

# Indiana Law Review

---

Volume 46

2013

Number 1

---

## NOTES

### A CRITICAL ANALYSIS OF *PLIVA, INC. V. MENSING*

MATTHEW J. CLARK\*

#### INTRODUCTION

A wealthy business executive gives her pharmacist a prescription from her doctor for a drug to help treat her disease. The pharmacist informs her that the doctor has prescribed the brand-name of the drug, but she could save 80% of the cost by getting the generic of the same drug. The business executive informs the pharmacist that she always buys brand-name. The pharmacist replies that there is absolutely no difference between the drugs other than the company that manufactures them; both of the drugs are equally effective. The business executive refuses the offer, convinced that the brand-name has to be better. Later, a blue-collar worker gives the pharmacist a prescription for the same drug to treat the same disease. The pharmacist informs him of the same information she gave the business executive. The man's face lights up at the sound of saving 80% of the price, and the pharmacist fills his order with the generic drug.

As a result of taking the drug for several years, both the business executive and the blue-collar worker develop a debilitating neurological disorder. Unfortunately, the warnings on the drugs' labels did not adequately inform practitioners of the dangers of taking the drug for more than one year. Even more unfortunate is both the brand-name manufacturer and the generic manufacturer had an abundance of medical information that established there was an extremely high risk of consumers developing the neurological disorder if the drug was taken longer than one year. Despite this information, neither manufacturer changed its label or even sought to supplement its label with a warning regarding this risk of the drug.

Because of this lack of warning, the business executive files a successful state failure-to-warn claim against the brand-name drug manufacturer. After hearing of the business executive's success in receiving compensation for her injury, the

---

\* J.D. Candidate, 2013, Indiana University Robert H. McKinney School of Law; M.F.A., 2006, Chapman University, Orange, California; B.A., 2001, Ball State University, Muncie, Indiana. First and foremost, I would like to thank my wife, Jennifer, for all her support, encouragement, and understanding. I would like to thank my family for their support as well. I am grateful to everyone who assisted in the development of this Note, especially all the editors of the *Indiana Law Review*. I would also like to give a special thanks to David Meehan for his efforts in getting this Note published. I dedicate this work to my son and best little buddy, Flynn.

blue-collar worker decides to sue the generic drug manufacturer. To his surprise, his lawyer informs him that he does not have a failure-to-warn claim against the generic drug manufacturer. The worker is confused because his situation is identical to the business executive's situation. The only distinction is that he took the generic form of the drug rather than the brand-name version. The lawyer informs the worker that taking the generic drug was his mistake.

The lawyer explains that as a result of the Supreme Court's decision in *PLIVA, Inc. v. Mensing*,<sup>1</sup> state failure-to-warn claims against generic drug manufacturers are preempted by federal drug regulations because the federal regulations require that a generic drug's label be the same as its equivalent brand-name drug's label at all times.<sup>2</sup> In other words, if a brand-name drug manufacturer fails to warn of a danger, then the generic equivalent, in order to keep the label the same, must fail to warn of the danger too. It would be unfair if a person injured from taking a generic drug could sue the generic drug manufacturer for failing to warn because it was just fulfilling its federal duty.<sup>3</sup> A brand-name manufacturer, on the other hand, can "unilaterally" change its label to add or update warnings on its label; hence, a person injured by a brand-name drug can sue the manufacturer.<sup>4</sup>

With a puzzled look on his face, the worker inquires whether he can sue the brand-name drug manufacturer because his generic drug had to have the same label. The lawyer sadly informs him that the worker's state, like most states, does not allow a person injured by the use of a generic drug to sue the manufacturer of its brand-name equivalent.<sup>5</sup> The lawyer regretfully tells the worker that, unlike the business executive, he has no remedy for his injury.<sup>6</sup>

As the lyric from the Genesis song "Land of Confusion" says, "This is the world we live in."<sup>7</sup> An injured person's ability to sue turns on whether the drug he or she had taken was either brand-name or generic.<sup>8</sup> The Supreme Court's

---

1. 131 S. Ct. 2567 (2011).

2. *Id.* at 2577-78.

3. *See id.* ("It was not lawful under federal law for the Manufacturers to do what state law required of them.").

4. *Id.* at 2581.

5. *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 706-07 (D. Vt. 2010); *see also Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994) ("As Wyeth has no duty to the users of other manufacturers' products, a negligent misrepresentation action cannot be maintained against it on the facts of this case."). *But see Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 320-321 (Cal. Ct. App. 2008) (holding that a brand-name drug manufacturer's duty to use care extends to users injured by the generic equivalent if the doctor relied on the brand-name drug's warning when prescribing the brand-name or generic drug).

6. *See PLIVA*, 131 S. Ct. at 2592 (Sotomayor, J., dissenting) ("The majority's pre-emption analysis strips generic-drug consumers of compensation when they are injured by inadequate warnings.").

7. GENESIS, *Land of Confusion*, on *INVISIBLE TOUCH* (Atlantic Recording Corp. 1986).

8. *PLIVA*, 131 S. Ct. at 2592 (Sotomayor, J., dissenting) (disagreeing with the majority's finding that an individual's right to a remedy "turns on the happenstance of whether her pharmacist

decisions in *Wyeth v. Levine*,<sup>9</sup> which held that federal law does not preempt state failure-to-warn claims against brand-name drug manufacturers,<sup>10</sup> and *PLIVA, Inc. v. Mensing* has set up this bizarre reality. As Justice Sotomayor, writing for the dissent in *PLIVA*, points out, the majority “decision leads to so many absurd consequences.”<sup>11</sup> One absurd result of the *PLIVA* decision is that Americans are supposed to believe that Congress intended to deprive people injured by generic drugs of a remedy while simultaneously promoting the use of generic drugs.<sup>12</sup> Another absurd result is that in a market with generic drugs constituting 75% of prescription drugs,<sup>13</sup> and in which many brand-name manufacturers leave the market once their patent expires, “there will [now] be no manufacturer subject to failure-to-warn liability.”<sup>14</sup>

This decision is especially unfortunate in that it comes at a time when people in the United States are protesting on Wall Street about corporate accountability and economic inequality.<sup>15</sup> Although the hypothetical given in this introduction does not have to be cast in terms of a wealthy individual compared with a middle class individual, it logically could be a likely effect because wealthier individuals, for the most part, are probably more able and willing to pay the higher cost of a brand-name drug. Thus, this decision might result not only in a drop in demand for generics,<sup>16</sup> but could also add a little fuel to the fire on class distinction amongst people in this country. This may be overstating the situation somewhat, but these are the types of ramifications that can come from absurdity. On the other hand, the *PLIVA* decision will most definitely add to the distrust and opposition of corporations. As Justice Sotomayor explains, “[M]any generic manufacturers . . . are huge, multinational companies . . . [that have] sold an estimated \$66 billion of drugs in [the United States] in 2009.”<sup>17</sup>

This Note analyzes the *PLIVA, Inc. v. Mensing* decision. Although Justice Thomas, writing for the majority, admitted that its decision could be seen as making “little sense” to the plaintiffs, he informed them that the majority’s hands were tied by the supremacy of federal law.<sup>18</sup> Despite the majority’s apparent dislike for the result of its decision, this Note argues that the majority’s hands were not as tied down by federal regulation and the supremacy of federal law as it so determined. Part I discusses the background of the case, starting with how

---

filled her prescription with a brand-name drug or a generic”).

9. 555 U.S. 555 (2009).

10. *Id.* at 580-81.

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

12. *Id.* at 2583-84, 2592.

13. *Id.* at 2583.

14. *Id.* at 2593.

15. Andrew Ross Sorkin, *On Wall Street, A Protest Matures*, N.Y. TIMES, Oct. 4, 2011, at B, available at <http://query.nytimes.com/gst/fullpage.html?res=9C04E1D91E31F937A35753C1A9679D8B63>.

16. *PLIVA*, 131 S. Ct. at 2593 (Sotomayor, J., dissenting).

17. *Id.* at 2584.

18. *Id.* at 2581-82 (majority opinion).

the FDA approves drugs and how changes are made to drug labels and then recapitulates the Court's decisions in *Levine* and *PLIVA*. Part II of this Note continues with the analysis of the *PLIVA* decision. Finally, Part III summarizes the analysis by concluding that the Court's deference to the FDA's interpretation of its regulations, rather than the regulations themselves, was ultimately responsible for denying the plaintiffs in *PLIVA* compensation for their injuries.

## I. BACKGROUND

### A. The Drug Approval Process

Prior to 1906, food and drug safety was overseen only by the states through regulations and common law liability.<sup>19</sup> After the Civil War, the drug industry saw a boom in manufacturing and "secret formula" drugs, meaning drugs whose ingredients were not disclosed to the public.<sup>20</sup> Because "neither medicine nor pharmacy had a firm scientific basis" during this time, public concern grew over the quality of drugs.<sup>21</sup> In addition, because of the inexpensive manufacturing cost for secret formula drugs, "pharmacists adulterat[ed] legitimate drugs in an attempt to compete" with "grocers and other uneducated formulators."<sup>22</sup> For example, public opposition existed during this time over "addictive 'soothing syrups,'"<sup>23</sup> which were "[r]ecommended for 'teething babies'" and contained morphine sulfate.<sup>24</sup> Obviously, these products were effective but addictive, and at the same time, imitations existed "with no effective active ingredients."<sup>25</sup> Fearing these altered and misbranded drugs were traveling through interstate commerce, state regulators urged the federal government to aid in the protection of consumers from fraudulent drugs.<sup>26</sup> In 1906, Congress responded by passing the Pure Food and Drugs Act,<sup>27</sup> which established the Food and Drug Administration (FDA)<sup>28</sup> and made the manufacturing or shipping of altered or misbranded drugs illegal.<sup>29</sup>

In the 1930s, sulfa was "one of the first effective anti-infective drugs . . .

---

19. *Wyeth v. Levine*, 555 U.S. 555, 565-66 (2009); see also Mary J. Davis, *The Battle Over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1100 (2007) ("State regulators encouraged . . . the national government to create a federal agency to aid in regulation because of concerns over the States' inability to reach the interstate sale of fraudulent products.").

20. FOOD & DRUG LAW INST., FDA: A CENTURY OF CONSUMER PROTECTION 30-31 & 273 n.31 (Wayne L. Pines ed., 2006).

21. *Id.* at 30.

22. *Id.*

23. *Id.*

24. *Id.*

25. *Id.*

26. Davis, *supra* note 19, at 1100.

27. 21 U.S.C. § 14 (repealed 1938).

28. U.S. Food & Drug Admin., *History*, FDA.GOV, <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm> (last updated July 29, 2010).

29. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009).

developed,” but it could not be given to children because sulfa’s composition as a “bulky powder” required oral administration via a large capsule.<sup>30</sup> In 1937, a chemist discovered that sulfa could be made into a liquid formulation by dissolving it in diethylene glycol, which is known today as antifreeze.<sup>31</sup> The only premarket test performed was a taste test.<sup>32</sup> After it was sold on the market, numerous “infants suffered slow, painful death[s] as the diethylene glycol . . . produced irreversible liver toxicity.”<sup>33</sup> In 1938, in part to respond to this tragic disaster, Congress went further for the protection of consumers by enacting the Federal Food, Drug, and Cosmetic Act (“FDCA”).<sup>34</sup> The FDCA not only prohibited the sale of altered or misbranded drugs, but it also required the FDA’s approval of any new drug before sale on the market.<sup>35</sup> As a result, drug manufacturers wanting to market a new drug had to submit to the FDA a new drug application (“NDA”) that included investigative reports about the drug and proposed labeling.<sup>36</sup> Although the manufacturer was prohibited from distributing the drug until it received approval from the FDA, the burden, prior to 1962, was on the FDA to prove the drug was unsafe.<sup>37</sup> If the FDA determined the drug was safe for its intended use as shown on the label, the manufacturer could sell the new drug on the market.<sup>38</sup>

Despite the FDCA requirement for premarket approval, drug testing was not very intensive.<sup>39</sup> Clinical trials of new drugs were not used for evaluation, labeling was more “promotional”<sup>40</sup> rather than informative, and the FDA only had a small staff to review the safety of drugs.<sup>41</sup> In 1961, the manufacturers of thalidomide, a drug used in Europe and Japan to help pregnant women manage morning sickness, was seeking approval in the United States.<sup>42</sup> While the drug was still pending approval, thousands of children in Europe and Japan were born with birth defects to mothers who had taken thalidomide.<sup>43</sup> Subsequently,

---

30. FOOD & DRUG LAW INST., *supra* note 20, at 161.

31. *Id.* at 161-62.

32. *Id.* at 162.

33. *Id.*

34. Davis, *supra* note 19, at 1100; Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-399(d) (2006)).

35. *Id.*

36. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009).

37. *Id.* at 566-67; see also Charlotte J. Skar, *Products Liability—Conflict Preemption: The United States Supreme Court Denies Preemption Defense for Drug Manufacturers Using FDA-Approved Warning Labels* *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), 86 N.D. L. REV. 405, 409 (2010).

38. *Kellogg v. Wyeth*, 612 F. Supp. 2d 421, 424 (D. Vt. 2008).

39. FOOD & DRUG LAW INST., *supra* note 20, at 165.

40. *Id.*

41. *Id.*

42. *Id.* at 19, 166.

43. *Id.*; see also U.S. Food & Drug Admin., *History*, FDA.GOV, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm> (last updated Dec. 14, 2011).

Congress passed amendments to the FDCA in 1962 that further strengthened control over new drugs.<sup>44</sup> The 1962 amendments required not only that the new drug be safe but also that it be effective for its intended use.<sup>45</sup> It also shifted the burden of proving the safety and effectiveness of the new drug to the manufacturer.<sup>46</sup> As part of the NDA, a manufacturer must include “full reports of investigations”<sup>47</sup> into the drug’s safety and effectiveness gathered from clinical trials and other adequate data; a list of the drug’s ingredients; a full statement of the drug’s composition; a description of how the drug was made, processed, and packaged; samples, if needed; and the manufacturer’s proposed labeling.<sup>48</sup> The FDA must disapprove the application if the FDA finds that the investigations lacked adequate tests, the reports indicate that the drug is unsafe for its intended use as described in the label, the methods used to manufacture and pack the drug were inadequate to preserve the drug’s purity, the information gathered from the reports was inadequate to make a determination of the drug’s safety or effectiveness, or the labeling is false or misleading.<sup>49</sup>

In addition to the 1962 amendments, Congress added a saving clause,<sup>50</sup> which stated, “a provision of state law would only be invalidated upon a direct and positive conflict with the FDCA.”<sup>51</sup> Later, in 1976, Congress enacted an express preemption clause for medical devices as part of the Medical Device Amendments<sup>52</sup> but declined to do so for prescription drugs.<sup>53</sup>

In an effort to make low-cost generic drugs more available to consumers, in 1984 Congress enacted the Drug Price Competition and Patent Term Restoration Act,<sup>54</sup> often referred to as the Hatch-Waxman Amendments, to the FDCA.<sup>55</sup> In the amendments, Congress established an abbreviated new drug application (“ANDA”) to allow generic drug manufacturers to gain FDA approval by showing that its new drug was essentially the same as the “bioequivalent” of the listed

---

44. FOOD & DRUG LAW INST., *supra* note 20, at 166.

45. *Kellogg v. Wyeth*, 612 F. Supp. 2d 421, 424 (D. Vt. 2008).

46. *Skar*, *supra* note 37, at 409-10.

47. 21 U.S.C. § 355(b)(1) (2006).

48. *Id.*; *Kellogg*, 612 F. Supp. 2d at 424.

49. 21 U.S.C. § 355(d), *amended by* Pub. L. No. 112-144, § 3187, 126 Stat. 993 (2012); *Kellogg*, 612 F. Supp. 2d at 424-25.

50. “A saving clause is generally used in a repealing act to preserve rights and claims that would otherwise be lost.” BLACK’S LAW DICTIONARY 1146 (9th ed. 2010). Here, the saving clause is saying that a state law would be repealed by the FDCA only if the state law presented a direct and positive conflict with the FDCA.

51. *Wyeth v. Levine*, 555 U.S. 555, 567 (2009) (internal quotation marks omitted).

52. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. § 360(k) (2006)).

53. *Levine*, 555 U.S. at 567.

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

55. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2583 (2011) (Sotomayor, J., dissenting).

drug, i.e., the approved brand-name drug.<sup>56</sup> Two drugs “are ‘bioequivalent’ if they are given at the same dose, contain the same active ingredient, and reach the same level at the site of action. Two bioequivalent drugs . . . are absorbed the same way by the body and result in the same clinical response in the patient.”<sup>57</sup>

Therefore, along with other requirements, a generic drug manufacturer must show that its drug has the same active ingredients as the brand-name drug, “the route of administration, the dosage form, and the strength of the new drug are the same as the brand-name drug,” its drug is the bioequivalent of the brand-name drug,<sup>58</sup> and that proposed labeling of the new drug “is the same as the labeling approved for the [brand-name] drug,” with some exceptions.<sup>59</sup> By establishing the ANDA, Congress was able to increase the availability of generic drugs because generic manufacturers did not have to conduct the costly clinical trials to get approval and thus could “bring [their] drugs to market . . . less expensively.”<sup>60</sup>

In implementing the Hatch-Waxman Amendments, the FDA requires the generic drug’s proposed labeling be the same as the labeling of its brand-name equivalent except for some allowed differences.<sup>61</sup> These exceptions include differences because of “expiration date, formulation, bioavailability,<sup>62</sup> or pharmacokinetics,<sup>63</sup> labeling revisions made to comply with current FDA labeling guidelines or other guidance.”<sup>64</sup> If any drug manufacturer obtains newly acquired information about the drug after it has been on the market that shows “reasonable evidence of an association of a serious hazard with a drug,” the drug manufacturer must revise the label.<sup>65</sup> All drug manufacturers are prohibited from distributing “a ‘misbranded’ drug, . . . including a drug whose ‘labeling is false or misleading in any particular.’”<sup>66</sup>

---

56. *Id.*; 21 U.S.C. § 355(j) (2006).

57. Melanie McLean, *ONADE Participates in Bioequivalence Workshop*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm222135.htm> (last updated Jan. 26, 2011).

58. *PLIVA*, 131 S. Ct. at 2583 (Sotomayor, J., dissenting); 21 U.S.C. § 355(j)(2)(A)(ii)-(iv).

59. *PLIVA*, 131 S. Ct. at 2574 (alteration in original); 21 U.S.C. § 355(j)(2)(A)(v).

60. *PLIVA*, 131 S. Ct. at 2583 (Sotomayor, J., dissenting); *see also* *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 606 (8th Cir. 2009) (noting that Congress passed the Drug Price Competition and Patent Term Restoration Act in order “to bring more affordable generic drugs to [the] market”).

61. *Kellogg v. Wyeth*, 612 F. Supp. 2d 421, 426 (D. Vt. 2008); 21 C.F.R. § 314.94(a)(8)(iii) (2011).

62. Bioavailability means a drug’s absorption into the blood. *PHARMACOTHERAPY: A PATHOPHYSIOLOGIC APPROACH* 53 (Joseph T. DiPiro et al. eds., 6th ed. 2005).

63. Pharmacokinetics is “the absorption, distribution, metabolism, and elimination of drugs in patients requiring drug therapy.” *Id.*

64. 21 C.F.R. § 314.94(a)(8)(iv) (2011).

65. *Id.* § 201.80(e); *accord id.* § 201.57(c)(6)(i).

66. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 606 (8th Cir. 2009) (quoting 21 U.S.C. §§ 331(a)-(b), 352(a) (2006), *amended by* Pub. L. No. 112-144, § 3187, 126 Stat. 993 (2012)), *vacated in part, reinstated in part*, 658 F.3d 867 (8th Cir. 2011).

FDA regulations establish a few ways in which a drug manufacturer may change its labeling. For major changes, defined as having “a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug,”<sup>67</sup> a manufacturer must submit a supplemental application and receive FDA approval of the label change before it can distribute the drug.<sup>68</sup> For moderate changes, defined as having a “moderate potential to have an adverse effect,”<sup>69</sup> which includes changes in the labeling “[t]o add or strengthen a . . . warning,”<sup>70</sup> a manufacturer can make the change and distribute the drug prior to obtaining approval from the FDA by submitting a supplemental application labeled “Changes Being Effected” (CBE).<sup>71</sup> In summary, to make any major changes to the drug, the manufacturer must get prior approval from the FDA, whereas for a moderate change that includes updating warnings, a manufacturer may change the label prior to FDA approval through the CBE process.

*B. The Wyeth v. Levine Decision*

Diana Levine, a musician, developed gangrene in her arm as a result of an injection of the brand-name drug Phenergan, which required the amputation of her right forearm.<sup>72</sup> Phenergan can cause gangrene if it makes contact with a patient’s arterial blood.<sup>73</sup> The drug was administered to Levine via an IV-push method, meaning it was injected into her arm with a needle, and thus the needle either directly made contact with an artery, or the drug escaped the vein and entered an artery.<sup>74</sup> Levine sued the manufacturer, Wyeth, for failing to have a strong enough warning of the danger of administering the drug via an IV-push method when it could have been more safely administered via an IV-drip method, where the drug is mixed “into a saline solution in a hanging intravenous bag and slowly descends through a catheter inserted in a patient’s vein.”<sup>75</sup>

Wyeth argued that federal regulations preempted<sup>76</sup> Levine’s suit because it

---

67. 21 C.F.R. § 314.70(b)(1).

68. *Id.* § 314.70(a)-(b).

69. *Id.* § 314.70(c)(1).

70. *Id.* § 314.70(c)(6)(iii)(A).

71. *Id.* § 314.70(c)(3)-(6)(iii)(A).

72. *Wyeth v. Levine*, 555 U.S. 555, 559 (2009).

73. *Id.*

74. *Id.*

75. *Id.* at 559-60.

76. The Supreme Court has developed three ways in which to find preemption of state law. Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 226 (2000). First, express preemption occurs when Congress has enacted a provision that specifically states that it is preempting state law. *Id.* Second, field preemption occurs when nothing in a federal statute explicitly states it is preempting state law, but the statutory scheme so dominates a field that it must be implied because “‘Congress left no room for the States to supplement it.’” *Id.* at 227 (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)). Finally, conflict preemption may exist if state law and federal law either conflict in a way that it is physically impossible to comply with both, or if state law “‘stands as an obstacle to



was impossible for Wyeth to comply with both state law—requiring a safer label—and federal law—prohibiting Wyeth from “unilaterally” changing its label.<sup>77</sup> Wyeth also argued that allowing a state failure-to-warn claim created an “‘obstacle to the . . . full purposes and objectives of Congress’ because it substitute[d] a . . . jury’s decision about drug labeling for” that of the FDA’s judgment.<sup>78</sup>

The Court began its analysis of the case with what it considered to be the “two cornerstones of . . . pre-emption [sic] jurisprudence”<sup>79</sup>: Congress’s intent is the ultimate guiding light, and when a case involves the police powers of the states, the Court needs “clear and manifest” proof that it was Congress’s intent to preempt state law.<sup>80</sup> Using this guidepost, the Court held that it was not “impossible for Wyeth to comply with both federal and state [law].”<sup>81</sup> Although Wyeth needed FDA approval of a label change, it could have unilaterally changed its label before receiving approval using the CBE process.<sup>82</sup> Newly acquired information, which the CBE process requires to make a change, did not have to come from new clinical trials, but instead also could come from new analysis of old data.<sup>83</sup> In addition, before Levine’s injury, she had submitted evidence of twenty incidents in which patients had developed gangrene after receiving Phenergan from the IV-push method.<sup>84</sup> The Court also found that unilaterally changing the label did not make it automatically misbranded because Wyeth would be fulfilling its federal duty to have adequate warnings.<sup>85</sup> To show impossibility, Wyeth needed “clear evidence that the FDA would not have approved a change,” and Wyeth had not done so in this case.<sup>86</sup> The Court stated:

[T]hrough many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.<sup>87</sup>

The Court also held that state failure-to-warn claims did not serve as an obstacle to Congress’s purposes in enacting federal drug labeling regulations.<sup>88</sup>

---

the accomplishment and execution of the full purposes and objectives of Congress.” *Id.* at 227-28 (quoting *Boggs v. Boggs*, 520 U.S. 833, 844 (1997)).

77. *Levine*, 555 U.S. at 563, 570.

78. *Id.* at 563-64 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

79. *Id.* at 565.

80. *Id.*

81. *Id.* at 571.

82. *Id.*

83. *Id.* at 569.

84. *Id.*

85. *Id.* at 570.

86. *Id.* at 571-72.

87. *Id.* at 570-71.

88. *Id.* at 573.

Instead, “Congress enacted the FDCA to bolster consumer protection.”<sup>89</sup> Congress must have been aware of state tort actions, but despite this information, it never enacted a federal remedy for injured consumers.<sup>90</sup> The Court reasoned that this was evidence of Congress’s belief that state tort actions provide injured consumers with enough relief, as well as evidence of Congress’s possible recognition of the fact that state tort actions help to protect consumers by incentivizing “manufacturers to produce safe . . . drugs” with “adequate warnings.”<sup>91</sup> Thus, “Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.”<sup>92</sup>

As further evidence that state tort actions are not an obstacle, the Court examined the FDA’s long history of supporting state tort law.<sup>93</sup> The FDA had consistently presented federal drug labeling regulations “as a floor upon which states could build.”<sup>94</sup> In fact, the FDA had previously stated that it did not believe state tort law would “be at odds with [its] regulations,”<sup>95</sup> and that it did not want to stop states from “imposing additional labeling requirements.”<sup>96</sup> The Court believed this to be evidence of the FDA’s belief that state tort law served a “complementary” position with federal regulation.<sup>97</sup> In addition, the Court found that this belief supported the reality that manufacturers were in the better position to monitor their drugs because they had better access to data, and the FDA lacked the resources necessary to oversee the 11,000 drugs on the market.<sup>98</sup> Finally, the Court stated that “[f]ailure-to-warn actions, in particular, lend force to the FDCA’s premise that manufacturers . . . bear primary responsibility for their drug labeling at all times.”<sup>99</sup> As a result, the Court concluded that federal law did not preempt state failure-to-warn claims against brand-name manufacturers.<sup>100</sup>

### C. *The PLIVA, Inc. v. Mensing Decision*

Gladys Mensing suffers from diabetic gastroparesis,<sup>101</sup> a disorder that slows the digestion of food and, as a result, can worsen diabetes by making it harder to

---

89. *Id.* at 574.

90. *Id.* at 574-75.

91. *Id.* at 574.

92. *Id.* at 575.

93. *Id.* at 577-79.

94. *Id.* at 577.

95. *Id.* at 578 (quoting Prescription Drug Product Labeling: Medication Guide Requirements, 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998)).

96. *Id.*

97. *Id.*

98. *Id.* at 578-79.

99. *Id.* at 579.

100. *Id.* at 581.

101. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 605 (8th Cir. 2009), *vacated in part, reinstated in part*, 658 F.3d 867 (8th Cir. 2011).

control blood glucose.<sup>102</sup> In 2001, Mensing's doctor prescribed the brand-name drug Reglan to treat her gastroparesis, and her pharmacist, following Minnesota law, substituted the Reglan with its generic bioequivalent, metoclopramide.<sup>103</sup> Mensing took the generic metoclopramide for four years as prescribed.<sup>104</sup>

Julie Demahy suffers from gastroesophageal reflux,<sup>105</sup> a disease that can cause frequent heartburn and regurgitation and, in severe cases, can cause narrowing of the esophagus.<sup>106</sup> In 2002, Demahy's doctor prescribed Reglan as well, and her pharmacist, following Louisiana law, substituted it with generic metoclopramide.<sup>107</sup> Like Mensing, Demahy took the drug for four years as prescribed.<sup>108</sup>

Metoclopramide is a drug that speeds digestion of food by "enhancing . . . contractions of the esophagus, stomach, and intestines,"<sup>109</sup> as well as blocking dopamine receptors in the brain,<sup>110</sup> which helps to prevent nausea and vomiting.<sup>111</sup> Because metoclopramide acts on dopamine receptors, it can affect the body's extrapyramidal system, which is responsible for controlling fine motor skills.<sup>112</sup> One type of severe extrapyramidal symptom is tardive dyskinesia, a severe neurological disorder that is "characterized by grotesque involuntary movements of the mouth, tongue, lips, and extremities, involuntary chewing movements, and a general sense of agitation."<sup>113</sup>

The FDA approved Reglan in 1980 for short-term use only, with no indication over twelve weeks.<sup>114</sup> In 1985, generic manufacturers were receiving approvals to make generic metoclopramide.<sup>115</sup> Although the drugs were intended for short-term use, data revealed that doctors were prescribing Reglan and metoclopramide for longer than one year.<sup>116</sup> Despite this information, from 1985 to 2005 (the years during which Mensing and Demahy were taking metoclopramide), the labels for Reglan and generic metoclopramide presented the

---

102. *Living with Diabetes*, AM. DIABETES ASS'N, <http://www.diabetes.org/living-with-diabetes/complications/gastroparesis.html> (last visited Jan. 16, 2012).

103. *Mensing v. Wyeth, Inc.*, 588 F.3d at 605.

104. *Id.*

105. *Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010), *overruled by* *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

106. *McNeil v. Wyeth*, 462 F.3d 364, 366 (5th Cir. 2006).

107. *Demahy*, 593 F.3d at 430.

108. *Id.*

109. *McNeil*, 462 F.3d at 366.

110. *Id.*

111. See Mayo Clinic, *Metoclopramide (Oral Route)*, MAYO CLINIC, <http://www.mayoclinic.com/health/drug-information/DR600921> (last visited Jan. 16, 2012).

112. *McNeil*, 462 F.3d at 366.

113. *Id.*

114. See *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 606 (8th Cir. 2009), *vacated in part, reinstated in part*, 658 F.3d 867 (8th Cir. 2011).

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

116. *McNeil*, 462 F.3d at 369.

risk of developing tardive dyskinesia at about .2%.<sup>117</sup> During this period, however, studies showed that 29% of patients taking metoclopramide for several years developed tardive dyskinesia.<sup>118</sup> One study in 1994 even found that 27% of patients taking metoclopramide for longer than thirty days developed tardive dyskinesia.<sup>119</sup> In 2004, the manufacturer of Reglan requested and received an approval from the FDA for a change in the label that stated “[t]herapy should not exceed [twelve] weeks in duration.”<sup>120</sup> The previous version stated less strenuously that therapy longer than twelve weeks was not recommended.<sup>121</sup> Finally, in 2009, acting on its own initiative, the FDA ordered brand-name and generic manufacturers of metoclopramide to add a black box warning—the FDA’s strongest warning—to their labels stating that “[t]reatment with metoclopramide can cause tardive dyskinesia,” and that “[t]reatment . . . longer than [twelve] weeks should be avoided in all but rare cases.”<sup>122</sup>

After taking generic metoclopramide for four years, both Mensing and Demahy developed tardive dyskinesia.<sup>123</sup> Both women sued the generic manufacturers of metoclopramide for failing to provide an adequate warning as the risk of developing tardive dyskinesia was much higher than indicated on their labels.<sup>124</sup> The generic manufacturers argued federal drug regulations preempted state failure-to-warn claims because the federal regulations required them to have the same label “as their brand-name counterparts.”<sup>125</sup> As a result, the manufacturers argued it was impossible for them to modify their labels to comply with state law.<sup>126</sup>

The Court framed the issue of the case as whether generic manufacturers could make changes to their label after initial approval of an ANDA.<sup>127</sup> The FDA interpreted its regulations to mean a generic manufacturer has a “duty of sameness,”<sup>128</sup> meaning its label must be the same as its brand-name counterpart at all times.<sup>129</sup> The Court began its analysis by indicating that it would follow *Auer v. Robbins*<sup>130</sup> in deferring to the FDA’s interpretation.<sup>131</sup> *Auer* held that a

---

117. *Id.* at 370; *Mensing v. Wyeth, Inc.*, 588 F.3d at 606.

118. *PLIVA*, 131 S. Ct. at 2572 (citing *McNeil*, 462 F.3d at 370 n.5).

119. *McNeil*, 462 F.3d at 370 n.5.

120. *PLIVA*, 131 S. Ct. at 2572-73 (alteration in original) (quoting Brief for the United States as Amicus Curiae Supporting Respondents at 8, *PLIVA*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501)).

121. *Id.*

122. *Id.* at 2573.

123. *Id.*

124. *Id.*

125. *Id.*

126. *Id.*

127. *Id.* at 2574.

128. *Id.* at 2574-75 (internal quotation marks omitted).

129. *Id.*

130. 519 U.S. 452 (1997).

131. *PLIVA*, 131 S. Ct. at 2575.

federal agency's interpretation is "controlling unless plainly erroneous or inconsistent with the regulation[s]" or there is any other reason to doubt that they reflect the FDA's fair and considered judgment."<sup>132</sup>

The plaintiffs, Mensing and Demahy, first argued that the generic drug manufacturers could have used the CBE process to change their label.<sup>133</sup> The FDA, however, determined that the CBE regulation only allowed the generic manufacturers to use that process to change their labels to match their brand-name counterpart that had recently changed its label.<sup>134</sup> The Court simply stated that it deferred to the FDA's interpretation because it was not "plainly erroneous or inconsistent with the regulation."<sup>135</sup> The plaintiffs also argued that the manufacturers could have utilized "Dear Doctor" letters, letters sent to health care professionals, that could have advised the professionals of the additional warnings.<sup>136</sup> The FDA argued that "Dear Doctor" letters qualified as "labeling" under 21 U.S.C. § 321(m).<sup>137</sup> The Court, again, stated that it deferred to the FDA for the same reasons as its prior interpretation.<sup>138</sup>

Although the FDA interpreted its regulations as prohibiting generic manufacturers from unilaterally changing their labels to strengthen a warning, it also interpreted its regulations as imposing an affirmative duty on generic manufacturers to propose stronger warnings to the FDA if needed.<sup>139</sup> According to the FDA, this duty exists under 21 C.F.R. § 201.57(e), which states, "[L]abeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug."<sup>140</sup> If the FDA agreed with the generic manufacturer, it would then work with the brand-name manufacturer to update the label.<sup>141</sup> The FDA believed this process allowed a generic manufacturer to simultaneously maintain its duty of sameness and its statutory obligation under 21 U.S.C. § 352(f)(2) to not distribute a drug misbranded with inadequate labeling.<sup>142</sup>

Assuming this duty existed, the Court still found preemption.<sup>143</sup> The Court

---

132. *Id.* (quoting *Auer*, 519 U.S. at 461-62).

133. *Id.*

134. *Id.*

135. *Id.* (quoting *Auer*, 519 U.S. at 461).

136. *Id.* at 2576.

137. *Id.*; see 21 U.S.C. § 321(m) (2006) (stating that "'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article").

138. *PLIVA*, 131 S. Ct. at 2576.

139. *Id.*

140. *Id.* (quoting 21 C.F.R. § 201.57(e) (2011)).

141. *Id.*

142. *Id.* (quoting 21 U.S.C. § 352(f)(2) (2006), amended by Pub. L. No. 112-144, § 3187, 126 Stat. 993 (2012)) ("[A] drug is 'misbranded . . . [u]nless its labeling bears . . . adequate warnings against . . . unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.'") (omissions in original).

143. *Id.* at 2577.

explained that state law required the manufacturers to use a different label, but federal law required generic manufacturers to keep the label the same as its brand-name drug counterpart and to propose a different label to the FDA.<sup>144</sup> Proposing a change in the label did not satisfy the state duty because “[s]tate law demanded a safer label; it did not instruct the [m]anufacturers to communicate with the FDA about the possibility of a safer label.”<sup>145</sup> Rather than beginning its analysis of these requirements with the two cornerstones of preemption cases, as it did in *Levine*, the Court just reiterated the basic idea of preemption—federal law is “the supreme Law of the Land.”<sup>146</sup> Although the Court admitted it was ultimately possible for the generic manufacturers to comply with both state law and federal law if the manufacturers had proposed stronger warnings and the FDA then approved of it and ordered the change, the Court thought that these additional actions made conflict preemption meaningless because many situations could be made possible by the actions of third parties.<sup>147</sup> As a result, the Court stated the test for impossibility was “whether the private party could independently do under federal law what state law requires of it.”<sup>148</sup> Therefore, because a generic manufacturer could not use the CBE process to unilaterally change its label prior to FDA approval, it could not independently comply with what state law requires.<sup>149</sup> Acknowledging that its decision from the perspective of the plaintiffs made “little sense” in light of the Court’s decision in *Levine*, this inability to use the CBE process, from the Court’s perspective, distinguished the plaintiffs’ case from *Levine*.<sup>150</sup> Realizing, too, that compensation turned on which version of the same drug was taken by the injured plaintiffs, the Court concluded that federal drug regulation had dealt the plaintiffs an “unfortunate hand,”<sup>151</sup> but reminded them it was up to Congress and the FDA to change the law.<sup>152</sup>

## II. ANALYSIS OF THE *PLIVA* DECISION

Because the Court in *Levine* found that federal law did not preempt state failure-to-warn claims as a brand-name drug manufacturer could use the CBE process to unilaterally strengthen the warnings on its label,<sup>153</sup> the dispositive issue in *PLIVA* was whether a generic drug manufacturer could utilize the CBE process as well.<sup>154</sup> In deciding this issue, the Court used the deference standard

---

144. *Id.* at 2578.

145. *Id.*

146. *Id.* at 2577 (internal quotation marks omitted).

147. *See id.* at 2578-79.

148. *Id.* at 2579.

149. *Id.* at 2575, 2578, 2581.

150. *Id.* at 2581.

151. *Id.*

152. *Id.* at 2581-82.

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

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

established in *Auer*.<sup>155</sup> Therefore, it makes sense to review how the Court developed this deference and subsequent decisions interpreting this standard of deference.

#### A. *Auer* Deference

In *Auer v. Robbins*, the Supreme Court held that a federal agency's interpretation of its own regulation is "controlling unless plainly erroneous or inconsistent with the regulation,"<sup>156</sup> or if there is some "reason to suspect that the interpretation does not reflect the agency's fair and considered judgment."<sup>157</sup> In *Auer*, St. Louis sergeants sued the city commissioners for overtime pay under the Fair Labor Standards Act of 1938 (FLSA).<sup>158</sup> In response, the commissioners argued the sergeants were not entitled to overtime pay because they were exempt from such pay under the FLSA.<sup>159</sup> The Secretary of Labor had established regulations that determined exempt status, one of which was the "salary-basis test."<sup>160</sup> According to the salary-basis test, an employee qualified for exemption if he received "a predetermined amount"<sup>161</sup> as compensation that is "not subject to reduction because of variations in the quality or quantity of the work performed."<sup>162</sup> The sergeants argued they failed this test because their salary could be subject to reductions for disciplinary infractions based on the "quality or quantity" of their work.<sup>163</sup> Thus, the primary issue of the case was whether a hypothetical possibility of a reduction in pay qualified as being "subject to" such reductions.<sup>164</sup>

At the Court's request, the Secretary of Labor filed an amicus brief interpreting the salary-basis test.<sup>165</sup> Specifically, the Secretary of Labor interpreted the "subject to" language to mean that there was "an actual practice of" deductions in compensation, or that there was a policy that made such deductions significantly likely.<sup>166</sup> The Court deferred to the Secretary's interpretation finding it was not "plainly erroneous or inconsistent with the regulation"<sup>167</sup> ("*Auer* deference"). The Court reasoned that the Secretary's

---

155. *Id.* at 2575.

156. 519 U.S. 452, 461 (1997) (internal quotation marks omitted).

157. *Id.* at 462.

158. *Id.* at 454-55; Fair Labor Standards Act of 1938, ch. 676, 52 Stat. 1060 (codified as amended at 29 U.S.C. §§ 201-219 (2006)).

159. *Auer*, 519 U.S. at 455.

160. *Id.* at 454-55.

161. *Id.* at 455.

162. *Id.*

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

164. *Id.* at 459 (internal quotation marks omitted).

165. *Id.* at 461.

166. *Id.*

167. *Id.* (quoting *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 359 (1989)).

interpretation of “subject to” easily fell within the phrase’s ordinary meaning.<sup>168</sup> The Court found that the police manual containing the rule violations applied to all employees, some of whom were not paid salary.<sup>169</sup> As a result, it was unclear whether the “pay deductions [were] an anticipated form of punishment for employees in [the sergeants’] category.”<sup>170</sup> Furthermore, the Court found that the single deduction in pay for one sergeant did not establish a significant likelihood of deductions.<sup>171</sup> Finally, the Court also held there was no reason to doubt the Secretary’s interpretation as reflecting the agency’s fair and considered judgment because it did not come as a “post hoc rationalizatio[n]” in response to a “past agency action [under] attack.”<sup>172</sup>

The Supreme Court further clarified its *Auer* deference in *Christensen v. Harris County*,<sup>173</sup> in holding the *Auer* deference to be only necessary when the agency’s regulation is ambiguous.<sup>174</sup> In *Christensen*, deputy sheriffs sued Harris County, Texas for violating the FLSA by making them use compensatory time they had accumulated by working overtime.<sup>175</sup> Under the FLSA, counties are allowed to compensate employees for overtime work by giving them compensatory time—time off work with full pay—instead of having to pay the higher hourly wage rate, provided the employee agrees to it.<sup>176</sup> Yet, when an employee reaches the maximum hours of compensatory time allowed, the employer must pay the employee the overtime rate for the overtime hours.<sup>177</sup> Because Harris County was afraid they would not be able to afford the overtime pay for the deputy sheriffs who had accrued the maximum amount of compensatory time, the County developed a policy under which it could order the deputy sheriffs to use their compensatory time.<sup>178</sup> The deputy sheriffs argued that the County’s policy violated 29 U.S.C. § 207(o)(5) of the FLSA, which provides that an employer could not deny a request of compensatory time off unless it would “unduly disrupt the operations of the public agency”<sup>179</sup> because that provision provided the only way to use compensatory time absent an agreement.<sup>180</sup>

Although the Court agreed with the principle “that when a statute limits a

---

168. *Id.*

169. *Id.* at 461-62.

170. *Id.* at 462 (emphasis omitted).

171. *Id.*

172. *Id.* (alteration in original) (quoting *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988)).

173. 529 U.S. 576 (2000).

174. *Id.* at 588.

175. *Id.* at 578, 581.

176. *Id.* at 578-79.

177. *Id.* at 579-80.

178. *Id.* at 580-81.

179. *Id.* at 582.

180. *Id.* at 581-82.



thing to be done in a particular mode, it includes a negative of any other mode,”<sup>181</sup> the Court rejected the deputy sheriffs’ argument that the “thing to be done” was the use of compensatory time.<sup>182</sup> Rather, the Court found the “thing to be done” was the approval of the request, meaning the county could not reject a request for any reason other than undue disruption of operations.<sup>183</sup> As a result, § 207(o)(5) restricted the employer’s ability “to *prohibit* the use of compensatory time” but did not restrict the employer from compelling the use of compensatory time.<sup>184</sup> The Court found support for its interpretation “in two other features of the FLSA”—one being that the FLSA allows an employer to reduce the hours an employee works, and the other being that 29 U.S.C. § 207(o)(3)(B) allows an employer to “cash out accumulated compensatory time by paying the employee his regular hourly wage for each hour accrued.”<sup>185</sup>

The deputy sheriffs also argued for deference to the Department of Labor’s interpretation of its regulations as prohibiting an employer from requiring the use of compensatory time without obtaining prior consent of the employee.<sup>186</sup> The Court held *Auer* deference was not applicable because the agency’s regulation was not ambiguous.<sup>187</sup> The Court reasoned the Secretary of Labor’s regulations clearly permitted compelled compensatory time.<sup>188</sup> The regulation implementing § 207(o)(5) prohibits an employer from using compensatory time to avoid paying overtime compensation.<sup>189</sup> The Court read this as confirming § 207(o)(5)’s purpose of safeguarding the employee from not being compensated at all for overtime work.<sup>190</sup> Another regulation stated that the agreement between the employer and employee regarding the use of compensatory time instead of overtime pay “*may* include other provisions governing the preservation, use, or cashing out of compensatory time . . . consistent with [§ 207(o)].”<sup>191</sup> The Court found this regulation unambiguously permissive, meaning nothing within it suggested that compelled compensatory time had to have been included within an agreement.<sup>192</sup> The Court further held that “[t]o defer to the agency’s position would be to permit the agency, under the guise of interpreting a regulation, to create *de facto* a new regulation.”<sup>193</sup>

The two prior cases detail the proper analysis to give to an interpretation of

---

181. *Id.* at 583 (internal quotation marks omitted).

182. *Id.* (referring to the definition of “thing to be done” set forth in 29 U.S.C. § 207(o)(5) (2006), preempted by *Jones v. United States*, 88 Fed. Cl. 789 (Fed. Cl. 2009)).

183. *Id.*

184. *Id.* at 585.

185. *Id.*

186. *Id.* at 586.

187. *Id.* at 588.

188. *Id.*

189. *Id.* at 584 (paraphrasing 29 C.F.R. § 553.25(b) (1999)).

190. *Id.*

191. *Id.* at 587-88 (alteration in original).

192. *Id.* at 588.

193. *Id.*

an agency regulation, beginning with whether the regulation in question is ambiguous and next providing a flushed-out analysis of whether the interpretation is plainly erroneous or inconsistent or whether some other reason exists to doubt the interpretation. Unfortunately, since *Auer*, most courts rarely conduct this type of thorough analysis when reviewing an agency's interpretation of its own regulation.<sup>194</sup> *PLIVA* is a case on point because the majority opinion only states that it defers to the FDA's interpretation regarding the CBE regulation without providing any reasoning behind its decision.<sup>195</sup> Because the Court does not provide any analysis, it appears that the Court is assuming the regulation is ambiguous. In addition, the lack of analysis suggests that the Court is relying heavily on the plainly erroneous standard of the *Auer* test because it does not take much for an interpretation to overcome it. Based on precedent and the importance of the issue, the majority in *PLIVA* should have provided a more thorough analysis, starting with whether the FDA regulations were ambiguous.

1. *The FDA's Regulations Are Unambiguous.*—Much like the analysis in *Christensen* that turned on the Secretary of Labor's use of the word "may" in its regulation, *PLIVA*, too, should have turned on the FDA's use of a particular word in its regulation. Before 2007, 21 C.F.R. § 201.57 specified the requirements for label content and form for both brand-name and generic drug manufacturers;<sup>196</sup> however, in 2006, the regulation was amended to divide the label content and form requirements between the two, with § 201.80 applying to generic drug manufacturers and § 201.57 applying to brand-name manufacturers.<sup>197</sup> Despite this amendment, the language regarding the revision of warnings on the label remains the same for generic drug manufacturers under both versions.<sup>198</sup> The FDA's regulation requires warnings on the drug's label "be revised . . . as soon as there is reasonable evidence of an association of a serious hazard with a drug."<sup>199</sup> In *PLIVA*, the FDA interpreted this regulation to mean only that a generic manufacturer had "to propose [a] stronger warning label[ ]" to the FDA if it deemed one was necessary.<sup>200</sup> If the FDA agreed, it would work with both the brand-name and generic drug manufacturer to change the label, and then the generic drug manufacturer could use the CBE process to adhere to the FDA's direction and match the brand-name drug's change in label.<sup>201</sup>

This interpretation does not make sense with the language in § 201.80(e).<sup>202</sup>

---

194. See Claire R. Kelly, *The Brand X Liberation: Doing Away with Chevron's Second Step as Well as Other Doctrines of Deference*, 44 U.C. DAVIS L. REV. 151, 204-06 (2010) (discussing a review of district courts showing they applied the doctrine in roughly half of the applicable cases from 2008-2009).

195. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2575-76 (2011).

196. See 21 C.F.R. §§ 201.56 to -.57(e) (1998).

197. *Id.* §§ 201.56 to -.57(c)(6), 201.80(e) (2007).

198. Compare *id.* § 201.57(e) (1998), with *id.* § 201.80(e) (2011).

199. *Id.* § 201.80(e) (2011); *PLIVA*, 131 S. Ct. at 2576.

200. *PLIVA*, 131 S. Ct. at 2576.

201. *Id.* at 2575-76.

202. See *Kellogg v. Wyeth*, 612 F. Supp. 2d 421, 435-36 (D. Vt. 2008).

The dictionary definition of “revise” means “to make a new, amended, improved, or up-to-date version of.”<sup>203</sup> In contrast, “propose” means “to form or put forward a plan or intention,” or “to engage in talk or discussion.”<sup>204</sup> The two verbs cannot be reconciled because putting forth a new plan or intention, in this case an intention to strengthen a warning, does not result in any change of the warning. Proposing a strengthening of a warning is strictly preparatory. Actually changing the warning results in a revision. In other words, to “propose” occurs before the action of changing the warning, and to “revise” occurs during and after the change in the warning. As the Court pointed out in *Christensen*, the word “may” is clearly permissive, and similarly here, the word “revise” clearly means an actual change. The requirement under former § 201.57(e) and current § 201.80(e) requires a revision, not a discussion about a revision.<sup>205</sup>

Furthermore, the amendment to move generic drug manufacturers’ label content and form requirements to § 201.80 affirms the argument that “revise” really means “revise” and not “to propose.” Again, under § 201.80(e) the FDA kept the same language regarding revisions under the warning section of the labeling as it had when the regulation applied to both brand-name and generic drugs under § 201.57(e) before the amendment.<sup>206</sup> If the FDA interpreted “revise” to mean “revise” for brand-name manufacturers but to mean “propose” for generic manufacturers, then the FDA would have changed the wording in its 2006 amendments. In other words, surely the FDA, when given the chance to rewrite its regulation in which it interprets a single word to have two different meanings for two different parties, would take advantage of that opportunity and apply the actual meaning and words it had intended from the start for each manufacturer.

A counterargument to this analysis is that § 201.80 does not necessarily apply to generic drug *manufacturers*, but rather it applies strictly to the generic drug’s label itself. In that respect, the regulation does not address who should implement the revision but rather only provides that the label needs to be changed when reasonable evidence exists suggesting it should be updated with a new warning; however, the FDA’s interpretation undermines this argument. The FDA determined a generic drug manufacturer had a duty to report the need for a stronger warning based on the language in § 201.57(e) (now codified at § 201.80(e)).<sup>207</sup> In support for this proposition, the FDA stated in its amicus brief to the Court that the language in § 201.57(e) “reflect[ed] the ‘central premise of federal drug regulation that the manufacturer bears responsibility for the content

---

203. MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/revise> (last visited Oct. 29, 2011).

204. MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/propose> (last visited Oct. 29, 2011).

205. See 21 C.F.R. § 201.57(e) (1998); *id.* § 201.80(e) (2011); *Kellogg*, 612 F. Supp. 2d at 436.

206. See 21 C.F.R. § 201.57(e) (1998); *id.* § 201.80(e) (2011).

207. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2576 (2011) (referring to the FDA’s interpretation of 21 C.F.R. § 201.57(e) (1998) (codified at 21 C.F.R. § 201.80(e) (2011)).

of its label at all times.”<sup>208</sup> As this statement shows, the FDA interprets § 201.57(e), and thus § 201.80(e), as applying to the manufacturer. In addition, other language within § 201.80(e) suggests the FDA is addressing generic drug manufacturers in regards to the requirements within the section. For example, the regulation explains that certain serious problems might need to be placed in a boxed warning and that the FDA itself will determine when it is necessary and where it will be placed on the label.<sup>209</sup> This language suggests the other language within the section, specifically the language regarding the revising of labels, is directed to generic drug manufacturers because if it was not, the FDA would have stated that it would revise the label to add new warnings. In other words, it would be odd for the FDA explicitly to state its responsibilities in some parts of the section and in other parts state its responsibilities implicitly.

Another counterargument is that the FDA construes § 201.80(e) to mean both a proposal and a revision, meaning that the generic drug manufacturer is supposed to propose a change in its label, and it actually accomplishes the revision by updating its label to match the brand-name drug. In other words, the generic drug manufacturer fulfills the mandate of revising its label per § 201.80(e) when it updates its label to match the brand-name drug label. Yet, this argument is undermined with the remaining language in the requirement. Again, § 201.80(e) mandates that the drug’s label “be revised . . . as soon as there is reasonable evidence of an association of a serious hazard with a drug.”<sup>210</sup> If the revision applies within the context of updating the generic drug’s label to match the brand-name drug label, then “reasonable evidence” necessarily means the direction from the FDA to the generic drug manufacturer to change its label and/or the brand-name drug’s actual change to its label. It makes no sense for the FDA to refer to either action—its own order to do something or a brand-name drug manufacturer’s change in label—as “reasonable evidence.” Only two actions could prompt the generic drug manufacturer to update its label; thus, it is reasonable to expect the FDA to explicitly state those occurrences when a generic drug manufacturer needed to revise its label.

In addition, § 314.97 of the FDA’s regulation requires generic drug manufacturers to follow the requirements under § 314.70 when submitting supplemental applications or other changes.<sup>211</sup> Section 314.70 details how a generic drug manufacturer can make changes to its approved application.<sup>212</sup> The regulation requires a generic drug manufacturer to notify the FDA of any changes via the prior approval process, CBE process, or in an annual report, depending on the type of change.<sup>213</sup> It also requires that when a generic drug manufacturer is

---

208. Brief for the United States as Amicus Curiae Supporting Respondents at 12, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501) (quoting *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009)).

209. 21 C.F.R. § 201.80(e) (2011).

210. *Id.*

211. *Id.* § 314.97.

212. *Id.* § 314.70.

213. *Id.*

making a change in accordance with an FDA regulation or guideline, the manufacturer is required to make the change in a way that provides for the least burdensome way of notifying the FDA of the change.<sup>214</sup> In other words, if a generic drug manufacturer is making a change that falls under the CBE procedure, then it must make the change using that procedure.<sup>215</sup> Thus, if a generic manufacturer had reasonable evidence of a hazard that required it to revise its warning on its drug's label, as required by § 201.80(e), then to comply with § 314.70(a)(3) the generic manufacturer would have to submit the change to the FDA via the CBE process because it is a change that either adds or strengthens the warning, one of the changes falling under the CBE process.<sup>216</sup>

Again, if the FDA's interpretation is correct that the generic drug manufacturer cannot make a change to its label with the CBE process unless to match its brand-name drug label and thus could only propose a change to the FDA upon reasonable evidence of hazard, then § 314.70(a)(3) is meaningless to generic drug manufacturers.<sup>217</sup> The FDA's interpretation means the generic drug manufacturer is not required to notify the FDA of a change in the least burdensome way. In fact, the FDA's interpretation requires the generic drug manufacturer to notify the FDA of a change in the *most* burdensome way, as evidenced by the requirement to work with the brand-name manufacturer to change its label first.<sup>218</sup> Like the Court in *Christensen* found that to defer to the Secretary of Labor's "interpretation 'would be to . . . create *de facto* a new regulation,'" here too, the FDA's interpretation creates a new regulation because it requires a unique process of notification for a particular section of a regulation, § 201.80(e), that is not found in the words of the regulation.<sup>219</sup>

The FDA bases its interpretation that a generic drug manufacturer can only use the CBE process to match a brand-name's drug label on the definition of an abbreviated application, which includes the application under § 314.94 and supplements to it.<sup>220</sup> Under § 314.94(a)(8)(iv), a generic drug's label must be the same as its brand-name drug that it is using to gain approval. Because supplements are a part of the abbreviated application, the FDA interprets this to mean the generic's drug label must always be the same as the brand-name drug's label.<sup>221</sup>

This interpretation, however, is undermined by language in the same section that the FDA purports requires the constant "sameness." Under § 314.94(a)(8)(iv), generic and brand-name drug labels are allowed to have differences, one of which being "labeling *revisions* made to comply with current

---

214. *Id.* § 314.70(a)(3).

215. *Id.*

216. *See id.* § 314.70(c)(6)(iii)(A).

217. *See Kellogg v. Wyeth*, 612 F. Supp. 2d 421, 436 (D. Vt. 2008).

218. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2575-76 (2011).

219. *See Kellogg*, 612 F. Supp. 2d at 436 (quoting *Christensen v. Harris Cnty.*, 529 U.S. 576, 588 (2000)).

220. Brief for the United States, *supra* note 208, at 16; 21 C.F.R. § 314.3(b).

221. Brief for the United States, *supra* note 208, at 15-16; 21 C.F.R. § 314.3(b).

FDA labeling guidelines or other guidance.”<sup>222</sup> Section 201.80 is an effective FDA guideline that details labeling requirements, and prior to that § 201.57 was an effective guideline that detailed labeling requirements. In other words, the guideline dictating when a warning on a label needs to be revised has always been effective since at least 2001 when Gladys Mensing received generic metoclopramide.<sup>223</sup> As a result, complying with § 201.80(e) is an allowed difference in labeling according to § 314.94(a)(8)(iv).

In summary, the regulations regarding the revising of warnings for generic drug manufacturers are clearly unambiguous. Section 314.3 defines an abbreviated application that generic drug manufacturers use for approval as the application described in § 314.94 and supplements to it. Section 314.94 requires that the labeling for the generic drug be the same as the brand-name drug it is seeking approval under except for certain differences, such as labeling revisions done in compliance with other FDA guidelines. Section 201.80, an aforementioned FDA guideline, details the requirements for the content and form of generic drug labels, one of which being that the label must “be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug.”<sup>224</sup> In making this change to the label, § 314.97 requires generic drug manufacturers to follow the requirements for supplements to an approved application under § 314.70, which requires applicants to make a change in the least burdensome way as allowed under the section. Because adding or strengthening a warning is allowed under the CBE process, the generic manufacturer is required to use that process to make the change.

2. *The FDA’s Interpretation Is Inconsistent with Its Regulation.*—Even if the FDA’s regulations are ambiguous, the FDA’s interpretation that a generic drug manufacturer could only use the CBE process to match a brand-name drug’s label<sup>225</sup> is inconsistent with its regulations because it conflicts with a guiding principle of FDA regulation: to “protect the public health by ensuring that . . . drugs are safe and effective.”<sup>226</sup> Congress empowered the Secretary of Health and Human Services to promulgate regulations to effectuate that purpose.<sup>227</sup> As the FDA confirmed in *PLIVA*,<sup>228</sup> and as the Supreme Court articulated in *Levine*, “a central premise” of FDA regulation in advancing this purpose is “that the manufacturer bears responsibility for the content of its label at all times.”<sup>229</sup> The Court found this premise of FDA regulation evident in the CBE process because it put “ultimate responsibility” on the manufacturer for its label and provided a procedure in which it could add safety information before receiving FDA

---

222. 21 C.F.R. § 314.94(a)(8)(iv) (emphasis added).

223. See *PLIVA*, 131 S. Ct. at 2573; 21 C.F.R. § 201.57(e); *id.* § 201.80(e).

224. 21 C.F.R. § 201.80(e).

225. *PLIVA*, 131 S. Ct. at 2575.

226. 21 U.S.C. § 393(b)(2)(B) (2006).

227. *Id.* § 371(a).

228. *PLIVA*, 131 S. Ct. at 2576.

229. *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009).

approval.<sup>230</sup> The premise is further supported under the FDA's regulation § 314.80, which requires both brand-name and generic drug manufacturers to review adverse drug experiences and report them to the FDA.<sup>231</sup>

If the FDA's interpretation is correct, then a generic manufacturer effectively has no responsibility for the content of its label *at any time* because having responsibility for content means being held accountable for its substance.<sup>232</sup> Here, any inadequacy with the substance of the label's content can be directed away from the generic drug manufacturer if it can show it matches the brand-name drug label. Thus, the FDA's interpretation actually means a generic drug manufacturer only has responsibility in confirming that its label is the same as its brand-name drug counterpart at all times. If a generic manufacturer could use the CBE process unilaterally to update its warning in compliance with § 201.80(e), then at some point in time it would be true that the generic manufacturer has actual responsibility for its label content because it could make a change to its label. It is implied in *Levine* that the Court found this ability to make a change to the label before FDA approval as a touchstone for responsibility.<sup>233</sup>

The responsibility of keeping the label the same as the brand-name drug does not advance the purpose of ensuring a drug is safe; in fact, this duty decreases a drug's safety because it safeguards a generic manufacturer from liability and disincentives the generic manufacturer from proposing a change.<sup>234</sup> Furthermore, if the brand-name drug leaves the market, as is often the case, the responsibility for providing adequate warnings is entirely on the FDA.<sup>235</sup> This proposition goes against the Court's finding in *Levine* that the reason the FDA puts the onus on manufacturers is because the FDA lacks the capability to oversee the 11,000 drugs on the market, and thus, the manufacturers are in the best position to monitor the information regarding their drugs.<sup>236</sup> Therefore, not only is the FDA's interpretation inconsistent with its regulations, but it is also inconsistent with the FDCA.

Furthermore, the FDA's interpretation of an "ongoing . . . sameness" in the warning labels<sup>237</sup> is inconsistent with the regulation because it is contrary to the section of federal regulation describing the content of an abbreviated application. As stated before, § 314.94(a)(8)(iv) allows many differences between the generic drug label and the brand-name drug label, including differences in "expiration date, formulation, bioavailability, . . . pharmacokinetics, [and] labeling revisions

---

230. *Id.* at 571.

231. 21 C.F.R. § 314.80 (2011); *id.* § 314.98.

232. See MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/responsible> (last visited Nov. 5, 2011) (defining "Responsible" as "liable to be called to account as the primary cause, motive, or agent" and "able to answer for one's conduct and obligations").

233. *Levine*, 555 U.S. at 571.

234. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2592-93 (2011) (Sotomayor, J., dissenting).

235. See *id.* at 2593.

236. *Levine*, 555 U.S. at 578-79.

237. *PLIVA*, 131 S. Ct. at 2574-75.

made to comply with current FDA labeling guidelines or other guidance.”<sup>238</sup> Besides the general tenor of non-sameness this language exudes, § 314.94(a)(8)(iv) makes reference to revisions in compliance with current FDA labeling guidelines, which implies changes throughout its time on the market, as what is “current” is constantly evolving. Section 314.94(a)(8)(iv) precedes this list of allowed differences by explicitly saying, “differences between the [generic drug manufacturer’s] proposed labeling and labeling approved for the [brand-name] drug *may* include.”<sup>239</sup> Just as the Court in *Christensen* found the word “may” is unambiguously permissive,<sup>240</sup> here, too, “may” indicates that the FDA can disapprove of a label revision but is in no sense required to disapprove of it. Thus, to say there is an ongoing sameness requirement is contrary to the language in § 314.94(a)(8)(iv).

*B. The Supremacy Clause Containing a Non Obstante Provision*

Unlike *Levine*, the Court did not begin its analysis with a presumption against preemption.<sup>241</sup> Instead, a plurality of the Court relied on a theory that the Supremacy Clause contained a non obstante provision—a theory presented in a law review article written by University of Virginia law professor Caleb Nelson.<sup>242</sup> The plurality used this theory to bolster their conclusion that the Court should not consider the actions of the FDA in determining whether it was possible for a generic drug manufacturer to comply with both state and federal law.<sup>243</sup>

According to Professor Nelson, two legal principles of legislative drafting were well established by the late eighteenth century: one, that newer laws abrogated older, conflicting laws, and two, a presumption against implied repeals, meaning a new law should not be read to conflict with an older law if it could be harmonized.<sup>244</sup> The presumption against implied repeals reflected the courts’ traditional reluctance to find that a new law repealed an older law.<sup>245</sup> These two principles conflicted when state legislatures actually wanted the new law to abrogate conflicting laws, and they did not want to distort the new law so as to harmonize it with the older law.<sup>246</sup> To solve this problem, state legislatures would add a non obstante clause, taken from the Latin word for “notwithstanding,” to the new law that said it would apply “notwithstanding any provisions to the contrary in prior laws.”<sup>247</sup> A non obstante clause informed courts that the state

---

238. 21 C.F.R. § 314.94 (2011).

239. *Id.* § 314.94(a)(8)(iv) (emphasis added).

240. *Christensen v. Harris Cnty.*, 529 U.S. 576, 588 (2000).

241. *See PLIVA*, 131 S. Ct. at 2575-81; *Levine*, 555 U.S. at 565.

242. *PLIVA*, 131 S. Ct. at 2579-80 (plurality opinion); *see generally* Nelson, *supra* note 76.

243. *PLIVA*, 131 S. Ct. at 2579-80 (plurality opinion).

244. Nelson, *supra* note 76, at 235-41.

245. *Id.* at 241.

246. *Id.*

247. *Id.* at 238-41.



legislature did not want it to try and harmonize the new law with the older law.<sup>248</sup> In other words, a non obstante clause told the court not to apply the presumption against implied repeals and instead give the new law its ordinary meaning.<sup>249</sup>

The Supremacy Clause of the United States Constitution states that the “Constitution, and the Laws of the United States . . . and all Treaties . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”<sup>250</sup> This clause means state laws that interfere with, or are contrary to, federal law must yield to federal law.<sup>251</sup> In other words, federal law nullifies contrary state law.<sup>252</sup> Professor Nelson argues that the end phrase of the Supremacy Clause is a non obstante provision and is intended to fulfill its traditional purpose—telling the “court[] not to apply the . . . presumption against implied repeals.”<sup>253</sup>

Professor Nelson first notes that the Court has interpreted the Supremacy Clause to mean that federal law is a part of state law and thus forms one jurisprudence within the state.<sup>254</sup> Second, the section of the Supremacy Clause describing federal law as supreme “substitute[d] a federal rule of priority for the traditional temporal rule of priority.”<sup>255</sup> This means that rather than having the temporal rule of priority in which new laws abrogate old, conflicting laws, the federal rule of priority provides that a federal law will reign supreme over a state law, even if a state law comes later in time.<sup>256</sup> Because the Supremacy Clause means that federal law and state law form one jurisprudence, and federal law always reigns supreme, “courts are always bound to apply the federal portion of in-state law.”<sup>257</sup>

Although the Supremacy Clause mandates courts to apply federal law, the federal rule of priority occurs only when state law forces the court to choose between them.<sup>258</sup> Like the test for implied repeals, the test for preemption is whether both state law and federal law can be followed or whether they create contradictory rules.<sup>259</sup> As a result, the last section of the Supremacy Clause works like a traditional non obstante provision because without it courts might seek to avoid finding a contradiction.<sup>260</sup> Rather than having each federal statute or treaty contain a non obstante provision, the founders established a “global non obstante

---

248. *Id.* at 241-42.

249. *Id.*

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

251. *Gibbons v. Ogden*, 22 U.S. 1, 210-11 (1824).

252. *Id.* at 210.

253. Nelson, *supra* note 76, at 232, 245-46.

254. *Id.* at 246-49, 246 n.61.

255. *Id.* at 250.

256. *Id.* at 250-51.

257. *Id.* at 252 (internal quotation marks omitted).

258. *Id.* at 251.

259. *Id.* at 252.

260. *Id.* at 255.

provision” in the Supremacy Clause.<sup>261</sup> Nelson argues the non obstante provision of the Supremacy Clause forces the Court to abandon its longstanding presumption against preemption because it actually instructs the Court not to try to harmonize state and federal law.<sup>262</sup>

As stated before, the plurality in *PLIVA* used this theory of the Supremacy Clause containing a non obstante provision to support its finding of impossibility.<sup>263</sup> The plurality reasoned that because the non obstante provision of the Supremacy Clause instructed the Court not to distort federal law so as to reconcile it with state law, the Court should “look no further than the ordinary meaning of [the] federal law.”<sup>264</sup> The plurality thought that considering the possible actions of the FDA and brand-name drug manufacturers in response to a generic drug manufacturer’s proposal for stronger warnings went beyond the ordinary meaning of the federal law because the supremacy of federal law would always be dependent on these third-party actions.<sup>265</sup> Thus, the non obstante provision supported the Court’s conclusion that determinations of impossibility should depend only on whether a generic drug manufacturer could independently do what state law required of it.<sup>266</sup> Because a generic drug manufacturer could not independently strengthen the warnings on its label without prior approval from the FDA, the Court determined it could not satisfy its state law duty to have a safer label, and thus state law was preempted.<sup>267</sup>

As the dissent in *PLIVA* points out, the plurality’s new theory of the Supremacy Clause goes against more than a half century of precedent of applying a presumption against preemption.<sup>268</sup> The dissent believed that if the Court had used its typical presumption against preemption, as it did in *Levine*, then it would have not found impossibility.<sup>269</sup> Although Professor Nelson’s article is very persuasive, the plurality missed several key points within the article. Of course, the majority is free to interpret the article as it pleases because it is not an authoritative document the majority must follow to the letter, like the Constitution; however, when the majority is effectively overturning a half-century of precedent, and potentially denying plaintiffs suffering a debilitating neurological disorder any remedy, based on one law review article, it is hard to argue that the author’s other views contained in the article are not important or informative. With this in mind, contrary to the dissent’s belief, if the plurality had closely followed Professor Nelson’s article on which it so heavily relied in reaching its decision, the plurality should not have found impossibility, even viewing the Supremacy Clause as containing a non obstante provision.

---

261. *Id.*

262. *Id.* at 304.

263. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2579-80 (2011) (plurality opinion).

264. *Id.* at 2580 (internal quotation marks omitted).

265. *Id.*

266. *Id.*

267. *Id.* at 2581 (majority opinion).

268. *Id.* at 2590-91 (Sotomayor, J., dissenting).

269. *Id.* at 2591-92.

The overall purpose of Professor Nelson's article is to simplify the Court's preemption analysis.<sup>270</sup> He sets out to convince readers that the Court's current preemption analysis, which contains three types of preemption (express, field, and implied), is confusing and preempts too much state law.<sup>271</sup> Nelson argues that, because the Supremacy Clause contains a non obstante provision, the doctrine of preemption should work like the "traditional doctrine of repeals," and as such, the Court should not use a presumption against preemption.<sup>272</sup> Thus, the only test for preemption is that the "[c]ourts are required to disregard state law if, but only if, it contradicts a rule validly established by federal law."<sup>273</sup> In other words, courts should disregard state law only in situations when they are forced to choose between both laws.<sup>274</sup>

Nelson refers to this test as the "logical-contradiction test," and he warns that it is not the same as the physical impossibility test that the Court uses to find conflict preemption under the umbrella of implied preemption.<sup>275</sup> Nelson states that many situations will prove physically possible, while still forcing the Court to choose between laws, such as a federal law giving a person a right to join a union and a state law prohibiting that person from joining a union.<sup>276</sup> Both laws may physically be possible to comply with if the person does not join a union, but a court is still forced to choose between them because enforcing the state law would require disregarding the federal law.<sup>277</sup>

In *PLIVA*, the Court does not use the notion of the Supremacy Clause containing a non obstante provision to overhaul its preemption analysis, but instead uses it only to buttress its new theory that proving physical impossibility within the context of an implied preemption analysis requires a determination of whether a party can take unilateral action.<sup>278</sup> The Court does not use the non obstante provision as a springboard for finding a contradiction between the laws, but instead uses it to establish how to determine whether something is physically impossible.<sup>279</sup> The Court does exactly what Nelson cautions not to do by confusing the concept of physical impossibility with the concept of contradiction.

If the Court had used the logical-contradiction test that necessarily follows from the Supremacy Clause's mandate to apply federal law, the Court would not have found a contradiction, and thus, no preemption of state law. For starters, federal law requires a drug manufacturer to have adequate warnings on its labels.<sup>280</sup> As the Court pointed out, Minnesota and Louisiana state law also

---

270. Nelson, *supra* note 76, at 231, 260.

271. *Id.* at 225-35.

272. *Id.* at 232, 245-46.

273. *Id.* at 260.

274. *Id.* at 251, 261.

275. *Id.* at 260-61.

276. *Id.*

277. *Id.* at 261.

278. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2589-90 (2011) (Sotomayor, J., dissenting).

279. *Id.* at 2579-80 (plurality opinion).

280. 21 U.S.C. § 352(a), (f) (2006); 21 C.F.R. § 201.57(e) (1998); *id.* § 201.80(e) (2011).

require that a drug manufacturer have labels with adequate warnings.<sup>281</sup> No contradiction exists here because clearly both federal and state laws express the same requirement. In other words, the Court is not forced to choose between state law and federal law.

Furthermore, assuming that federal law does prevent a generic drug manufacturer from using the CBE process to unilaterally change its drug label, and instead requires it to propose a label change to the FDA, this still does not reveal a contradiction with state law. The Court found that the state law duty required generic drug manufacturers “to use a different, stronger label than the label they actually used.”<sup>282</sup> Yet, this duty does not force the Court to choose between both federal and state law. State law only mandates that a drug manufacturer have an adequate label and does not prescribe how a manufacturer is to affect that change.<sup>283</sup> Federal law, on the other hand, does instruct a manufacturer as to how it can make a change to its label.<sup>284</sup> In contrast, a contradiction between state law and federal law would exist if the state law required a manufacturer to not only have adequate warnings, but it also required the manufacturer to unilaterally update its label to address any new or stronger warnings. This would force the Court to choose between the state law and federal law because, according to the Court, federal law would not allow a generic drug manufacturer to unilaterally update its label.<sup>285</sup>

Although the Court states there is a contradiction between the state law duty for adequate labeling and the federal law duty of sameness for a generic drug manufacturer regarding its label,<sup>286</sup> this is not a contradiction because it is not a duty of sameness no matter what. The duty of sameness, according to the FDA, is not telling a manufacturer that despite whatever evidence it finds that the current label is inadequate and not safe that it must keep the label the same and sit idle.<sup>287</sup> As the FDA argues, and the Court assumes to be true, the FDA requires the generic drug manufacturer to seek help from the FDA in effecting a change to make the label adequate.<sup>288</sup> This is how the FDA argues that a generic drug manufacturer fulfills its other duty to have adequate warnings under 21 U.S.C. § 352(f)(2) regarding misbranding.<sup>289</sup> If a generic drug manufacturer’s action of seeking help from the FDA to update a warning is good enough to fulfill

---

281. *PLIVA*, 131 S. Ct. at 2577; see also MICHAEL K. STEENSON, MINNESOTA PRACTICE SERIES: PRODUCTS LIABILITY LAW §§ 4.1, 16.6 (West 2011); LA. REV. STAT. ANN. §§ 9:2800.54, preempted by *Green v. BDI Pharm.*, 803 So. 2d 68 (La. Ct. App. 2001), 9:2800.57 (West 2011), preempted in part by *PLIVA*, 131 S. Ct. 2567.

282. *PLIVA*, 131 S. Ct. at 2577.

283. See STEENSON, *supra* note 281, at §§ 4.1, 16.6; LA. REV. STAT. ANN. §§ 9:2800.54, 9:2800.57 (West 2011).

284. 21 C.F.R. § 314.70 (2011).

285. See *PLIVA*, 131 S. Ct. at 2575, 2578.

286. *PLIVA*, 131 S. Ct. at 2576-78.

287. *Id.* at 2576.

288. *Id.*

289. *Id.*

its federal duty of having adequate warnings, why would that not be good enough to fulfill the same state duty to have adequate warnings?

Although Professor Nelson argues the Supremacy Clause's non obstante provision instructs courts not to use a presumption against preemption, he makes a qualification regarding this premise. He warns about taking the non obstante provision's mandate "too far."<sup>290</sup> The goal in deciding preemption cases is "to give effect to congressional intent."<sup>291</sup> Although the non obstante provision of the Supremacy Clause instructs courts not to apply a presumption against preemption, it does not prevent courts from applying other rules of statutory interpretation.<sup>292</sup> Nelson points out that even without a presumption, "there may well be other reasons to believe that Congress did not intend a particular statute to have much preemptive effect," as evidenced, for example, in either the context of the federal law or even within a "pattern of legislation."<sup>293</sup>

One reason Congress might not have intended the FDCA or the federal regulations implementing it to have a preemptive effect on state law is that it did not want to deny a person any compensation for harm caused by an inadequate warning. As the dissent in *PLIVA* points out, 75% of prescriptions in the United States are for generic drugs.<sup>294</sup> With so many consumers using generic drugs, it is not plausible that Congress intended to deny such a large portion of the population a remedy if harmed by an unsafe or ineffective drug. Moreover, the purpose of the Hatch-Waxman Amendments is to increase Americans' accessibility to inexpensive drugs.<sup>295</sup> With no right to compensation for an injury, people might be inclined to seek expensive brand-name drugs, thus decreasing the demand for generic drugs.<sup>296</sup> This in turn could have an adverse effect on consumer health as many consumers would likely curb their medication plans to adjust to the increase in prices.

As Nelson suggests, other evidence that Congress did not intend to have preemptive effect on state law is observed through its pattern of legislation. As the Court stated in *Levine*, Congress enacted the FDCA "to bolster consumer protection against harmful products."<sup>297</sup> The Court found further support for this proposition in the 1962 amendments to the FDCA, which shifted the burden of proof of a drug's safety to the manufacturers;<sup>298</sup> this strengthened consumer protection because manufacturers have better access to information regarding

---

290. Nelson, *supra* note 76, at 294.

291. *See id.* at 292.

292. *Id.* at 294.

293. *Id.*

294. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2583 (2011) (Sotomayor, J., dissenting).

295. *Id.*; *see also* *Mensing v. Wyeth*, 562 F. Supp. 2d 1056, 1059-60 (D. Minn. 2008) (stating that the "primary purpose" of the Hatch-Waxman Amendments "was to increase the availability of low cost generic drugs" via the abbreviated application process), *rev'd*, 588 F.3d 1056 (8th Cir. 2011), *vacated in part, reinstated in part by* *Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011).

296. *PLIVA*, 131 S. Ct. at 2592-93 (Sotomayor, J., dissenting).

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

298. *Id.* at 567.

their drugs than the FDA.<sup>299</sup> This, in conjunction with state failure-to-warn claims, which provide the incentive for manufacturers to pay attention to data and studies regarding their drugs, increases the chances of discovering and disclosing drug risks.<sup>300</sup> The Court stated that the importance of the state failure-to-warn claims in this process was evidenced within the same 1962 amendments to the FDCA by the enactment of the saving clause that stated, “a provision of state law would only be invalidated upon a direct and positive conflict with the FDCA.”<sup>301</sup> Ultimately, the Court found that because Congress had never enacted an express preemption provision, like it had done for medical devices, along with its apparent awareness of state failure-to-warn claims, Congress did not intend for federal law to preempt state law in this area.<sup>302</sup>

Finally, the Court’s acceptance of the FDA’s interpretation of a constant duty of sameness in *PLIVA* is inconsistent with its established opinion in *Levine* that the Congressional purpose of the FDCA is to bolster consumer protection. In *Levine*, the Court rejected the FDA’s interpretation that the point of the FDCA was to “entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives.”<sup>303</sup> However, an interpretation requiring generic manufacturers to have the same label at all times as their brand-name counterpart supports the FDA’s interpretation in *Levine* because it effectively makes the FDA the decision maker for generic drug labeling. The Court arguably is now interpreting the point of the FDCA, at least as it applies to generic drug manufacturers, as to establish an expert, decision-making agency.

Again, all the non obstante provision is telling the Court is “not to assume automatically that Congress did not want to displace state law[ ].”<sup>304</sup> If the majority in *PLIVA* had kept this in the forefront of its analysis, the other normal tools of statutory construction would have led the majority to the same conclusion reached in *Levine*.

#### CONCLUSION

Although Justice Thomas believed that federal regulation had dealt the plaintiffs an “unfortunate hand,”<sup>305</sup> the reality is the judicial deference given to the FDA’s interpretation of its regulations dealt the plaintiffs the unfortunate hand. This is evident in the inconsistency between the Court’s interpretation of state law and the FDA’s interpretation of its regulations regarding label content. The Court stated that Minnesota law required that “‘where the manufacturer . . . of a product has actual or constructive knowledge of danger to users, the . . .

---

299. *Id.* at 578-79.

300. *Id.*

301. *See id.* at 567 (internal quotation marks omitted).

302. *Id.* at 574-75.

303. *Id.* at 573 (internal quotation marks omitted).

304. Nelson, *supra* note 76, at 295.

305. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581 (2011).

manufacturer has a duty to give warning of such dangers.”<sup>306</sup> The Court stated that under the applicable Louisiana law, “‘a manufacturer’s duty to warn includes a duty to provide adequate instructions for safe use of a product.’”<sup>307</sup> From this language, the Court interpreted Minnesota and Louisiana state law as “demand[ing] a safer label.”<sup>308</sup> Both laws actually use somewhat broad language in regards to the manufacturer’s duty: Minnesota’s duty “to give” a warning and Louisiana’s duty “to provide” a warning. One can imagine the many ways a drug manufacturer could fulfill this duty. For example, a drug manufacturer could post the added warning on its website. Yet, the Court infers from this language a commandment to literally have a different label with nothing short of that satisfying the duty.<sup>309</sup> On the other hand, FDA regulations specifically applying to label content require a manufacturer to revise its label.<sup>310</sup> Revise has a narrow meaning, yet the Court defers to the interpretation of the FDA and gives it a broad meaning that includes merely proposing a change, which, as stated earlier, does not even fall within the definition of revise.<sup>311</sup> It seems apparent then that had the Court interpreted the FDA regulations without any deference, the Court would have interpreted “revise” to mean generic drug manufacturers had to literally change the label. In other words, if “to give” and “to provide” are interpreted by the Court to be commands to have a different label, then surely “to revise” would mean the same thing.

The Court apparently finds value in the legal teachings of the eighteenth and early nineteenth century, as shown in its reliance on Professor Nelson’s theory of the Supremacy Clause.<sup>312</sup> In expounding the meaning of the Supremacy Clause to the plaintiffs, however, the majority could have also harkened back to Justice Marshall’s declaration in *Marbury v. Madison*<sup>313</sup> to explain the Court’s role in preemption cases—that “[i]t is emphatically the province and duty of the judicial

---

306. *Id.* at 2573 (omissions in original) (quoting *Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 788 (Minn.1977)); *see also* STEENSON, *supra* note 281, at §§ 4.1, 16.6 (stating that the Minnesota Supreme Court has embraced the principle that “[o]ne who supplies directly or through a third person a chattel for another to use, is subject to liability . . . for bodily harm caused by the use of the chattel . . . if the supplier . . . fails to exercise reasonable care to inform them of its dangerous condition or of the facts, which make it likely to be so”).

307. *PLIVA*, 131 S. Ct. at 2573 (quoting *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 269–70 (5th Cir. 2002); *see also* LA. REV. STAT. ANN. §§ 9:2800.54, *preempted by* *Green v. BDI Pharm.*, 803 So. 2d 68 (La. Ct. App. 2001), 9:2800.57 (West 2011) (“A product is unreasonably dangerous because an adequate warning about the product has not been provided if . . . the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic.”), *preempted in part by* *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

308. *PLIVA*, 131 S. Ct. at 2578 (emphasis added).

309. *See id.*

310. 21 C.F.R. § 201.57(e) (1998); *id.* § 201.80(e) (2011).

311. *See PLIVA*, 131 S. Ct. at 2576–78.

312. *See id.* at 2579–80.

313. 5 U.S. (1 Cranch) 137 (1803).

department to say what the law is.”<sup>314</sup> Unfortunately, this role seems to be greatly diminished when the Court exercises such a high degree of deference. It seems especially harmful and contradictory to the Court’s stated role when it is very likely the Court would have reached a different interpretation. This begs the question whether the Court is saying what the law is, or merely just saying what the law is not. There is a difference, and unfortunately Gladys Mensing and Julie Demahy learned this the hard way.

---

314. *Id.* at 177.