

# Into the Preemption Thicket Again—Five Times!

Roger Pilon\*

Two years ago on these pages, I ventured into the preemption thicket in *Wyeth v. Levine*,<sup>1</sup> a decision noteworthy for the Supreme Court's having made a hash of things.<sup>2</sup> Writing in dissent, Justice Samuel Alito remarked that the majority had turned a simple medical malpractice suit "into a 'frontal assault' on the FDA's regulatory regime for drug labeling."<sup>3</sup> Undaunted, or perhaps spurred on, by the frequent criticisms of its long string of "difficult-to-reconcile preemption rulings,"<sup>4</sup> the Court this term decided no fewer than five preemption cases,<sup>5</sup> almost equaling the six it decided in its 2007 term.<sup>6</sup> And once again it has produced a mixed record, getting it right in three of the cases, not in the other two—or so I shall argue.

Although each of the cases decided this term turns on statutory interpretation, preemption itself takes us to basic constitutional principles. To place the discussion in a constitutional context, therefore,

\* Roger Pilon is vice president for legal affairs at the Cato Institute, director of Cato's Center for Constitutional Studies, and publisher of the *Cato Supreme Court Review*.

<sup>1</sup> 555 U.S. 555; 129 S. Ct. 1187 (2009).

<sup>2</sup> Roger Pilon, *Into the Pre-emption Thicket: Wyeth v. Levine*, 2008–2009 *Cato Sup. Ct. Rev.* 85 (2009).

<sup>3</sup> *Wyeth*, 129 S. Ct. at 1218 (Alito, J., dissenting).

<sup>4</sup> See, e.g., Eric G. Lasker, *U.S. Supreme Court Preemption Trilogy: The Sequel*, 26 *Wash. Legal Found. Background* 7, Mar. 25, 2011, available at <http://www.wlf.org/publishing/publication;usdetail.asp?id=2236>.

<sup>5</sup> Six, if you count *Am. Elec. Power Co. v. Connecticut*, 131 S. Ct. 2527 (2011), where the Court simply noted at the end that "[i]n light of our holding that the Clean Air Act displaces federal common law, the availability *vel non* of a state lawsuit depends, *inter alia*, on the preemptive effect of the federal Act," suggesting that the Act preempts any such state law remedy. *Id.* at 2540.

<sup>6</sup> See Daniel E. Troy & Rebecca K. Wood, *Federal Preemption at the Supreme Court, 2007–2008 Cato Sup. Ct. Rev.* 257 (2008).

and for the benefit of readers unfamiliar with this complex area of our law, I will begin with a brief outline of those principles.

### Preemption as Federal Supremacy

To better protect liberty, the Constitution institutes federalism, a system of dual sovereignty between the federal and state governments, sometimes pitting power against power, other times allowing overlapping power.<sup>7</sup> Although the Tenth Amendment makes it clear that the federal government's powers are delegated and hence limited, the balance of power being reserved to the states or the people,<sup>8</sup> the Supremacy Clause of Article VI resolves conflicts between federal and state law by providing that federal law "shall be the supreme Law of the Land, . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." Thus, although the Tenth Amendment establishes a fairly clear presumption in favor of the states, when state law conflicts with—is "to the Contrary" of—federal law, the presumption, by virtue of the Supremacy Clause, is on the other side, with federal law.

In any preemption case, therefore, the crucial question is whether the relevant federal and state laws do in fact conflict—oftentimes not an easy question to answer. In some cases, federal law *expressly* preempts state law, yet even there the statutory terms may be ambiguous or subject to manipulation.<sup>9</sup> Moreover, as in three of the cases

<sup>7</sup> See The Federalist No. 51 (James Madison).

<sup>8</sup> "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." U.S. Const. amend. X.

<sup>9</sup> See, e.g., Michael Greve, Preemption Strike, Nat'l Review Online, Mar. 23, 2009, <http://www.nationalreview.com/articles/227135/preemption-strike/michael-greve>:

Because Congress cannot possibly foresee [all state] stratagems, it cannot "clearly" preempt them. For example, the clearest federal preemption provision of all prohibits states from administering "a law or regulation related to fuel economy standards." California's proposed greenhouse-gas standards do not simply "relate to" fuel economy; they *are* fuel-economy standards. Even so, federal courts have upheld them against preemption challenges because California describes them as emission standards instead. (original emphasis)

For examples of courts rejecting preemption challenges of this type, see, e.g., Cent. Valley Chrysler-Jeep v. Goldstene, 529 F. Supp. 2d 1151 (E.D. Cal. 2007) and Green Mountain Chrysler-Plymouth-Dodge v. Crombie, 508 F. Supp. 2d 295 (D. Vt. 2007).

this term, a federal statute that expressly preempts state law may contain a “saving clause” that preserves at least some of the state law over the matter at issue. Quite often, however, courts face only *implied* preemption, of which there are two kinds. Field preemption concerns limited but exclusive areas of federal authority, even without any express congressional statement to that effect. More common, and more difficult, are cases in which preemption is implicit insofar as a party finds it impossible to comply with both federal and state law, or, more difficult still, insofar as state law stands as an obstacle to the accomplishment and execution of the full “purposes and objectives” of the federal law.

Finally, as Justice Clarence Thomas notes in one of this term’s cases, *PLIVA v. Mensing*,<sup>10</sup> the *non obstante* (“notwithstanding”) provision of the Supremacy Clause “suggests that federal law should be understood to impliedly repeal conflicting state law, . . . that courts should not strain to find ways to reconcile federal law with seemingly conflicting state law,” and “that pre-emption analysis should not involve speculation about ways in which federal agency and third-party actions could potentially reconcile federal duties with conflicting state duties.”<sup>11</sup> In a word, a statute’s “ordinary meaning” should speak for itself. And even if the Court does “get it right” in a preemption case by reading the law correctly, that does not mean, of course, that the decision necessarily secures or advances the liberty the Constitution was written, at bottom, to secure. That will be a function, rather, of whether Congress and federal agencies, on one hand, or states, on the other, have done a better job of regulating toward that end.

Before turning to the cases, a note on the “politics” of preemption is in order, not least because it can be confusing. As I wrote two years ago:

One ordinarily thinks of conservatives and libertarians as supporting limited federal power, especially police power over health and safety matters, a power that belongs mainly with the states. Yet here, for constitutional reasons just discussed, most such people believe that in many if not most cases federal power should trump state power. By contrast,

<sup>10</sup> 131 S. Ct. 2567 (2011).

<sup>11</sup> *Id.* at 2580.

modern liberals are ordinarily thought to favor federal power, especially federal regulatory power over economic affairs under Congress's power to regulate interstate commerce. Yet many of those liberals, in the tort bar and among consumer advocates and state officials, will be found arguing for the supremacy of state law as providing more protection for individual "rights" than federal law may provide.<sup>12</sup>

Those political tendencies can be seen, in part, in the five preemption cases the Court decided this term. Federal preemption was found in three of the five, and in all three the Court's conservatives were in the majority; two were decided 5-4, the other was decided 6-2, with Justice Stephen Breyer joining the conservatives, but writing separately. Of the two decisions that went for the states, one was unanimous; the other was decided 5-3, but here again it was the Court's conservatives who were in the majority. Yet this case, *Chamber of Commerce v. Whiting*,<sup>13</sup> upheld the Legal Arizona Workers Act against a challenge by business interests, so one could read the decision "politically" as saying that, for the conservatives, immigration trumped business, and for the liberals, the other way around. Or one could say, more charitably, that the two sides simply read the law differently.

In any case, my concern here is less with politics than with what the Constitution requires, and so I turn now to the cases, starting with *Whiting*.

### *Chamber of Commerce v. Whiting*

*Whiting* is a fairly straightforward case. Again, the U.S. Chamber of Commerce and various business and civil rights organizations brought a pre-enforcement suit against state officials charged with administering Arizona's Legal Arizona Workers Act, which provides that the licenses of state employers who knowingly or intentionally employ unauthorized aliens may be, and in certain circumstances must be, suspended or revoked. Arizona's law also requires that all Arizona employers use the federal E-Verify system to determine the immigration status of their employees.

<sup>12</sup> Pilon, *supra* note 2, at 87 (internal citations omitted).

<sup>13</sup> 131 S. Ct. 1968 (2011).

In its suit, the Chamber argued that the provisions of Arizona's law "allowing the suspension and revocation of business licenses for employing unauthorized aliens were both expressly and impliedly preempted by federal immigration law, and that the mandatory use of E-Verify was impliedly preempted"<sup>14</sup>—citing the federal Immigration Reform and Control Act, which expressly preempts "any State or local law imposing civil or criminal sanctions (*other than through licensing and similar laws*) upon those who employ . . . unauthorized aliens."<sup>15</sup> Clearly, however, a saving clause is embedded within the express preemption provision. Accordingly, Chief Justice John Roberts, writing for the Court in the 5-3 decision (Justice Elena Kagan took no part in the decision), held that because "the State's licensing provisions fall squarely within the federal statute's savings clause and . . . the Arizona regulation does not otherwise conflict with federal law, . . . the Arizona law is not preempted."<sup>16</sup> He thus affirmed both the district court and the Ninth Circuit panel that had previously ruled in the case.

Given IRCA's plain text, a brief summary of Roberts's opinion will suffice here. He makes three main points. First, because "Arizona's licensing law falls well within the confines of the authority Congress chose to leave to the States,"<sup>17</sup> it is not expressly preempted—a conclusion he buttresses by showing, in excruciating detail, how the state's definition of "license" largely "parrots" the definition that Congress codified in the Administrative Procedure Act.<sup>18</sup> Second, he responds to the Chamber's contention that the state's law is impliedly preempted because it conflicts with federal law by showing, again in painstaking detail, that there is no conflict and that "Arizona's procedures simply implement the sanctions that Congress expressly allowed Arizona to pursue through licensing laws."<sup>19</sup> Here, he notes in particular that "Arizona went the extra mile in ensuring that its law closely tracks IRCA's provisions in all material

<sup>14</sup> *Id.* at 1977.

<sup>15</sup> *Id.* at 1973 (quoting 8 U.S.C. § 1324a(h)(2)) (emphasis added).

<sup>16</sup> *Id.*

<sup>17</sup> *Id.* at 1981.

<sup>18</sup> *Id.* at 1978.

<sup>19</sup> *Id.* at 1981.

respects.”<sup>20</sup> Finally, he shows that Arizona’s E-Verify mandate neither conflicts with the federal scheme nor obstructs federal objectives. “In fact,” he points out, “the Federal Government has consistently expanded and encouraged the use of E-Verify” and, indeed, recently referenced Arizona’s mandate as a permissible use of the system.<sup>21</sup> Thus, the mandate cannot be shown to be impliedly preempted.

In their dissents, Justice Breyer, writing for himself and for Justice Ruth Bader Ginsburg, and Justice Sonia Sotomayer, writing for herself, rely heavily on legislative history. But as Roberts notes, “It is not surprising that the two dissents have sharply different views on how to read the statute. That is the sort of thing that can happen when statutory analysis is so untethered from the text.”<sup>22</sup> In sum, quite apart from the merits or demerits of our current immigration law, policy, and practices, given the text and the facts, this was not a difficult case, as three courts found.

### *AT&T v. Concepcion*

*Concepcion*<sup>23</sup> is rather more complicated. Here too a saving clause was at issue, but here—where AT&T argued that the Federal Arbitration Act preempted state law, not expressly but by implication, due to a conflict between the two—the clause did not save state law. In brief, the Court held, 5-4, that the FAA preempted a California state court ruling that standard-form (“adhesion”) consumer arbitration contracts that prohibit class arbitration are unconscionable and hence unenforceable. But a core purpose of the FAA, the Supreme Court said, was to allow and encourage companies to use arbitration as a fast and efficient way to resolve consumer disputes, which class arbitration would only frustrate. Thus, California’s law was in direct conflict with the federal law.

The case arose when the Concepcions charged AT&T with false advertising and fraud after they were charged a \$30.22 sales tax on the retail value of a “free” phone under a standard-form service contract with AT&T. The contract provided for arbitration of all

<sup>20</sup> *Id.*

<sup>21</sup> *Id.* at 1986.

<sup>22</sup> *Id.* at 1980 n.6.

<sup>23</sup> *AT&T Mobility LLC v. Concepcion*, 131 S. Ct. 1740 (2011).

disputes, but required plaintiffs to arbitrate as individuals, not as members of a class. In defense, AT&T invoked the FAA, which makes agreements to arbitrate “valid, irrevocable, and enforceable, *save upon such grounds as exist at law or in equity for the revocation of any contract.*”<sup>24</sup> To try to revoke the contract as provided for in that saving clause, the Concepcions cited the California Supreme Court’s *Discover Bank* decision, which held that class waivers in consumer arbitration agreements are unconscionable if the agreement is in an adhesion contract, the damages are small, and the party with inferior bargaining power alleges a deliberate scheme of fraud.<sup>25</sup> The courts below found for the Concepcions: the FAA’s saving clause was satisfied by the *Discover Bank* rule, they held; thus, the FAA did not preempt the state law. The Supreme Court reversed, finding that the state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”<sup>26</sup> Thus, the FAA does indeed preempt the state law.

Writing for the Court, Justice Antonin Scalia begins by noting that the FAA was enacted in 1925 in response to widespread judicial hostility to arbitration agreements, that it reflects both a federal policy favoring arbitration and the “fundamental principle that arbitration is a matter of contract,”<sup>27</sup> and that “courts must place arbitration agreements on an equal footing with other contracts and enforce them according to their terms.”<sup>28</sup> Turning then to the central question, the force and effect of the FAA’s saving clause, he writes that it “permits agreements to arbitrate to be invalidated by ‘generally applicable contract defenses, such as fraud, duress, or unconscionability,’ but not by defenses that apply only to arbitration or that derive their meaning from the fact that an agreement to arbitrate is at issue.”<sup>29</sup> Thus, he concludes, the question is whether the FAA “preempts California’s rule classifying most collective-arbitration waivers in consumer contracts as unconscionable,” or, one could

<sup>24</sup> *Id.* at 1744 (citing 9 U.S.C. § 2) (emphasis added).

<sup>25</sup> *Discover Bank v. Superior Court*, 113 P.3d 1100 (Cal. 2005).

<sup>26</sup> *Concepcion*, 131 S. Ct. at 1753 (citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

<sup>27</sup> *Id.* at 1745 (citing *Rent-A-Center, West, Inc. v. Jackson*, 130 S. Ct. 2772, 2776 (2010)).

<sup>28</sup> *Id.* at 1745 (citations omitted).

<sup>29</sup> *Id.* at 1748 (citing *Doctor’s Associates, Inc. v. Casarotto*, 517 U.S. 681, 687 (1996)) (emphasis added).

add, whether the *Discover Bank* rule satisfies the brake imposed on preemption by the FAA's saving clause.

The issue here, Scalia argues, goes back to the long-standing hostility of courts to arbitration agreements, especially in California,<sup>30</sup> and to the tendency of courts to expand the body of "generally applicable contract defenses" to include ever narrower grounds for contract revocation. Thus, he writes that although the FAA's saving clause

preserves generally applicable contract defenses, nothing in it suggests an intent to preserve state-law rules that stand as an obstacle to the accomplishment of the FAA's objectives. As we have said, a federal statute's saving clause "cannot in reason be construed as [allowing] a common law right, the continued existence of which would be absolutely inconsistent with the provisions of the act. In other words, the act cannot be held to destroy itself."<sup>31</sup>

Yet that is what allowing the *Discover Bank* rule as a ground for revoking the arbitration agreement at issue here would do, Scalia continues. Requiring class-wide arbitration to be available if a party requests it, notwithstanding the terms of the arbitral agreement, not only fails to enforce those terms but "interferes with fundamental attributes of arbitration and thus creates a scheme inconsistent with the FAA," the "principal purpose" of which is "to 'ensure that private arbitration agreements are enforced according to their terms.'"<sup>32</sup>

Scalia then goes on to show, first, how allowing parties discretion in designing arbitral agreements allows for efficient dispute resolution tailored to their circumstances and, second, how allowing parties to opt out of their agreements regarding class-wide arbitration would utterly frustrate the purposes of arbitration. Indeed, the Court had previously held that the "changes brought about by the shift

<sup>30</sup> *Id.* at 1747 ("it is worth noting that California's courts have been more likely to hold contracts to arbitrate unconscionable than other contracts") (citing Stephen A. Broome, *An Unconscionable Applicable of the Unconscionability Doctrine: How the California Courts are Circumventing the Federal Arbitration Act*, 3 *Hastings Bus. L. J.* 39, 54, 66 (2006)); Susan Randall, *Judicial Attitudes toward Arbitration and the Resurgence of Unconscionability*, 52 *Buffalo L. Rev.* 185, 186–87 (2004).

<sup>31</sup> *Concepcion*, 131 S. Ct. at 1748 (citations omitted).

<sup>32</sup> *Id.*

from bilateral arbitration to class-action arbitration” are “fundamental.”<sup>33</sup> Class-action arbitration, for example, sacrifices informality—in fact, requires *procedural* formality—“and makes the process slower, more costly, and more likely to generate procedural morass than final judgment,” as the evidence clearly shows.<sup>34</sup> Moreover, the formality that class arbitration requires in turn imposes duties on arbitrators that are inconsistent with quick and efficient arbitration. And with limited judicial review, class arbitration greatly increases the risks for defendants, especially when the stakes are high from aggregation, pressuring them to settle questionable claims. Those are just a few of the ways class arbitration shifts the balance and conflicts with the FAA’s purposes.

In his dissent for himself and Justices Ginsburg, Sotomayor, and Kagan, ending in a stern plea for honoring federalist principles, Justice Breyer never really addresses the importance of honoring contracts. His focus instead is on the power of the California court to say what contracts it will and will not enforce. Thus, he writes that “California is free to define unconscionability as it sees fit, and its common law is of no federal concern so long as the State does not adopt a special rule that disfavors arbitration.”<sup>35</sup> That, of course, is just what the California court did, as Scalia details—adding that “[w]e find it hard to believe that defendants would bet the company with no effective means of review, and even harder to believe that Congress would have intended to allow state courts to force such a decision.”<sup>36</sup>

But Breyer continues:

Because California applies the same legal principles to address the unconscionability of class arbitration waivers as it does to address the unconscionability of any other contractual provision, the merits of class proceedings should not factor into our decision. If California had applied its law of duress to void an arbitration agreement, would it matter if the procedures in the coerced agreement were efficient?<sup>37</sup>

<sup>33</sup> *Stolt-Nielsen S.A. v. AnimalFeeds Int’l Corp.*, 130 S. Ct. 1758, 1776 (2010).

<sup>34</sup> *Concepcion*, 131 S. Ct. at 1751.

<sup>35</sup> *Id.* at 1760 (Breyer, J., dissenting).

<sup>36</sup> *Id.* at 1752 (majority opinion).

<sup>37</sup> *Id.* at 1760 (Breyer, J., dissenting).

Here, of course, the merits matter, because the question is whether the class proceedings conflict with the purposes of the federal law. Indeed, here we have a “special rule that disfavors arbitration,” the very subject of that law. Unlike the law of duress, that special rule does not apply to “any” contract, just to those that prohibit class-wide arbitration. Moreover, with duress there is no contract in the first place. Here there is a contract, enforceable in other states if not in California—the kind of contract the California court has singled out and made unenforceable, for *policy* reasons. As Scalia points out, of the two main purposes of the federal statute—enforcement of private agreements and encouragement of efficient and speedy dispute resolution—both are frustrated by the California court’s rule and the dissent’s view.

That brings us to one of the more interesting aspects of *Concepcion*, which is found in Justice Thomas’s concurrence. Describing himself as reluctant to join the Court’s opinion because of his (well-known) views on purposes-and-objectives preemption—the Court’s approach here—Thomas writes separately to say that he would read the FAA’s text as requiring

that an agreement to arbitrate be enforced unless a party successfully challenges the *formation* of the arbitration agreement, such as by proving fraud or duress. Under this reading, I would reverse the Court of Appeals because a district court cannot follow both the FAA and the *Discover Bank* rule, which does not relate to defects in the *making* of an agreement.<sup>38</sup>

Thus, rather than resting preemption on the Court’s discernment of the FAA’s purposes, a methodology he has long criticized as fraught with subjectivity, Thomas would rest it on a kind of “impossibility” principle—not the impossibility of parties to comply with both federal and state law, which often justifies conflict preemption, but the impossibility of a *court’s* following both laws.

Thomas supports his narrowing of the reach of the FAA’s saving clause with a close analysis of the FAA’s text. He first notes that the statute requires courts to enforce arbitration agreements as written, and that an arbitration provision “shall be valid, irrevocable, and enforceable, save upon such grounds as exist at law or in equity for

<sup>38</sup> *Id.* at 1753 (Thomas, J., concurring) (emphasis added).

the revocation of any contract.” But, second, he points out that only “revocation” is used in the saving clause: “the conspicuous omission of ‘invalidation’ and ‘nonenforcement’ suggest[s] that the exception does not include all defenses applicable to any contract but rather some subset of those defenses.”<sup>39</sup>

Conceding that the ordinary meanings of the terms at issue overlap, and that the Court has referred to them interchangeably, Thomas adds that this alone cannot justify ignoring Congress’s clear decision to repeat only one of the three terms. Moreover, he continues, when read in light of the broader statutory scheme, which says that when a party seeks to enforce an arbitration agreement, the court, “upon being satisfied that the *making* of the agreement for arbitration or the failure to comply therewith is not in issue,” must order arbitration “in accordance with the terms of the agreement.”<sup>40</sup> Thomas concludes, therefore, that “[t]his would require enforcement of an agreement to arbitrate unless a party successfully asserts a defense concerning the formation of the agreement to arbitrate, such as fraud, duress, or mutual mistake. Contract defenses unrelated to the making of the agreement—such as public policy—could not be the basis for declining to enforce an arbitration clause.”<sup>41</sup> Thus, as he reads the federal statute, California’s *Discovery Bank* rule “is not a ‘groun[d] . . . for the revocation of any contract.’”<sup>42</sup> It is, accordingly, preempted.

In sum, it takes no leap to discern in Thomas’s concurrence a certain unease with modern doctrines of substantive unconscionability, an uneasiness that one senses, though less surely, in the Court’s opinion as well. *Concepcion* may have been argued and decided as a preemption case, but at bottom it’s a contracts case.

\* \* \*

We turn now to the three other preemption cases the Court decided this term, all concerning torts, and all raising the question,

<sup>39</sup> *Id.* at 1754.

<sup>40</sup> *Id.* (quoting 9 U.S.C. § 4) (emphasis added).

<sup>41</sup> *Id.* (citations omitted).

<sup>42</sup> *Id.* at 1756 (citations omitted).

in particular, of how best to handle risk. Two involve pharmaceuticals, the other automobile safety—staples in the preemption corpus. The policy questions are thus never far below the surface: whether the risks at issue are better handled through state police power—*ex ante* through regulation or *ex post* through adjudication—or through federal legislation and executive branch regulation and adjudication. Here again, however, our main concern will not be with such questions but rather with the constitutional question of whether federal or state power should prevail.

### *PLIVA v. Mensing*

With *PLIVA*<sup>43</sup> we have a case that looks simple on the surface, but in the end it is not, and the dissent has the better of it. The question was whether individuals injured by generic drugs they claimed had inadequate warning labels could sue the manufacturers for damages under state law, or whether federal Food and Drug Administration regulations for drug labeling preempted such suits. The Court ruled 5-4 that the manufacturers could not be sued because it was impossible for them to comply with both federal and state law. Thus, the majority saw *PLIVA* as a straightforward case of conflict preemption.

This case was brought by plaintiffs who suffered from stomach ailments for which they had taken the generic drug metoclopramide—sold under the brand name Reglan—for an extended period of time, after which they developed tardive dyskinesia, a serious neurological disorder. Because evidence had accumulated that long-term use can result in the condition, warning labels have been strengthened and clarified several times over the years. Nevertheless, the plaintiffs charged that the warnings were inadequate. The manufacturers responded that federal statutes and FDA regulations required them to use the same safety and efficacy labeling as brand-name manufacturers. Thus, it was impossible for them to comply with both federal law and state tort law that required, by implication, different or stronger labeling. The Fifth and Eighth Circuits rejected the manufacturer's claims. The Supreme Court reversed, Justice Thomas writing for the majority.

<sup>43</sup> *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

Thomas begins his opinion by comparing federal and state law on the subject. State tort law, he says, requires a drug manufacturer “that is or should be aware of its product’s danger to label that product in a way that renders it reasonably safe.”<sup>44</sup> By contrast, federal drug labeling law is far more complex. Manufacturers of new drugs must first conduct lengthy and expensive testing to satisfy the FDA that the drug is safe and effective and that the labeling is accurate and adequate, all of which must be approved by the FDA before the drug can be marketed. To better enable manufacturers to develop inexpensive *generic* drugs, however, which usually appear on the market several years after brand-name drugs are approved, Congress in 1984 passed the Hatch-Waxman Amendments, which allow generic drugs to gain FDA approval simply by showing equivalence to the brand-name drug and, important here, by having the same labeling, which the FDA had already approved for the brand-name drug.<sup>45</sup> Thus, “[a] brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label,” Thomas notes. “A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name’s.”<sup>46</sup>

None of which the parties dispute, Thomas continues, “What is in dispute is whether, and to what extent, generic manufacturers

<sup>44</sup> *Id.* at 2573. In truth, a label cannot, of course, render a drug safe; it can only render the risk associated with its use *known*, after which the user can decide whether to assume that risk. Noticing that, however, helps explain why we have relied mainly on *ex ante* federal regulation of drug labeling. An *ex post* state tort decision for a plaintiff can imply only that the labeling was “inadequate,” not what it should have been to be “adequate.” And more often than not the decision is circular: if the injury occurred, then *ipso facto* the warning was inadequate. (In *Wyeth*, the label had no fewer than six warnings **in bold**, prompting Justice Alito to ask whether a seventh warning would have made any difference.) After each adverse decision, the manufacturer can strengthen its warning, of course, and raise the price of the drug to cover its losses—or, ultimately, remove the drug from the market. But since the jury sees only the injured plaintiff, not those costs, including the costs of the drug’s ultimate unavailability, we rarely if ever get a rational assessment of risk and adequate labeling from the tort system. The system serves instead simply to compensate plaintiffs for their losses, regardless of whether the labeling may in fact have been adequate to warn a rational user or whether plaintiffs or their health care providers may have ignored the warnings, as happened in *Wyeth*. I have discussed this issue more fully in Pilon, *supra* note 2, at 101–07.

<sup>45</sup> 21 U.S.C. § 355 (2006).

<sup>46</sup> PLIVA, 131 S. Ct. at 2574.

may change their labels *after* initial FDA approval.” The plaintiffs claimed that several avenues were open to manufacturers to change their labels. The FDA disagreed, saying the labeling must be the same “because the [brand-name] drug product is the basis for the [generic drug] approval.”<sup>47</sup> Thus were the issues joined.

Thomas turns then to the plaintiffs’ claim that manufacturers have “several avenues” to make changes. The FDA’s “changes-being-effected” (CBE) process is one: it allows brand-name manufacturers to change their labels if evidence warrants it and then to seek FDA approval afterward; but that process, the FDA said, allows changes to generic drug labels only when the brand-name label is changed. Were the generic manufacturer to change its label unilaterally, it would violate the statute and regulations. Again, plaintiffs claimed that manufacturers could have sent “Dear Doctor” letters indicating additional warnings. But the FDA counts such letters as “labeling,” which if sent would inaccurately imply a therapeutic difference between brand-name and generic drugs and thus be misleading. Finally, the FDA itself points to a “duty” *all* manufacturers have to propose stronger labels if evidence warrants it, after which the FDA, if it agreed, would work with brand-name manufacturers to change the labels of both brand-name and generic drugs. But there is disagreement over whether any such “duty” exists, Thomas says: there is no evidence of a generic drug manufacturer ever acting pursuant to it; and even if it did exist, performing it, he concludes, would not have satisfied the state-law duty to provide adequate warning. “State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label.”<sup>48</sup>

With that, Thomas turns to the preemption question. Here, he notes, we have no express preemption—nor any saving clause preserving state law.<sup>49</sup> But that does not mean that conflict preemption principles do not apply. And here they apply straightforwardly, he believes: “state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action.”<sup>50</sup> This is a case of simple impossibility preemption.

<sup>47</sup> *Id.* at 2575 (quoting Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17961 (Apr. 28, 1992)).

<sup>48</sup> *Id.* at 2578.

<sup>49</sup> *Id.* at 2577 n.5.

<sup>50</sup> *Id.* at 2581.

Writing a lengthy dissent for herself and Justices Ginsburg, Breyer, and Kagan, Justice Sotomayor challenges the manufacturers' and the majority's impossibility thesis, arguing that it is not impossible for manufacturers to satisfy both state and federal law. All they need do is persuade the FDA to change the label, which is entirely possible.

She begins by observing, first, that the purpose of Congress is the touchstone of every preemption case and, second, that particularly when Congress legislates in such traditional areas of state authority as the police power, aimed at protecting the rights of a state's citizens, the presumption is against preemption, absent an express congressional indication to the contrary. And here, when Congress amended FDA's generic statute in 1962, it expressly preserved a role for state law that did not conflict. Under state law, manufacturers have a duty to provide adequate drug labeling. And under federal law, especially given FDA's limited resources and the superior knowledge manufacturers have about their drugs, both brand-name and generic manufacturers are obliged to monitor the safety of their products.

Thus, Sotomayor continues, she does not need to decide whether the uncertain "duty" Thomas considered

in fact obliges generic manufacturers to approach the FDA to propose a label change. The majority assumes that it does. And even if generic manufacturers do not have a duty to propose label changes, two points remain undisputed. First, they do have a duty under federal law to monitor the safety of their products. And, second, they *may* approach the FDA to propose a label change when they believe a change is required.<sup>51</sup>

Turning to the manufacturer's basic claim, Sotomayor notes that the sole ground on which the manufacturers rest their argument, impossibility, is an affirmative defense, and a demanding one: "the mere possibility of impossibility is not enough."<sup>52</sup> She continues:

The Manufacturers had available to them a mechanism for attempting to comply with their state law duty to warn. . . . [H]ad they approached the FDA, the FDA may well have

<sup>51</sup> *Id.* at 2586 (Sotomayor, J., dissenting) (emphasis added).

<sup>52</sup> *Id.* at 2587.

agreed that a label change was necessary. Accordingly, . . . I would require the Manufacturers to show that the FDA would not have approved a proposed label change. They have not made such a showing: They do “not argue that [they] attempted to give the kind of warning required by [state law] but [were] prohibited from doing so by the FDA.”<sup>53</sup>

Nor would it be impossible or even difficult for a generic manufacturer to show impossibility. Sotomayor homes in on the heart of the matter:

If a generic-manufacturer defendant proposed a label change to the FDA but the FDA rejected the proposal, it would be impossible for that defendant to comply with a state-law duty to warn. Likewise, impossibility would be established if the FDA had not yet responded to a generic manufacturer’s request for a label change at the time a plaintiff’s injuries arose. A generic manufacturer might also show that the FDA had itself considered whether to request enhanced warnings in light of the evidence on which a plaintiff’s claim rests but had decided to leave the warnings as is. (The Manufacturers make just such an argument in these cases.) *But these are questions of fact to be established through discovery.* Because the burden of proving impossibility falls on the defendant, I would hold that federal law does not render it impossible for generic manufacturers to comply with a state-law duty to warn as a categorical matter.<sup>54</sup>

Thomas has two main responses, by implication. (He offers very little in the way of a direct response to the dissent’s arguments.) First, he claims that the proper test for impossibility is whether the defendant could have *independently* satisfied both federal and state law; generic manufacturers could not, he argues, because not only is the CBE process not available to them, but they require the cooperation of both the FDA and the brand-name manufacturer before they can make a label change. Sotomayor answers that there is no precedent for such a rule and, moreover, only two years earlier, in *Wyeth*, the Court had held that *brand-name* manufacturers could be

<sup>53</sup> *Id.* at 2588 (quoting *Wyeth*, 129 S. Ct. at 1198).

<sup>54</sup> *Id.* at 2589 (emphasis added).

held liable under state law for not changing their labels even though they too require FDA approval after they've made such a change. Thus, they too, at least other than temporarily, cannot "independently" satisfy their state-law duty—and Sotomayor would hold them to the same impossibility test as generic manufacturers.

Second, following on his first point, Thomas argues that "[t]he only action the Manufacturers could independently take—asking for the FDA's help—is not a matter of state-law concern."<sup>55</sup> Sotomayor never really addresses that point, likely because to make her argument she did not need to assume that that action was a "duty" under federal law. In any event, assuming, as the FDA claims, that there is a "duty" all manufacturers have to propose stronger labels if evidence warrants it, Thomas is right: that is not a matter of state-law concern. *But that is irrelevant to the issue before the Court*, which is whether the *state-law* duty to provide adequate labeling is preempted by federal law. (This is truly a case of overlapping jurisdictions.) As the dissent makes clear, nothing in federal law *prevents* generic manufacturers from taking steps that *might* enable them to satisfy their state-law duties. And if in fact there is this federal-law "duty"—albeit not a matter of *state-law* concern—all the more reason there is to take such steps when the evidence warrants it. None of which is to say, of course, that the evidence warranted it here: that is yet another matter to be determined at trial. The point here, however, is that the manufacturer's duty, under state law, is to its customers. Insofar as federal law does not frustrate but rather facilitates that duty with one of its own, however uncertain, all the better. And that, I submit, is what the Court should have found here.

As *PLIVA* was coming up, the question was how the Court would distinguish it from *Wyeth*, where the Court found for the plaintiff. That was a brand-name case, finding no preemption because *Wyeth's* state-law duty to strengthen its labeling was held not to conflict with the "purposes and objectives" of federal law. Again, the decision was in error, I believe, because the case involved simple medical malpractice, not a failure to warn: unlike what the evidence suggests here, in *Wyeth* the physician's assistant ignored six warnings in bold and administered a double dose of the medication in the one place most likely to produce the injury, all the while ignoring

<sup>55</sup> *Id.* at 2581 (majority opinion).

the complaints of pain from the patient plaintiff, all of which was clearly addressed by the several warnings. As the dissent said, no additional warnings would likely have made a bit of difference.

More to the point, however, *Wyeth's* holding clearly conflicted with the purposes and objectives of federal drug law, which are to ensure the availability of both safe *and effective* drugs. The plaintiffs claim in *Wyeth*, which the Court implicitly sanctioned, was that the more risky *but more effective* IV-push method of administering the drug at issue “was not reasonably safe” and therefore, impliedly, should be banned. But the FDA had already determined, through its testing and labeling requirements, the proper balance between safety and efficacy. After *Wyeth*, however, that determination was turned over to state juries, who of course have no expertise in such matters, but do have an injured plaintiff before them. After *PLIVA*, the error goes the other way, with manufacturers being shielded from their failure to take the steps that may be necessary to provide us with an adequate measure of safety. None of which is to say, again, that a jury would have done any better here than it did in *Wyeth*. But if Congress and the FDA want to shield such determinations from juries, they have the power to do so. Here, they have not done so. Thus, the question should have remained one of state law.

### ***Bruesewitz v. Wyeth***

*Bruesewitz*<sup>56</sup> is another complex drug decision. Here, however, the Court decided for the defendant, ruling 6-2, with Justice Kagan again recusing herself, that plaintiffs injured by vaccines they claim were improperly designed cannot sue vaccine manufacturers but must seek remedies instead from the no-fault compensation system Congress created in 1986 to address the problem that manufacturers, fearful of such suits, would simply not produce vaccines. Thus, the Court held that the federal law creating that system expressly preempted state tort liability “for a vaccine’s unavoidable, adverse side effects.”<sup>57</sup>

Although compensation for vaccine-related injuries had been left for years to state tort law, by the mid-1980s suits for such injuries had increased to such an extent that many manufacturers, including

<sup>56</sup> *Bruesewitz v. Wyeth*, 131 S. Ct. 1068 (2011).

<sup>57</sup> *Id.* at 1074.

those producing vaccines against diphtheria, tetanus, and pertussis (DTP), had left the market, while others were threatening to leave.<sup>58</sup> Into the breach stepped Congress with the National Vaccine Injury Compensation Act of 1986. The Act was designed to handle the risks inherent in vaccinations through a federal no-fault system rather than through the vagaries of state tort law. No liability without fault is a principle that works well in a great range of tort claims. But here the inability to make vaccines entirely safe, plus uncertainty surrounding causation, coupled with the penchant of state juries to discount those issues in favor of sympathetic plaintiffs, had rendered most manufacturers unwilling to produce essential vaccines at reasonable costs.

The Act created a mandatory federal vaccine court—a less adversarial no-fault forum designed to enable alleged victims to be compensated quickly from federal funds drawn from surcharges on vaccines. With “table injuries,” found to result from particular vaccines, the system seems to have worked well.<sup>59</sup> If victims suffer a non-table injury, however, they can still prevail, but they must prove that the vaccine caused the injury. Nonetheless, critics claim that the court has not worked as intended, with unconscionable delays, among much else, and victims are wrongly being denied relief.<sup>60</sup>

One such case was that of Hannah Bruesewitz, who was administered her third dose of DTP vaccine on schedule, just short of her six-month birthday. She then suffered a series of seizures, later diagnosed as residual seizure disorder and developmental delay. Now a teenager, she’ll likely require medical care related to her condition for the rest of her life.

<sup>58</sup> “Whereas between 1978 and 1981 only nine product-liability suits were filed against DTP manufacturers, by the mid-1980s the suits numbered more than 200 each year. This destabilized the DTP vaccine market, causing two of the three domestic manufacturers to withdraw; and the remaining manufacturer, Lederle Laboratories, estimated that its potential tort liability exceeded its annual sales by a factor of 200.” *Id.* at 1072–73.

<sup>59</sup> This refers to the Vaccine Injury Table, which delineates common injuries resulting from vaccinations. The table can be found at <http://www.hrsa.gov/vaccinecompensation/table.htm>.

<sup>60</sup> See Brief of Vaccine Injured Petitioners Bar Association, the George Washington Univ. Law School Vaccine Injury Clinic, et al. as Amici Curiae Supporting Petitioners at 9-18, *Bruesewitz v. Wyeth*, 131 S. Ct. 1068 (2011) (No. 09-152).

Hannah's parents filed a petition with the vaccine court when she was three, one month after new regulations deleted her disorder as a DTP table injury. Nearly eight years later, the court ruled that they had not proved causation, dismissing the claim with prejudice. The parents then filed a federal suit against Wyeth, which manufactured the vaccine, claiming, among other things, that Wyeth was strictly liable for a design defect. Again they lost in both the district and appellate courts.<sup>61</sup>

Hard cases make bad law, but bad law also makes hard cases. And the law in this case has taxed the interpretive skills of more than one court. The narrow question before the Supreme Court was whether a unanimous Third Circuit panel had correctly applied the Act's preemption language—made more pressing because only five months before the panel ruled, a unanimous Georgia Supreme Court, facing a similar case, read the same language as *not* preempting design defect suits.<sup>62</sup> In relevant part, that language reads:

No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.<sup>63</sup>

Although the Act allows victims to sue over manufacturing defects, conduct that would subject a manufacturer to punitive damages, and a manufacturer's failure to provide a proper warning or exercise due care, nowhere does it define "unavoidable"—and there is the nub of the matter. The fact that Congress included that term implies, the Georgia court argued, that at least some vaccine-related injuries could be avoided, and so in those cases federal law did not preempt state civil suits to determine whether the injury was in fact "avoidable." Indeed, preempting all design-defect suits would render the text superfluous, the Georgia court added, contrary to a

<sup>61</sup> *Bruesewitz v. Wyeth*, 508 F. Supp. 2d 430 (E.D. Pa. 2007), *aff'd* 561 F.3d 233 (3d Cir. 2009).

<sup>62</sup> *Am. Home Prod. Corp. v. Ferrari*, 668 S.E.2d 236 (2008).

<sup>63</sup> 42 U.S.C. § 300aa-22(b)(1) (2006).

cardinal principle of statutory construction that text is there for a reason.<sup>64</sup>

But the Third Circuit countered that if that reading were correct, statutory construction rules aside, the Act would not bar *any* design-defect claims, because *every* such claim would be subject to case-by-case determination by a court—precisely what Congress sought to avoid.<sup>65</sup>

Sound as that rejoinder may have been, based on the Act's purpose as seen in its structure and, mostly, its legislative history, it hardly helped that that history included two inconsistent committee reports following the Act's passage.<sup>66</sup> Thus, the report of the House Energy and Commerce Committee, which had jurisdiction over the matter, focused on the core problem of state-imposed strict liability without fault, the implications for vaccine manufacturing, and the need for a no-fault victim compensation system—which would be undermined, the Third Circuit argued, if state courts were permitted to determine case-by-case whether a manufacturer might have created a safer vaccine.<sup>67</sup>

But a year later, when Congress finally provided funding for the program, the House Budget Committee's report claimed that Congress never undertook "to decide as a matter of law whether vaccines were unavoidably unsafe."<sup>68</sup> It left that decision instead to the courts, the report said, prompting this from the Third Circuit: "The views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one."<sup>69</sup>

In his concurrence, Justice Breyer found the textual question a close call, although the majority, he thought, had the better argument. Thus, like the dissent, he looks to legislative history, statutory purpose, agency views, and medical opinion to conclude, unlike the dissent, that each reinforces the Court's conclusion. His principal concern, however, seems to be that allowing design-defect suits would upset the Act's central purposes: to provide the safest possible

<sup>64</sup> Am. Home Prod., 668 S.E.2d at 238, 240, 242.

<sup>65</sup> Bruesewitz, 561 F.3d at 246.

<sup>66</sup> *Id.* at 249.

<sup>67</sup> *Id.*

<sup>68</sup> Bruesewitz, 131 S. Ct. at 1092 (Sotomayor, J., dissenting) (citation omitted).

<sup>69</sup> *Id.* at 250 (quoting *United States v. Price*, 361 U.S. 304 (1960)).

vaccines plus a compensation system for those who may be injured.<sup>70</sup> And in that connection, he is particularly concerned that to allow juries to decide complex design-defect and causal questions “is to substitute less expert for more expert judgment,”<sup>71</sup> thereby threatening to undermine the entire system.

Justice Scalia, writing for the Court, devotes the better part of his opinion to answering the lengthy dissent of Justice Sotomayor, joined by Justice Ginsburg, so we can weigh the two opinions together. He begins by analyzing the crucial text, which I repeat:

No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.<sup>72</sup>

Again, “unavoidable” is the problematic term. The “even though” clause clarifies it, Scalia says: it tells us what preventative measures a manufacturer *must* have taken—proper manufacture, proper warning—for the side effects to be considered “unavoidable” under the statute. Given that those measures were taken, “any remaining side effects, including those resulting from design defects, are deemed to have been unavoidable.”<sup>73</sup> Those side effects are “unavoidable,” one might add, because there will always be *some* risk of injury, which is avoidable only by avoiding the vaccine—thereby, as a practical matter, making *other* risks unavoidable.

Continuing with his textual analysis, Scalia points out that “[i]f a manufacturer could be held liable for failure to use a different design, the word ‘unavoidable’ would do no work.”<sup>74</sup> The work it does, he seems to say next (the argument is abstruse), is to focus on *this* design, not some other *possible* design that *might* have been used: “The language of the provision thus suggests that the *design* of the vaccine is a given, not subject to question in a tort action.”<sup>75</sup> And

<sup>70</sup> Bruesewitz, 131 S. Ct. at 1084 (Breyer, J., concurring).

<sup>71</sup> *Id.* at 1085.

<sup>72</sup> 42 U.S.C. § 300aa-22(b)(1) (2006).

<sup>73</sup> Bruesewitz, 131 S. Ct. at 1075 (majority opinion).

<sup>74</sup> *Id.*

<sup>75</sup> *Id.* (emphasis in original).

he elaborates in a footnote: “The dissent advocates for another possibility: ‘[A] side effect is ‘unavoidable’ . . . where there is no feasible alternative design that would eliminate the side effect of the vaccine without compromising its cost and utility.’”<sup>76</sup> But the dissent makes no effort to ground that reading in the text, Scalia notes, nor are “cost” and “utility” judicially administrable factors. Notice too that if a manufacturer must demonstrate unavoidability by showing that there was no other “feasible” vaccine, proving that negative is impossible. Unlike in *PLIVA*, where proving impossibility *within a finite regulatory system* was possible, here the domain is open-ended. One can always *imagine* a safer, more effective vaccine.

Scalia’s textual analysis turns next to the well-known triumvirate of grounds for products liability: design defects, manufacturing defects, and inadequate directions and warnings. “If all three were intended to be preserved,” he writes, “it would be strange to mention specifically only two, and leave the third to implication.”<sup>77</sup> He then launches into a textual and structural exegesis that in places is all but inscrutable—and will not be examined here—observing in the process, in response to the dissent, that “the rule against giving a portion of text an interpretation which renders it superfluous does not prescribe that a passage which could have been more terse does not mean what it says.”<sup>78</sup> To be sure, Congress here could have made its intent more clear, but working with what it gave him, he has made far more sense out of its language than has the dissent.

Scalia concludes by making short work of the dissent’s attempt to muddy the waters of congressional intent. Assuming that legislative history is even needed here, not only does the dissent quote incompletely from a report by a committee of the Congress that enacted the vaccine statute, but it relies on a committee report from a *later* Congress that it believes “authoritative[ly]” vindicates its interpretation. Echoing the Third Circuit, Scalia notes that “[t]his is a courageous adverb since we have previously held that the only authoritative source of statutory meaning is the text that has passed through

<sup>76</sup> *Id.* at 1076 n.35.

<sup>77</sup> *Id.*

<sup>78</sup> *Id.* at 1078.

the Article I process,<sup>79</sup> adding that post-enactment legislative history is “a contradiction in terms.”<sup>80</sup>

Based, then, on text, structure, and legislative history, the Court was right to hold that “the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects.”<sup>81</sup> Were it otherwise, as the Third Circuit said, the Act would not bar *any* design-defect claims, because *every* such claim would be subject to case-by-case determination by a court—precisely what Congress sought to avoid in order to enable a viable vaccine market to exist.

### *Williamson v. Mazda*

*Williamson*,<sup>82</sup> our final case, takes us from drugs to automobiles, but the basic policy question remains the same: whether risk is best regulated at the federal or state level. Here, the Court ruled unanimously, with Justice Kagan recusing herself, that the family of a woman killed in an auto accident may sue the manufacturer of the minivan in which she was riding for its failure to install a lap-and-shoulder belt in the rear middle seat rather than simply a lap belt. Although the decision was unanimous—Justice Breyer writing for the Court, with concurrences by Justices Sotomayor and Thomas—it raises some of the most interesting and perplexing questions about our current preemption law, and was wrongly decided, I believe.

The Court reversed two lower state courts that had ruled, along with several other courts in recent years, that Federal Motor Vehicle Safety Standard 208, written pursuant to the National Traffic and Motor Vehicle Safety Act of 1966, preempted the plaintiffs’ suit in light of the Court’s 2000 decision in *Geier v. Honda American Motor Co.*<sup>83</sup> *Geier* concerned passive restraint systems: it held that the regulation preempted a suit based on the manufacturer’s failure to install airbags instead of automatic seatbelts. There, the Court found that

<sup>79</sup> *Id.* at 1081 n.72.

<sup>80</sup> *Id.* at 1081.

<sup>81</sup> *Id.* at 1082.

<sup>82</sup> *Williamson v. Mazda Motor of Am., Inc.*, 131 S. Ct. 1131 (2011).

<sup>83</sup> *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000).

regulators intended to assure manufacturers a choice between several different systems, a choice the state suits would deny them. Here, the Court held that assuring manufacturers a choice of seat-belt types was not, as with the choice in *Geier*, “a significant regulatory objective,”<sup>84</sup> and so the Williamsons’ suit was not preempted.

To understand those disparate rulings in seemingly similar cases we need to look first at the Court’s 5-4 decision in *Geier*, where Breyer also authored the majority opinion. The question before the Court there, as here, was whether the regulation preempted a state tort suit that would have held manufacturers liable and effectively denied them the choice the regulation seemed to give them. Breyer divided that inquiry into three steps.

First, he noted that the statute expressly preempted state law: “no State” may “establish, or . . . continue in effect . . . any safety standard applicable to the same aspect of performance” of a motor vehicle or item of equipment “which is not identical to the Federal standard.”<sup>85</sup> But he added, “We had previously held that a word somewhat similar to ‘standard,’ namely, ‘requirements’ (found in a similar statute) included within its scope state ‘common-law duties,’ such as duties created by state tort law.”<sup>86</sup> That interpretation raises a problem, which Thomas brings out in his concurrence: “standard,” especially as used in the statute here, ordinarily denotes a *regulatory* standard, not a tort judgment. The two are different, and they function differently. Eliding that difference, Breyer wrote next, “But we nonetheless held that the state tort suit in question fell *outside* the scope of this particular pre-emption clause. That is primarily because the statute also contains a saving clause, which says that ‘[c]ompliance with’ a federal safety standard ‘does not exempt any person from any liability under common law.’”<sup>87</sup> Thus, state tort suits, he concluded, fall outside the statute’s express preemption clause.

Second—and at this point in *Geier*, Breyer’s argument took an interesting turn, as Thomas will discuss in his concurrence:

We asked the converse question: The saving clause *at least* removes tort actions from the scope of the express pre-emption clause. But does it do more? Does it foreclose or limit

<sup>84</sup> *Williamson*, 131 S. Ct. at 1137.

<sup>85</sup> *Id.* at 1135 (quoting 15 U.S.C. § 1392(d)) (emphasis in the original).

<sup>86</sup> *Id.* (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 502 (1996) (plurality opinion)).

<sup>87</sup> *Id.* at 1135 (quoting 15 U.S.C. § 1397(k)) (emphasis in original).

‘the operation of ordinary pre-emption principles insofar as those principles instruct us to read’ federal statutes as pre-empting state laws (including state common-law standards) that ‘actually conflict’ with the federal statutes (or related regulations)? We concluded that the saving clause does not foreclose or limit the operation of ‘ordinary pre-emption principles, grounded in longstanding precedent.’<sup>88</sup>

Thus, he concluded that “the statute’s express pre-emption clause cannot pre-empt the common-law tort action; but neither can the statute’s saving clause foreclose or limit the operation of ordinary *conflict* pre-emption principles.”<sup>89</sup> Accordingly, third, the question there, as here, was “whether, in fact, the state tort action conflicts with the federal regulation.”<sup>90</sup>

In *Geier*, Breyer answered that question in the affirmative, unlike here. He did so because the *Geier* tort action conflicted with—stood as an obstacle to—the federal agency’s accomplishment and execution of its full “purposes and objectives.” Turning to numerous sources concerning everything from the state of airbag technology to ignition interlocks to public backlash and more, Breyer concluded that giving manufacturers a choice among passive restraint systems was “an important regulatory objective” that, as the solicitor general told the Court, a tort suit would stand in the way of accomplishing. Examining similar sources here, however, concerning consumer acceptance, safety, child car seats, ingress and egress concerns, cost, and more—including the solicitor general’s representation of the agency’s views—Breyer concludes that allowing manufacturers a choice between seat-belt types was *not* “a significant regulatory objective.”<sup>91</sup>

In her concurrence, Justice Sotomayor only reinforces Breyer’s “rejection of an overreading of *Geier*.”<sup>92</sup> For Justice Thomas, however, Breyer’s conflict analysis is, of course, fodder for his long-standing antipathy to the Court’s “purposes and objectives” preemption jurisprudence. Thomas would reach the same result the Court does, but

<sup>88</sup> *Id.* at 1135–36 (quoting *Geier*, 529 U.S. at 874).

<sup>89</sup> *Id.* at 1136 (emphasis added).

<sup>90</sup> *Id.*

<sup>91</sup> *Id.* at 1137.

<sup>92</sup> *Id.* at 1140 (Sotomayor, J., concurring).

“by a more direct route: the Safety Act’s saving clause, which speaks directly to this question and answers it.”<sup>93</sup> The Court does not rely on the saving clause, Thomas says, “because [it] read it out of the statute in *Geier*. . . . That left the Court free to consider the effect of conflict preemption principles on such tort actions.”<sup>94</sup>

Thomas then draws the distinction noted above between state *regulatory* law and state *tort* actions, which Breyer elided:

The [statute’s] express pre-emption clause bars States from having any safety “standard applicable to the same aspect of performance” as a federal standard unless it is “identical” to the federal one. That clause pre-empts States from establishing “objective rule[s] prescribed by a legislature or an administrative agency” in competition with the federal standards; it says nothing about the tort lawsuits that are the focus of the saving clause. Read independently of the express pre-emption clause, the saving clause simply means what it says: [the federal regulation] does not pre-empt state common-law actions.<sup>95</sup>

Having elided that distinction, however, rather than take the text at face value, the Court tries to determine “whether the regulators *really* wanted manufacturers to have a choice,”<sup>96</sup> Thomas continues. And it does so by “engag[ing] in a freewheeling, extratextual, and broad evaluation of the ‘purposes and objectives’” of the regulation, “wad[ing] into a sea of agency musings and Government litigating positions [to] fish[] for what the agency may have been thinking 20 years ago when it drafted the relevant provision.”<sup>97</sup> In fact, “[t]he dispositive difference between this case and *Geier*—indeed, the only difference—is the majority’s ‘psychoanalysis’ of the regulators,” he concludes.<sup>98</sup>

Thomas is certainly right to flag the problems inherent in the Court’s “purposes and objectives” jurisprudence. But insofar as he

<sup>93</sup> *Id.* at 1141 (Thomas, J., concurring in the judgment).

<sup>94</sup> *Id.*

<sup>95</sup> *Id.* at 1141–42.

<sup>96</sup> *Id.* at 1142 (emphasis in original).

<sup>97</sup> *Id.* (citation and some internal quotation marks omitted).

<sup>98</sup> *Id.* at 1143 (citing *Public Util. Comm’n of Cal. v. United States*, 345 U.S. 295, 319 (1953) (Jackson, J., concurring) (describing reliance on legislative history)).

attempts here to preserve the saving clause through a textual reading, plus the distinction he draws just above, his argument is problematic. The statute's preemption clause states, again, that "no State" may "establish, or . . . continue in effect . . . *any safety standard* applicable to the same aspect of performance" of a motor vehicle or item of equipment "which is not identical to the Federal standard."<sup>99</sup> Thomas reads that, along with the saving clause, as distinguishing state *regulatory* standards (preempted) from state *tort* actions (allowed, due to the saving clause). But a successful state tort suit concerning "the same aspect of performance"—say, seatbelts: finding lapbelts "unsafe"—would imply a state safety standard that is *not* "identical to the Federal standard," which means that state tort suits *too* should be preempted, by operation of the preemption clause—save for the flat-out contradictory saving clause. (But see below for a reading that reconciles the two clauses.)

Thus, the "floor and ceiling" metaphor common in preemption cases does not work here, not if we take the preemption clause at face value. If no state may establish any safety standard that is not *identical to the federal standard*, then that "floor" is in fact a "ceiling" too, which means that a state tort suit that implies otherwise is barred—unless we read the saving clause, again, as undercutting the plain text of the preemption clause. And notice: the saving clause doesn't simply *qualify* the preemption clause, as Thomas seems to be arguing; again, it flat-out *undercuts* it. There is either one (federal) standard—to which state standards, if there are such, must be "identical"—or there is not.

Neither Breyer nor Thomas addresses that point, although Breyer, toward the end of his opinion and in a different context, merely mentions, implying the contrary, that he "cannot reconcile" the idea that the federal agency intended to set a "maximum" standard "with a statutory saving clause that foresees the likelihood of a continued meaningful role for state tort law."<sup>100</sup> Neither can I; but, unlike Breyer, for textual reasons: there is no reconciling a contradictory statute. Not noticing the contradiction, Breyer moves ahead, with his "converse question," whether an express preemption clause, followed by a saving clause, leaves us still with the need to ask

<sup>99</sup> 15 U.S.C. § 1392(d) (2006) (emphasis added).

<sup>100</sup> Williamson, 131 S. Ct. at 1139 (majority opinion).

about “ordinary conflict preemption”—which takes us, of necessity, to the purposes-and-objectives preemption that Thomas dismisses, not without reason.

Sharing no such reservations, Breyer wades right into the job of discerning the purposes and objectives not only of the Congress that wrote the statute but of the regulators who wrote the regulations under it and of the lawyers who litigated the cases to which the statute and regulations gave rise. Thus, he writes that here, unlike in *Geier*, the Department of Transportation “was not concerned about consumer acceptance; it was convinced that lap-and-shoulder belts would increase safety; it did not fear additional safety risks arising from use of those belts; it had no interest in assuring a mix of devices; and, though it was concerned about additional costs, that concern was diminishing.”<sup>101</sup> In sum, and again, providing manufacturers with a seatbelt choice was not a “significant objective” of the regulation, so unlike in *Geier*, allowing state tort actions here would not conflict with the purposes and objectives of the federal statute.

But we are still left with the question: to what end were tort actions left available, pursuant to the saving clause, especially given the plain text of the preemption clause, which clearly requires a single standard, even if that “standard” gives manufacturers options? The Court upheld that standard in *Geier*, but not here, where it allowed the state to impose a *different* standard, one “not identical to the *Federal* [seatbelt] standard” that allowed manufacturers a choice. A better reading of the statute, I submit, would make state tort actions available *not* against manufacturers who made “the wrong choice” among federally *approved* options but against manufacturers *who failed to choose one of those federally approved options—manufacturers who ignored federal law*. That may be the null set, given the sanctions for regulatory noncompliance. And that reading of the saving clause may not conform to what we ordinarily think of when we think of state tort actions. But at least it renders the statute coherent—and avoids the often incoherent and conclusory “purposes and objectives” methodology that Breyer is so fond of.

What then is the result of the Court’s decision? The *Williamsons*, of course, will now go back to court to make out their case. But what is their case? That Mazda was negligent in installing lap belts

<sup>101</sup> *Id.* at 1138.

rather than lap-and-shoulder belts in their minivan inner seats? Where is the negligence in that? That Mazda could have made the vehicle safer? Yes, it could have, at a higher cost, as DOT recognized, which is one of the more important reasons it allowed Mazda the choice. But we are not talking here about some hidden risk, known only to the manufacturer. The risk was “open and obvious,” in the nomenclature of the old, more rational, common law—not the tort law that today presumes that for every loss a deep pocket must be found, a system that socializes losses not simply through strict but through what amounts to absolute liability.

And so we come to what is so often at issue in this preemption debate, namely, that manufacturers favor preemption because, first, as a matter of simple efficiency they want a single standard, not 50 ever-changing standards; and because, second, they want some relief from a state tort system that, as Justice Alito said in *Wyeth*, turns an ordinary medical malpractice case into a frontal assault on the FDA’s arguably rational regulation of risk, thereby rendering the regulation pointless if it cannot function to determine who assumes the risk and hence who suffers the loss if it materializes.

When *Williamson* is reargued below, Mazda should be able, of course, to raise DOT’s regulation as an affirmative defense, because the regulation implied that *either* choice—either lap belts or lap-and-shoulder belts—was “safe enough” in a context in which it is impossible to eliminate *all* risk. That is, Mazda should be held liable only if it was “at fault.” But again, where is the fault here? DOT was right to raise the cost issue, but it cuts in favor of the assumption-of-risk principle and hence in favor of choice and liberty. The *Williamsons* could have chosen a vehicle with lap-and-shoulder belts on the inner rear seats. Likely it would have been a bit more expensive. They chose instead the less expensive model, and paid the price—unless they can prevail upon the court below to shift at least some of their tragic losses to Mazda, which is likely, given our current tort system. And so Mazda, like most manufacturers, was hoping that preemption, together with the modern regulatory state, operating here in a domain that is perfectly legitimate under our Constitution,<sup>102</sup> would do the job that modern tort law fails to do, namely, police risk rationally.

<sup>102</sup> I discussed that issue more fully in *Pilon*, *supra* note 2, at 95–107.

## **Conclusion**

Five more preemption decisions, but not much more clarity. Perhaps we are expecting too much from the Court. After all, it often is no easy matter to determine just whether state law is “to the Contrary” of federal law. The Court made short work of it this term in *Whiting*, where the text was fairly clear. But in *Concepcion*, Justice Scalia had to employ the often-difficult purposes-and-objectives approach, which was fairly straightforward there, to uphold the federal arbitration statute. In *PLIVA*, however, it fell to Justice Sotomayor to show the majority that the case was not one of straightforward impossibility and that federal law did not trump state law. *Bruesewitz* was an equally hard case, thanks to Congress’s drafting, but Justice Scalia again cut to the quick, parsing the text in a way not only to make the most sense of it but to ensure, as a policy matter, the survival of a federal scheme designed itself to ensure the survival of the vaccine industry. But perhaps the hardest case of all was *Williamson*, despite the Court’s unanimous ruling, because here the statute, if read in an ordinary way, was internally inconsistent when its full implications were drawn out—which neither Justice Breyer’s opinion for the Court nor the concurrences of Justices Sotomayor or Thomas did. Instead, Breyer’s wide-ranging purposes-and-objectives analysis led him, and the Court, to find that federal law written to set auto safety standards could be undermined simply by the Court’s “psychoanalysis” of the regulators, as Thomas colorfully put it. As in so many of these cases, that leaves the law uncertain for plaintiffs and defendants alike, in this most uncertain area of our law of dual sovereignty.

