for government suits. In fact:

Over the past 20 years, more than 165 cases of civil and criminal actions by federal and state governments were settled in the US by pharmaceutical companies, with total penalties of approximately US\$19.8 billion. Of those, about 73 percent of the settlements and 75 percent of the penalties were awarded from 2006–10. Moreover, more than half of these penalties were imposed on four leading companies—GlaxoSmithKline (GSK), Pfizer, Eli Lilly and Schering-Plough (which was later acquired by Merck).

Id. at 4 (citing SAMMY ALMASHAT ET AL., PUB. CITIZEN HEALTH RESEARCH GRP., RAPIDLY INCREASING CRIMINAL AND CIVIL MONETARY PENALTIES AGAINST THE PHARMACEUTICAL INDUSTRY: 1991 TO 2010, at 2 (2010), available at <http://www.citizen.org/documents/rapidlyincreasingcriminalandcivilpenalties.pdf>).

132. *Id.* at 6.

133. *Id.* at 7.

For instance, in December 2009, GlaxoSmithKline paid \$1 billion to settle a class action suit for its drug Paxil, which caused birth defects during pregnancy, and more than 600 other Paxil cases are pending.¹³⁴ In December 2007, Merck agreed to settle by paying \$4.85 billion to plaintiffs claiming that its drug Vioxx caused heart attacks and strokes.¹³⁵ Now, after *PLIVA*, manufacturers like GlaxoSmithKline and Merck will no longer be liable under state law for the harm caused to American consumers as a result of their generic drugs' inadequate warnings.

These enormously profitable corporations,¹³⁶ which are poised to expand in the upcoming decade,¹³⁷ certainly came out on top when the Court decided *PLIVA*. This is no surprise. For years big business in the pharmaceutical and medical industry has fought to control business losses and liability exposure through both the courts and legislation. In 1975, in response to the growing trend of malpractice claims and large jury awards, the California legislature passed the Medical Injury Compensation Reform Act (MICRA),¹³⁸ essentially gutting the amount a patient can receive in a malpractice suit and reducing severely what a lawyer can receive in bringing such claims.¹³⁹ Similarly, in a 2008 decision favorable to medical device manufacturers, the Supreme Court held that certain state law claims against medical device manufacturers were expressly preempted by the 1976 Medical Device Amendments.¹⁴⁰ As recently as February 2011, the Supreme Court ruled in *Bruesewitz v. Wyeth LLC* on preemption grounds that pharmaceutical companies are

134. *Id.* (citing *Paxil Lawsuit Settlements Amount to \$1 Billion So Far*, PARKER WAICHMAN LLP (Dec. 14, 2009), <http://www.yourlawyer.com/articles/title/paxil-lawsuit-settlements-amount-to-1-billion-so-far>).

135. *Id.* (citing David Voreacos & Jef Feeley, *Merck Wins Judge's Ruling Against Vioxx Class Action (Update 1)*, BLOOMBERG (Mar. 17, 2009, 5:12 PM), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=ac3chipK8C7o&refer=home>).

136. *See supra* Part II.

137. *See supra* Part II. In fact, one report noted in 2006 that the drug maker Wyeth had "set aside a reserve of \$21 billion to deal with litigation related to the obesity medication Fen-Phen. Merck's exposure to Vioxx lawsuits may total as much as \$50 billion . . ." *Litigation Raising Health Care Cost, Study Says*, HEARTLANDER MAG. (Jan. 1, 2006), <http://news.heartland.org/newspaper-article/2006/01/01/litigation-raising-health-care-costs-study-says> (citing CTR. FOR LEGAL POLICY, MANHATTAN INST., TRIAL LAWYERS, INC.: HEALTH CARE (2005), *available at* <http://www.triallawyersinc.com/healthcare/hc01.html>).

138. *See* Medical Injury Compensation Reform Act (MICRA) of 1975, 1975 Cal. Stat. 3949 (codified as amended at CAL. BUS. & PROF. CODE § 6146 (West 2003); CAL. CIV. CODE §§ 3333.1–.2 (West 1997); CAL. CIV. PROC. CODE § 667.7 (West 2009)).

139. *See MICRA History*, CALIFORNIANS ALLIED FOR PATIENT PROTECTION, <http://www.micra.org/about-micra/micra-history.html> (last visited Sept. 9, 2012). Specifically, MICRA limited attorney contingency fees on a sliding scale and placed a \$250,000 limit on noneconomic damages. *Id.*

140. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

protected by the 1986 National Childhood Vaccine Injury Act¹⁴¹ from lawsuits by parents alleging harm to their children as a result of a design defect in vaccines.¹⁴² This decision marked a giant “victory for vaccine makers such as Wyeth and GlaxoSmithKline,”¹⁴³ but a huge loss for vaccine consumers, namely children who suffer serious side effects from vaccines. For instance, as a result of the Supreme Court’s holding, the victim in the case, Hannah Bruesewitz, who began to have seizures after receiving the third of five scheduled doses of Wyeth’s Tri-Immunol diphtheria-pertussis-tetanus vaccine as an infant, is prevented from suing the manufacturers for causing her harm and will receive no compensation for her injuries or the costs of her treatment.¹⁴⁴ Today, given the historically favorable jurisprudence towards the medical and pharmaceutical industry, it is no surprise that the *PLIVA* decision came out on the side of pharmaceutical manufacturers.¹⁴⁵

In connection with this sweeping victory for the pharmaceutical industry, on the micro level, the generic-pharmaceutical defendants in the case themselves received a staggering financial win.¹⁴⁶ For example, Teva Pharmaceutical Industries Ltd., one of the main defendants in *PLIVA*, received a legal victory worth approximately \$500 million to the company.¹⁴⁷ Had the decision gone the other way, Teva would have had

141. 42 U.S.C. §§ 300aa-1 to -34 (2006).

142. *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1082 (2011).

143. Robert Barnes, *Supreme Court Rules Vaccine Makers Protected from Lawsuits*, WASH. POST (Feb. 22, 2011, 10:46 PM), <http://www.washingtonpost.com/wp-dyn/content/article/2011/02/22/AR2011022206008.html>.

144. *See Bruesewitz*, 131 S. Ct. at 1074–75, 1082. Also note that the vaccine’s manufacturer, now owned by Pfizer, has since taken the drug at issue off the market. Barnes, *supra* note 143. Furthermore, any other vaccine claims, aside from those in *Bruesewitz*—because they can no longer be brought—must go through the Act’s administrative court before a tort case can be filed, making it far more difficult for plaintiffs to get adequate representation and awards. *See* 42 U.S.C. §§ 300aa-11(a)(1), -12(d)(3), -12(e), -12(g), -21(a). This special tribunal is commonly called the “Vaccine Court.” Barnes, *supra* note 143.

145. *See infra* Part V (looking into how the Court and government have been influenced by Big Pharma in decisionmaking). In fact, “Actavis Inc. CEO Doug Boothe called the decision ‘an important and necessary step by the Supreme Court to clarify the proper interpretation of the regulations governing pharmaceutical labeling.’” Press Release, Actavis Inc., Actavis Hails US Supreme Court Decision in Labeling Cases (June 23, 2011), available at http://www.actavis.us/en/news/Actavis_hails_Court_Decision.htm.

146. The suit, filed against Actavis and *PLIVA*, marked a victory for the pharmaceutical giants Teva, Mylan Inc. unit UDL Laboratories, and Actavis. Yael Gruntman, *US Supreme Court Saves Teva \$500m*, GLOBES (June 24, 2011, 8:47 PM), <http://www.globes.co.il/serveen/globes/docview.asp?did=1000657521&fid=1725>.

147. *Id.*

to pay out this sum to the plaintiffs. Teva was also saved from the stigma attached to tort liability, which would have had serious ramifications for its reputation in existing and future markets—a major concern as Teva is gearing up to enter emerging markets abroad.¹⁴⁸

Based on these facts, it is clear that *PLIVA* was a big win for Big Pharma, but a huge loss for consumers. Given the weak legal basis for *PLIVA*'s outcome,¹⁴⁹ this result brings up the question of what role the pharmaceutical industry plays in shaping public policy and even judicial decisions.

V. THE REAL MOTIVATION BEHIND *PLIVA*

A. *The Private Sector: Big Pharma Has Big Power*

In the past two decades, as the pharmaceutical industry's profits have skyrocketed, so has its political clout. From 1998 to 2012, the pharmaceutical industry was ranked number one as the top lobbying spender in the United States, spending more than \$2 billion over the course of fourteen years.¹⁵⁰ From 1998 to 2005, the pharmaceutical and health products industry spent in excess of \$800 million in federal lobbying and campaign donations at both the federal and state levels.¹⁵¹ During this period, the pharmaceutical lobbying operation, the largest lobbying operation in America, was reported to have spent more than \$675 million, more than any other industry.¹⁵² In the most recent years it has maintained its first place position, spending \$272.8 million in 2009,¹⁵³ \$245.3 million in 2010,¹⁵⁴ \$241.5 million in 2011,¹⁵⁵ and \$124.4 million in 2012 as of September.¹⁵⁶ In 2009, "the pharmaceutical and health products industry's federal lobbying expenditures not only outpaced all other business industries and special interest areas . . . , but

148. See *supra* notes 36–40 and accompanying text.

149. See *supra* Part III.B.

150. *Lobbying Top Industries: 1998–2012*, OPENSECRETS.ORG, <http://www.opensecrets.org/lobby/top.php?indexType=i> (last visited Sept. 9, 2012).

151. M. Asif Ismail, *Drug Lobby Second to None*, CENTER FOR PUB. INTEGRITY (July 7, 2005, 12:00 AM), <http://projects.publicintegrity.org/rx/report.aspx?aid=723>.

152. *Id.*

153. *Lobbying Top Industries: 2009*, OPENSECRETS.ORG, <http://www.opensecrets.org/lobby/top.php?showYear=2009&indexType=i> (last visited Sept. 9, 2012).

154. *Lobbying Top Industries: 2010*, OPENSECRETS.ORG, <http://www.opensecrets.org/lobby/top.php?showYear=2010&indexType=i> (last visited Sept. 9, 2012).

155. *Lobbying Top Industries: 2011*, OPENSECRETS.ORG, <http://www.opensecrets.org/lobby/top.php?showYear=2011&indexType=i> (last visited Sept. 9, 2012).

156. *Lobbying Top Industries: 2012*, OPENSECRETS.ORG, <http://www.opensecrets.org/lobby/top.php?showYear=2012&indexType=i> (last visited Sept. 9, 2012).

[also stood] as the greatest amount ever spent on lobbying efforts by a single industry for one year.”¹⁵⁷

By 2005, pharmaceutical manufacturers had hired approximately “3,000 lobbyists, more than a third of them former federal officials, to advance their interests before the House, the Senate, the FDA, the Department of Health and Human Services, and other executive branch offices.”¹⁵⁸ In 2004, of the 1,291 lobbyists listed as representing pharmaceutical corporations, 52% were former federal officials.¹⁵⁹ “The top 20 drug corporations and the industry’s two trade groups, PhRMA and the Biotechnology Industry Organization, . . . disclosed lobbying on more than 1,600 bills between 1998 and 2004.”¹⁶⁰ These fleets of pharmaceutical lobbyists largely target Congress and the FDA.¹⁶¹ Additionally, as of 2005, the industry—notorious for “employing former [government] officials to lobby on bills sponsored by their ex-bosses”—ensured that “[a] third of all [its] lobbyists . . . [were] former federal government employees, including more than 15 former Senators and more than 60 former members of the U.S. House of Representatives.”¹⁶²

As for political contributions, from 2000 to 2005, the top drug corporations and their employees and PhRMA gave more than \$10 million to 527 organizations, tax-exempt political committees which operate in the grey area between federal and state campaign finance laws.

Nearly \$87 million of the contributions went to federal politicians in campaign donations, with almost 69 percent going to Republican candidates.¹⁶³

The pharmaceutical industry’s top recipients of campaign money included former President George W. Bush, who received in excess of \$1.5

157. Communications, *Federal Lobbying Climbs in 2009 as Lawmakers Execute Aggressive Congressional Agenda*, OPENSECRETS.ORG (Feb. 12, 2010, 10:30 AM), <http://www.opensecrets.org/news/2010/02/federal-lobbying-soars-in-2009.html#>.

158. Ismail, *supra* note 151.

159. *Id.*

160. *Id.*

161. *Id.* (“In 2003 alone, the industry spent nearly \$116 million lobbying the government. That was the year that Congress passed, and President George W. Bush signed, the Medicare Modernization Act of 2003, which created a taxpayer-funded prescription drug benefit for senior citizens.”). Additionally, lobbying Congress has paid off with “a series of favorable laws [for Big Pharma] on Capitol Hill” being passed. *Id.* Focusing on the FDA similarly results in a more pharmaceutical-friendly FDA policy. *See id.*

162. *Id.*

163. *Id.*

million,¹⁶⁴ and members of Congress who sit on committees with jurisdiction over pharmaceutical issues.¹⁶⁵ In total, for the 2007 to 2010 election cycles, pharmaceutical industry contributions were reported to be approximately \$4.3 million.¹⁶⁶

Through its lobbying and campaign donation efforts, the pharmaceutical industry has great influence on politics via its associations with Capitol Hill, federal administrative bodies, and the Presidents it supports. For example, Congress's enactment of the Hatch-Waxman Amendments, promoting the use of generic drugs in the first place, was a big boost to

164. *Id.*; see also PUB. CAMPAIGN ACTION FUND, BUYING A LAW: BIG PHARMA'S BIG MONEY AND THE BUSH MEDICARE PLAN 2 (2004) available at http://www.paxilprogress.org/pdf/PCAF-Buying_Law.pdf ("President Bush maintains very close personal and political relationships with the industry and with [its] major corporations At least seven 'Pioneers' or 'Rangers'—well-connected wealthy individuals who pledged to raise \$100,000 or \$200,000, respectively, for Bush's campaigns—come from the pharmaceutical industry.".) One clinical psychologist, in a study on the Bush-Lilly relationship, recited:

If Americans want to take on Lilly, they might want to do it during a time when the Bush family is out of power. Sidney Taurel, former Lilly CEO and George W. Bush appointee to the Homeland Security Advisory Council, is not the only Bush family-Lilly connection. George Herbert Walker Bush once sat on the Eli Lilly board of directors, as did Bush family crony Ken Lay, the Enron chief convicted of fraud before his death. Mitch Daniels, George W. Bush's first-term Director of Management and Budget, had actually been a Lilly vice president, and in 1991 he had co-chaired a Bush-Quayle fundraiser that collected \$600,000. This is the same Mitch Daniels who is now governor of Indiana, Lilly's home state.

Bruce E. Levine, *Eli Lilly and the Case for the Corporate Death Penalty*, ALLIANCE FOR HUM. RES. PROTECTION (Mar. 8, 2009), <http://www.ahrp.org/cms/content/view/534/109/> [hereinafter Levine I]; see also Bruce Levine, *Big Pharma: Eli Lilly, Zyprexa, & the Bush Family*, Z MAG. (May 2004), <http://psychrights.org/articles/LevineLillyandBush.htm> [hereinafter Levine II] (providing further details on the relationship between the Bush family and Eli Lilly). Also note that former President Bush was behind the congressional legislation insulating manufacturers of vaccines from liability:

[S]oon after George W. Bush signed the Homeland Security Act, New York Times columnist Bob Herbert discovered that "[b]uried in this massive bill, snuck into it in the dark of night by persons unknown . . . was a provision that—incredibly—will protect Eli Lilly and a few other big pharmaceutical outfits from lawsuits by parents who believe their children were harmed by thimerosal."

Levine I, *supra* (quoting Bob Herbert, *Whose Hands Are Dirty?*, N.Y. TIMES (Nov. 25, 2002), <http://www.nytimes.com/2002/11/25/opinion/whose-hands-are-dirty.html?src=pm>).

165. Ismail, *supra* note 151.

166. *Curious Clusters of Cash: Major Lobbyist-Client Connections Among Health Care Interests, 2007-2009*, OPENSECRETS.ORG, http://www.opensecrets.org/lobby/lm_health.php?type=C (last visited Sept. 9, 2012). This number does not account for the additional contributions from the clients of the pharmaceutical companies. Additionally, "[m]embers of Congress and their aides accepted more than \$600,000 in free travel from pharmaceutical interests during a 5½-year period [in the early 2000s] in which drug company profits climbed, in part due to federal legislation favorable to the industry." Robert Brodsky, *Drug Makers' Dime Funds Congressional Travel*, CENTER FOR PUB. INTEGRITY (Aug. 16, 2011, 12:46 PM), <http://www.publicintegrity.org/2006/08/30/5577/drug-makers-dime-funds-congressional-travel>.

the generic industry.¹⁶⁷ The latest example of the industry's influence is the *PLIVA* decision itself.¹⁶⁸ The pharmaceutical industry's longtime lobbying presence influenced the case, as the Court relied on the interpretation of the FDA, having long been lobbied by the industry.¹⁶⁹ Thus, with billions of dollars at stake, the pharmaceutical industry puts ample money into lobbying and campaign efforts to exact influence on its areas of interest, including liability, via Congress, the President, and the FDA, ensuring favorable legislation, regulation, and even judicial appointments.

B. Insulating Big Pharma from Legal Liability: The Leanings of the Supreme Court and the Power of the President To Appoint

Generally, Supreme Court Justices attempt to maintain a reputation of impartiality, claiming that they make their decisions based on the letter of the law. However, as commonly believed, a Landes-Posner study on judicial behavior confirmed that despite the Justices' reputation of impartiality, they really do appear to vote along ideological lines.¹⁷⁰ With only a few exceptions, over the course of the past seventy years, Justices appointed by Republican Presidents tended to vote conservatively, while Justices appointed by Democratic Presidents tended to vote liberally.¹⁷¹ Today, four of the five most conservative Justices since 1937 are on the bench—Justice Thomas ranking the most conservative, Justice Scalia ranking third, Chief Justice Roberts ranking fourth, and Justice Alito ranking fifth.¹⁷² Justice Kennedy, generally known as a conservative, though not as extreme as his previously mentioned colleagues, is also known for his sometime alignment with the liberal faction of the Court.¹⁷³ These five Justices, making up a majority of the

167. See *supra* notes 12–24 and accompanying text.

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

169. See Ismail, *supra* note 151.

170. See William M. Landes & Richard A. Posner, *Rational Judicial Behavior: A Statistical Study* 27 (Univ. of Chi. Law & Econ., Working Paper No. 404, 2008), available at <http://ssrn.com/abstract=1126403>.

171. *Id.* at 27–29; see also Justin Ewers, *Ranking the Politics of Supreme Court Justices*, U.S. NEWS (May 12, 2008), http://www.usnews.com/news/national/articles/2008/05/12/ranking-the-politics-of-supreme-court-justices_print.html (summarizing the Landes-Posner study).

172. Ewers, *supra* note 171.

173. See Nate Silver, *Supreme Court May Be Most Conservative in Modern History*, N.Y. TIMES FIVETHIRTYEIGHT BLOG (Mar. 29, 2012, 8:06 PM), <http://fivethirtyeight.blogs.nytimes.com/2012/03/29/supreme-court-may-be-most-conservative-in-modern-history/>.

members of the Supreme Court, were appointed by Republican Presidents.¹⁷⁴ The remainder, Justices Ginsberg, Breyer, Sotomayor, and Kagan, are considered liberal and were appointed by Democratic Presidents.¹⁷⁵

PLIVA is a striking example of how the Court's conservative faction dominates the outcome of decisions. In a five-to-four split, with conservatives Chief Justice Roberts and Justices Scalia, Kennedy, Thomas, and Alito in the majority,¹⁷⁶ the Court gave a victory to the generic-pharmaceutical manufacturers, their conservative allies.¹⁷⁷ Although the Court recognized the large disparity that its decision created between brand-name and generic prescription drug users,¹⁷⁸ it reasoned that it would not "distort the Supremacy Clause in order to create similar pre-emption" for both kinds of drug manufacturers.¹⁷⁹ The Court's reasoning turned on its purported adherence to the law, reading the federal law strictly with a focus on congressional intent and the FDA's interpretation of its own regulations.¹⁸⁰ However, the majority's decision in fact fails for faulty reasoning and illogicality.¹⁸¹ Justice Sotomayor's opinion reflects the view that "the problem was the court majority, not lawmakers or agencies."¹⁸² "Today's decision leads to so

174. See Lawrence Baum & Neal Devins, *Split Definitive*, SLATE (Nov. 11, 2011, 5:27 PM), http://www.slate.com/articles/news_and_politics/jurisprudence/2011/11/supreme_court_s_partisan_divide_and_obama_s_health_care_law.html.

175. See *id.*

176. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2571 (2011).

177. See *supra* Part V.A (discussing Big Pharma's lobbying efforts and campaign contributions, most of which go to Republican leaders to influence legislation and regulations). For a recent example of this alliance, in November 2010, it was reported that the CEO of Pharmaceutical Product Development had given \$3.38 million to a conservative advocacy group, which in turn spent almost \$3 million on ads supporting Republicans and opposing Democrats. Chris Kromm, *NC Pharmaceutical Baron Spends \$3 Million To Help Republicans*, INST. FOR S. STUD. (Nov. 1, 2010, 6:02 PM), <http://www.southernstudies.org/2010/11/nc-pharmaceutical-baron-spends-3-million-to-help-republicans.html>. However, note that the pharmaceutical industry also has ties to the Democratic Party, as the industry also aims to sway Democrats and those who may have leanings against its political agenda. See *Top Recipients of Contributions from Lobbyists, 2010 Cycle*, OPENSECRETS.ORG, http://www.opensecrets.org/lobby/lobby_contribs.php?cycle=2010&type=P (last visited Sept. 9, 2012) (charting politicians who received money from lobbyists).

178. *PLIVA*, 131 S. Ct. at 2581 ("We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated.").

179. *Id.* at 2582.

180. See *supra* Part III.A.

181. See *supra* Part III.B.

182. Robert Barnes, *Supreme Court Protects Generic-Drug Makers from Being Sued for Lack of Warning*, WASH. POST (June 23, 2011), http://www.washingtonpost.com/politics/supreme-court-protects-generic-drug-makers-from-being-sued-for-lack-of-warning/2011/06/23/AGPfb1hH_story.html.

many absurd consequences that I cannot fathom that Congress would have intended to preempt state law in these cases.”¹⁸³

*C. Who Is Left To Regulate? The Interaction of the Court with
Federal Agency Interpretation and the Resultant
Failure To Control Big Pharma*

In 1945, the Supreme Court first held that “administrative interpretation [of an agency’s own regulations] . . . becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation.”¹⁸⁴ Since then, the courts have given extreme deference to the interpretation of federal agencies, even when such deference may be inappropriate. *PLIVA* is such a case.

In *PLIVA*, the Court gave extreme deference to the FDA’s own interpretation of its regulations, despite the fact that the FDA’s interpretation led to illogical and unfair results.¹⁸⁵ Because the Court, relying on the FDA’s interpretation, determined that there were no means available to the manufacturers to change their labels in accordance with state law without violating federal law, it found conflict preemption based on impossibility.¹⁸⁶ As a result, generic manufacturers cannot be sued for state failure-to-warn claims, but brand-name manufacturers can—a consumer’s right to sue now depends on whether he or she is prescribed a generic or brand-name drug.¹⁸⁷ The FDA’s interpretation is inconsistent with its own regulations. The purpose of its regulations on label warnings is to protect consumers,¹⁸⁸ but its interpretation, according to the *PLIVA* Court, essentially leads to the destruction of the strongest form of consumer protection—the right for consumers to sue for injuries. This outcome is utterly illogical. And although Supreme Court jurisprudence does give great deference to an agency’s interpretations of its own regulations, by no means would or could the Court ever vitiate its own power as the ultimate adjudicator of the law. However, in *PLIVA* we see the Court doing just that—the majority essentially

183. *PLIVA*, 131 S. Ct. at 2592 (Sotomayor, J., dissenting).

184. *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945).

185. *See supra* Part III.A–B.

186. *See PLIVA*, 131 S. Ct. at 2575–76; *see also supra* Part III.A.

187. *PLIVA*, 131 S. Ct. at 2583 (Sotomayor, J., dissenting).

188. *See Wyeth v. Levine*, 555 U.S. 555, 566–68 (2009) (describing the history and purpose of the FDA’s regulation of drug warning labels).

relegated all of its judicial power to the FDA.¹⁸⁹ It is also important to note that the FDA, as a main target of the Big Pharma lobby,¹⁹⁰ is susceptible to interpreting its regulations favorably to the pharmaceutical industry, and in the case of *PLIVA*, most likely did. This is a huge problem.

Handing over such power to the FDA without judicial oversight is troubling. Government agencies are often overly influenced by the industries they are supposed to regulate.¹⁹¹ Budgetary limitations also make it impossible to keep tabs on such a fast-growing global industry. A recent study found that “[i]n FDA applications for new generic drugs, nearly 90 percent of the factories providing active ingredients [for the drugs] are located overseas, where the agency’s inspection rate dropped 57 percent between 2001 and 2008.”¹⁹² The former Associate Commissioner for Policy and Planning for the FDA from 1991 to 2005 stated: “The average citizen would want to know that someone is checking that manufacturers are making the drugs they got approval to make. . . . That’s not happening, and the risk to consumers is potentially huge.”¹⁹³ What is worse is that although the FDA purports to have stringent regulations on generic drug approvals, “the FDA’s reforms have largely fallen by the wayside. . . . Between 2000 and 2008, the number of new generic drugs put forth for FDA approval went up 40 percent and approvals doubled.”¹⁹⁴ The fact that the FDA has essentially ignored its consumer protection role is a problem, and change is needed.¹⁹⁵

189. See *supra* Part III.A–B.

190. See Ismail, *supra* note 151.

191. Additionally, as seen here, “[f]ederal law empowers the FDA to regulate the content of drug warning labels as part of the agency’s approval process for new brand-name drugs.” Ken Klukowski, *Supreme Court’s Pliva Decision Is Another Blow Against Trial Lawyers*, AM. C.R. UNION (June 26, 2011) http://theacru.org/acru/supreme_courts_pliva_decision_is_another_blow_against_trial_lawyers/. However, with the FDA’s leanings in *PLIVA*, its role as consumer protector is in doubt.

192. Katherine Eban, *Are Generic Drugs a Bad Bargain?*, NBCNEWS.COM TODAY HEALTH (May 26, 2009, 8:50 AM), http://today.msnbc.msn.com/id/30940044/ns/today-today_health/t/are-generic-drugs-bad-bargain/#.TmgAInNZVe4.

193. *Id.* (internal quotation marks omitted).

194. *Id.* (referring to *SELF Magazine’s* findings).

195. In fact, Scott Gottlieb, doctor and Deputy Commissioner for Medical and Scientific Affairs for the FDA from 2005 to 2007, commented on the pressure for the FDA to support Big Pharma: “Generic companies are popular on Capitol Hill because the industry is powerful and voters are anxious for cheaper drugs. There was always pressure on us to reduce barriers to entry. . . .” *Id.* (internal quotation marks omitted); see also Leonard H. Glantz & George J. Annas, *Impossible? Outlawing State Safety Laws for Generic Drugs*, NEW ENG. J. MED. (Aug. 25, 2011), <http://healthpolicyandreform.nejm.org/?p=15106> (“Congress or the FDA can change the Supreme Court’s conclusion. Better postmarketing surveillance should be combined with a more proactive FDA to ensure adequate labeling of all the drugs available for physicians to prescribe.”). However, although finding the political will to make change to protect consumers should not be impossible, with the power of Big Pharma, it is going to take a lot of work and political change.

VI. THE SERIOUS NEED FOR REASSESSMENT AND
CHANGE TO PROTECT OUR CONSUMERS

In a five-to-four vote, led by the conservative Justices, the Court essentially insulated generic-pharmaceutical manufacturers from any liability for state tort law claims for failure to warn.¹⁹⁶ The pharmaceutical industry consistently ranks as one of the most profitable industries in the world, with projections of future growth, particularly in the generic drug market¹⁹⁷—and *PLIVA* is its most recent victory. The victims of *PLIVA* are average American citizens who use generic drugs to cut costs or use them without even knowing because their insurance company requires it.¹⁹⁸ The consumers are women like Mensing and Demahy, who suffered a neurological disorder as a result of their generic drug prescription, and families like that of the Iraq war soldier whose child was born with serious birth defects as a result of the mother's generic drug prescription.¹⁹⁹ Over the years, consumers' rights have been chiseled away for the benefit of an industry that has grown more profitable and more powerful. Now, the vast majority of the U.S. population can no longer seek justice and exercise state rights when an inadequately labeled generic drug causes them harm.

Our Congress, our federal agencies, and our courts have some serious considerations to make. Justice Thomas acknowledged the “unfortunate hand” that was dealt to the patients whose suits were dismissed, conceding that divergent treatment of brand-name and generic companies likely makes “little sense” to consumers.²⁰⁰ However, Justice Thomas also stated that “[i]t is not this Court’s task to decide whether the statutory scheme established by Congress is unusual or even bizarre.”²⁰¹ Justice Thomas further noted that Congress and the FDA could “change the law and regulations if they so desire.”²⁰²

196. See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2582 (2011) (Sotomayor, J., dissenting).

197. Zacks Equity Research, *supra* note 1.

198. EXPANDING THE USE OF GENERIC DRUGS, *supra* note 4, at 3–4.

199. See *Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010), *rev'd sub nom. PLIVA*, 131 S. Ct. 2567; *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 605 (8th Cir. 2009), *rev'd sub nom. PLIVA*, 131 S. Ct. 2567; *supra* text accompanying note 125.

200. See *PLIVA*, 131 S. Ct. at 2581.

201. *Id.* at 2582 (quoting *Cuomo v. Clearing House Ass'n*, 557 U.S. 519, 556 (2009) (Thomas, J., concurring in part and dissenting in part)) (internal quotation marks omitted).

202. *Id.*

Lawmakers should welcome this invitation to close legal loopholes and assure accountability from those reaping financial rewards. Any new laws could take years to work their way through the legislative process if elected officials do not stand up to the power wielded by the well-heeled pharma lobby. What physicians, pharmacists, and patients need, however, is not delay or diluted legal language. Congress promoted the rise of generics; now it has a responsibility to protect consumers from the dangers they pose. We need updated, enforceable laws requiring all pharmaceuticals to be safe and effective, and requiring labels—brand-name and generic—to stay accurate, complete, and *current* as new knowledge comes to light, even after patents expire. If drug manufacturers do not meet their obligations, they should face consequences, and *all* consumers must be allowed to seek remedy in court.

In August 2011, Public Citizen, a consumer organization, petitioned the FDA to counteract *PLIVA* by authorizing generic drug manufacturers to revise generic drug labeling through the CBE and prior-approval-supplement (PAS) procedures.²⁰³ The FDA should respond by updating its administrative process to reflect the current pharmaceutical landscape in which generics now comprise three-fourths of all prescription drugs sold. The agency should require that generic manufacturers do more than just photocopy the branded label, especially for drugs that have been “off patent” for years. A substantial number of branded drugs are now essentially retired, with scant attention paid by the original manufacturer to medical research and adverse event reports. The FDA needs to ensure that under its regulations each one of the ever-growing number of generic drugs has a manufacturer fulfilling the duty to be an expert on current risks. With limited funds and reach, the FDA needs rules that clearly place accountability on the *entire* pharmaceutical industry for the financially lucrative products it sells, and for the labels on those products.

Other health stakeholders cannot ignore *PLIVA*. Health insurers and state health programs now must rethink whether it is wise to cut costs by mandating patients to use generics when these generics are now shielded from state failure-to-warn laws. Not only do they have an ethical obligation to disclose the generic manufacturer’s lack of liability to patients, but insurers and taxpayers could themselves end up footing the bill for harm caused by prescription drugs. Now, physicians and pharmacists must hesitate before automatically prescribing or filling a generic drug. In fact, health professionals at all levels must update counseling to let

203. *Generic Drug Manufacturers Should Be Able To Warn of Products’ Risks, Public Citizen Tells FDA*, PUB. CITIZEN (Aug. 29, 2011), <http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=3406>.

unsuspecting consumers know that generics and brand-name prescription drugs have an important difference. Patients must educate themselves on pharmaceutical products now more than ever, and weigh the risks involved in choosing generics when they know that the manufacturer has little or no legal responsibility. In the meantime, generic manufacturers are moving for dismissal of failure-to-warn claims, while attorneys for patients who have been harmed are looking at alternative ways to defend their rights, ways that do not rely on label inadequacies.

