

# Into the Pre-emption Thicket: *Wyeth v. Levine*

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## Introduction

One is easily entangled in a thicket. That seems the condition of the Supreme Court after *Wyeth v. Levine*<sup>1</sup>—entangled in a thicket of its own making, its pre-emption jurisprudence. Pre-emption flows from the Constitution’s Supremacy Clause.<sup>2</sup> Stated simply, given the Constitution’s provisions for dual sovereignty, its division of powers between the federal and state governments, pre-emption stands for the idea that, in a conflict between the two, federal law trumps state law.<sup>3</sup> Yet for all that simplicity—“conflict” is deceptively simple—the Court over the years, as one seasoned litigator has put it, “has issued a confusing, erratic succession of fragmented tort preemption decisions involving various types of federally regulated products and state-law causes of action. . . . Practicing attorneys, as well as judges and legal scholars, have found it virtually impossible to reconcile these decisions.”<sup>4</sup>

Undaunted, I shall wade into this thicket to try to make such sense as I can of *Wyeth*, where the Court found that federal law

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<sup>1</sup> 555 U.S. \_\_\_, 129 S. Ct. 1187 (2009).

<sup>2</sup> “The Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” U.S. Const. art. VI, cl. 2.

<sup>3</sup> For a useful overview of the subject in these pages, analyzing the six pre-emption cases the Court considered in its 2007 term, see Daniel E. Troy and Rebecca K. Wood, *Federal Preemption at the Supreme Court, 2007–2008* Cato Sup. Ct. Rev. 257 (2008).

<sup>4</sup> Lawrence S. Ebner, *Four Myths About Federal Preemption of State Tort Claims*, 24 (19) Washington Legal Foundation Legal Backgrounder, June 5, 2009. Although I will be focusing on the operation of pre-emption in the area of pharmaceuticals, pre-emption issues arise in virtually every area of federal activity.

regulating a drug warning label did not protect pharmaceutical giant Wyeth against a failure-to-warn claim under state common law. I will begin by setting forth the facts of the case, then summarize, critically, Justice John Paul Stevens's opinion for the Court. Next, using as a springboard Justice Clarence Thomas's concurrence in the judgment alone, I will set forth some first principles of the matter to reach a quite different judgment than he did. Finally, I will turn to Justice Samuel Alito's dissent, joined by Chief Justice John Roberts and Justice Antonin Scalia, which gets it largely right, I believe, and should have been the opinion for the Court.

Before beginning, however, three preliminary points need noting. First, as with so many complex and confused areas of the modern Court's jurisprudence, the problems surrounding the Court's pre-emption jurisprudence stem in significant part from the felt imperatives of *stare decisis*, which is all the more reason to return to first principles, as Justice Thomas attempts to do, rather than try to square current cases with past mistakes.

Second, and following closely, something of a cottage industry has arisen around this matter, with its own nomenclature, not surprisingly. It would be useful, therefore, to repeat the outline of the subject that Daniel Troy and Rebecca Wood set forth here a year ago:

[F]ederal pre-emption may be “expressed or implied” in the pertinent federal regime. Express pre-emption involves discerning the meaning of an explicit preemption provision. There are at least two types of implied pre-emption: field pre-emption . . . and conflict pre-emption. Field pre-emption recognizes limited, but exclusive, areas of federal domain even in the absence of an explicit preemption provision from Congress. Conflict pre-emption tends to paint with a narrower brush and applies to particular issues where it is impossible for a private party to comply with both state and federal law, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress or of a federal agency acting within the scope of its congressionally delegated authority.<sup>5</sup>

<sup>5</sup> Troy and Wood, *Federal Preemption*, *supra* note 3 at 258–260 (internal quotation marks and citations omitted) (four spellings of “preemption” changed to “pre-emption” for consistency within block quote).

*Wyeth* involved a claim by the company, defending against the plaintiff's failure-to-warn claim, of implied conflict pre-emption, which the Court rejected.

Finally, the "politics" of this issue are not straightforward. 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 discussed below, most such people believe that in many if not most cases federal power should trump state power.<sup>6</sup> By contrast, 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>7</sup> My concern here is less with politics, however, than with what the Constitution requires. Accordingly, I turn now to the case.

#### **"Tragic Facts Make Bad Law"<sup>8</sup>**

In brief, on April 7, 2000, plaintiff-respondent Diana Levine, seeking relief for the second time that day from severe migraine headaches and nausea, suffered irreversible gangrene followed by amputation of her right forearm after her physician's assistant administered defendant-petitioner Wyeth's drug Phenergan by the "IV-push" method. The injectable form of the drug could be administered either intramuscularly or intravenously. And intravenous administration could be performed by either the slow "IV-drip" method or the faster, but more risky, IV-push method, where inadvertent intra-arterial injection would lead to the tragic results that followed here.

<sup>6</sup> See *Review & Outlook, Pre-empting Drug Innovation*, *Wall St. J.*, Mar. 5, 2009, at A16.

<sup>7</sup> See Supreme Court Decision in *Wyeth v. Levine* Victory for Consumers, *Alliance for Justice* Press Release, March 4, 2009, available at <http://www.afj.org/about-afj/press/03042009.html> ("The six justices who stood up for accountability sent a clear message that FDA approval does not necessarily grant a corporation a license to hit and run," said AFJ president Nan Aron.).

<sup>8</sup> Thus does Justice Alito begin his dissent. *Wyeth*, 129 S. Ct. at 1217 (Alito, J., dissenting).

The risks of inadvertent intra-arterial injection from using the IV-push method were well known. In fact, Phenergan's labeling contained both detailed instructions about the procedure and no fewer than six separate warnings about its risks, warnings that had evolved over the years and been approved by the federal Food and Drug Administration (FDA). Notwithstanding those warnings, Levine and her physician decided to employ the procedure to obtain the benefits it promised.

Levine brought and won a negligence action in Vermont state court against the clinic, her doctor, and the doctor's assistant, who "disregarded Phenergan's label and pushed [a double dose of] the drug into the single spot on [Levine's] arm that is *most* likely to cause an intra-arterial injection."<sup>9</sup> She then sued Wyeth, alleging

that the labeling was defective because it failed to instruct clinicians to use the IV-drip method of intravenous administration instead of the higher risk IV-push method. More broadly, she alleged that Phenergan is not reasonably safe for intravenous administration because the foreseeable risks of gangrene and loss of limb are great in relation to the drug's therapeutic benefits.<sup>10</sup>

The trial court rejected Wyeth's motion for summary judgment, which argued that Levine's failure-to-warn claims were preempted by federal law, holding that there was no merit in either Wyeth's field pre-emption argument or its conflict pre-emption argument. Regarding Wyeth's conflict argument, the court found no evidence that the company had tried to strengthen the warning or that the FDA had disallowed a stronger warning. After reviewing FDA's 45-year history of Phenergan regulation, the trial judge instructed the jury that Wyeth's compliance with FDA requirements "did not establish that the warnings were adequate."<sup>11</sup> The jury found "that Wyeth was negligent, that Phenergan was a defective product as a result of inadequate warnings and instructions, and that no intervening cause had broken the causal connection between the product defects and the plaintiff's injury."<sup>12</sup> It awarded Levine \$6.7 million.

<sup>9</sup> *Id.* at 1226 (original emphasis).

<sup>10</sup> *Id.* at 1191–1192.

<sup>11</sup> *Id.* at 1193.

<sup>12</sup> *Id.*

In a “comprehensive opinion,” the court denied Wyeth’s motion for judgment as a matter of law and determined further “that there was no direct conflict between FDA regulations and Levine’s state-law claims because those regulations permit strengthened warnings without FDA approval on an interim basis.”<sup>13</sup> The Vermont Supreme Court affirmed, with a dissent by its chief justice. It found that the jury verdict did not conflict with FDA’s labeling requirements and that “federal labeling requirements create a floor, not a ceiling, for state regulation.”<sup>14</sup>

### **Justice Stevens for the Court**

Justice Stevens began his opinion for the Court by noting that Wyeth raised two separate pre-emption arguments: first, that it would have been impossible for the company to comply with the state-law duty to modify Phenergan’s label without violating federal law; and, second, that recognizing the state-law duty creates an unacceptable “obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”<sup>15</sup> As discussed below, those two arguments are more closely connected than the Court seemed to appreciate. Before it addressed them, however, the Court offered a “preface”—identifying two factual propositions decided at trial, emphasizing two legal principles that guided its analysis, and reviewing the history of the controlling federal statute.

The two factual propositions are: first, “that Levine’s injury would not have occurred if Phenergan’s label had included an adequate warning about the risks of the IV-push method of administering the drug;” and, second, “that the critical defect in Phenergan’s label was the lack of an adequate warning about the risks of IV-push administration.”<sup>16</sup> It’s hard to know what to make of those “factual propositions:” as Justice Alito wrote in dissent, “it is unclear how a ‘stronger’ warning could have helped respondent; after all, the physician’s assistant who treated her disregarded at least six separate warnings that are already on Phenergan’s labeling, so respondent

<sup>13</sup> *Id.*

<sup>14</sup> *Id.* (internal quotation marks and citations omitted).

<sup>15</sup> *Id.* at 1193 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (internal quotation marks omitted)).

<sup>16</sup> *Id.* at 1194.

would be hard pressed to prove that a seventh would have made a difference.”<sup>17</sup> Since the jury found only that the six warnings were insufficient, not what additional or different warnings would have been sufficient, one suspects that *no* warning would have been found sufficient if the result warned against had materialized.

The two guiding legal principles are: first, that “the purpose of Congress is the ultimate touchstone in every pre-emption case;”<sup>18</sup> and, second, that “the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”<sup>19</sup> Reviewing the history of the Federal Food and Drug Act and the later Federal Food, Drug, and Cosmetic Act (FDCA), the Court took note of the 1962 amendments that shifted the burden of proof for drug safety and efficacy from the FDA to the manufacturer and, in addition, “added a saving clause, indicating that a provision of state law would only be invalidated upon a ‘direct and positive conflict’ with the FDCA.”<sup>20</sup> Moreover, the Court noted that “when Congress enacted an express pre-emption provision for medical devices in 1976, it declined to enact such a provision for prescription drugs.”<sup>21</sup>

#### *Wyeth’s Impossibility Argument*

Its preface completed, the Court turned to Wyeth’s first argument, that it would be impossible for the company to comply with the state-law duty to modify Phenergan’s label without violating federal law. But rather than address the substantive purposes and objectives that Congress may have had, which implicitly underpin Wyeth’s impossibility argument, the Court offered what in the end is a vacuous analysis of regulatory changes and inferences to be drawn from them: Generally speaking, the Court said, after FDA approval of a label, subsequent changes require FDA approval; but, FDA “changes being effected” (CBE) regulations allow *strengthening* a warning “to reflect newly acquired information” or “new analyses of previously

<sup>17</sup> *Id.* at 1217–1218.

<sup>18</sup> *Id.* at 1219 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (internal quotation marks omitted)).

<sup>19</sup> *Id.* at 1194–1195 (quoting *Lohr*, 518 U.S. at 485) (internal quotation marks and citation omitted).

<sup>20</sup> *Id.* at 1196.

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

submitted data" prior to receiving FDA approval,<sup>22</sup> and the burden remains on the manufacturer to make such changes.

Plainly, the implication of the Court's analysis is that Wyeth did not strengthen its label "to reflect newly acquired information" or "new analyses of previously submitted data."<sup>23</sup> The issue turns, then, on whether there was any such information or data. And on that, the Court was vague, at best:

The record is limited concerning what newly acquired information Wyeth had or should have had about the risks of IV-push administration of Phenergan because Wyeth did not argue before the trial court that such information was required for a CBE labeling change. Levine did, however, present evidence of at least 20 incidents prior to her injury in which a Phenergan injection resulted in gangrene and an amputation.<sup>24</sup>

Absent further information, however, we have no way of knowing whether 20 incidents over 45 years is an acceptable number—all drugs and drug administration procedures entail risk, after all. The Court noted that the first incident came to Wyeth's attention in 1967, and it added that Wyeth notified FDA and worked with the agency to change Phenergan's label. But it then said that in later years (which years we're not told), "as amputations continued to occur, Wyeth could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug."<sup>25</sup> And it concluded that, "when the risk of gangrene from IV-push injection of Phenergan became apparent"—again, just what point in time that was we don't know—"Wyeth had a duty to provide a warning that adequately described that risk."<sup>25</sup>

Wyeth responded, of course, that it did just that, that it did provide warnings that adequately described the risk, but that the physician's assistant ignored them. Given that failure, the dissent raised the crucial question—whether yet another warning would have made any difference at all. Indeed, we don't know how many of the 20 other incidents over the years arose from a similar cause, from a

<sup>22</sup> 73 Fed. Reg. 49603, 49609.

<sup>23</sup> *Id.* at 1197.

<sup>24</sup> *Id.*

<sup>25</sup> *Id.* at 1198.

failure to heed the warnings that were given. In the end, clearly, the Court’s conclusion is little more than a prescription for ever more failure-to-warn rulings, because it flows not from any independent risk assessment based on costs and benefits, but simply from the occurrence of the untoward incident. In sum, the Court’s analysis is circular: if there is an incident, the warning, *ipso facto*, will be deemed inadequate.

#### *Wyeth’s Purposes and Objectives Argument*

Thus, as noted above, the Court failed to recognize that Wyeth’s “impossibility” or “conflict” argument is intimately connected to its second argument, that recognizing a state-law duty to modify Phenergan’s label creates an unacceptable “obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” The connection stems from the fact that the FDA, pursuant to Congress’s purposes and objectives in enacting the FDCA, provides that independent cost-benefit risk assessment, at least in principle if not in fact. To be sure, incidents such as the Levine case factor into such assessments. But it is the FDA’s cost-benefit assessment, not some jury verdict, *ex post*, that is the standard for deciding whether a warning is adequate. Here, the warning was to give notice about the risk involved in the procedure, not to discourage all use of the procedure and the benefits it provided.

We come, then, to the first of the Court’s two “guiding principles,” that “the purpose of Congress is the ultimate touchstone in every pre-emption case,” and to the Court’s analysis of Wyeth’s second argument. Unfortunately, the analysis all but ignores that first principle, focusing instead on the *second* of its guiding principles, that “the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress”—the so-called presumption against pre-emption. In fact, the Court appears to read the first principle’s “purpose of Congress” as denoting simply Congress’s *pre-emptive* purpose, or lack thereof, not its *substantive* purpose in enacting the statute in the first place. The closest the Court comes to the latter is in its characterization of Wyeth’s claim: quoting from Wyeth’s brief, the Court says that Wyeth maintains that Levine’s tort claims are pre-empted “because they interfere with ‘Congress’s purposes to entrust

an expert agency to make drug labeling decisions that strike a balance between competing objectives.”<sup>26</sup>

Well what are those “competing objectives”? The Court never grapples with that substantive question, with Congress’s “purposes and objectives” in enacting the FDCA and establishing the FDA. Yet, absent an express pre-emption provision, understanding those substantive purposes and objectives is absolutely crucial to understanding whether and how pre-emption operates in the FDCA context. In brief, to be discussed a bit more fully below, Congress’s objective clearly was to ensure that drugs and the procedures for administering them are safe and effective. But “safe” and “effective” are sometimes themselves competing objectives. In fact, that precisely is the case here. The IV-drip method of administering Phenergan is safer but less effective than the IV-push method—that’s why, on her second visit to the clinic that day, Levine and her physician decided to pursue the less safe but more effective IV-push method. Yet the Court is oblivious to this trade-off. It is as if the Court were trying to eliminate all risk. If the IV-push method is effectively prohibited, so too will be the risk associated with it—and the benefits from its availability.

Thus deprived of the issues required for a full and proper implied pre-emption analysis—issues found in Congress’s *substantive* purposes and objectives—the Court narrowed its focus, looking only to “secondary” sources, so to speak. Responding to Wyeth’s contention that the FDA’s labeling requirements establish both a floor and a ceiling, for example, the Court found the evidence all to the contrary. Congress’s silence constituted the bulk of that evidence, however: in particular, the Court noted that Congress had not provided a federal remedy for consumers harmed by unsafe or ineffective drugs. “Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers.”<sup>27</sup> That may be so, but how probative is that evidence of the question at issue? After all, many claims are properly adjudicated under state law—perhaps claims about adulterated or mislabeled drugs, or about design or manufacturing defects more generally. But if among such claims is the language of drug warnings—which follows, under the FDCA,

<sup>26</sup> *Id.* at 1999 (citation omitted).

<sup>27</sup> *Id.*

only from extensive FDA testing—then what is the point of FDA testing? If 50 states remain free, in effect, to draft that language themselves, then in any given adjudication the FDA “floor” will be meaningless. (More on this in the next section.)

It appears, however, that the FDA did eventually become concerned about the problem state common-law decisions might pose for the drug labeling part of its mission. Thus, in 2000 it issued a notice of proposed rulemaking pertaining to the content and format of prescription drug labels, saying that the rule “did not propose to preempt State law.”<sup>28</sup> But when the agency finalized the rule in 2006—“without offering States or other interested parties notice or opportunity for comment,”<sup>29</sup> the Court notes—the preamble to the rule, on which Wyeth relied before the Court, declared that the FDCA establishes “both a ‘floor’ and a ‘ceiling,’” so that “FDA approval of labeling . . . preempts conflicting or contrary State law.”<sup>30</sup>

Thus, the question for the Court was how much weight to give “an agency’s mere assertion that state law is an obstacle to achieving its statutory objectives.”<sup>31</sup> Not much, it seems, since the Court found that the FDA’s views on this point were “inherently suspect” in light of its notice-and-comment “procedural failure[s].”<sup>32</sup> Moreover, the Court continued, the preamble “reverses the FDA’s own long-standing position” that state law not only posed no obstacle but, in fact, complemented its statutory mission by uncovering “unknown drug hazards and provid[ing] incentives for drug manufacturers to disclose safety risks promptly.”<sup>33</sup> To be sure, there are cases in which state law suits have uncovered unknown hazards, but where were the unknown hazards here, and what was not disclosed by the FDA-approved labeling? On its facts, this is not a complicated case: Wyeth gave a proper warning; the physician’s assistant ignored it.

Clearly, to have properly determined whether state law like this is an obstacle to the FDA’s mission, the Court would have had to consider evidence beyond Congress’s silence and the agency’s

<sup>28</sup> 71 Fed. Reg. 3922, 3969.

<sup>29</sup> Wyeth, 129 S. Ct. at 1201.

<sup>30</sup> *Id.* at 1200.

<sup>31</sup> *Id.* at 1201.

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

<sup>33</sup> *Id.* at 1202.

evolving views. It would have had to engage with the substance of the matter, with Congress's "purposes and objectives" in passing the FDCA in the first place—at least sufficiently to take notice of the two sides of this issue, the costs *and* the benefits. That it did not do. Like the jury, it saw only costs, which it attributed to an inadequate warning. And even then it did not see all of the costs: it was oblivious to the costs of *overwarning*, for example, which discourages and may even eliminate the use of efficacious drugs and effective procedures for administering them. The FDA's mission is two-fold: to ensure the safety of drugs; but to ensure their availability as well.

### **Justice Thomas and First Principles**

It may be noteworthy that in his 6,000-word opinion for the Court, not once did Justice Stevens use the word "Constitution" or any of its cognates. Justice Thomas made up for that, grounding his concurrence with the Court's judgment in the Constitution's provisions for dual sovereignty, but taking strong exception to the Court's "implicit endorsement of far-reaching implied pre-emption doctrines," especially its "'purposes and objectives' jurisprudence. Under this approach," he wrote, "the Court routinely invalidates state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law."<sup>34</sup> Taking thus a narrow textualist approach to the pre-emption question, he concurred only with the Court's judgment.

### *Beginning with First Principles*

Thomas began his concurrence by drawing from the theory of Federalist No. 51 and from recent cases invoking its argument that dual sovereignty was meant to provide "a double security . . . to the rights of the people."<sup>35</sup> Although the Constitution provides for concurrent federal and state power, the power of the states, he noted, is "subject only to limitations imposed by the Supremacy Clause."<sup>36</sup> That clause gives the federal government a decided advantage, however: "[a]s long as it is acting within the powers granted it under

<sup>34</sup> *Id.* at 1205.

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

<sup>36</sup> *Id.* (quoting *Taffin v. Levitt*, 493 U.S. 455, 458 (1990) (internal quotation marks omitted)).

the Constitution, Congress may impose its will on the States.”<sup>37</sup> But there, precisely, is a fundamental limitation on federal power, which Thomas stressed: as James Madison wrote in Federalist No. 45, “[t]he powers delegated by the proposed constitution to the federal government, are few and defined,” while “[t]hose which are to remain in the state governments, are numerous and indefinite.”<sup>38</sup> And there is a second limitation as well: if this “delicate balance” is to be preserved, “the Supremacy Clause must operate only in accordance with its terms,”<sup>39</sup> which means that the clause must give “supreme” status “only to those [federal laws] that are ‘made in Pursuance’ of [t]his Constitution.”<sup>40</sup>

There are thus “two key structural limitations in the Constitution that ensure that the Federal Government does not amass too much power at the expense of the States:” the doctrine of enumerated and thus limited federal powers, and “the complex set of procedures that Congress and the President must follow to enact ‘Laws of the United States’”<sup>41</sup>—in particular, the bicameral and Presentment Clause requirements. In sum, pre-emptive effect can be given only to those federal laws that flow from Congress’s enumerated powers and those “federal standards and policies that are set forth in, or necessarily follow from, the statutory text that was produced through the constitutionally required bicameral and presentment procedures.”<sup>42</sup>

Given those constitutional principles, “[c]ongressional and agency musings . . . do not satisfy the Art. I, § 7 requirements for enactment of federal law and, therefore, do not pre-empt state law under the Supremacy Clause.”<sup>43</sup> Emphasizing his textualism, Thomas added that when analyzing statutes or regulations, “[e]vidence of pre-emptive purpose [must be] sought in the text and structure of the [provision] at issue’ to comply with the Constitution.”<sup>44</sup> And again:

<sup>37</sup> *Id.* (quoting *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) (internal quotation marks omitted)).

<sup>38</sup> *Id.* at 1206 (internal quotation marks omitted).

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

<sup>40</sup> *Id.*, citing the Supremacy Clause, *supra* n.2.

<sup>41</sup> *Id.* at 1206–1207, citing *INS v. Chadha*, 462 U.S. 919, 945–946 (1983).

<sup>42</sup> *Id.* at 1207.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.* (quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)).

“Pre-emption must turn on whether state law conflicts with the text of the relevant federal statute or with the federal regulations authorized by that text.”<sup>45</sup>

Those constitutional and interpretive principles established, Thomas turned at last to the Court’s *Wyeth* analysis, again distinguishing the Court’s two categories of implied conflict pre-emption—where compliance with both federal and state law is “impossible,” and where state law stands as an obstacle to Congress’s “purposes and objectives.” He would be focusing his fire on the second, he explained, since “[t]he Court has generally articulated a very narrow ‘impossibility standard’—in part because the overly broad sweep of the Court’s ‘purposes and objectives’ approach has rendered it unnecessary for the Court to rely on ‘impossibility’ pre-emption.”<sup>46</sup>

Largely agreeing with the Court’s impossibility analysis in the case at hand, and concerned more about the Court’s broader pre-emption jurisprudence, Thomas reflected first on the Court’s less-than-clear distinction between a narrow “physical impossibility” standard and its more general “direct conflict” standard. Under either, however, “[t]he text of the federal laws at issue [here] do [sic] not require that the state-court judgment at issue be pre-empted.”<sup>47</sup> It was not physically impossible for Wyeth to strengthen its label and still comply with federal law. And “there is no ‘direct conflict’ between the federal labeling law and the state-court judgment.”<sup>48</sup> Of particular importance for the discussion of first principles just below, Thomas concluded that “the text of the statutory provisions governing FDA drug labeling, and the regulations promulgated thereunder, do not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA,”<sup>49</sup> a conclusion he summarized succinctly as: “the relevant federal law did not give Wyeth a right that the state-law judgment took away.”<sup>50</sup>

<sup>45</sup> *Id.* at 1208.

<sup>46</sup> *Id.* at 1209 (internal citation omitted).

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

<sup>48</sup> *Id.* at 1210.

<sup>49</sup> *Id.*

<sup>50</sup> *Id.* at 1211.

Turning finally to his larger concern, the Court’s “entirely flawed” purposes and objectives jurisprudence, Thomas’s main objections were threefold: first, constitutional fidelity; second, the Court’s reliance on extra-textual materials such as legislative history, divined notions of congressional purpose, and even congressional inaction; and, third, the implications of such reliance for judicial review and its proper limits.

He located the origins of this “flawed” approach in *Hines v. Davidowitz*,<sup>51</sup> then turned to *Geier v. American Honda Motor Co.*<sup>52</sup>—distinguished by the *Wyeth* majority, but relied on by the dissent—where the statute contained an express pre-emption provision, but also a seemingly contradictory saving clause. In his analysis of the two cases, Thomas charged the Court with “look[ing] far beyond the relevant federal statutory text and instead embark[ing] on its own freeranging speculation about what the purposes of the federal law must have been.”<sup>53</sup> In *Hines* the Court looked at statements by members of Congress, public sentiment, and other things; in *Geier* its inquiry included agency comments made when promulgating its regulation and statements made by the government in its brief to the Court.

Turning to *Wyeth*, Thomas faults the Court for relying on Congress’s silence—its failure here to exempt drug labeling from state tort judgments—which may be pertinent, he said: “But the relevance is in the fact that no statute *explicitly* pre-empts the lawsuits, and not in any inferences that the Court may draw from congressional silence about the motivations or policies underlying Congress’ failure to act.”<sup>54</sup> Indeed, he added, the Court’s willingness to guess about the inferences to be drawn from Congress’s silence could just as easily be used to give unduly broad pre-emptive effect to federal law.<sup>55</sup>

Drawing his argument to its conclusion, Thomas returned to the Constitution: “[O]ur federal system in general, and the Supremacy Clause in particular, accords pre-emptive effect to only those policies

<sup>51</sup> 312 U.S. 52 (1941).

<sup>52</sup> 529 U.S. 861 (2000).

<sup>53</sup> *Wyeth*, 129 S. Ct. at 1212.

<sup>54</sup> *Id.* at 1216 (emphasis added).

<sup>55</sup> *Id.* at 1216–1217.

that are actually authorized by and effectuated through the statutory text.”<sup>56</sup> That being so, the Court’s “purposes and objectives” pre-emption jurisprudence takes it “beyond the scope of proper judicial review.”<sup>57</sup> The Court’s role “is merely ‘to interpret the language of the statute[s] enacted by Congress.’”<sup>58</sup>

In sum, like the *Wyeth* majority, but for more searching reasons, Thomas did not grapple with the substantive issues underlying the FDCA and their implications for the pre-emption question at issue here. Drawing on fundamental constitutional and interpretive principles, he argued even more narrowly than did the majority, emphasizing textualism and seeming to say that only explicit or express pre-emption will do. The question for us is whether his is a true account of the First Principles of the matter.

#### *First Principles Reconsidered*

Justice Thomas is to be commended for his willingness, without embarrassment, to turn frequently to the Constitution’s First Principles—modern “constitutional law” notwithstanding.<sup>59</sup> And his insistence on textualism and judicial restraint (or modesty) are virtues as well. In his concurrence he has raised serious issues that need to be addressed. In the end, however, one must ask whether so narrow a textualism is appropriate when the Court is wrestling with pre-emption, one of the Constitution’s more difficult because more textually underdetermined matters. Not even express pre-emption provisions, after all, are invariably unambiguous.<sup>60</sup> Thus, the Court will

<sup>56</sup> *Id.* at 1216.

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

<sup>58</sup> *Id.* at 1217 (citing *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 461 (2002)).

<sup>59</sup> See, e.g., *United States v. Lopez*, 514 U.S. 549, 584 (1995) (Thomas, J., concurring).

<sup>60</sup> See, e.g., Michael Greve, *Preemption Strike*, National Review Online, March 23, 2009 (available at <http://article.nationalreview.com/?q=YTE0N2ZjNDEyYmQ3MTAxYTQ0Y2I2Y2I4MmFiOGJlMmQ=>) (original emphasis):

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.

For examples of courts rejecting pre-emption challenges of this type, see, e.g., *Central 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).

often have to turn to extra-textual materials to properly understand and interpret even those texts—and will have to do so *a fortiori* when the claim is one of implied pre-emption.

The question, then, is whether the Court’s interpretive responsibilities in any pre-emption case are executed well or poorly. And given the range of subjects over which pre-emption may be at issue, that is no easy question to answer, which is one reason why this is such a legal thicket. It may be, in fact, that general principles will take one only so far in a given case, after which the facts take over. Still, it is important to begin with the principles of the matter, as Thomas did, and take them as far as possible.

And the place to start as a general matter is with the theory of dual sovereignty, as Thomas rightly saw. But immediately upon doing so we’re taken to the “purposes and objectives” of dual sovereignty, namely, to provide “a double security . . . to the rights of the people.”<sup>61</sup> And that takes us to more fundamental “First Principles,” to questions about “the rights of the people,” and to our founding document, the Declaration of Independence, where the Founders, in the name of those rights, set forth the theory of government that the Framers would institute through the Constitution 11 years later.

In a nutshell,<sup>62</sup> the Declaration, grounding the nation in the natural rights strain of natural law, makes it clear that we’re born with our rights, we don’t get them from government, and we institute government mainly to secure those rights through powers “derived from the consent of the governed.” By implication—given the wide variety of ways individuals might exercise their right to pursue happiness, and the considerable difficulties, accordingly, of achieving the kind of broad consent the theory requires for political legitimacy—the scope of the governmental powers envisioned is decidedly limited, leaving us free to pursue happiness as we wish, mostly in our private capacities.

The Constitution captures that vision of individual liberty and limited government in several ways: the Preamble, like the Declaration, invoking the tradition of state-of-nature theory, wherein the

<sup>61</sup> Federalist No. 51; see also *supra*, note 35 and accompanying text.

<sup>62</sup> I have discussed these issues more fully in Roger Pilon, *The Purpose and Limits of Government*, Cato’s Letters No. 13 (1999).

people, by right, “do ordain and establish this Constitution” and hence the government authorized by it; the doctrine of delegated, enumerated, and thus limited federal powers; the separation of powers, defined functionally; the division of powers, leaving most power with the states; provision for a bicameral legislature, a unitary executive, an independent judiciary, and periodic elections to fill the offices set forth in the document—those were among the ways the people at once both empowered and limited the government they created.

As a practical legal charter, the Constitution was of course far more detailed and specific than the Declaration, even as it sought to secure, institutionally, the Declaration’s vision.<sup>63</sup> Yet the 18 powers delegated to Congress and enumerated in Article I, section 8, were still aimed largely at securing our rights—the function of government set forth in the Declaration—either directly (the war powers, the power to establish lower courts, to secure intellectual property) or instrumentally (the power to tax and to borrow to support those other powers).

But most of our right-securing power<sup>64</sup> was left with the states in the form of the general police power—the power to define and enforce our substantive and procedural rights through either common-law adjudication or statutory declaration. Ideally, those adjudicative and declaratory functions would be grounded in reason, not mere political will.<sup>65</sup> But objective reason goes only so far before subjective values have to be brought into the process. That occurs

<sup>63</sup> With the Constitution’s oblique recognition of slavery, failing which there would have been no “united” states, the Declaration’s vision was imperfectly secured, to be sure. It would take the ratification of the Civil War Amendments to “complete” the Constitution, at least in principle. See Robert J. Reinstein, *Completing the Constitution: The Declaration of Independence, Bill of Rights and Fourteenth Amendment*, 47 Temple L. Rev. 361 (1993).

<sup>64</sup> John Locke, the philosophical father of the nation, called that the “Executive Power”—the power each of us has in the state of nature to secure his rights, which we yield up to government to exercise on our behalf when we enter the state of civil society. John Locke, *The Second Treatise of Government*, in *Two Treatises of Government* § 13 (1690).

<sup>65</sup> On the evolution of those processes, see Edward S. Corwin, *The “Higher Law” Background of American Constitutional Law* (1955), at 26 (“[T]he notion that the common law embodied right reason furnished from the fourteenth century its chief claim to be regarded as higher law.”).

in at least four areas in particular: nuisance, risk, remedies, and enforcement. Regarding nuisances like noise, particulate matter, odors, and the like, “public lines” need to be drawn defining where one man’s right to the active enjoyment of his rights ends and his neighbor’s right to the quiet enjoyment of his rights begins. Likewise, the remedial value of a life or a limb is not a matter for pure reason; nor are the second-order investigative and prosecutorial rights that arise when first-order substantive rights are violated, as is evidenced by such evaluative words as “unreasonable” and “probable” in the Fourth Amendment.

Our focus here, however, is on risk, which arises in infinite variety. As with those other categories, there is no bright line, rooted in reason, defining how much risk one may put one’s neighbor to before his right to be free from such risk is implicated. On one hand, a risk-free world is a world without action and hence without life. On the other hand, we don’t allow people to drive down city streets at any speed they wish. Obviously, people have different tastes for risk. Mutual consent can accommodate many of those differences. But where consent is not an option, for whatever reason, *notice* serves to reduce risk. Some risks are “open and obvious,” to use an old common-law term. Others are hidden, at least to strangers, and need to be made open and obvious by giving notice so that strangers, by being made aware of the risk, may adjust their behavior accordingly.

Pharmaceutical drugs provide extraordinary benefits but entail risks as well. As the manufacturers of those drugs learn about the benefits and risks, through FDA testing procedures or otherwise, they can reduce the risks to users by giving notice about use, dosages, administration, and the like. That is what labeling is all about. Proper labeling does not eliminate the risk. It simply makes it known to the physician or user. Just how much or what kind of notice (or warning) is “proper” is not a matter written in stone or subject to determination by pure reason. The “reasonable man” standard comes to the fore here. Again, too little notice may introduce more risk than is desirable. Too much may reduce the availability of benefits that are desirable.

But once a balance is struck, and a public line has been drawn, the parties know their respective rights and obligations in this otherwise uncertain domain. Drug manufacturers know the kind of notice they must give to discharge their obligation not to put users at too great

a risk. Potential users now know the risk associated with the drug and, accordingly, can decide whether and how to approach it.

What if there is no public line, however? Or what if there are many—say, 50—ever-changing public lines? In that case, our rights and obligations are uncertain and unstable. On one hand, juries could tell injured drug consumers that they used at their peril (not likely). On the other hand, they could tell drug manufacturers that they sold at their (legal) peril. Since the second is the far more likely scenario—certainly under our current tort law—the regime of strict (absolute?) manufacturer liability that follows either discourages the research, development, and sale of drugs or vastly raises the prices for all concerned, including consumers. It is, in short, an uncertain and inefficient world.

In fact, *mutatis mutandis*, that scenario is not entirely unlike the one the Framers faced at the time they drafted the Constitution, and so we return to that story, which sheds light on the question of who gets to draw the public lines the theory of rights requires if “the rights of the people” are to be fleshed out fully. Under the Articles of Confederation, states had erected tariffs and related measures to protect local merchants and manufacturers from out-of-state competitors. That was leading, in turn, to the breakdown of trade among the states—not unlike the scenario envisioned if 50 different sovereigns require, in effect, 50 different risk warnings. (And even then the warning may not be deemed “adequate” if the risk materializes.) In fact, one of the main reasons a new Constitution was thought necessary was to enable the federal government to check that growing state protectionism.<sup>66</sup> Thus, Congress was given the power to regulate—or “make regular”—commerce among the states—essentially, a power to negate state actions that frustrated free interstate trade and to do the few other things that might be needed to facilitate that commerce.<sup>67</sup>

Properly understood, then, Congress’s commerce power, notwithstanding its use today as an instrument of virtually unbounded

<sup>66</sup> The other main reason was the need for a stronger national government and a stronger federal executive to deal with foreign affairs. See John Yoo, *The Powers of War and Peace*, ch. 3 (2005).

<sup>67</sup> See, e.g., Randy E. Barnett, *The Original Meaning of the Commerce Clause*, 68 U. Chi. L. Rev. 101 (2000). Cf. Richard A. Epstein, *The Proper Scope of the Commerce Power*, 73 Va. L. Rev. 1387 (1987).

federal policy, is at bottom a limited federal police power. Aimed mainly at ensuring a national market free from invidious state interference, it enables Congress not only to negate such interference but also, affirmatively, to facilitate free trade by regularizing otherwise potentially balkanized markets. As one aspect of that function, Congress may need to draw the “public lines” just discussed to more surely define the rights and obligations of parties engaged in interstate commerce. That, in fact, is one of the basic “purposes and objectives” of the FDA, at least as its functions have evolved. Here, it is to determine, after extensive testing, just what warning label is “adequate” such that drug manufacturers can meet their obligation to give notice about the risks associated with their products and users can have that notice so they can then act accordingly.

In this context, then, the FDA’s function—pursuant to Congress’s “purposes and objectives” in enacting the FDCA—is to assess both the risks and the benefits of a drug and, with labeling, to set both a “floor” and a “ceiling.” It is to draw that line, in this inherently line-drawing context, that defines the rights and obligations of the respective parties. Through the *positive* law that emerges, manufacturers can meet their inherently unclear *natural* law obligation to give adequate notice to users about the risk. Having done so, having respected the right of the user to be given such notice, the manufacturer has a right to immunity from suit for damages if the user decides to approach the risk and the outcome warned against materializes—to say nothing of the case here, where the user’s assistant ignored the warning.

By contrast, for the Court to treat the FDA-determined warning as a “floor,” on which states may add further warnings, is to render Congress’s responsibility under the Commerce Clause and the agency’s function under the statute all but pointless. Further, by rendering that federal “check” on state power pointless, the Court compromises the “purposes and objectives” of dual sovereignty—to provide “a double security . . . to the rights of the people,” in this case, the rights of manufacturers. In effect and in fact, the Court creates an unfounded “right” in users, at the expense of the manufacturer’s genuine rights. For having been warned of the risk, the user here, now informed, has a right to pursue the risky procedure and enjoy the benefits that flow from it. But if the untoward outcome warned against materializes, then the user has yet a second “right,”

at the expense of the manufacturer, to be made whole. It's a "risk-free" scenario for the user.

Finally, recasting this with reference to the so-called presumption against pre-emption, given that our system of dual sovereignty leaves the general police power over health and safety with the states, that presumption is sound, for rights are initially defined and enforced by the states. And in the absence of federal regulation, state common-law decisions based on *rational* tort law might very well draw reasonable and fairly uniform lines concerning adequate and inadequate warnings such that all parties have a fairly clear understanding of their respective rights and obligations. But whatever the original impetus for Congress's having decided to exercise its commerce power and regulate drug safety and efficacy, there is today, given the tort law we see at play in cases like *Wyeth*, ample support for federal regulation under the *original* rationale for that power—to cure the inefficiencies of regulatory balkanization. But given that rationale plus the Supremacy Clause, there is no constitutional support for adding state regulation on top of federal regulation. On the contrary, the very "purposes and objectives" that justify federal regulation justify pre-empting state regulation.

None of that is to say that FDA regulation has been flawless, of course. The agency has been too risk-averse, if anything, keeping efficacious drugs off the market for too long and denying access to potentially life-saving drugs when individuals would be only too willing to assume the risk.<sup>68</sup> (Allowing state tort law to regulate labeling would only exacerbate that problem, of course.) But the question here is whether, absent an express pre-emption provision, FDA labeling regulations should be read as implicitly pre-empting state common-law judgments. Given Congress's substantive "purposes and objectives" in enacting the FDCA in the first place, the answer is yes.

In sum, then, express pre-emption is not necessarily valid: as Thomas noted, the underlying regulation may be beyond Congress's authority under the doctrine of enumerated powers, assuming there is anything left of that doctrine after *Gonzales v. Raich*,<sup>69</sup> or the scope

<sup>68</sup> See Roger Pilon, *New Right to Life*, Wall St. J., Aug. 10, 2007, at A11 (discussing *Abigail Alliance v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007)).

<sup>69</sup> 545 U.S. 1 (2005).

of the pre-emption may not reach the issue before the Court. But neither is implied pre-emption necessarily invalid, especially if Congress is pre-empting a field or, as here, if state regulation would be inconsistent with the substantive objects and purposes of Congress.

It seems, therefore, that Justice Thomas's understandable concern for text-based adjudication and judicial restraint led him to a narrower vision of the Constitution's First Principles than is needed when pre-emption is before the Court. Often, laws "made in Pursuance" of "[t]his Constitution" cannot be understood properly on their text alone, without inquiry into the "purposes and objectives" of Congress in enacting them and of agencies in executing them. Moreover, when one factors in the true "purposes and objectives" of the Commerce Clause, under which so much federal regulation is enacted, and adds the Supremacy Clause as well, a richer conception of dual sovereignty emerges, protecting "the rights of the people" against both federal *and* state power.

Interestingly, as the dissent notes, the Court's first great Commerce Clause case, *Gibbons v. Ogden*, was arguably an implied conflict pre-emption case, where the Court found that a federal coasting statute, enacted under the commerce power, trumped a state law that restricted the rights of would-be entrepreneurs.<sup>70</sup> For present purposes, however, what is more interesting about the case is how Chief Justice John Marshall, in deciding it, went out of his way to emphasize that constitutional text must be interpreted in light of its "purposes and objectives." Thus, he was concerned to avoid not only "an enlarged construction" but a "narrow construction, which would cripple the government, *and render it unequal to the object for which it is declared to be instituted . . .*"<sup>71</sup> Marshall's focus, plainly, was on the very purpose of the government the Constitution created. He continued in that vein: "If . . . there should be serious doubts respecting the extent of any given power, it is a well settled rule, *that the objects for which it was given . . . should have great influence in the construction.*"<sup>72</sup> Finally, to the same effect: "We know of no rule for construing the extent of such powers [as the commerce power],

<sup>70</sup> Wyeth, 129 S. Ct. at 1229, n.14 (Alito, J., dissenting) (citing *Gibbons v. Ogden*, 22 U.S. 1 (1824)).

<sup>71</sup> *Gibbons*, 22 U.S. at 233–234 (emphasis added).

<sup>72</sup> *Id.* at 234 (emphasis added).

other than is given by the language of the instrument which confers them, *taken in connexion with the purposes for which they were conferred.*<sup>73</sup> Today, of course, the commerce power is used promiscuously to run roughshod over the powers of states and “the rights of the people” alike. But it has its uses to protect those rights, and they need to be rediscovered.

### **Justice Alito’s Dissent**

In his trenchant dissent, Justice Alito made it clear from the start that this was not a complicated case. (Accordingly, I will simply summarize the dissent.) Its tragic facts aside, it was a simple medical malpractice case. Ignoring that conclusion, drawn from the facts, the Court turned “a common-law tort suit into a ‘frontal assault’ on the FDA’s regulatory regime for drug labeling,”<sup>74</sup> Alito charged. In so doing, it upset “the well-settled meaning of the Supremacy Clause and [the Court’s] conflict pre-emption jurisprudence,” holding “that a state tort jury, rather than the . . . FDA, is ultimately responsible for regulating warning labels for prescription drugs.”<sup>75</sup>

Showing no reluctance to examine Congress’s “purposes and objectives,” Alito began his argument by going not to Congress’s pre-emptive but straight to its substantive purpose in enacting the FDCA: “Congress made its ‘purpose’ plain in authorizing the FDA—not state tort juries—to determine when and under what circumstances a drug is ‘safe.’”<sup>76</sup> After reviewing several relevant statutory and regulatory provisions and procedures—“spanning an entire part of the Code of Federal Regulations, with seven subparts and 70 separate sections”—he concluded that “a drug’s warning label ‘serves as the standard under which the FDA determines whether a product is safe and effective.’ Labeling is ‘[t]he centerpiece of risk management,’ as it ‘communicates to health care practitioners the agency’s formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively.’”<sup>77</sup> And

<sup>73</sup> *Id.* at 235 (emphases added).

<sup>74</sup> *Wyeth*, 129 S. Ct. at 1218 (Alito, J., dissenting) (quoting the brief for the United States as amicus curiae, at 21).

<sup>75</sup> *Id.* at 1217–1218.

<sup>76</sup> *Id.* at 1219.

<sup>77</sup> *Id.* (quoting 50 Fed. Reg. 7470 (1985) and 71 Fed. Reg. 3934 (2006)).

he added that “[n]either the FDCA nor its implementing regulations suggest that juries may second-guess the FDA’s labeling decisions.”<sup>78</sup>

Turning to the cases, Alito found that once the FDA had decided that a drug was safe and effective, no state could countermind that decision.<sup>79</sup> Thus, “it is irrelevant in conflict pre-emption cases whether Congress ‘enacted an express pre-emption provision at some point during the FDCA’s 70-year history.’ . . . Rather, the ordinary principles of conflict pre-emption turn solely on whether a State has upset the regulatory balance struck by the federal agency.”<sup>80</sup> Analyzing conflict pre-emption, he continued, involves a simple “two-step process of first ascertaining the construction of the federal and state laws and then determining the constitutional question whether they are actually in conflict.”<sup>81</sup> Likewise, “it is irrelevant [here] that the FDA’s preamble does not ‘bear the force of law,’” a charge the majority had made, “because the FDA’s labeling decisions surely do.”<sup>82</sup> Here, as in all such cases, “the sole question is whether there is an ‘actual conflict’ between state and federal law; if so, then pre-emption follows automatically by operation of the Supremacy Clause.”<sup>83</sup>

## Conclusion

In sum, even for textualists, if the text of a constitutionally authorized statute or regulation implies the purposes or objectives of the measure, as invariably it does after thoughtful analysis, and a state law conflicts with the administrative execution of those purposes or objectives, in the sense that the law upsets the balance the agency has struck between competing objectives, then the effect of the Supremacy Clause is clear: The state law must yield. It’s no more complicated than that.

The pre-emption problem is prevalent today, of course, because regulations—federal, state, and local—are ubiquitous. The expansion of the commerce power beyond its original purpose is the main

<sup>78</sup> *Id.* at 1220.

<sup>79</sup> *Id.* (citing *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001)).

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

<sup>81</sup> *Id.* (internal quotation marks and citations omitted).

<sup>82</sup> *Id.* at 1228 (citing 21 U.S.C. § 355).

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

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source of the problem. But adding yet more conflicting regulations at the state and local level is no answer to that problem. After its decision in *Wyeth v. Levine*, however, it is the answer the Court has given us.

