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## A HARD PILL TO SWALLOW: SYMPTOMS AND PROGNOSIS OF THE DRUG MANUFACTURER PREEMPTION DEFENSE IN 2018

*Brandon Stephens\**

### I. INTRODUCTION

The Hatch-Waxman Act<sup>1</sup> (HWA) was enacted to facilitate rapid availability of affordable generic drugs to the public by sparing manufacturers the cost and risk associated with a protracted application process.<sup>2</sup> While the HWA has certainly proliferated generic drug availability, an externality arising from interpretative caselaw has had the unintended consequence of absolving generic manufacturers from tort liability.<sup>3</sup> Plaintiffs injured by generic drugs have found it exceedingly difficult to recover for their injuries in recent years due to interpretative caselaw concerning manufacturer preemption doctrine.<sup>4</sup> A new branch of preemption defense even emerged around 2016 which extends manufacturer preemption protection to brand-name manufacturers.<sup>5</sup> This note explores the progeny of the pharmaceutical manufacturer preemption defense, its origination from the U.S. Supreme Court's application of the Hatch-Waxman Act's provisions, and a prediction about the preemption doctrine's direction in light of recent cases and the Trump administration. It argues that the Supreme Court erroneously deferred to the Food and Drug Administration (FDA) on issues of

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<sup>1</sup> Drug Price Competition and Patent Term Restoration Act of 1981, 98 Pub. L. No. 417, 98 Stat. 1585 (1984).

<sup>2</sup> See *infra* Part II.

<sup>3</sup> See *infra* Part III.

<sup>4</sup> See *infra* Part IV.

<sup>5</sup> See *infra* Part V. A.

preemption and interpretation of law, and that the FDA acted arbitrarily and capriciously in denying generics the ability to unilaterally change their labels. Lastly, this note concludes with an argument that all manufacturers should be subject to the same duty to strengthen labels and liability for defective designs.

## II. AN OVERVIEW OF THE HATCH-WAXMAN ACT AND ITS EFFECTS

The Hatch-Waxman Act<sup>6</sup> amended the Federal Food, Drug, and Cosmetic Act (FDCA) in 1984 to expedite patient access to affordable generic drugs by making them available upon the expiration of brand-name patents.<sup>7</sup> Generic manufacturers can “essentially piggy-back on a pioneer drug’s human clinical trials and labeling”<sup>8</sup> by filing an abbreviated new drug application (ANDA) with the FDA.<sup>9</sup> The ANDA process spares generic manufacturers from performing redundant and considerably expensive clinical trials required of new drug applications (NDA).<sup>10</sup> The intent of Congress was to incentivize rapid entry into the generic market and to drive prices down with competition.<sup>11</sup> Generics are identical to brand-name drugs except for substituted binders and fillers; ANDAs require that a generic drug precisely matches its brand-name referent in active ingredients, dosage form, route of administration, bioequivalence, and label indications.<sup>12</sup> Inactive ingredients added to generics (such as fillers and binders) can create minor variability but are essentially identical.<sup>13</sup> In this respect, the HWA has been enormously successful in achieving patient access to affordable generic drugs.

However, discovery of latent health effects of drugs can take years or even decades to become apparent. These revelations can

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<sup>6</sup> Drug Price Competition and Patent Term Restoration Act of 1981, 98 Pub. L. No. 417, 98 Stat. 1585 (1984).

<sup>7</sup> *SmithKline Beecham Consumer Healthcare v. Watson Pharms.*, 211 F.3d 21, 26 (2d Cir. 2000).

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *SmithKline Beecham Consumer Healthcare v. Watson Pharms.*, 211 F.3d 21, 26 (2d Cir. 2000).

<sup>13</sup> *What are Generic Drugs and Are They Safe?*, CONSUMER REPORTS (Published: Aug. 2012), <http://www.consumerreports.org/cro/2012/08/are-generic-drugs-safe/index.html>.

occur long after a brand-name manufacturer has exited the market. However, only brand-name manufacturers are permitted to update label precautions according to FDA rules and doctrine.<sup>14</sup> Such unilateral changes must be accompanied by a “changes being effected” (CBE) submission to the FDA detailing the changes.<sup>15</sup> Generic manufacturers, on the other hand, are not permitted to make unilateral label changes without prior authorization, according to the FDA’s interpretation of the Food, Drug, and Cosmetic Act (FDCA) as affirmed by the Supreme Court,<sup>16</sup> although generics are similarly obligated to report adverse events.<sup>17</sup> Therefore, no meaningful incentive exists for generic manufacturers to petition the FDA to permit stronger labels, and following a brand-name manufacturer’s departure from the market, there is no one piloting the amendment process towards safer destinations.

Between 2004 and 2018, 8,068,279 reports of adverse side effects were submitted to the FDA.<sup>18</sup> Generics now constitute eighty-eight percent of the United States pharmaceutical market;<sup>19</sup> therefore, it is reasonable to assume that generics are a significant contributor to adverse events based on their overall market share. In spite of this alarming trend, both brand-name and generic drug manufacturers are effectively immune from state torts such as failure-to-warn and defective design claims.<sup>20</sup> Provided that manufacturers have complied with FDA rules enacted pursuant to federal law, tort claims challenging label or design sufficiency are preempted.<sup>21</sup>

### III. GENESIS OF GENERIC DRUG MANUFACTURER PREEMPTION DEFENSE AND ITS FLAWS

In the first case in which the Supreme Court considered pharmaceutical preemption, it concluded that Congress did not intend

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<sup>14</sup> See *infra* Part III. B.

<sup>15</sup> *Wyeth v. Levine*, 555 U.S. 555, 568 (2009).

<sup>16</sup> *PLIVA v. Mensing*, 564 U.S. 604, 614-15 (2011).

<sup>17</sup> *Id.* at 630-33 (Sotomayor, J., dissenting).

<sup>18</sup> *Who Reports Adverse Events?*, U.S. FOOD AND DRUG ADMINISTRATION, <https://open.fda.gov/drug/event/> (last visited Mar. 4, 2018).

<sup>19</sup> *The Generic Drug Approval Process*, U.S. FOOD AND DRUG ADMINISTRATION, <https://www.fda.gov/Drugs/NewsEvents/ucm508150.htm>, (page last updated: 11/28/2017).

<sup>20</sup> See *infra* Part III.

<sup>21</sup> See *infra* Part III.

the FDCA to preempt state tort law.<sup>22</sup> It also determined that impossibility preemption is a demanding affirmative defense that shifts the burden to the defendant to demonstrate impossibility through clear evidence.<sup>23</sup> However, the two subsequent Supreme Court decisions concerning manufacturer preemption in the context of generics eroded consumer protection by imposing impossibility preemption.<sup>24</sup> At present, generic manufacturers owe consumers no ostensible tort duties.<sup>25</sup> In both of the most recent manufacturer preemption cases, Justice Sonia Sotomayor dissented, saying that precedent has been ignored and lamenting about the policy ramifications.<sup>26</sup>

### A. Clear Evidence Of Impossibility Originally Required For Preemption Defense

The first in the trilogy of formative drug manufacturer preemption defense cases, *Wyeth v. Levine*,<sup>27</sup> was a 6-3 decision and the most pro-consumer of the three. The majority of the Supreme Court in *Levine* held that the FDCA preserves tort suits and that federal law did not preempt plaintiff's failure-to-warn claim against the brand-name manufacturer because it was possible for the manufacturer to comply with both state tort standards and federal obligations imposed by FDA rules.<sup>28</sup> The plaintiff suffered irreversible corrosion from the direct arterial administration of the manufacturer's drug, Phenergan.<sup>29</sup> A physician administered the drug through a high-risk IV-push method rather than a safer IV-drip, which plaintiff alleged was not sufficiently warned of on the label.<sup>30</sup> The drug caused the patient to develop gangrene, resulting in the amputation of her arm.<sup>31</sup> The FDA had authorized the sale of the

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<sup>22</sup> See *infra* Part III. A.

<sup>23</sup> See *infra* Part III. A.

<sup>24</sup> See *infra* Parts III. B, C.

<sup>25</sup> See *infra* Part III. B, C.

<sup>26</sup> See *infra* Part III. B, C.

<sup>27</sup> 555 U.S. 555, 556 (2009) (Stevens delivered the opinion of the court in which Kennedy, Souter, Thomas, Ginsburg and Breyer joined. Justice Alito delivered the dissent in which Scalia and Roberts joined.).

<sup>28</sup> *Id.* at 572-75.

<sup>29</sup> *Id.* at 559.

<sup>30</sup> *Id.* at 560.

<sup>31</sup> *Id.* at 559.

injectable drug in 1955,<sup>32</sup> and the defendant had been aware of the danger of IV-push administration since 1967.<sup>33</sup> The Court reasoned that the defendant had an affirmative duty under both state and federal law to update its labels to reflect recently discovered IV-push dangers and that there was no obstacle preemption, stating that “[i]n keeping with Congress’ decision not to preempt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation.”<sup>34</sup> The Court observed that Congress recognizes that tort suits provide a vital role in protecting consumers from previously unknown risks.<sup>35</sup> Tort suits also incentivize product safety and require manufacturers, which have superior knowledge, to take responsibility rather than rely on the FDA, which is ill equipped to continuously monitor more than 11,000 approved drugs.<sup>36</sup> The Court held that “absent clear evidence that the FDA would not have approved a change to Phenergan’s label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.”<sup>37</sup>

In his dissent that would foreshadow cases to come, Justice Samuel Alito framed the legal issue as a question of whether a Vermont state jury should be empowered to substitute its opinion of label adequacy for the considered and expert opinion of the FDA.<sup>38</sup> Justice Alito relied heavily on a previous decision in *Geier v. American Honda Motor Company*<sup>39</sup> for the proposition that state tort law can never modify an agency’s safety determinations.<sup>40</sup> However, *Geier* differed from *Levine* in an essential respect. In *Geier*, the plaintiff’s claim that the manufacturer was negligent for failing to install an airbag presented a direct obstacle to the options for compliance provided in the agency rule, which the agency deliberately anticipated to permit a gradual, mixed fleet of passive restraints to allow for experimentation with safety standards.<sup>41</sup> *Levine* was not obstacle preempted because the FDCA’s manifest

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<sup>32</sup> *Levine*, 555 U.S. at 561.

<sup>33</sup> *Id.* at 569.

<sup>34</sup> *Id.* at 569, 578.

<sup>35</sup> *Id.* at 579.

<sup>36</sup> *Id.*

<sup>37</sup> *Levine*, 555 U.S. at 571.

<sup>38</sup> *Id.* at 605 (Alito, J., dissenting).

<sup>39</sup> *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000).

<sup>40</sup> *Levine*, 555 U.S. at 621 (Alito, J., dissenting).

<sup>41</sup> *Id.* at 579, 580.

objective was to promote drug manufacturers' continuous responsibility for product safety by leaving state tort suits intact.<sup>42</sup> The FDCA allows pharmaceutical drugs to be sold upon meeting an initial threshold of safety, but with the caveat that they are susceptible to future charges of misbranding and mandatory label changes.<sup>43</sup> The FDA rules create a CBE pathway to label strengthening that manufacturers are obligated to follow, reinforcing the clear federal objective to place the onus on manufacturers to bear responsibility for their labels at all times.

*Geier* also acknowledged that state tort suits directed at specific models of cars that pose unique safety risks may not pose an obstacle to a broadly applying agency rule.<sup>44</sup> This reasoning as applied to *Levine* suggests that although a label may be sufficient in most cases, it might be flawed with respect to particular indications or uses in predisposed populations. Additionally, the potential for state torts to present an obstacle to agency rules is far narrower with pharmaceuticals because the sufficiency of labels varies with each individual case, whereas a tort duty to impose airbags in cars is mutual to all manufacturers in that state and therefore supplants the broader federal rule.

### **B. Failure-to-Warn Preemption Defense for Generic Manufacturers**

Before the Supreme Court addressed generic manufacturer preemption on writ of certiorari, the Eighth and Fifth Circuits first confronted the issue and held that a generic manufacturer cannot remain idle when on notice of a drug's serious adverse effects.<sup>45</sup> Conflict preemption principles provided no help to generics of nothing. The Eighth Circuit reasoned that the generic manufacturer defendant did not surmount *Levine*'s "clear evidence" of impossibility requirement because the defendant failed to prove that the FDA would have rejected a proposed label change, or that the CBE process was foreclosed to them.<sup>46</sup> The Eighth Circuit also

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<sup>42</sup> *Id.* at 581.

<sup>43</sup> *Id.* at 570, 571.

<sup>44</sup> *Geier*, 529 U.S. at 885.

<sup>45</sup> *Mensing v. Wyeth*, 588 F.3d 603, 608 (8th Cir. 2009); *Demahy v. Actavis*, 593 F.3d 428, 449 (5th Cir. 2010).

<sup>46</sup> *Mensing*, 588 F.3d at 608.

quickly dispatched any obstacle preemption challenge by observing that *Levine* determined that tort suits are not an obstacle to the goal of the FDCA: “[a]fter *Wyeth*, we must view with a questioning mind the generic defendants’ argument that Congress silently intended to grant the manufacturers of most prescription drugs blanket immunity from state tort liability when they market inadequately labeled products.”<sup>47</sup> The Fifth Circuit similarly applied *Levine*’s “clear evidence” impossibility preemption standard and discussed “three avenues for complying with both state and federal law: the CBE process, the prior approval process, and letters sent directly to healthcare providers.”<sup>48</sup> The court found no evidence of Congress’s “clear and manifest purpose” to preempt, recognizing the historical context of the FDCA *disfavoring* preemption and Congress’s omission of a preemption provision.<sup>49</sup> The Fifth Circuit further explained that Congress could not have implicitly intended to have a wanton rule which allowed brand-name consumers to recover for injuries but provided no remedy to generic consumers.<sup>50</sup>

In a decision that surely astonished both the circuit courts and plaintiffs, the Supreme Court in *PLIVA v. Mensing*<sup>51</sup> narrowed *Levine*’s preemption exemption to brand-name manufacturers.<sup>52</sup> In other words, the Court decided that generic manufacturers cannot be subjected to failure-to-warn claims and extended a significant immunity. In so doing, the Supreme Court reversed the Fifth and Eighth Circuits.<sup>53</sup> *PLIVA* was a 5-4 decision, with Justice Alito joining the majority in holding that product liability claims against generic manufacturers are preempted, even when the manufacturer has notice of severe health risks and has neglected to act.<sup>54</sup> The Court unquestioningly deferred to the FDA’s interpretation that an original manufacturer has a duty to maintain the “adequacy” of label warnings through the CBE process while a generic company has no such affirmative obligations.<sup>55</sup> Under this premise, the Court held

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<sup>47</sup> *Id.* at 607.

<sup>48</sup> Demahy, 593 F.3d at 445, 446.

<sup>49</sup> *Id.* at 435, 448, 449.

<sup>50</sup> Demahy, 593 F.3d at 449.

<sup>51</sup> *PLIVA v. Mensing*, 564 U.S. 604, 604 (2011).

<sup>52</sup> *Id.* at 609, 624.

<sup>53</sup> *Id.* at 626.

<sup>54</sup> *See id.* at 625.

<sup>55</sup> *See id.* at 614, 615.



that a generic manufacturer is only “responsible for ensuring that its warning label is the same as the brand name’s” at all times.<sup>56</sup>

Even though the FDA foreclosed generic use of doctor letters and the CBE process, it maintained that label adequacy is the responsibility of the manufacturer which is under a constant duty to petition the FDA to update labels upon discovery of adverse effects.<sup>57</sup> This would seemingly dispense with the defense that a defendant manufacturer’s actions were physically impossible. Instead, the Supreme Court expressed skepticism towards the FDA that such a duty existed despite showing deference to the agency regarding sameness requirements, and proceeded to conclude that even if the duty existed, preemption analysis forbids consideration of scenarios that reconcile federal and state law.<sup>58</sup> According to the Court’s reasoning, the defendant established an impossibility preemption defense because in order to strengthen its labels sufficiently to avoid state tort liability, it would have needed to consult the FDA; thus independent compliance was allegedly “impossible.”<sup>59</sup>

*PLIVA* turned manufacturer preemption defense on its head. What began in *Levine* as an onerous affirmative defense requiring “clear and convincing evidence” of physical impossibility instead became an automatic and impregnable barrier to tort suit against generics. The Court in *PLIVA* reconciled *Levine* by reducing it to a brief paragraph at the end of the opinion.<sup>60</sup> The Court notably glossed over the “clear evidence” burden of pleading a preemption defense and gave *Levine* the narrowest holding that preemption exemption depends upon a manufacturer’s “unilateral” ability to act.<sup>61</sup> The opinion supported this harsh constraint by hyperbole that without a categorical rule, the supremacy clause would be rendered

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<sup>56</sup> *PLIVA*, 564 U.S. at 613.

<sup>57</sup> *Id.* at 616.

<sup>58</sup> *Id.* at 620.

<sup>59</sup> *PLIVA*, 564 U.S. at 618.

<sup>60</sup> “*Wyeth* is not to the contrary. In that case, as here, the plaintiff contended that a drug manufacturer had breached a state tort-law duty to provide an adequate warning label. The Court held that the lawsuit was not pre-empted because it was possible for *Wyeth*, a brand-name drug manufacturer, to comply with both state and federal law. Specifically, the CBE regulation, 21 C.F.R. § 314.70(c)(6)(iii), permitted a brand-name drug manufacturer like *Wyeth* ‘to unilaterally strengthen its warning’ without prior FDA approval. Thus, the federal regulations applicable to *Wyeth* allowed the company, of its own volition, to strengthen its label in compliance with its state tort duty.” *Id.* at 624, 625. (internal citations omitted).

<sup>61</sup> *Id.*

“illusory” and “meaningless.”<sup>62</sup> Where federal law and state law can hypothetically conflict, state law is preempted despite identifiable courses of action that could lead to their agreement.

In her dissent, Justice Sotomayor highlighted several flaws in the majority’s reasoning. Sotomayor mentioned that Congress omitted a federal remedy from the FDCA precisely because it understood that state tort law complements the FDCA and accompanying rules, not because it intended to deprive injured consumers of a remedy.<sup>63</sup> She explained that public health and safety are traditional state “police powers,” and in the absence of an express intention by Congress, there is a presumption *against* usurping the states’ historic abilities.<sup>64</sup> She pointed out that hypothetical impossibility of complying with state and federal law is not sufficient to invoke a drastic remedy like preemption; rather, conflict must be actual and impossibility literal.<sup>65</sup> A defendant pleading the affirmative defense bears the burden of showing unavoidable conflict resulting in physical impossibility,<sup>66</sup> though no such showing was made or demanded of defendant in *PLIVA*.

Sotomayor also discussed a logical inconsistency in the majority’s premise that impossibility preemption in the context of failure-to-warn claims turns on whether a manufacturer can “unilaterally” act independently of FDA consultation. She explained that brand-name amendments are not truly unilateral either because their approval ultimately depends on FDA ratification, just as a generic manufacturer’s petition to amend its label can be denied by the FDA.<sup>67</sup> Sotomayor contended that generic label liability is not a novel concept in the record, as generic defendants already have an FDA-recognized duty to monitor and report instances of adverse reactions and vigilantly propose label changes.<sup>68</sup>

Sotomayor is convincing. The distinction between generic and brand-name manufacturers with respect to legal impossibility is arbitrary because both manufacturers are empowered to take corrective action that ultimately relies on FDA approval. Simply

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<sup>62</sup> *Id.* at 620.

<sup>63</sup> *PLIVA*, 564 U.S. at 643 (Sotomayor, J., dissenting) (joined by Justices Ginsburg, Breyer, and Kagan).

<sup>64</sup> *Id.* at 637, 638, 641.

<sup>65</sup> *PLIVA*, 564 U.S. at 626, 627 (Sotomayor, J., dissenting).

<sup>66</sup> *Id.* at 634.

<sup>67</sup> *Id.* at 635, 636.

<sup>68</sup> *Id.* at 631, 632.

because brand-name manufacturers can initiate proposed changes does not make their capacity to act more convincingly “possible” than generic manufacturers that can, and indeed are obligated to, attempt changes. Liability is the most appropriate enforcement mechanism to ensure generic manufacturers are honoring this duty because it creates a significant financial motive to be proactive in order to avoid costly and embarrassing suits.

### C. Generic Manufacturers Absolved of Liability for Selling Defective Products

In another 5-4 decision, the Supreme Court in *Mutual Pharmaceutical Company v. Bartlett*<sup>69</sup> revisited generic manufacturer preemption defense in the context of defective-design torts.<sup>70</sup> Justice Alito delivered the opinion of the Court, which held that generic manufacturer preemption extends to design-defect claims since generics are under a duty of sameness with respect to both design and label.<sup>71</sup> The plaintiff ingested generic sulindac for shoulder pain and developed “a horrendous disease that caused sixty to sixty-five percent of the plaintiff’s skin to either burn off or turn into an open wound. The plaintiff was left severely disfigured and nearly blind.”<sup>72</sup> A toxicologist testified at trial that the manufacturer knew that sulindac posed a higher risk of toxic epidermal necrosis and Stevens-Johnson Syndrome than other available drugs evidenced by incident reports to the FDA, and that sulindac had a similar safety profile to another NSAID withdrawn from the market for misbranding.<sup>73</sup> A jury found the drug to be unreasonably dangerous and defective as designed under the state’s risk-utility analysis, which included label sufficiency among the factors to consider.<sup>74</sup> The Court of Appeals affirmed and the Supreme Court reversed, finding claim preemption because generic manufacturers can neither redesign a drug nor

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<sup>69</sup> *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

<sup>70</sup> *Bartlett*, 133 S. Ct. at 2470.

<sup>71</sup> *Bartlett*, 133 S. Ct. at 2474-77.

<sup>72</sup> *Guidry v. Janssen Pharms.*, No. 15-4591 SECTION F, 2016 U.S. Dist. LEXIS 115447, at \*\*32 (E.D. La. Aug. 29, 2016) (giving a concise and poignant description of Bartlett’s facts).

<sup>73</sup> *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 35 (5th Cir. 2012).

<sup>74</sup> *Bartlett*, 133 S. Ct. at 2476.

change its label to avoid state liability.<sup>75</sup> The Court shirked responsibility by blaming Congress for the “tragic circumstances.”<sup>76</sup>

In an apparent effort to downplay the obvious breadth and considerable harm to consumers, Justice Alito qualified the decision with dicta that purported to offer two viable claims. The first potentially viable claim parallels the misbranding statute which forbids the sale of a drug that is unreasonably dangerous even when used in the manner and dosage ordinarily prescribed.<sup>77</sup>

The construction of state law necessary to invoke the misbranding statute protection is unclear, because plaintiff effectively made this argument by presenting expert testimony that sulindac shared a profile of danger similar to other drugs withdrawn from the market. Presumably Alito meant that a state tort claim must explicitly adopt the federal misbranding statute as a statutory tort in order to avoid preemption, since he refused to recognize market withdrawal as an option that overcomes impossibility preemption even under circumstances suggestive of misbranding.<sup>78</sup> If market withdrawal could overcome impossibility preemption, we would see prospectively misbranded products removed by manufacturers at an earlier stage to reduce liability exposure. This approach would further the HWA’s consumer-oriented purpose. At present, the misbranding statute relies on ex post facto tort suits and FDA action for teeth.

Justice Alito also suggested that a state’s imposition of absolute liability rather than strict liability may not be preempted.<sup>79</sup> According to Justice Alito, this avoids impossibility preemption because a generic manufacturer would have no “affirmative duties” that could conflict with federal obligations.<sup>80</sup> However, the Supreme Court would undoubtedly deem strict liability state torts to be obstacle preempted. Imposing strict liability on generic companies would undermine the generic market and create a far more overt obstacle to the HWA than standard tort liability. Manufacturers would have no means of defense and would be subjected to a

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<sup>75</sup> *Id.* at 2475.

<sup>76</sup> *Id.* at 2480 (Alito, J., delivering the opinion of the court) (joined by Justices Roberts, Scalia, Kennedy, and Thomas).

<sup>77</sup> *Id.* at 2477 n.4.

<sup>78</sup> *Id.* at 2477.

<sup>79</sup> *Bartlett*, 133 S. Ct. at 2473, 2474 n.1.

<sup>80</sup> *Id.*

constant barrage of automatic liability that would discourage market participation and therefore undermine public access to generics.

In her dissent, Justice Sotomayor reiterated many points from her dissent in *PLIVA*<sup>81</sup> while addressing new concerns. She stated that while state tort law only requires a liable manufacturer to compensate victims, it imposes no affirmative actions that would conflict with federal duties.<sup>82</sup> According to Sotomayor, a generic manufacturer can avoid liability by voluntarily discontinuing sales in the forum, paying damages, or even approaching the FDA.<sup>83</sup> She took issue with the majority's conflation of impossibility preemption and obstacle preemption in rejecting the stop-selling rationale.<sup>84</sup> Sotomayor argued that impossibility preemption requires a thorough evaluation of the pre- and post-market review framework for generics and then contrasting them with state obligations, whereas the majority purports to invoke impossibility preemption but devotes the bulk of its opinion to considering policy and historical contexts characteristic of obstacle preemption analysis.<sup>85</sup> Sotomayor argued that the majority rejected the stop-selling rationale under the bizarre and inappropriately considered premise that Congress's purpose when enacting the FDCA was to grant a license to generic manufacturers to sell unreasonably dangerous drugs without tort liability.<sup>86</sup>

Sotomayor pointed out that even under obstacle preemption (which was not an issue before the Court), the majority completely ignored the savings clause added in the 1962 amendment to the FDCA, which called for preemption only when there was a "direct and positive" conflict with state law.<sup>87</sup> She asserted that the majority's conclusion is even more illogical because manufacturers have the resources, responsibility, and greater access to health-related information than the FDA, which is incapable of vigilantly monitoring thousands of drugs.<sup>88</sup> Sotomayor also pointed out that the majority deferred to the FDA's "close call" decision of the

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<sup>81</sup> See *infra* Part III. B.

<sup>82</sup> *Bartlett*, 133 S. Ct. at 2487-90.

<sup>83</sup> *Id.* at 2491.

<sup>84</sup> *Id.* at 2493-96.

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *Id.* at 2484.

<sup>88</sup> *Bartlett*, 133 S. Ct. at 2485.

preemptive effect of its own rules, despite the Supreme Court's consistently holding that an agency declaring preemptive effect without congressional invitation is entitled to little weight.<sup>89</sup> Lastly, Sotomayor mentioned the greatest concern about the majority's reasoning is that holding premarket FDA review to have preemptive effect would imply that torts against brand-name manufacturers are also preempted.<sup>90</sup> This turns out to have been an accurate prediction.<sup>91</sup>

#### IV. THEORIES OF RECOVERY IN THE AFTERMATH OF GENERIC MANUFACTURER TORT PREEMPTION

Fraud has had some success as a stand-alone recovery theory for injured patients post-*PLIVA/Bartlett*. Misbranding is also emerging as a potential loophole to generic manufacturer preemption, but that means that a drug must be unreasonably dangerous for any approved purpose, even as prescribed. Therefore, uniquely predisposed populations are without recourse, which defies fundamental tort principles like the eggshell plaintiff rule and duty assigned by contract. In general, remedies are inconsistently applied and often deprive injured patients of redress. Courts have generally declined to shift responsibility to brand-name manufacturers when a plaintiff has only ingested the generic version. Liability shifting, however, is preferable to a complete bar on plaintiff recovery.

##### A. Misbranding as a Means of Introducing “Parallel” State Claims Against Generics

As the District Court for the Southern District of Illinois pointed out in a 2014 case, *Bartlett* leads to the ironic and confusing implication that a parallel state law *requiring* a dangerous generic drug be taken off the market may actually avoid conflict with federal labeling rules, whereas a state tort law indirectly having the same effect is preempted by the Hatch-Waxman Act:

In *Bartlett*, the Supreme Court expressly noted an exception for state-law claims that parallel the federal misbranding statute. (“We do not address state design-

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<sup>89</sup> *Id.* at 2494.

<sup>90</sup> *Id.* at 2494-95.

<sup>91</sup> *See infra* Part V.A.

defect claims that parallel the federal misbranding statute.”). The federal statute requires a manufacturer to pull a drug from the market (even though approved by the FDA) if it is “dangerous to health” even when used in accordance with the FDA-approved directions. This exception only applies where the plaintiff’s claim is based on scientific information that was not available when the FDA approved the drug.<sup>92</sup>

Therefore, a narrow exception to generic manufacturer preemption exists when a plaintiff can demonstrate that the drug in question is misbranded for any approved use based upon information obtained post-approval, and state law imposes a similar duty. The definition section of the Hatch-Waxman Act describes some of the criteria to be considered in evaluating whether a drug is misbranded; both implied and express misrepresentations of material consequences from regularly prescribed use are relevant.<sup>93</sup> However, the FDCA provisions do not provide a private cause of action. State negligence laws modeled on federal misbranding will still be preempted, whereas negligence per se claims that integrate misbranding will be more likely to survive.<sup>94</sup>

### **B. Courts Should Not Refuse to Shift Generic Failure-to-Warn Liability to Brand-Name Manufacturers**

The “overwhelming” majority of courts have declined to shift liability for generic drug-related injuries to brand-name manufacturers under any theory of liability due to either a lack of

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<sup>92</sup> *Gannon v. Bayer Healthcare Pharms., Inc. (In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.)*, No. 3:13-cv-10143-DRH-PMF, 2014 U.S. Dist. LEXIS 56862, at \*31 (S.D. Ill. Apr. 23, 2014) (internal citations omitted).

<sup>93</sup> 21 U.S.C.S. § 321 (n): “If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.”

<sup>94</sup> Gwendolyn McKee, *Injury Without Relief: The Increasing Reluctance of Courts to Allow Negligence Per Se Claims Based On Violations of FDA Regulations*, 83 UMKC L. REV. 161, 171 (2014).

privity or obvious attempts to circumvent preemption.<sup>95</sup> An outlier case shifted total liability onto the brand-name manufacturer for off-label use, notwithstanding the fact that plaintiff ingested only the generic version. Christmas came a few days early for plaintiffs on December 21, 2017 in *T.H. v. Novartis*,<sup>96</sup> a case where the California high court boldly acknowledged that no other jurisdiction has recognized such expansive brand-name duties.<sup>97</sup> The court held that brand-name manufacturers are liable for failing to amend their labels to reflect known risks even when plaintiff only consumed the generic version and the defendant has since exited the market.<sup>98</sup> In *T.H.*, plaintiffs suffered serious and sustained neurological damage while in the womb when their mother took a generic drug for the off-label purpose of preventing premature labor contractions.<sup>99</sup> The court reasoned that because only brand-name manufacturers may unilaterally add or strengthen warning indications that apply to generics, they therefore bear the fault for failing to update labels to reflect foreseeable risks known to them and may not avoid liability by offloading their business.<sup>100</sup>

The court reached the right decision. Holding brand-name manufacturers liable for generic torts is of course not ideal, but given the preemption landscape, it is the most nearly fair option. Brand-name manufacturers are exclusively responsible for the ongoing adequacy of their labels, which affect the labeling requirements of generic manufacturers that must conform. Brand-name manufacturers ought to bear both the risk as well as the reward for their products. By the time generics enter the market, a brand-name manufacturer will already have enjoyed exclusive sales bestowed by their patent. While holding brand-name manufacturers accountable as a last resort might seem unfair, it is significantly worse policy to deprive consumers of any tort rights. Creating a stronger impetus for brand-name manufacturers to acknowledge and address safety defects will force generic manufacturers to be more proactive in following suit. Neglectful generics will appropriately be subjected to tort liability for

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<sup>95</sup> *Germain v. Teva Pharms. USA.*, 756 F.3d 917, 938-39 (6th Cir. 2014).

<sup>96</sup> 407 P.3d 18 (Cal. 2017).

<sup>97</sup> *T.H.*, 407 P.3d at 22, 47.

<sup>98</sup> *Id.* at 22.

<sup>99</sup> *Id.* at 23.

<sup>100</sup> *Id.* at 41, 43.



their products, thereby absolving brand-name manufacturers of culpability and reinforcing brand-name manufacturers' vigilance.

### B. Are Generic Manufacturers Liable for Fraudulent and Unapproved Off-label Promotion?

It is estimated that nearly twenty percent of prescriptions are for off-label uses and doctors are free to prescribe medications for off-label purposes.<sup>101</sup> Off-label prescriptions include the use of so-called "orphan drugs," or drugs that treat individuals with rare conditions but do not have a large enough market to justify undergoing the costly FDA approval process.<sup>102</sup> According to the U.S. General Accounting Office, one-third of cancer drugs are orphan drugs, and half of all cancer patients take at least one orphan medication.<sup>103</sup>

As discussed, an overwhelming majority of courts have held that a brand-name drug manufacturer may not be liable under any theory of tort liability when the plaintiff was injured by a generic counterpart, even in the case of off-label marketing facilitated by the brand-name manufacturer.<sup>104</sup> However, in *Priest v. Sandoz*<sup>105</sup> the District Court of Texas, joining several other district courts, refused defendant manufacturer's defense that off-label promotion claims against it were preempted.<sup>106</sup> Unfortunately, the court in *Sandoz* still held that plaintiffs insufficiently pled their claims.<sup>107</sup> According to the court, off-label promotion must meet heightened Rule 9(b) pleading standards: "[P]laintiff may have an off-label promotion claim if the plaintiff alleges that the manufacturer influenced the prescribing physician to prescribe the patient off-label amiodarone or if the plaintiff alleges the manufacturer concealed the risks of off-label use of amiodarone."<sup>108</sup> The rule requires a plaintiff to identify the specific instances and content of alleged misrepresentations to

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<sup>101</sup> David Kwok, *Controlling Excessive Off-Label Medicare Drug Costs Through the False Claims Act*, 27 HEALTH MATRIX 185, 193.

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> *See supra* Part IV. B

<sup>105</sup> No. A-15-CV-00822-LY-ML, 2016 U.S. Dist. LEXIS 186635 (W.D. Tex. Dec. 29, 2016).

<sup>106</sup> *Priest*, 2016 U.S. Dist. LEXIS 186635, at \*18.

<sup>107</sup> *Id.* at 33-38.

<sup>108</sup> *Priest*, 2016 U.S. Dist. LEXIS 186635, at \*33-34.

their prescribing physician, along with the time, place, contents, and responsible parties.<sup>109</sup> Although plaintiff's off-label claim initially escaped preemption dismissal, the plaintiff could not identify the content or time of allegedly fraudulent statements.<sup>110</sup> It is difficult to imagine how a plaintiff could have access to these marketing materials at the pleading stage without allowing discovery to proceed via interrogatories and subpoenas for marketing materials. If the plaintiff had access to these materials, one could argue there would be no suit since plaintiff would have already been on notice of the dangers. Despite the viability of off-label fraud claims against generics, premature dismissal under stringent pleading standards offers plaintiffs little hope. Plaintiffs are left to rely on the cooperation of doctors and the manufacturers themselves to furnish materials necessary for developing their case.

#### V. THE TRAJECTORY OF MANUFACTURER PREEMPTION DOCTRINE

At present, the trajectory of manufacturer preemption does not look hopeful for patients injured by pharmaceutical drugs. Most troubling is that some recent cases have even found preemption applicable to brand-name manufacturers. The FDA failed to consider CBE for generic manufacturers as they were slated to do in April 2017. The appointments of Supreme Court Justice Neil Gorsuch and FDA Commissioner Scott Gottlieb under the Trump administration provide uncertain opportunity for changing manufacturer preemption. Dr. Gottlieb has been an opponent of altering generic preemption<sup>111</sup> while Justice Gorsuch seems to disfavor unrestrained agency deference.<sup>112</sup> This could be crucial because a close reading of the FDA rules demonstrates the agency acted arbitrarily and capriciously in denying generic manufacturers the ability to make unilateral label changes.

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<sup>109</sup> *Id.*

<sup>110</sup> *Id.* at 37-38.

<sup>111</sup> *Infra* Part V.B.

<sup>112</sup> *Infra* Part V.B.

### A. District Court Division Over Preempting Design Defect Claims Against Brand-Name Manufacturers

Post-approval-based design-defect theories are preempted because changes to an approved brand-name formula are prohibited after approval, as are dosage adjustments which require prior FDA approval.<sup>113</sup> However, district courts have diverged on whether defective design torts against brand-name manufacturers premised upon a preapproval defective design theory are also preempted.<sup>114</sup> In *Yates v. Ortho-McNeil-Janssen Pharmaceuticals*, a case about a birth control drug, the court relied upon *Bartlett's* disavowal of the “stop-selling rationale” in holding that the plaintiff’s preapproval defective design claim against the brand-name manufacturer was preempted.<sup>115</sup> The court reasoned that plaintiff’s argument amounted to a stop-selling claim because the premise was that the defective birth control composition, “Ortho Evra,” was so foreseeably dangerous that it should never have been brought to application before the FDA.<sup>116</sup> The court stated that to hold otherwise would call for speculation over an alternate formula, its effects, and whether the FDA would have approved the proposed formula.<sup>117</sup> This rationale is dubious. All product liability claims based on defective design entail a demonstration of safer alternatives, and it is not too attenuated to envision a safer drug’s meeting FDA approval.<sup>118</sup>

On the other hand, the district court in *Guidry v. Janssen Pharmaceuticals*<sup>119</sup> held that defective design and failure-to-warn claims against a brand-name manufacturer are not preempted by federal law if the drug’s design (and label based thereon) was “unreasonably risky” at the time of application: “The dispositive question presented here is simply: Can a drug manufacturer independently design a reasonably safe drug in compliance with its state-law duties before seeking FDA approval? The answer is yes.”<sup>120</sup> This holding is aligned with *Levine* and common sense.

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<sup>113</sup> *Yates v. Ortho-McNeil-Janssen Pharms.*, 808 F.3d 281, 298 (6th Cir. 2015).

<sup>114</sup> *Young v. Bristol-Myers Squibb*, No. 4:16-CV-00108-DMB-JMV, 2017 U.S. Dist. LEXIS 24730, at \*17-22 (N.D. Miss. Feb. 22, 2017).

<sup>115</sup> *Yates*, 808 F.3d at 300.

<sup>116</sup> *See id.*

<sup>117</sup> *Id.* at 299-300.

<sup>118</sup> *Young*, 2017 U.S. Dist. LEXIS 24730, at \*18-20.

<sup>119</sup> *Guidry v. Janssen Pharms.*, 206 F. Supp. 3d 1187 (E.D. La. 2016).

<sup>120</sup> *Id.* at 1207-08.

Nothing in the FDCA alludes to construing the FDA's permission to sell a new drug as an absolute defense to liability. Underlying generic preemption is a policy to incentivize generic manufacturers to rapidly enter the market with a low barrier to entry to compensate for enhanced competition. Brand-name manufacturers, on the other hand, are not as vulnerable because they typically enjoy a patent monopoly on their product in which to recoup their investment. Therefore, the same need for protective preemption defense does not exist for brand-name manufacturers.

### **B. Trump Administration and Manufacturer Preemption Defense**

A proposed amendment to the FDA's rules, 78 Fed. Reg. 67985, would enable unilateral label changes to be made by generic manufacturers.<sup>121</sup> The rule was proposed in 2013 presumably as a response to *PLIVA* and *Bartlett*, though it has yet to be ratified despite an April 2017 consideration deadline.<sup>122</sup> The FDA supposedly still plans to issue a final rule despite ardent manufacturer lobbying against it, but has yet to do so as the proposed rule yields to more "immediate priorities."<sup>123</sup> Unfortunately, the rule appears destined for the FDA's proposed rules archive for the foreseeable future. The Trump administration's FDA Commissioner, Dr. Gottlieb, has been an outspoken opponent of any rule that would enable unilateral labeling change by manufacturers, believing them to endanger access to generic drugs by a proliferation of litigation.<sup>124</sup> Prior to assuming the role of commissioner, he condoned off-label advertisement, and since becoming commissioner, he has issued few letters of admonishment for such practices.<sup>125</sup> Furthermore, Gottlieb

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<sup>121</sup> Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985, 67989 (proposed Nov. 13, 2013).

<sup>122</sup> Erin Bosman, Julie Park, Brittany Scheinok, *Trump's Nominee for FDA Commissioner Likely Doooms Generic Drug Labeling Rule*, CLASS DISMISSED (March 30, 2017), <http://classdismissed.mofo.com/product-liability/trumps-nominee-for-fda-commissioner-likely-dooms-generic-drug-labeling-rule/>.

<sup>123</sup> Brownwyn Mixter, *FDA's Generic Drug Labeling Rule Delayed Again*, BLOOMBERG BNA: HEALTH CARE BLOG (Aug. 4, 2017), <https://www.bna.com/fdas-generic-drug-b73014462786/>.

<sup>124</sup> See Bosman et. al., *Trump's Nominee*.

<sup>125</sup> Sheila Kaplan and Katie Thomas, *F.D.A. Chief Goes Against the Administration Stereotype*, N.Y. TIMES: HEALTH (Feb. 11, 2018), <https://www.nytimes.com/2018/02/11/health/gottlieb-fda-drugs.html>.

has been vocal about making generic drugs more affordable by expediting the approval process and has even publicly condemned brand-name companies that will not offer generic manufacturers samples of their drugs for development.<sup>126</sup> While making generics more affordable clearly benefits the public, implementing such measures without addressing manufacturer preemption will also increase the growing number of uncompensated pharmaceutical drug victims. Nevertheless, Gottlieb has acquired a reputation for being responsive to both consumer and pharmaceutical interests.<sup>127</sup> However, for that same reason, already proposed policies that harm the bottom line of generic manufacturers are unlikely to be followed up by a generic CBE rule that exposes manufacturers to tort liability as well.

The trajectory of the manufacturer preemption defense from a judicial perspective is more hopeful when considering Justice Gorsuch's skeptical views on agency deference may lead him to reject the manufacturer preemption defense. In a previous opinion, Gorsuch asserted that a judicially created doctrine on administrative law affords too much power to administrative agencies to interpret the law, which is the domain of the court:

Chevron and Brand X permit executive bureaucracies to swallow huge amounts of core judicial and legislative power and concentrate federal power in a way that seems more than a little difficult to square with the Constitution of the framers' design. Maybe the time has come to face the behemoth.<sup>128</sup>

Still, it is difficult to infer too much about his potential views on manufacturer preemption from this observation. In *Caplinger v. Medtronic*,<sup>129</sup> Gorsuch declined to defer to the FDA's most recent position on the preemptive effect of the Medical Device Act's provisions, as the FDA had contradicted an earlier pronouncement on the issue.<sup>130</sup> Gorsuch would likely be skeptical of the FDA's committed position in manufacturer preemption doctrine given that

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<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

<sup>128</sup> *Gutierrez-Brizuela v. Lynch*, 834 F.3d 1142, 1149 (10th Cir. 2016) (Gorsuch, J., concurring).

<sup>129</sup> 784 F.3d 1335 (10th Cir. 2015).

<sup>130</sup> *Caplinger*, 784 F.3d at 1346.

the agency has been inconsistent on the subject.<sup>131</sup> In fact, the FDA's offered interpretation for disallowing a generic manufacturer to unilaterally invoke the CBE process is actually contrary to a close reading of its own rule. The Illinois District Court seemed to recognize this back in 2009:

Although Congress intended for ANDA applicants to submit identical labeling to the FDA when seeking ANDA approval--see 21 U.S.C. § 355(j)(2)(A)(v)--the statute is silent as to the manufacturer's obligation after the ANDA is granted. But 21 C.F.R. § 314.97 is not silent--it states that generic drug manufacturers are obligated to comply with the same CBE provisions as brand-listed manufacturers are.<sup>132</sup>

The "sameness requirement" applies to an initial, preapproval ANDA application to assure conformity with a drug already presumed to be safe.<sup>133</sup> The FDA's own rule on post-approval ANDA changes<sup>134</sup> explicitly incorporates the labeling changes section from which the CBE rule derives.<sup>135</sup> The FDA therefore violated its own rules arbitrarily and capriciously by excluding generics from CBE without formal amendment, a consideration overlooked by the Supreme Court in deferring to the FDA's inconsistent views.

However, a proper interpretation of the FDA rule only defeats impossibility preemption, but not necessarily obstacle preemption. *Caplinger* also happens to be the most analogous preemption case considered by Gorsuch involving state tort claims against a medical device manufacturer for off-label advertising.<sup>136</sup> In following precedent while interpreting the express preemption provision in the Medical Device Act, Gorsuch explained that even off-label state tort suits impose additional or different safety requirements that trigger obstacle preemption.<sup>137</sup> Applying this reasoning to manufacturer preemption would suggest that Gorsuch would agree with the

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<sup>131</sup> *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2481-82 (2013) (Breyer, J., dissenting).

<sup>132</sup> *Stacel v. Teva Pharms.*, 620 F. Supp. 2d 899, 907 (N.D. Ill. 2009).

<sup>133</sup> 21 U.S.C. § 355(j)(2)(A)(v).

<sup>134</sup> 21 C.F.R. § 314.97(a): "General requirements. The applicant must comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental ANDAs and other changes to an approved ANDA."

<sup>135</sup> 21 C.F.R. § 314.70(c)(6)(iii).

<sup>136</sup> *Caplinger*, 784 F.3d at 1336-37.

<sup>137</sup> *Id.* at 1345.

holdings in *PLIVA* and *Bartlett* that state tort suits impose an obstacle to federal objectives. However, Gorsuch took care in *Caplinger* to qualify that the holding was compelled by the express preemption provision within the Medical Device Act, and referred to the legislative history to support that conclusion.<sup>138</sup> In visiting manufacturer preemption, Gorsuch would likely give special consideration to the relevant savings clause and legislative history that support the preservation of state tort suits.<sup>139</sup> Therefore, Justice Gorsuch's views seem to offer a possible prospect for overturning generic manufacturer preemption if the Court reaches obstacle preemption .

## VI. CONCLUSION

*Bartlett* and *PLIVA* should be overruled as contrary to the FDCA and the precedent established by the pioneer case, *Levine*. In the alternative, the Supreme Court should reconsider the deference given to the FDA's inconsistent statements on generic CBE and failure to observe its own rules. If the Supreme Court will not take action, the FDA should pass a rule permitting generics to make unilateral changes or stating that consultation should not be construed as creating impossibility preemption. Justice Sotomayor pointed out many of the failings of generic manufacturer preemption that seemingly disregard the FDCA's savings clause and congressional intent to preserve state torts as determined in *Levine*.<sup>140</sup> The result has effectually afforded drug manufacturers a license to sell dangerous products free from liability.

The goal of the Hatch-Waxman Act was to increase consumer confidence in generics, promote public health, and create uniformity.<sup>141</sup> There is no sounder and more sensible way to accomplish this than to subject all manufacturers to the same expectations, rights, and duties of care. If inconsistent label enhancements are a concern, the FDA can consolidate them and issue notices to all manufacturers to compel unanimous adherence. Non-compliant manufacturers will be subjected to a prima facie case of negligence, thereby enhancing safety while making recovery for

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<sup>138</sup> *Id.* at 1346-47.

<sup>139</sup> *See supra* Part III. A.

<sup>140</sup> *See supra* Part III.

<sup>141</sup> *See supra* Part III.A.

plaintiffs easier. As for design defects, there is no meaningful difference between other product defect cases and pharmaceutical defect cases in particular. In fact, the pervasive use of pharmaceutical products should reinforce the need for design scrutiny. Moreover, generic manufacturers should share responsibility for defective design liability. The notion that generic manufacturers are helpless belies the fact that market acquisition is a strategic business decision with inherent risks based on available market data and capable of hedging and insuring against.