

## PREEMPTION AS INVERSE NEGLIGENCE PER SE

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Federal preemption of state tort claims has been a controversial and frequently litigated issue over the past decade, arguably constituting the most important, if confusing, development in tort law over that period. Books,<sup>1</sup> law review symposia,<sup>2</sup> and much of a blog<sup>3</sup> are devoted to the topic. But a grand unified theory of preemption doctrine has been elusive, and preemption cases come to wildly unpredictable results. Sometimes statutory text is said to control the outcome of a case, but sometimes statutory text is all but ignored.<sup>4</sup>

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1 See, e.g., THOMAS O. MCGARITY, *THE PREEMPTION WAR* (2008) (discussing the federal agency preemption over state common law claims); *PREEMPTION CHOICE 2* (William W. Buzbee, ed., 2009) (addressing preemption, including a focus of the “antecedent political and regulatory choice of whether to preempt”).

2 See e.g., Symposium, *Tort Law in the Shadow of Agency Preemption*, 65 N.Y.U. ANN. SURV. AM. L. 435 (2010); Symposium, *Ordering State-Federal Relations Through Federal Preemption Doctrine*, 102 NW. U. L. REV. 503 (2008); Symposium, *Administrative Law’s Federalism: Preemption, Delegation, and Agencies at the Edge of Federal Power*, 57 DUKE L.J. 1933 (2008).

3 See James M. Beck, *DRUG AND DEVICE LAW BLOG* (NOV. 11, 2012, 10:48 AM), <http://druganddevicelaw.blogspot.com/>.

4 As discussed below, Justice Breyer, writing for the majority in *Geier v. American Honda*, acknowledged that the statute had a saving clause that appeared to preserve state common law claims but concluded that “the saving clause (like the express preemption provision) does not bar the ordinary working of conflict pre-emption principles.” 529 U.S. 861, 869 (2000) (emphasis removed). In dissent, Justice Stevens argued that “neither the text of the statute nor the text of the regulation contains any

Sometimes questions of state sovereignty are placed at the forefront of preemption analysis, but other times the demand for a uniform federal scheme of regulation trumps state common law.<sup>5</sup> Sometimes courts defer to an agency's view about the preemptive effect of an agency's own regulations, but other times courts refuse to defer at all.<sup>6</sup> It is little wonder that scholars have described the Supreme Court's preemption jurisprudence as a muddle or as simply a veiled assertion of political power on behalf of either plaintiffs' lawyers or defendant manufacturers.<sup>7</sup> How can we account for the apparently inconsistent and unsatisfying results in preemption cases?

Part of the problem, I suggest, is that federal preemption of state tort claims is particularly susceptible to the tendency to hit every legal nail with a public law hammer. What almost everyone in the preemption debate assumes is that the resolution of preemption cases is primarily a question of public law, involving various aspects of constitutional law, administrative law, and statutory interpretation. My argument here is that this apparent consensus fails to account for the divergent contexts to which preemption doctrine applies. In particular, the preemption of common law tort claims raises specific *tort* issues that have been largely neglected by courts and scholars. Most assume that common law tort remedies are state "regulations" in the relevant sense and so are subject to review through considerations of agency deference, regulatory competence, or national versus state power. This view obscures the fact that federal preemption, in whatever context, is always an argument about preemption of *something*—a state law tort claim, a local government's effort to engage in

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indication of an intent to pre-empt" the state tort claim and that the Court had engaged in an "unprecedented use of inferences from regulatory history and commentary as a basis for implied pre-emption[.]" *Id.* at 912–13 (Stevens, J., dissenting).

5 Though there are cases involving financial regulation rather than preemption of state tort claims, *Cuomo v. Clearing House Ass'n, L.L.C.*, 557 U.S. 519 (2009) and *Watters v. Wachovia Bank, N.A.* 550 U.S. 1 (2007) are notable examples of a disagreement between interests of uniform federal regulation and state sovereignty in preemption analysis.

6 See Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 521 (2008).

7 Richard A. Epstein & Michael S. Greve, *Introduction: Preemption in Context*, in FEDERAL PREEMPTION 1, 2 (Richard A. Epstein & Michael S. Greve, eds., 2007) ("[N]o one is very happy with the Supreme Court's muddled doctrine and meandering decisions in this field."); Sharkey, *supra* note 6, at 471 ("Given the contentious territory of preemption, frequently summed up as 'a muddle[.]'").

foreign affairs,<sup>8</sup> state regulation of health insurers,<sup>9</sup> or state labor law.<sup>10</sup>

But once the question of whether federal law preempts state tort law has been raised, it does not require—or so I shall argue—that traditional principles of common law adjudication be discarded as well, particularly where the only available substitutes for common law categories are versions of textualist statutory interpretation or free-wheeling “purposes and objectives” tests for implied preemption.<sup>11</sup> This Article suggests that the missing element in much of the case law and scholarship on preemption of tort claims is attention to the underlying character of the common law tort claims themselves. Such attention has been neglected partly on account of the dominant constitutional and administrative law approaches to preemption, but also on account of the tendency even in tort law to treat products liability as if it were a separate field with its own, quite different set of doctrines. Though such issues are beyond the scope of this Article, the shift in the *Restatement (Third) of Torts: Products Liability* toward bringing negligence considerations back into design defect claims,<sup>12</sup> arguments for the bearing of negligence factors on failure to warn claims,<sup>13</sup> and recent scholarship on such traditional tort topics as causation in products liability claims<sup>14</sup> suggest that the effort to employ

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8 See *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 366 (2000).

9 See *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 359 (2002).

10 See *Chamber of Commerce v. Brown*, 554 U.S. 60, 62 (2008).

11 RICHARD A. EPSTEIN, *TORTS* 161 (1999) (“It is very difficult to offer any generalizations from this unruly mass of cases. Although the presumption is set against preemption, the strength of that presumption varies with the language of the particular provision and nature of the overall Congressional program. But there is no general answer to the question: What did Congress intend? So long as those intentions are left unclear, litigation will veer this way and that. Who said that ancient common law principles lack the precision of modern statutes?”).

12 See *RESTATEMENT (THIRD) OF TORTS: PROD. LIAB.* § 2 (1998) (“A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product: . . . (b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe[.]”).

13 See generally James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265 (1990).

14 See, e.g., Aaron D. Twerski & Neil B. Cohen, *Resolving the Dilemma of Non-Justiciable Causation in Failure-to-Warn Litigation*, 84 S. CAL. L. REV. 125, 130 (2010) (arguing for “the elements of fault and causation be addressed together, rather than separately, to provide a unified fault-cause metric for determining the extent of liability”).

traditional common law tort doctrine in an area touching on products liability is not as odd as it might at first appear. My suggestion in this Article is that preemption analysis in the context of state tort claims would benefit both descriptively and normatively, by invoking the traditional tort doctrine of negligence per se but, in the preemption context, on behalf of defendants—*inverse* negligence per se.

My argument will proceed in three steps. First, I will summarize the deep confusion around preemption doctrine, most recently on display in a series of cases in the regulation of medical devices, automobile safety, and the labeling of prescription drugs. Second, I will take up the traditional doctrine of negligence per se and reframe preemption of state tort law claims as “inverse negligence per se.” Third and finally, I will argue that preemption as inverse negligence per se as applied to recent preemption case law offers a superior descriptive account of the outcomes in recent cases and a superior normative account for understanding federal preemption.

### I. THE CONFUSION OF TRADITIONAL PREEMPTION DOCTRINE

Scholars are frequently tempted to characterize any area they happen to be working in as deeply confused or in need of thorough reworking, but with respect to preemption such characterizations happen to be true. The Supreme Court’s preemption jurisprudence traces back to such cases as *San Diego Building Trades Council v. Garmon*,<sup>15</sup> involving the National Labor Relations Act, and *Silkwood v. Kerr-McGee Corporation*,<sup>16</sup> in which the Court held that an award of punitive damages was not preempted by the Atomic Energy Act.<sup>17</sup> Courts and scholars struggle to explain why preemption cases come to divergent results, even in regulatory areas that are closely related. State tort claims for design defects in medical devices that have received pre-market approval from the FDA are preempted,<sup>18</sup> but claims that medical devices that were approved based on their similarity to previously approved devices are not.<sup>19</sup> Claims that automobiles without airbags are defectively designed are preempted,<sup>20</sup> but claims that automobiles with lap-only seat belts (instead of lap and shoulder belts) in rear inner seats are not.<sup>21</sup> Design defect claims against man-

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15 359 U.S. 236 (1959).

16 464 U.S. 238 (1984).

17 *Id.*

18 *See* Riegel v. Medtronic, Inc., 552 U.S. 312, 324–25 (2008).

19 *See* Medtronic v. Lohr, 518 U.S. 470, 494 (1996).

20 *See* Geier v. Am. Honda Motor Co., 529 U.S. 861, 874 (2000).

21 *See* Williamson v. Mazda Motor of Am., Inc., 131 S. Ct. 1131, 1139–40 (2011).

manufacturers of routinely administered childhood vaccines<sup>22</sup> and failure to warn claims against manufacturers of generic drugs are preempted,<sup>23</sup> but failure to warn claims for labeling of brand-name prescription drugs are not.<sup>24</sup> Commentators routinely characterize the Supreme Court's preemption case law as a "muddle,"<sup>25</sup> turning on narrowly technical discussions of statutory interpretation, agency deference, and federalism. But in recent years the pace of preemption decisions has quickened considerably, particularly cases in which defendants argue that federal law preempts state common law tort claims.<sup>26</sup>

### A. Overview of Preemption Doctrine

Preemption is the apparently straightforward constitutional doctrine based in the Supremacy Clause that a "state law that conflicts with federal law is 'without effect.'"<sup>27</sup> Preemption is traditionally divided among "express," "conflict," and "field" preemption:

Congress' intent may be "explicitly stated in the statute's language or implicitly contained in its structure and purpose." In the absence of an express congressional command, state law is preempted if that law actually conflicts with federal law, or if federal law so thoroughly occupies a legislative field "as to make reasonable the inference that Congress left no room for the States to supplement it."<sup>28</sup>

Traditional preemption analysis begins with statutory interpretation.<sup>29</sup> If the federal statute contains an express preemption clause, then inconsistent state laws within the scope of the clause are pre-

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

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

24 See *Wyeth v. Levine*, 555 U.S. 555, 581 (2009).

25 Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 232 (2000).

26 See Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967, 969 n.9 (2002) ("A search by the author of preemption cases decided by the Supreme Court since 1940 disclosed approximately 150 decided between 1940 and 1980 and an additional 150 in the twenty years between 1980 and 2000, roughly double the amount of the previous forty years.") This section is an updated survey of tort preemption doctrine from Michael P. Moreland, *Tort Reform by Regulation: FDA Prescription Drug Labeling Rules and Preemption of State Tort Claims*, 1 J. HEALTH & LIFE SCI. L. 39 (2007).

27 *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

28 *Id.* (citations omitted)

29 See, e.g., Nelson, *supra* note 25, at 227 (explaining preemption analysis).

empted.<sup>30</sup> If there is no express preemption clause, courts typically then consider whether state law is impliedly preempted, either because Congress has occupied the relevant regulatory field or because state law would pose an obstacle to federal objectives.<sup>31</sup> Most controversial is consideration of federal “purposes and objectives” in preemption cases, where courts attempt to isolate congressional purposes in enacting a statute and then try to determine whether state law stands in the way of that purpose.<sup>32</sup>

Though the preemption debate had simmered for many years in such contexts as federal nuclear safety statutes<sup>33</sup> and cigarette warnings,<sup>34</sup> the most recent spate of controversy and litigation began in January 2006 with the FDA’s release of a revision to its physician labeling rule for prescription drugs and an accompanying preamble asserting that the rule preempted state common law causes of action. Some states had already enacted statutes that provide measures of protection against liability for pharmaceutical defendants demonstrating compliance with FDA requirements,<sup>35</sup> and I will discuss below the differences between such regulatory compliance arguments and my category of “inverse negligence per se.” Preemption at the federal level by the FDA would, of course, have been a much more powerful defense in pharmaceutical products liability litigation than relying on a patchwork of state statutes. The FDA’s action, then, represented a newer, more aggressive approach to federal preemption that some termed “silent tort reform.”<sup>36</sup>

As the debate unfolded, five questions were at the heart of the FDA preemption debate that are also pertinent to other regulatory

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30 Among the cases discussed in this Article, *Riegel v. Medtronic*, 552 U.S. 312 (2008), provides the clearest example of express preemption. Though outside the scope of this Article’s subject, cases involving ERISA preemption provide a leading example of express preemption analysis. See, e.g., *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 57 (1987) (holding that a state law claim was preempted because of the “savings clause, the McCarran-Ferguson Act factors defining the business of insurance, and, most importantly, the clear expression of congressional intent that ERISA’s civil enforcement scheme be exclusive”).

31 See *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)

32 *Id.* (citation omitted).

33 See e.g., *id.*; *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984).

34 See *Altria Group, Inc. v. Good*, 555 U.S. 70 (2008); *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504 (1992).

35 See e.g. MICH. COMP. LAWS § 600.2946(5) (2007); N.D. CENT. CODE § 28-01.1-05(3) (1991); N.J. REV. STAT. § 2A:58C-4 (2001); OHIO REV. CODE ANN. § 2307.80(C) (West 2005); OR. REV. STAT. § 30.927 (2003); TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 (VERNON 2003); UTAH CODE ANN. § 78B-8-203. (West 2002).

36 Stephen Labaton, ‘*Silent Tort Reform*’ Is Overriding States’ Powers, N.Y. TIMES, Mar. 10, 2006, at C5.

settings. Part of my argument in defending an alternative approach to preemption is that the interminable debates around these questions frustrate progress in adequately understanding preemption. First, where Congress has not expressly preempted state law (or where a statute is ambiguous) how broadly may courts invoke principles of conflict preemption to find state tort claims preempted? Beginning in 2000 with *Geier v. American Honda Motor Company*,<sup>37</sup> the Supreme Court has decided a series of preemption cases involving statutes that did not *expressly* preempt state common law claims but in which the Court has occasionally adopted a broader doctrine of implied *conflict* preemption. Because the FDA labeling cases based on failures to warn and the automobile design defect cases discussed below did not, almost everyone would agree, pose an example of express or implied field preemption, the cases turned on obstacle conflict preemption analysis.<sup>38</sup>

Second, are state tort claims “regulations” that pose a potential conflict with federal regulations? A recurring question in the preemption debate is whether permitting judges and juries to second-guess federal administrative safety determinations undermines the federal safety regime. Justice Blackmun’s partial concurrence and dissent in *Cipollone v. Liggett Group*<sup>39</sup> is the most forceful statement of the view—now widely discarded—that tort law simply serves different purposes than regulation and that defendant manufacturers should view common law judgments for damages simply as the “cost of doing business”.<sup>40</sup> That view stands in stark contrast to Justice Breyer’s claim in *Geier*—now widely accepted—that common law liability poses effi-

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37 529 U.S. 861 (2000).

38 But see Richard A. Epstein, *The Case for Field Preemption of State Laws in Drug Cases*, 103 NW. U. L. REV. 463 (2009).

39 505 U.S. 504 (1992).

40 *Id.* at 536 (Blackmun, J., concurring in part and dissenting in part) (internal citations omitted):

The effect of tort law on a manufacturer’s behavior is necessarily indirect. Although an award of damages by its very nature attaches additional consequences to the manufacturer’s continued unlawful conduct, no particular course of action (*e.g.*, the adoption of a new warning label) is required. A manufacturer found liable on, for example, a failure-to-warn claim may respond in a number of ways. It may decide to accept damages awards as a cost of doing business and not alter its behavior in any way. Or, by contrast, it may choose to avoid future awards by dispensing warnings through a variety of alternative mechanisms, such as package inserts, public service advertisements, or general educational programs. The level of choice that a defendant retains in shaping its own behavior distinguishes the indirect regulatory effect of the common law from positive enactments such as statutes and administrative regulations. Moreover, tort law has an entirely separate

ciency and administrative obstacles that may thwart the federal safety regime.<sup>41</sup>

Third, how should traditional considerations of federalism affect the preemption debate? Invocations of state sovereignty and deference to the traditional role of the states in such areas as tort law dominate the preemption case law. One side, as expressed by Erwin Chemerinsky, argues that “[c]onservatives are hypocrites when it comes to federalism,” because judicial and political conservatives favor federalism in many contexts but not when it helps corporations evade state tort liability.<sup>42</sup> Others argue that preemption serves the goals of a national market and that constitutional federalism is consistent with a national regulatory approach.<sup>43</sup> This disagreement over the role of the states and the federal government is reflected in lobbying and public relations efforts over preemption by, on one side, the business lobby (such as the U.S. Chamber of Commerce and the National Association of Manufacturers)<sup>44</sup> and on the other, state and consumer-interest groups (such as the National Conference of State Legislatures).<sup>45</sup> More generally, the preemption debate has often focused narrowly on details of statutory interpretation and avoided structural constitutional questions, leading Richard Epstein and Michael Greve to argue in their introduction to a set of essays on preemption that “[w]hat the preemption debate needs . . . is an examination that reflects the delicate interplay between broad institutional considera-

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function—compensating victims—that sets it apart from direct forms of regulation.

*Id.* at 536–37.

41 *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 865 (2000). An interesting related issue but beyond the scope of my topic is whether tort plaintiffs have a right to redress under common law that an expansive doctrine of federal preemption would jeopardize. See John C.P. Goldberg, *The Constitutional Status of Tort Law: Due Process and the Right to a Law for the Redress of Wrongs*, 115 *YALE L.J.* 524, 587–89 (2005).

42 Erwin Chemerinsky, *Empowering States: The Need to Limit Federal Preemption*, 33 *PEPP. L. REV.* 69, 69 (2005).

43 See Alan Schwartz, *Statutory Interpretation, Capture, and Tort Law: The Regulatory Compliance Defense*, 2 *AM. L. & ECON. REV.* 1 (2000); see also Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 *J. TORT LAW* 1 (2006) (arguing the adoption of a contrary position whereby the comprehensive nature of FDA regulation should be treated as occupying the field).

44 *Federal Preemption Cases*, NAT’L CHAMBER LITIG. CTR., available at <http://www.chamberlitigation.com/cases/issue/federal-preemption> (last visited Nov. 22 2012).

45 *Preemption Monitor*, NAT’L CONFERENCE OF STATE LEGS., available at <http://www.ncsl.org/state-federal-committees.aspx?tabs=854,14,825> (last visited Nov. 22, 2012).

tions and regulatory detail.”<sup>46</sup> Or as Ernest Young observes in the same volume, “[w]e need a *Democracy and Distrust* for federalism doctrine—that is, a doctrine of judicial review constructed to protect the self-enforcing nature of the federalist system.”<sup>47</sup>

Fourth, should one’s view of the adequacy of the agency’s safety oversight affect preemption analysis? Justice Stevens’ opinions for the Court in *Medtronic v. Lohr*<sup>48</sup> and *Wyeth v. Levine*<sup>49</sup> raised the issue of whether the FDA and other agencies charged with overseeing safety regimes are capable of effectively approving new products and monitoring their safety once brought to market. Such a concern is based in the view, however accurate, that “[t]he FDA is an underfunded agency charged with regulating products that collectively constitute nearly 25% of the US gross domestic product.”<sup>50</sup> If concerns about agency effectiveness amid budget constraints continue, how, if at all, should that shape courts’ willingness to find preemption of state common law claims?

Fifth, are agency determinations with respect to preemption entitled to administrative deference? Arguably, the issue that most divides the courts that have addressed preemption over the past several years is whether agency conclusions about preemption—whether express or implied—are entitled to administrative deference. Justice Breyer’s opinions for the Court in *Geier* and in *Williamson v. Mazda* clearly signal the Court’s willingness to treat the preemptive determinations of agencies with deference in some contexts, perhaps even where the agency has changed its position over time. But the Court in *Wyeth v. Levine* was unwilling to defer to the FDA and called into doubt the objectivity of the agency’s conclusion that its labeling rule was preemptive. Preemption frequently turns on whether courts defer toward agency views on preemption for the reasons articulated in *Geier* or, instead, worry that political considerations have undermined agency expertise and judgment, thereby rendering agency views unworthy of deference as argued in *Levine*.

With those questions in mind, this section of the Article will survey three particular settings for preemption of state tort claims: medi-

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46 Richard A. Epstein & Michael S. Greve, *Introduction: Preemption in Context*, in *FEDERAL PREEMPTION: STATES’ POWERS, NATIONAL INTERESTS* 1, 2 (Richard A. Epstein & Michael S. Greve eds., 2007).

47 Ernest A. Young, *Two Cheers for Process Federalism*, 46 *VILL. L. REV.* 1349, 1395 (2001).

48 518 U.S. 511 (1995).

49 555 U.S. 555 (2008).

50 Bruce M. Psaty & R. Alta Charo, *FDA Responds to Institute of Medicine Drug Safety Recommendations—In Part*, 297 *JAMA* 1917, 1917 (2007).

cal devices, automobile safety, and the labeling of prescription drugs. In each area, we will find two cases that come to opposing conclusions about whether federal regulations preempt the state product liability claim. While many of the foregoing considerations are brought to bear by the Court in deciding that the products liability claim is preempted here but not there, such considerations are, I will argue in Part II, under-determinative of the wildly unpredictable results that the Court has reached. Instead, consideration of the traditional tort doctrine of negligence per se, albeit inversely (because employed here by defendants), will help to make better sense of the Court's patchwork of preemption jurisprudence.

*B. Medical Devices: Medtronic v. Lohr and Riegel v. Medtronic*

In *Medtronic v. Lohr*, the Court faced a preemption claim based on the 1976 Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA), which regulate the "safety and effectiveness of medical device intended for human use."<sup>51</sup> The plaintiff in *Lohr* alleged that her pacemaker failed due to a product defect.<sup>52</sup> Medtronic argued that the conflicting "requirement" provision of the MDA preempted the state products liability claim:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.<sup>53</sup>

The Court held that the Lohrs' claims were not preempted by the MDA.

[W]hen Congress enacted § 360k [of the MDA] Justice Stevens wrote for the majority, it was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions. . . . In each instance, the word is linked with language suggesting that its focus is device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries.<sup>54</sup>

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51 Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976).

52 *Medtronic*, 518 U.S. at 480–81.

53 21 U.S.C. § 360k(a) (1938).

54 *Medtronic*, 518 U.S. at 489.

More particularly, the Court argued that the MDA preempts state law that imposes requirements, according to the statute, with respect to medical devices. “[T]he general state common-law requirements in this suit were not,” according to the Court,

specifically developed “with respect to” medical devices. . . . These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that [the MDA] envisioned to be “with respect to” specific devices such as pacemakers.<sup>55</sup>

Additionally, in the background of Justice Stevens’ opinion for the Court in *Lohr* was a public policy concern that the FDA’s approval process for the pacemaker was not sufficiently protective of patient safety. Amid a detailed recitation of the FDA medical device approval process, the Court drew a distinction between the “rigorous” pre-market approval process that new devices undergo and the cursory review accorded to devices that are “substantially equivalent” to preexisting devices and are granted approval without needing to undergo the full pre-market approval process.<sup>56</sup> On account of the FDA’s limited ability to conduct full-scale pre-market review of many devices, “the § 510(k) premarket notification process became the means by which most new medical devices . . . were approved for the market.”<sup>57</sup>

In a concurrence that provided a fifth vote for the judgment in the case, Justice Breyer argued that the plurality opinion was wrong to foreclose the possibility that the MDA could preempt a state tort claim. “One can,” Justice Breyer argued, “reasonably read the word ‘requirement’ as including the legal requirements that grow out of the application, in particular circumstances, of a State’s tort law.”<sup>58</sup> In support, Justice Breyer relied on the Court’s (and Justice Stevens’s) own words in *Cipollone v. Liggett Group, Inc.*, holding that “similar language ‘easily’ encompassed tort actions because ‘[state] regulation can be as effectively exerted through an award of damages as through some form of preventative relief.’”<sup>59</sup> Attacking the plurality’s asserted distinction between a conflicting state regulation and a conflicting state court judgment, Justice Breyer argued that “[t]o distinguish between them for pre-emption purposes would grant greater

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55 *Id.* at 501–02.

56 *Id.* at 476–79.

57 *Id.* at 479.

58 *Id.* at 504.

59 *Id.* (quoting *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 521 (1992)) (alteration in original).

power . . . to a single state jury than to state officials acting through state administrative or legislative lawmaking processes.”<sup>60</sup>

Justice Breyer agreed with the plurality, however, that the MDA’s statutory language with respect to preemption of product defect claims for medical devices that underwent the cursory premarket notification process was ambiguous and that, in turn, the Court should look to the preemption determination of the relevant agency: “[I]n the absence of a clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect.”<sup>61</sup> Because the FDA itself had issued a narrowing preemption regulation in this context, Justice Breyer concurred with the Court’s conclusion that the plaintiff’s claim in *Lohr* was not preempted and that the FDA’s determination was entitled to deference. But in a passage that would have lasting effect for the Court’s preemption jurisprudence, Justice Breyer noted that an agency can communicate preemptive intentions “through statements in ‘regulations, preambles, interpretive statements, and responses to comments,’ as well as through the exercise of its explicitly designated power to exempt state requirements from pre-emption.”<sup>62</sup>

In dissent, Justice O’Connor, joined by Chief Justice Rehnquist, Justice Scalia, and Justice Thomas, argued that the MDA preempted the common law claims. Justice O’Connor agreed with Justice Breyer that common law claims “impose ‘requirements’ and are therefore pre-empted where such requirements would differ from those imposed by the FDCA.”<sup>63</sup> Justice O’Connor would not, however, have deferred to the FDA’s own views regarding preemption: “It is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference . . . . Where the language of the statute is clear, resort to the agency’s interpretation is improper.”<sup>64</sup>

In retrospect, *Lohr* stands for at least two propositions, one “pre-emption” and one “anti-preemption.” Most squarely, of course, the decision holds that the MDA does not preempt state common law claims for defects in medical devices that undergo cursory premarket notification. But Justice Breyer’s concurrence signaled the potential

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60 *Id.*

61 *Id.* at 505.

62 *Id.* at 506 (citation omitted) (quoting *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 721 (1985)).

63 *Id.* at 509 (O’Connor, J., concurring in part and dissenting in part).

64 *Id.* at 512.

for finding preemption in related contexts and provided the basis for favoring preemption in later cases through his argument about the effect of state tort claims on the federal safety regime. The countervailing policy considerations of FDA safety oversight (in Justice Stevens' opinion for the Court) and of concerns about judicial second-guessing of agency safety determinations (in Justice Breyer's concurrence) were clearly framed in *Lohr*. Similarly, the dispute between Justice Breyer's concurrence and Justice O'Connor's dissent with respect to deference to agency preemption determinations arises in subsequent preemption cases.

Twelve years later, in *Riegel v. Medtronic*,<sup>65</sup> the Court held that the preemption clause enacted in the MDA *does* bar common law claims challenging the safety or effectiveness of a medical device that went through the full premarket approval process before the FDA.<sup>66</sup> Writing for the Court, Justice Scalia began by giving a detailed explanation of the regulatory regime that establishes various levels of oversight from the FDA of the medical device approval process. Class III devices receive the most federal oversight, including the device at issue in the case (a balloon catheter). "Premarket approval is a 'rigorous' process," which includes hours of reviewing each application, reporting requirements, and the authority to withdraw premarket approval based on new information.<sup>67</sup>

The plaintiff's complaint alleged that Medtronic's catheter was defectively designed, labeled, and manufactured. Since the MDA expressly preempts only state requirements "different from, or in addition to, any requirement applicable . . . to the device" under federal law, the Court had to determine, first, whether the federal government established requirements applicable to defendant's catheter, and, if so, whether the plaintiffs' common law claims were based upon New York requirements with respect to the device that were "different from, or in addition to" the federal requirements.<sup>68</sup>

Relying on *Lohr*, the Court answered the first question in the affirmative, noting that "[p]remarket approval . . . imposes 'requirements' under the MDA."<sup>69</sup> As to the second issue, the question was "whether New York's [common law] tort duties constituted 'requirements' under the MDA."<sup>70</sup> The Court adhered to the view in *Lohr* in which "five Justices concluded that common-law causes of action for

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65 552 U.S. 312 (2008).

66 *Id.*

67 *Id.* at 317–18.

68 *Id.* at 316.

69 *Id.* at 322.

70 *Id.* at 323.

negligence and strict liability do impose ‘requirement[s]’ and would be pre-empted by federal requirements specific to a medical device.”<sup>71</sup>

In deciding that design defect claims about devices approved by the FDA through the full pre-market approval process were pre-empted, the Court rejected the view that “it is difficult to believe that Congress would, without comment, remove all means of judicial recourse” for consumers injured by FDA-approved devices.<sup>72</sup> Justice Scalia noted that this is simply what a preemption clause does, and “[i]t is not [the Court’s] job to speculate upon congressional motives.”<sup>73</sup> The Court rejected plaintiffs’ arguments that “the duties underlying negligence, strict-liability, and implied-warranty claims are not pre-empted even if they impose ‘requirements’ because general common law duties are not requirements maintained with respect to devices.”<sup>74</sup>

Justice Stevens concurred and attempted to reconcile the Court’s holding in *Riegel* with his own opinion for the Court in *Lohr*. He noted that the MDA’s text does, in fact, preempt state law requirements that differ and that “the language of the provision reaches beyond such regulatory regimes to encompass other types of ‘requirements.’ Because common-law rules administered by judges, like statutes and regulations, create and define legal obligations, some of them unquestionably qualify as ‘requirements.’”<sup>75</sup> Justice Ginsburg’s lone dissent argued that Congress could not have “intend[ed] § 360k(a) to effect a radical curtailment of state common-law suits seeking compensation for injuries caused by defectively designed or labeled medical devices”<sup>76</sup> and that statutes “containing a preemption clause do not . . . escape the presumption against preemption.”<sup>77</sup>

### C. *Automobile Safety: Geier v. American Honda and Williamson v. Mazda*

It took only four years for Justice Breyer’s concurrence in *Medtronic* to become the basis for his opinion for the Court in *Geier*,<sup>78</sup> arguably the most important products liability preemption decision of the past 25 years, though its lasting effect on preemption jurispru-

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71 *Id.* at 323–24.

72 *Id.* at 326.

73 *Id.*

74 *Id.* at 327 (internal quotation marks).

75 *Id.* at 332 (Stevens, J., concurring).

76 *Id.* at 333 (Ginsburg, J., dissenting).

77 *Id.* at 334.

78 *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000).

dence has been called into question by *Williamson* and *Levine*.<sup>79</sup> At issue in *Geier* was whether a Federal Motor Vehicle Safety Standard (FMVSS) regarding airbags issued by the Department of Transportation would preempt a tort suit brought in the District of Columbia in which the plaintiff claimed that the manufacturer should have installed an airbag in her vehicle.<sup>80</sup>

Turning first to Honda's argument that the underlying federal statute in *Geier* (the National Traffic and Motor Vehicle Safety Act of 1966) expressly preempted the plaintiff's claims, the Court noted that the statute contained a "saving" clause that preserved common law claims.<sup>81</sup> Specifically, the clause stated that compliance with a federal safety standard "does not exempt any person from any liability under common law."<sup>82</sup> But the Court quickly moved to analyze conflict preemption and noted that "the saving clause . . . does *not* bar the ordinary working of conflict pre-emption principles."<sup>83</sup>

Justice Breyer argued that permitting state courts to entertain common law claims would necessarily interfere with achieving federal objectives. According to Justice Breyer, such an approach would "avoid the conflict, uncertainty, cost, and occasional risk to safety itself that too many different safety-standard cooks might otherwise create."<sup>84</sup> Conflict preemption is applicable in such cases, the Court contended, because "the rules of law that judges and juries create or apply in such [state common law] suits may themselves similarly create uncertainty and even conflict, say, when different juries in different States reach different decisions on similar facts."<sup>85</sup> Adopting a view of common law claims that sharply contrasts with the view of Justice Blackmun in *Cipollone*, the Court in *Geier* asserted that "[i]nsofar as [plaintiffs'] argument would permit common-law actions that 'actually conflict' with federal regulations, it would take from those who would enforce a federal law the very ability to achieve the law's congressio-

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79 See *Davis*, *supra* note 26, at 1012 ("*Geier* represents a seismic shift in the Court's preemption doctrine.").

80 *Geier*, 529 U.S. at 864–65.

81 *Id.* at 867–68.

82 *Id.* at 868 (quoting 15 U.S.C. § 1397(k) (1988)).

83 *Id.* at 869; see also *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995) ("The fact that an express definition of the pre-emptive reach of a statute 'implies'—*i.e.*, supports a reasonable inference—that Congress did not intend to pre-empt other matters does not mean that the express clause entirely forecloses any possibility of implied pre-emption.").

84 *Geier*, 529 U.S. at 871.

85 *Id.*

nally mandated objectives that the Constitution, through the operation of ordinary preemption principles, seeks to protect.”<sup>86</sup>

On the issue of deference to an agency’s own determination with respect to the preemptive effect of federal statutory or regulatory requirements, the Court accorded significant weight to the Department of Transportation’s interpretation of the FMVSS as expressed by the views of the Solicitor General in *Geier*. As summarized by the Court:

The agency is likely to have a thorough understanding of its own regulation and its objectives and is ‘uniquely qualified’ to comprehend the likely impact of state requirements. And DOT has explained [the FMVSS’s] objectives, and the interference that ‘no airbag’ suits pose thereto, consistently over time. In these circumstances, the agency’s own views should make a difference.<sup>87</sup>

In taking such a forceful position on deference to an agency’s views about preemption, the Court did not address whether it was employing the same deferential standard the Court applies in other administrative law settings pursuant to *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*,<sup>88</sup> and later cases have been erratic in their discussion of agency deference.<sup>89</sup>

Joined by Justices Souter, Thomas, and Ginsburg, Justice Stevens dissented in *Geier*.<sup>90</sup> Agreeing with the Court that the federal statute did not expressly preempt the state common law claims, Justice Stevens proceeded to argue that neither did the federal statute impliedly preempt the claims under principles of conflict preemption.<sup>91</sup> With respect to the central issue in the conflict preemption analysis—whether the state requirement would frustrate or undermine the federal safety interest—Justice Stevens argued that the safety standard imposed “minimum, rather than fixed or maximum, requirements.”<sup>92</sup> Exposure to tort liability would, in fact, help achieve the federal safety goal, according to Justice Stevens: “The possibility that exposure to potential tort liability might accelerate the rate of increase [of airbag installation] would actually further the only goal explicitly mentioned

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86 *Id.* at 872.

87 *Id.* at 883 (citations omitted).

88 467 U.S. 837 (1984).

89 See Nina A. Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737 (2004) (arguing that *Chevron* deference should not apply to agency interpretation of preemptive effect of statutes).

90 *Geier*, 529 U.S. at 886 (Stevens, J., dissenting).

91 *Id.* at 899.

92 *Id.* at 903.

in the standard itself: reducing the number of deaths and severity of injuries of vehicle occupants.”<sup>93</sup>

Finally, Justice Stevens raised a public policy argument grounded in federalism and the presumption against preemption, particularly “when the pre-emptive effect of an administrative regulation is at issue.”<sup>94</sup>

The signal virtues of this presumption are its placement of the power of pre-emption squarely in the hands of Congress, which is far more suited than the Judiciary to strike the appropriate state/federal balance (particularly in areas of traditional state regulation), and its requirement that Congress speak clearly when exercising that power. In this way, the structural safeguards inherent in the normal operation of the legislative process operate to defend state interests from undue infringement.<sup>95</sup>

This so-called presumption against preemption dates to the Supreme Court’s 1947 decision in *Rice v. Santa Fe Elevator Corporation*<sup>96</sup> (a field preemption case) in which the Court stated that “in a field which the States have traditionally occupied . . . [the Court] start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”<sup>97</sup> Following *Geier*, many commentators have followed Justice Stevens’s lead and claimed that the Court has eliminated the presumption against preemption.<sup>98</sup> In defense of the Court’s disregard of the presumption against preemption in *Geier*,

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93 *Id.* at 903–04.

94 *Id.* at 908.

95 *Id.* at 907; *see also* *Watters v. Wachovia Bank, N.A.*, 550 U.S. 1, 44 (2007) (Stevens, J., dissenting) (“[T]he fact that [the Tenth] Amendment was included in the Bill of Rights should nevertheless remind the Court that its ruling affects the allocation of powers among sovereigns. Indeed, the reasons for adopting that Amendment are precisely those that undergird the well-established presumption against preemption.”).

96 331 U.S. 218 (1947).

97 *Id.* at 230.

98 *See e.g.*, Calvin Massey, “Joltin’ Joe Has Left and Gone Away”: *The Vanishing Presumption Against Preemption*, 66 ALB. L. REV. 759 (2003); Susan Raeker-Jordan, *A Study in Judicial Sleight of Hand: Did Geier v. American Honda Motor Co. Eradicate the Presumption Against Preemption?*, 17 BYU J. PUB. L. 1 (2002). *But see* Roderick M. Hills, Jr., *Against Preemption: How Federalism Can Improve the National Legislative Process*, 82 N.Y.U. L. REV. 1, 62 (2007) (“The rumors of the death of the *Rice* presumption against preemption may be exaggerated. Against *Geier*, one can set three more recent decisions that refused to preempt state law, one of which recited *Rice*’s clear statement rule as a justification for its holding. If the Court were so inclined, there is little doubt that the ambiguity in its preemption precedents would leave it ample room to convert *Rice* into a more powerful default rule disfavoring preemption by ambiguous federal

however, one could argue that the presumption is primarily a rule of statutory interpretation in *express* preemption cases (and so was rightly prominent in *Lohr*) but has generally and rightly not been invoked by the Court in conflict preemption cases, though, the invocation of the presumption against preemption (as with principles of agency deference) has been erratic and unhelpful to resolving preemption cases.

In *Geier*, the fault lines on preemption were sharply drawn, even if shifting and unstable majorities on the Court have come to different holdings in later cases. Justice Stevens's insistence on a broad presumption against preemption and reluctance to find preemption based solely on administrative determinations has found expression in several subsequent cases.<sup>99</sup> But Justice Breyer's majority opinion for the Court signals all of the major themes of the argument on behalf of federal preemption:

The conflict between state common law claims and the aims of federal uniform safety regulation,

Deference to an administrative agency's own determinations about the preemptive effect of its statutes or regulations, and

The potentially expansive scope of implied conflict preemption even where express preemption is not available as a matter of statutory interpretation.

In *Williamson v. Mazda Motor of America, Inc.*,<sup>100</sup> the Court confronted a case that, on its face, seemed to pose the same issues as *Geier*. Just as the automobile manufacturers in *Geier* had a choice under the federal regulatory regime among different types of passive safety restraints, so also Mazda argued that the choice between lap-and-shoulder belts or only lap belts preempted a jury from second-guessing the manufacturer's decision.<sup>101</sup> But the Court—indeed, Justice Breyer, the same member of the Court who had written for the Court in *Geier*—held that the state tort suit was not preempted.<sup>102</sup>

The key distinction between *Geier* and *Williamson* is the different answers given to the question of whether the manufacturer's choice among safety measures is a "significant objective of the federal regulation."<sup>103</sup> In drawing this distinction, the Court looks to the regulation itself, its history, and the agency's views about the regulation's objec-

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laws.") (citing *Gonzales v. Oregon*, 546 U.S. 243 (2006); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002)).

99 See, e.g., *Watters*, 550 U.S. at 22–44 (Stevens, J., dissenting).

100 131 S. Ct. 1131 (2011).

101 *Id.* at 1140.

102 *Id.* at 1134.

103 *Id.*

tives and its preemptive effect. The Court held that the 1989 version of Federal Motor Vehicle Safety Standard 208 (FMVSS 208) does not preempt state tort suits claiming that manufacturers should have installed lap-and-shoulder belts, instead of lap belts, on rear inner seats because providing manufacturers with this seatbelt choice is not a “significant objective” of the federal regulation.<sup>104</sup>

As explained by Justice Breyer in *Williamson*, in *Geier* the Court held that the 1984 version of FMVSS 208 preempted a state law tort suit that would have deprived the manufacturers of the choice, given to them by the federal regulations, to choose a mix of several different passive restraint systems because such a choice was a significant objective of the federal regulation.<sup>105</sup> The history of the 1984 regulation, the agency’s contemporaneous explanation, and the federal government’s current understanding of the regulation convinced the Court that manufacturer choice was an important regulatory objective. (For instance, in *Geier*, the Department of Transportation hoped that a mix of passive restraint systems would lead to better information about the devices’ comparative effectiveness and to the eventual development of “alternative, cheaper, and safer passive restraint systems.”<sup>106</sup>)

Justice Breyer explained that, in *Geier*, the Court divided the pre-emption question into “three subsidiary questions”: (1) “[W]hether the statute’s *express* pre-emption provision preempted the state tort suit;” (2) whether the saving clause “foreclose[d] or limit[ed] ‘the operation of ordinary pre-emption principles insofar as those principles instruct us to read’ federal statutes as pre-empting state laws . . . that ‘actually conflict’ with the federal statutes;” and (3) “whether . . . the state tort action conflicts with the federal regulation.”<sup>107</sup> In *Williamson*, the Court again looked to those three questions and noted that “[i]n light of *Geier*, 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>108</sup> As a result, the Court turned its attention once again to *Geier*’s third subsidiary question.

Although the history of the regulation of seat belts for rear inner seats was somewhat similar to the history of the regulation of airbags, there were some crucial differences. Unlike with airbags,

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104 *Id.* at 1137.

105 *Id.*

106 *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 879 (2000).

107 *Williamson*, 131 S. Ct. at 1135–36 (citing *Geier*, *ibid.*).

108 *Id.* at 1136.

DOT here 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>109</sup>

There was evidence that the reason the federal agency did not require lap-and-shoulder belts in these seats was because of possible entry and exit problems on account of stretching the shoulder belt across the aisle, but it encouraged manufacturers to address this issue through innovation.<sup>110</sup> Also, the agency did not require lap-and-shoulder belts because it did not think the requirement would be cost-effective, though costs would presumably not remain frozen.<sup>111</sup> Thus, although the state tort suit may restrict the manufacturer's choice, it does not "stan[d] as an obstacle to the accomplishment . . . of the full purposes and objectives' of federal law," and the regulation does not preempt the tort action in *Williamson*.<sup>112</sup>

Writing in concurrence, Justice Sotomayor—now the leading opponent of federal preemption on the Court following Justice Stevens's retirement—agreed with the majority and wrote separately only to emphasize the Court's rejection of an overreading of *Geier* that had developed in the lower courts and that:

*Geier* does not stand . . . for the proposition that any time an agency gives manufacturers a choice between two or more options, a tort suit that imposes liability on the basis of one of the options is an obstacle to the achievement of a federal regulatory objective and may be pre-empted.<sup>113</sup>

#### D. Prescription Drug Labeling: *Wyeth v. Levine* and *PLIVA v. Mensing*

In *Wyeth v. Levine*, the Court held that claims against the manufacturer of an antihistamine (used to treat nausea) for failing to adequately warn of the dangers of administering the drug intravenously using an IV-push (rather than IV-drip) were not preempted.<sup>114</sup> The

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109 *Id.* at 1138.

110 *Id.*

111 *Id.* at 1139.

112 *Id.* at 1140 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

113 *Id.* at 1140 (Sotomayor, J., concurring) (citations omitted). Justice Thomas also concurred on the grounds that the Safety Act's saving clause speaks directly to the question: "Read independently of the express pre-emption clause, the saving clause simply means what it says: FMVSS 208 does not preempt state common law actions." *Id.* at 1141–42 (Thomas, J., concurring).

114 555 U.S. 555, 555 (2009).

Court rejected the defendant's arguments that (1) the manufacturer could not have modified the warning label placed on the drug once it had been approved by the FDA and that it was impossible for the manufacturer to comply with both state law duties underlying failure-to-warn claims and its federal labeling duties, or (2) requiring the manufacturer to comply with a state law duty to provide stronger warning about IV-push administration—after the FDA had previously approved the warning label placed on the drug—would obstruct the purposes and objectives of the federal prescription drug labeling regulation.<sup>115</sup>

The issue in *Levine* was whether FDA approval of Wyeth's labeling of the drug Phenergan provided Wyeth with a complete defense to plaintiff's tort claim.<sup>116</sup> In answering whether federal law preempted the plaintiff's claim that Phenergan's label did not contain an adequate warning about using the IV-push method of administration, the Court noted two guides to its reasoning: First, "the purpose of Congress is the ultimate touchstone in every pre-emption case,"<sup>117</sup> and, second:

[I]n all pre-emption cases, and particularly in those in which Congress has "legislated . . . in a field which the States have traditionally occupied" . . . we "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."<sup>118</sup>

Wyeth's arguments were based on conflict preemption. Wyeth first argued that *Levine*'s state law claims were preempted, because it would be impossible for Wyeth to comply both with the state law duties underlying those claims and with its federal labeling duties under the FDCA.<sup>119</sup> While, generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application, if a manufacturer is changing a label to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may make the labeling change upon filing its supplemental application to the FDA and need not wait for FDA approval—the so-called "'changes being effected' (CBE) regulation."<sup>120</sup> Wyeth's argument was that a manufacturer may only change its label "to reflect newly acquired information,"<sup>121</sup> but

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115 *Id.* at 564–65.

116 *Id.* at 555.

117 *Id.* at 565 (citations omitted) (alterations in original).

118 *Id.* (citations omitted).

119 *Id.* at 560–61.

120 *Id.* at 568 (citation omitted).

121 *Id.* (citation omitted).

the Court held that this misunderstood the federal regulatory scheme.<sup>122</sup> Strengthening the drug's warning in this case would not cause Wyeth to run afoul of the federal law governing unauthorized distribution and misbranding—in fact, the CBE regulation permitted it.<sup>123</sup> Thus, Wyeth's impossibility preemption defense failed.<sup>124</sup>

Wyeth's second argument was that requiring it to comply with a state law duty to provide a stronger warning about IV-push administration would conflict with the purposes and objectives of federal drug labeling regulation.<sup>125</sup> Wyeth asserted that the plaintiff's product liability claims should be preempted because they interfered with "Congress's purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives."<sup>126</sup> The Court rejected this argument and noted that the FDA cast federal labeling standards as a floor upon which states could build, not a ceiling.<sup>127</sup> Likewise, the FDA had long maintained that state law offers an additional and important layer of consumer protection that complements FDA regulation.<sup>128</sup> Most importantly, Wyeth's argument misconstrued the intent of Congress behind the FDCA, because Congress did not intend the FDCA to preempt state law failure-to-warn claims.<sup>129</sup>

Justice Thomas wrote separately to register his disagreement with the majority's employment of implied preemption analysis and the use of "purposes and objectives" preemption tests.<sup>130</sup> Justice Thomas argued, "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>131</sup> Justice Thomas signaled his view that the Court's entire body of "purposes and objectives" jurisprudence relating to Wyeth's second argument is inherently flawed because the cases "improperly rely on legislative history, broad atextual notions of congressional purpose, and even congressional inaction in order to pre-empt state law."<sup>132</sup> He argued that such an

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122 *Id.* at 569.

123 *Id.* at 570.

124 *Id.* at 573.

125 *Id.*

126 *Id.* (citation omitted).

127 *Id.* at 577–78.

128 *Id.* at 578.

129 *Id.* at 574–75.

130 *Id.* at 583 (Thomas, J., concurring in the judgment).

131 *Id.*

132 *Id.* at 594.

approach to implied preemption encourages an overly expansive reading of statutory text and requires inquiry into matters beyond the scope of judicial review:

[T]his . . . Court's [purposes and objectives] pre-emption jurisprudence facilitates freewheeling, extra-textual, and broad evaluations of the "purposes and objectives" embodied within federal law. This, in turn, leads to decisions giving improperly broad pre-emptive effect to judicially manufactured policies, rather than to the statutory text enacted by Congress pursuant to the Constitution and the agency actions authorized thereby. Because such a sweeping approach to pre-emption leads to the illegitimate—and thus, unconstitutional—invalidation of state laws, I can no longer assent to a doctrine that pre-empts state laws merely because they "stan[d] as an obstacle to the accomplishment and execution of the full purposes and objectives" of federal law as perceived by this Court.<sup>133</sup>

Justice Thomas's concurrence in *Wyeth v. Levine* summarizes the depth of the confusion surrounding the Supreme Court's preemption jurisprudence, particularly in cases of implied preemption. *Levine* was the culmination of several years of litigation and administrative rulemaking over whether the FDA's physician-label approval process for prescription drugs preempted state failure to warn claims.<sup>134</sup> In agreeing with the majority in *Levine* that implied preemption did not apply to the plaintiff's claims, Justice Thomas broke with the other conservatives on the Court in agreeing that plaintiff's claims were not preempted, but he took the occasion to voice his frustration with the Court's overall approach to implied preemption cases. A freewheeling "purposes and objectives" analysis has led, he argued, to an unpredictable and unprincipled set of decisions in implied preemption cases.<sup>135</sup> This problem is compounded by use of the "presumption against preemption" in express preemption cases.<sup>136</sup> Justice Thomas's proposed solution to this confusion was to do away with any narrowing construction of express preemption clauses (thus no longer any "presumption against preemption"), but also for the Court to get out of the business of finding implied preemption where the statute is silent.<sup>137</sup> Such a textualist approach, Justice Thomas argues, is required by constitutional structural considerations such as bicameralism, presentment, and federalism.<sup>138</sup>

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133 *Id.* at 604 (citation omitted).

134 *Id.* at 561–63 (majority opinion).

135 *See id.* at 588 (Thomas, J., concurring in the judgment).

136 *See id.* at 624 (Alito, J., dissenting).

137 *See id.* at 602 (Thomas, J., concurring in the judgment).

138 *Id.* at 585–87.

It is hard to argue with Justice Thomas's view that the Court's preemption jurisprudence is unpredictable and confused, particularly for an area of law that confronts the Court so frequently. The hope that throwing preemption cases into the morass of administrative law levels of agency deference has proven especially unpromising. But it is not clear that Justice Thomas's textualist solution will appreciably resolve the problems of preemption jurisprudence. Even if more members of the Court were inclined to agree that express preemption cases should not adopt a presumption against preemption, Justice Thomas's outright rejection of implied preemption flies in the face of overwhelming precedent for the view that state tort claims can, in some cases, frustrate the aims of federal safety regulation. But, as Catherine Sharkey has recently noted, Justice Thomas, in this respect, offers perhaps the only principled and consistent approach to preemption cases—rejecting any “presumption against preemption” in express preemption cases and refusing even to recognize a doctrine of implied preemption.<sup>139</sup>

In dissent, Justice Alito (joined by Chief Justice Roberts and Justice Scalia) lamented that with the decision in *Levine*, “a state tort jury, rather than the Food and Drug Administration (FDA), is ultimately responsible for regulating warning labels for prescription drugs.”<sup>140</sup> Justice Alito noted that juries are ill-equipped to perform the FDA's cost-benefit-balancing function,<sup>141</sup> and he argued that the holding in *Levine* cannot be reconciled with *Geier*<sup>142</sup> or with the general principles of conflict preemption.<sup>143</sup> According to the dissent, in order to evade *Geier*'s application to the case, the Court compounded both factual and legal errors.<sup>144</sup> For example, Justice Alito asserted that the Court's comment that the 2000 Phenergan label “did not contain a specific warning about the risks of IV-push administration” was untrue, and the physician's assistant who treated the plaintiff disregarded at least six separate warnings on Phenergan's labeling.<sup>145</sup>

The Court's rejection of preemption in *Wyeth v. Levine* seemed to spell the end of defendant manufacturers' argument for FDA preemption of failure to warn claims in labeling cases, particularly when Justice Thomas joined with the more liberal members of the Court in

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139 See Catherine M. Sharkey, *Against Freewheeling, Extratextual Obstacle Preemption: Is Justice Clarence Thomas the Lone Principled Federalist?*, 5 N.Y.U. J. L. & LIBERTY 63 (2010).

140 *Levine*, 555 U.S. at 604 (Alito, J., dissenting).

141 *Id.* at 626.

142 See *id.* at 612, 621.

143 See *id.* at 609–10.

144 *Id.* at 612.

145 *Id.* at 605, 619.

opposing FDA preemption. This conventional wisdom was short-lived, though, for Justice Thomas himself commanded a majority of the Court in upholding a preemption defense just two years later in another prescription drug labeling case, *PLIVA, Inc. v. Mensing*.<sup>146</sup>

The drug in *Mensing*, metoclopramide, aids in treating digestive ailments.<sup>147</sup> FDA approved the drug under the brand-name Reglan in 1980, and, five years later, generic manufacturers began to produce the drug. Evidence has shown that it can cause tardive dyskinesia, a severe neurological disorder.<sup>148</sup> Warning labels on metoclopramide have gradually been strengthened over the years, with the most recent warning stating expressly that treatment can cause tardive dyskinesia.<sup>149</sup> Two separate plaintiffs, Gladys Mensing (Minnesota) and Julie Demahy (Louisiana), were prescribed the generic drug in 2001 and 2002 and developed tardive dyskinesia after taking it for several years.<sup>150</sup>

Mensing and Demahy brought separate claims in which they sued the generic manufacturers, alleging that the drug caused their conditions and that the manufacturers were liable under Minnesota and Louisiana law for failing to provide adequate labels in light of evidence showing the risk was greater than the label indicated.<sup>151</sup> The manufacturers argued the claims were preempted by the federal statute and FDA regulations requiring them to use the same labels as their brand-name counterparts and making it impossible to comply with both state and federal law.<sup>152</sup>

Justice Thomas began by comparing state and federal law. He noted that Minnesota and Louisiana law require a manufacturer that is, or should be, aware of a product's danger to label it in a way that renders it reasonably safe.<sup>153</sup> In Minnesota, there is a duty to warn if the manufacturer has actual or constructive knowledge of a danger.<sup>154</sup> In Louisiana, there is also a duty to provide adequate instructions for the product's safe use.<sup>155</sup> Federal law, Justice Thomas noted, imposes far more complex drug labeling requirements.<sup>156</sup> Under the FDCA, a

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146 131 S. Ct. 2567 (2011).

147 *Id.* at 2572.

148 *Id.*

149 *Id.*

150 *Id.* at 2573.

151 *Id.*

152 *Id.*

153 *Id.* at 2570.

154 *Id.* at 2573.

155 *Id.*

156 *Id.* at 2574.

manufacturer seeking federal approval to market a new drug has to prove the drug's safety and effectiveness and to show that the label is accurate and adequate.<sup>157</sup> Justice Thomas noted that while this formerly applied to all drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Amendments)<sup>158</sup> in 1984 to facilitate the manufacture of generic drugs by allowing generic drugs to gain FDA approval by showing equivalence to an FDA-approved brand-name drug.<sup>159</sup> The generic manufacturer also has to show that the label used on the generic drug is the same as the brand-name drug's approved label.<sup>160</sup>

As a result of Hatch-Waxman, brand-name and generic drug manufacturers have different federal drug labeling duties: the brand-name manufacturer is responsible for the accuracy and adequacy of the label, while the generic manufacturer is responsible for making its label the same as the brand-name drug's label.<sup>161</sup> Justice Thomas pointed out that the parties agreed on this but disagreed over whether generic manufacturers may change their labels after initial FDA approval. The plaintiffs argued that federal law provided avenues through which the defendants could have altered the labels,<sup>162</sup> but the FDA interpreted its regulations to require *identical* labels.<sup>163</sup> The Court noted that the FDA's views were controlling unless they were "'plainly erroneous or inconsistent with the regulation[s]'" or there [was] any other reason to doubt they reflect[ed] the FDA's fair and considered judgment."<sup>164</sup>

The Court then considered the avenues that the plaintiffs claimed the defendants could have used to strengthen the warning label. First and as in *Levine*, the plaintiffs claimed that the FDA's "changes-being-effected" (CBE) process allowed the defendants to change the labels when necessary, because it allowed manufacturers to add or strengthen a warning or instruction without waiting for FDA approval.<sup>165</sup> The FDA said, however, that the generic drug manufacturer defendants could not have used the CBE process unilaterally to strengthen the labels, because the CBE process was intended to allow

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157 *Id.*

158 Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, 282 (2006)).

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

160 *Id.*

161 *Id.*

162 *Id.*

163 *Id.* at 2574–75.

164 *Id.* at 2575 (internal citation omitted).

165 *Id.*

changes only when generic labels were being changed to match updated brand-name labels or to follow FDA instructions.<sup>166</sup> Because the FDA's interpretation was not plainly erroneous, the Court deferred to it.<sup>167</sup>

Second, the plaintiffs argued that the defendants could have used "Dear Doctor" letters to send warnings to prescribing physicians and healthcare professionals.<sup>168</sup> The FDA rejected this as well, because the letters would qualify as labeling and so would be required to be consistent with the drug's approved labeling.<sup>169</sup> A letter with new warnings would be inconsistent with the brand-name labels.<sup>170</sup>

Third, the FDA suggested that the defendants were required themselves to propose stronger warning labels if they thought they were necessary.<sup>171</sup> If the FDA agreed with the need for a stronger warning, it would have worked to create a new label for both the brand-name drug and the generic equivalent. The manufacturers argued that this was not required of them, but the Court noted that this issue did not need to be resolved to decide the case and it could be assumed that such a requirement did exist.<sup>172</sup>

In the Court's view, all of this meant that where state and federal law conflict, and it is impossible for a private party to comply with both, state law gives way to federal law.<sup>173</sup> If the defendants had changed their labels independently, they would have complied with state law but violated federal law. The federal duty to request FDA assistance does not change anything—that would satisfy the federal duty but not the state duty to provide adequate labeling, because state law demanded a *safer label*, not communication with FDA about the *possibility* of a safer label. Thus, it was impossible for the defendants to comply with the state duty to change the label and the federal duty to keep the same label as the brand-name drug.<sup>174</sup>

The Court argued that the holding in *Mensing* was consistent with the Court's holding in *Levine* because the defendant in *Levine* could (unlike the defendants in *Mensing*) have acted unilaterally to change the label through the CBE process.<sup>175</sup> But there is no getting around

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166 *Id.*

167 *Id.*

168 *Id.* at 2576.

169 *Id.*

170 *Id.*

171 *Id.*

172 *Id.* at 2577.

173 *Id.* at 2577–78.

174 *Id.* at 2578.

175 *Id.* at 2580–82.

the odd implication that if the plaintiffs in *Mensing* had been given a brand-name drug then their claims would not have been preempted. The Court's best explanation for this apparent inconsistency is that the FDA's own view is that new information about drugs in long use (such as generic drugs) appears infrequently, because patent protections prevent generic drugs from arriving on the market for several years after the brand-name drug. In the end, the Court simply asserted that it is not the Court's job to decide whether the statutory scheme established by Congress is unusual, and Congress and the FDA can always change the statute or the accompanying regulations.<sup>176</sup>

Part of Justice Thomas's opinion only had the support of a four Justice plurality of the Court. In this portion, Justice Thomas argued that the Supremacy Clause is a *non obstante* provision used to specify the degree to which new statutes are intended to repeal older statutes, and the Supremacy Clause suggests that federal law should be understood as impliedly repealing conflicting state laws.<sup>177</sup> Justice Thomas argued that the Clause also indicated that courts should not strain to find ways to reconcile federal law with seemingly conflicting state law.<sup>178</sup> Further, he argued that considering the contingencies inherent in preemption analysis of these types of cases would be inconsistent with the *non obstante* provision of the Supremacy Clause, because it would force manufacturers to continually prove that the FDA and brand-name manufacturer would not change the label in order to establish the supremacy of federal law, and the Supremacy Clause does not contemplate this sort of "contingent supremacy."<sup>179</sup>

In a strongly worded dissent, Justice Sotomayor (joined by Justices Ginsburg, Breyer, and Kagan) explained that generic drugs have become very popular and make up approximately 75 percent of prescription drugs on the market, which are the fruits of legislative efforts to expand production and consumption of generic drugs, so much so that when generic versions of a drug enter the market the brand-name manufacturer often stops selling the drug.<sup>180</sup> She noted that the Hatch-Waxman Amendments were designed to make more low-cost generic drugs available by establishing generic drug approval procedures that involved an abbreviated application process and that all states have legislation allowing pharmacists to substitute generic drugs

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176 *Id.* at 2582.

177 *Id.* at 2579–80.

178 *Id.* at 2580.

179 *Id.*

180 *Id.* at 2584 (Sotomayor, J., dissenting).

for brand-name drugs.<sup>181</sup> Harkening to the presumption against preemption, Justice Sotomayor argued that, while Congress enacted an express preemption provision for medical devices in 1976, it did not include an express preemption provision in the Hatch-Waxman Amendments eight years later, and this is evidence that Congress did not intend for FDA oversight to be the only way to ensure drug safety and effectiveness.<sup>182</sup>

According to the dissent, while the defendants and the majority both relied on the fact that the defendants could not change their labels unilaterally to distinguish the case from *Levine*, the defendants in *Levine* could have used the CBE process unilaterally but would still have had to wait for FDA approval of the change.<sup>183</sup> Thus, compliance with state and federal law in *Levine* required the action of both the defendants and the FDA. The *Levine* Court required the defendants to show that the FDA would not have approved the changes in order to show impossibility.<sup>184</sup> The same approach, argued Justice Sotomayor, should have applied to *Mensing*.<sup>185</sup> The defendants had a means of complying with the state duty to warn. If the FDA rejected a proposal, did not respond to a proposal, or had considered and rejected the same change earlier, manufacturers could show impossibility, but those considerations were not present in *Mensing*.

Finally, Justice Sotomayor also criticized the plurality's view of the Supremacy Clause. She noted that it adopted a novel interpretation of the Supremacy Clause as a *non obstante* provision, indicating that courts should not apply a presumption against implied repeals.<sup>186</sup> But, in her view, the Court's precedents run to the contrary and presume that congressional action does not supersede the historic police powers of the states unless it is the clear and manifest purpose of Congress.<sup>187</sup>

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181 *Id.* at 2583.

182 *Id.* at 2586–87.

183 *Id.* at 2582–83.

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

185 *PLIVA*, 131 S. Ct. at 2582 (Sotomayor, J. dissenting).

186 *Id.* at 2590–91.

187 *Id.* The Supreme Court will revisit *PLIVA v. Mensing* and preemption of state law design-defect claims against generic drugs during October Term 2012. See *Bartlett v. Mutual Pharmaceutical Co.*, 678 F.3d 30 (1st Cir. 2012), *cert. granted*, 133 S. Ct. 694 (U.S. Nov. 30, 2012) (No. 12-142).

## II. PREEMPTION AND INVERSE NEGLIGENCE PER SE

A. *The Private Law Foundations of Inverse Negligence Per Se*

In *The Idea of Private Law*, Ernest Weinrib notes the dominant tendency of functionalist accounts of law to understand law merely in terms of its purposes. As Weinrib explains, “[t]he functionalist is concerned with whether the results of cases promote the postulated goals. Private law, however, is more than the sum of its results. It also includes a set of concepts, a distinctive institutional setting, and a characteristic mode of reasoning.”<sup>188</sup> So pervasive are such functionalist accounts that in the law of torts we have a difficult time thinking in alternative terms. Negligence in tort law, for example, comes to be understood simply as incentivizing would-be defendants to take the optimal level of precaution, and strict liability is applicable to cases in which there is no optimal level of a defendant’s reasonable care (in cases of ultrahazardous activities) or where the defendant is in the best position to spread the costs of the plaintiff’s injury.<sup>189</sup>

This functionalist approach to tort law is a product of various jurisprudential forces from the late-nineteenth and twentieth centuries. As John Goldberg has traced out, the moral skepticism of Oliver Wendell Holmes led torts scholars of succeeding generations to ascribe to tort law a minimalist, compensation and deterrence-based justification, for any richer conception of tort law’s aims was thought to be too uncertain and too contested to account for tort law’s features.<sup>190</sup> The leading mid-twentieth century treatise on torts by William Prosser, for example, discussed tort law in precisely such compensation and deterrence categories.<sup>191</sup> And when Prosser’s compensation and deterrence view was supplemented by law and economics analysis, torts scholarship substituted one functionalist account for another.

Against this tide of functionalist views, a recent body of work in tort theory has sought to recover the distinctly private law aspects of

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188 ERNEST J. WEINRIB, *THE IDEA OF PRIVATE LAW* 4–5 (1995).

189 *Id.* at 36–37.

190 See John C.P. Goldberg, *Twentieth-Century Tort Theory*, 91 GEO. L.J. 513, 520–21 (2002); John C. P. Goldberg, *Style and Skepticism in The Path of the Law*, 63 BROOK. L. REV. 225, 273–75 (1997); see also John C.P. Goldberg & Benjamin C. Zipursky, *The Moral of MacPherson*, 146 U. PA. L. REV. 1733, 1752–56 (1998) (discussing Holmes’s “assault on duty” and its current place in negligence theory, rooted in his positivism and leanings toward classical liberalism). For a comprehensive and mostly sympathetic view of Holmes’s effect on the evolution of tort law, see DAVID ROSENBERG, *THE HIDDEN HOLMES* (1995).

191 See WILLIAM L. PROSSER, *HANDBOOK OF THE LAW OF TORTS* (4th ed. 1971).

tort law. In addition to Weinrib's broadly Kantian account in *The Idea of Private Law*, so also the civil recourse or "torts as wrongs" view developed by John Goldberg and Benjamin Zipursky<sup>192</sup> and the corrective justice view advanced by Jules Coleman seek—albeit in quite different ways—to question the dominance of functionalist account of tort law.<sup>193</sup> But as Goldberg and Zipursky point out, much work remains to be done by those arguing for a private law account of torts if it is to be vindicated.<sup>194</sup> This is not merely a normative task—that is, arguing for the view that tort law *should* be conceived in private law terms—but also a descriptive task, for much of tort law appears to be based on deterrence-based reasons, or incentive-balancing, and the like.<sup>195</sup> I have chosen an unlikely topic to help make this descriptive and normative case for the private law aspects of torts: federal preemption of state products liability claims.

Preemption as inverse negligence per se seeks to recover an overlooked but obvious feature of preemption cases, namely that they arise as private law tort claims in which an allegedly injured *plaintiff* is suing a particular *defendant*. Preemption is an argument by the *defendant* that a federal statute (expressly or impliedly) prevents the plaintiff's claim from going forward. Much of the preemption debate proceeds as if this were a *jurisdictional* argument of a kind, that is, as if the federal statute or regulation removed a court's jurisdiction to adjudicate the plaintiff's common law tort claim (except for the jurisdiction to hold that the claim has been preempted). A better account would instead emphasize the conflicts of law aspects of preemption and the relation between the choice of federal or state law in torts cases.

The preemption-as-jurisdictional view has been called into doubt by Caleb Nelson's important historical work on preemption, even if one does not follow Justice Thomas and the plurality in *Mensing* in adopting some of the implications of Nelson's historical argument. As

192 John C.P. Goldberg & Benjamin C. Zipursky, *Torts as Wrongs*, 88 TEX. L. REV. 917, 920 (2010); Benjamin C. Zipursky, *Rights, Wrongs, and Recourse in the Law of Torts*, 51 VAND. L. REV. 1, 5 (1998).

193 JULES COLEMAN, *THE PRACTICE OF PRINCIPLE* 3–63 (2001); JULES COLEMAN, *RISKS AND WRONGS* 303–28 (1992).

194 Goldberg & Zipursky, *supra* note 192, at 978.

195 But as Weinrib and others have pointed out, law and economics run into problems with, for example, including causation among the elements of negligence. See WEINRIB, *supra* note 188, at 47–48 (“[E]conomic analysis operates independently of the doctrines, concepts, and institutions that characterize private law. While economists applaud legal results that coincide with efficiency, their framework does not respect the law's characteristic features on their own terms. The economists ‘dispense with’ or regard as ‘alien’ even so central a feature as causation . . .”).

Nelson argues, the Supremacy Clause is best interpreted as an example of an eighteenth century *non obstante* provision: “[The Supremacy Clause] requires courts to ignore [sic] state law if (but only if) state law contradicts a valid rule established by federal law, so that applying the state law would entail disregarding the valid federal rule.”<sup>196</sup> Federal statutes that preempt state law effectively become part of state law.<sup>197</sup> This interpretation allows the different aspects of the Supremacy Clause to be read together; for example, the provisions about state courts and about the supremacy of federal law. A state court (or a federal court sitting in diversity and applying state law) adjudicating a tort claim in which there is a colorable argument for federal preemption should, then, read the federal provision of law as if it were a (supreme) part of state law.<sup>198</sup>

But if a federal statute or regulation is to be read as part of a state’s law—for our purposes, state tort law—what role should it play in deciding the case? My argument is that the most plausible rendering of the role of potentially preemptive federal law in a state tort claim is that the federal law provides a defense to the defendant that is the inverse of negligence per se. By bringing the federal law—a statute or regulation setting a safety standard—within the ambit of state law, we make the best sense of what the effect of federal preemption is

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196 Nelson, *supra* note 25, at 234.

197 *Id.* at 246 (“The first aspect of the Supremacy Clause may strike modern readers as highfalutin rhetoric. But it serves a straightforward function: It sets out what might be called a ‘rule of applicability,’ making clear that federal law applies even in state courts. At least as far as the courts are concerned, then, federal statutes take effect automatically within each state and form part of the same body of jurisprudence as state statutes.”).

198 See Evan H. Caminker, *State Sovereignty and Subordinacy: May Congress Commandeer State Officers to Implement Federal Law?*, 95 COLUM. L. REV. 1001, 1022–23 (1995) (“The relationship between the lawmaking powers of these dual agents [of the federal and state governments] is specified by the Supremacy Clause, which declares that the federal ‘Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land . . .’ The Clause’s injunction that the various forms of federal law (Constitution, statute, treaty, regulatory, and judge-made) constitute the ‘supreme law of the land’ establishes the following picture of dual governance. Within the territory of each state there reigns what I call a corpus of ‘in-state law,’ which itself combines two sets of law from different sources. These are: (a) state law as conventionally understood, meaning the state constitution, statutes, and other forms of positive law; and (b) federal law as conventionally understood, that is by its terms applicable in the state. Because federal law in category (b) supersedes state law in category (a) when they conflict, federal law may also be thought of as ‘supreme in-state law.’ The important conceptual point is that in-state law is comprised of both state and federal law, with the latter dominating the former.”).

within the law of torts, make available to courts a body of well-developed tort doctrine, and avoid the confused meanderings that currently mark preemption cases.

When the federal government acts to preempt state tort law, it operates just as a legislative or administrative determination with respect to the standard of care in the doctrine of negligence per se. The justifications for negligence per se—preference for democratically accountable legislative determination over case-by-case jury adjudication and party reliance on such standards—were classically expressed in such early cases as Judge Cardozo’s opinion in *Martin v. Herzog*<sup>199</sup> and map onto successful claims for preemption. So also cases in which courts refuse to find negligence per se applicable—notably, where the class of protected persons and the type of injury suffered are not within the scope of the statute or regulation—help us understand when courts have not found preemption.<sup>200</sup>

The advantage of this account is that it avoids the confusing, erratic, and under-determinative matrix of express and implied preemption analysis. While normally lumped into questions of administrative law, products liability preemption cases arise as tort claims, in which an allegedly injured plaintiff seeks a remedy against the defendant who (in the *Third Restatement’s* formulation for design and infor-

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199 126 N.E. 814, 815 (N.Y. 1920) (“We think the unexcused omission of the statutory signals is more than some evidence of negligence. It *is* negligence in itself. . . . By the very terms of the hypothesis, to omit, willfully or heedlessly, the safeguards prescribed by law for the benefit of another that he may be preserved in life or limb, is to fall short of the standard of diligence to which those who live in organized society are under a duty to conform.”).

200 From within a modified law and economics framework, Kyle Logue has also recently advanced an argument for undertaking such case-by-case tort-related considerations in preemption cases. See Kyle D. Logue, *Coordinating Sanctions in Tort*, 31 CARDOZO L. REV. 2313, 2346 (2010) (“Courts (at least appellate courts, who are given the ultimate task of interpreting and implementing the boundaries between common law tort claims and non-tort regulatory regimes) should consider the nature of the non-tort regulation at issue and whether the goal of efficient deterrence (i.e., creating optimal ex ante accident-avoidance incentives at the lowest administrative cost) would best be achieved if that regulation is understood as an efficient floor or as both an efficient floor and an efficient ceiling. If the regulation in question is an efficient floor only, then a conclusion of no displacement—or no preemption—would be optimal; and negligence per se should be applied in cases of noncompliance. If the regulation is likely to involve an efficient floor-and-ceiling (a precisely efficient standard of care) but additional state-level enforcement would be useful, then a symmetrical rule of negligence and non-negligence per se would make sense—or one-way displacement/preemption. And, of course, if it happens to be a case in which federal regulation seems to be fully optimizing, the court could reach the full displacement/preemption conclusion, although, again, that would be an extreme result and should not be reached lightly.”).

mational defects) allegedly failed to reduce or avoid the foreseeable risks of harm to a product's user by adopting a reasonable alternative design that rendered the product not reasonably safe.<sup>201</sup> The defense of preemption can, then, be viewed as the inverse of a plaintiff's argument in garden-variety negligence cases that defendant's breach can be established on account of violation of a statutorily- or administratively-established standard of care.

Of course, the traditional use of negligence per se by plaintiffs against defendants in negligence cases is known to every first-year law student. The *Restatement (Second)*'s familiar factors provide that:

The court may adopt as the standard of conduct of a reasonable man the requirements of a legislative enactment or an administrative regulation whose purpose is found to be exclusively or in part

(a) to protect a class of persons which includes the one whose interest is invaded, and

(b) to protect the particular interest which is invaded, and

(c) to protect that interest against the kind of harm which has resulted, and

(d) to protect that interest against the particular hazard from which the harm results.<sup>202</sup>

In Ezra Ripley Thayer's classic formulation:

The true attitude of the courts, therefore, is to ascertain the legislature's expressed intent, to refrain from conjecture as to its unexpressed intent (except in so far as that inquiry is necessary in order to give effect to what is expressed), and then to consider the resulting situation in the light of the common law.<sup>203</sup>

And in Thayer's formulation we see the warrant for case-by-case inquiry in determining the effect of a statute or regulation that frequently evades courts in preemption cases.<sup>204</sup> Where a federal statute displaces manufacturer choice, preemption applies—Congress or the regulatory agency is setting the safety standard. But where a statute or regulation is not intended to cover the class of persons including the plaintiff or (more importantly, because more often the deciding fac-

201 See, e.g., Aaron D. Twerski & James A. Henderson, Jr., *Manufacturers' Liability for Defective Product Design*, 74 BROOK. L. REV. 1061 (2009) (analyzing case law regarding proving the existence of a reasonable alternative design).

202 RESTATEMENT (SECOND) OF TORTS § 286 (1965)

203 Ezra Ripley Thayer, *Public Wrong and Private Action*, 27 HARV. L. REV. 317, 320 (1914).

204 Though I disagree with many of the article's conclusions, a helpful summary of several cases of negligence per se can be found in Robert F. Blomquist, *The Trouble with Negligence Per Se*, 61 S.C. L. REV. 221 (2009).

tor) to protect against the harm suffered by the plaintiff, then preemption should not apply. As summarized by Benjamin Zipursky, in negligence per se:

The plaintiff cannot win unless the injury was a realization of a risk that captures the relevant aspect of the statutory duty imposed upon the defendant. Just as courts doing negligence-per-se analysis must scrutinize the statutory duty-imposing norm to establish the fit with the injury in the case before it, so courts doing scope-of-the-risk analysis in common-law negligence claims must scrutinize the common-law duty-imposing norm to ascertain whether the injury was properly correlated with the imposition of the duty.<sup>205</sup>

Viewing preemption as inverse negligence per se helps to explain two highly peculiar features of preemption doctrine. First, the unevenness and unpredictability of preemption decisions is explained as a failure to attend to more than just slight differences in statutory text or as the federal regulatory objective not being significant. By emphasizing the variation among statutory and regulatory frameworks with regard to protected persons and interests, inverse negligence per se analysis might help to explain the otherwise seemingly random outcomes of preemption cases and to justify judicial scrutiny of the standard of care set by the statute or regulation. Second, the seemingly drastic choice confronting a court in a preemption case—either allow the common law claim to go forward to resolution or deprive the plaintiff of recovery on preemption grounds—is allayed by the judicial discretion to determine in the first instance whether a statute sets a standard of care, which statutory standard to adopt, and whether “a statutory duty is always a valid substitute for common law duty.”<sup>206</sup>

Of course, there is an asymmetry between negligence per se and inverse negligence per se. A court finding negligence per se never addresses the question of whether a legislature or agency intended to displace the plaintiff’s right to bring a claim—indeed, the right to bring the claim is assumed, and negligence per se merely establishes the relevant standard of care. Inverse negligence per se, by contrast, operates to foreclose the plaintiff’s claim and to displace the tort remedy.<sup>207</sup>

Applied to the cases summarized above, we can begin to see how an inverse negligence per se analysis would work. In the pair of medi-

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205 Benjamin C. Zipursky, *Foreseeability in Breach, Duty, and Proximate Cause*, 44 WAKE FOREST L. REV. 1247, 1271 (2009).

206 Paul Yowell, *Judicial Discretion in Adopting Legislative Standards: Texas’s Solution to the Problem of Negligence Per Se?*, 49 BAYLOR L. REV. 109, 126 (1997).

207 I am grateful to John Goldberg for this observation about the asymmetry between negligence per se and inverse negligence per se.

cal device cases, the difference between the anti-preemption holding of *Lohr* and the pro-preemption holding of *Riegel* is more than just an exercise in statutory interpretation, which is too often an under-determinative guide to resolving cases arising under express preemption. It was Congress's intent in enacting the Medical Device Amendments that design defect or failure to warn claims brought by plaintiffs allegedly injured by medical devices that had gone through the full pre-market FDA approval process were foreclosed by the establishment of a federal standard of care with respect to such plaintiffs for such harms. By contrast, in *Lohr* the MDA's silence on preemption for claims for products that have been brought to market by showing similarity to an already-approved device did not set a federal standard of care and leaves intact common law remedies, again with respect to such plaintiffs for such harms.<sup>208</sup>

In *Williamson* and *Geier*, some of the puzzling features of Justice Breyer's discussion of whether manufacturer choice is a substantial federal objective can be reframed as whether claims by classes of prospective plaintiffs who have been injured as a result of particular products are included within the ambit of the federal regulatory standard of care. Some such plaintiffs and injuries caused by some products (such as automobiles designed with lap-only seat belts) will, upon inspection, fall outside the federally established standard of care. But in other cases, design defect claims against automobile manufacturers will fail—as in *Geier*—because the agency contemplated that there would be a class of potential plaintiffs who would suffer injury on account of the lack of an airbag in an automobile and yet intended that manufacturers not face liability for failing to install airbags.<sup>209</sup> In such a case, the agency set the standard of care so as to leave the manufacturer free to adopt the standard as a floor (and to install airbags) or as a ceiling (by not installing airbags) without the prospect of tort liability forcing second-guessing of the decision.<sup>210</sup>

Finally, in both *Wyeth* and *Mensing*, much of the preemption analysis turned on whether the pharmaceutical manufacturer could have altered the label by strengthening the warning or was foreclosed from doing so without FDA approval.<sup>211</sup> While, once again, the Supreme Court's different holdings on the preemption question in *Levine* and *Mensing* seem to turn on statutory interpretation (in Justice Stevens's

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208 *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495–97 (1996).

209 *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000).

210 *Id.* at 868.

211 *See* *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2578 (2011); *Wyeth v. Levine*, 555 U.S. 555, 570–72 (2009).

and Justice Thomas's majority opinions respectively) or in disagreements about the scope of implied preemption (in Justice Alito's dissent in *Levine* or Justice Sotomayor's dissent in *Mensing*), less attention was paid to the class of patients, types of drugs, and potential harms (and countervailing benefits) in the prescription drug labeling cases. Viewed through the guise of inverse negligence per se, it was important in *Levine* that the FDA never had the opportunity to consider whether the risk to a patient buying a particular brand-name drug should be covered by a stronger warning on the label, and so the FDA never established a standard of care for defendant manufacturers in such cases.<sup>212</sup> In *Mensing*, the class of patients protected by the federal regulatory regime (buyers of generic as opposed to brand-name drugs) was different, and the agency rebutted the plaintiffs' arguments that there were steps available to the defendant to strengthen the warning on the label (to conform to a higher standard of care).<sup>213</sup> In such a case, the federal safety regime sets a ceiling on the standard of care such that conformity with that standard is, to adapt Judge Cardozo's formulation, non-negligence in itself.

### B. *Inverse Negligence Per Se and Regulatory Compliance*

My account of inverse negligence per se differs in important respects, if only slightly at some points, from the more familiar regulatory compliance defense. Debates about preemption of state tort claims and the regulatory compliance defense are both debates in which courts struggle with the relationship between standards set by regulatory agencies and standards set by imposition of tort liability. Preemption—a doctrine based in the Supremacy Clause—is a question of constitutional law and federalism that requires courts to consider whether federal law expressly or impliedly displaces state law. The regulatory compliance defense provides that a defendant's compliance with a safety regulation establishes due care as a matter of law.<sup>214</sup> As noted above, only a few states permit the regulatory compli-

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212 *Wyeth*, 555 U.S. at 570–72.

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

214 See Catherine M. Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 J.L. & POL'Y 1013, 1018–19 (2007) (“[T]he recurrent debate—in the academy and the courts—regarding the interplay between federal regulations and state common law tort actions has, in less than a decade, radically shifted from regulatory compliance to federal preemption. If state courts have an institutional interest in preserving the autonomy of state common law from broad federal overrides, then presumably one should expect the same resistance to claims of outright preemption. Perhaps most striking, then, is not the fact that federal courts’ enthusiasm for preemption outpaces state courts, but the fact that pre-

ance defense to serve as a complete defense to liability, and the *Restatements* have been hostile (*Second*) or cautious (*Third*) to regulatory compliance defense. As the *Restatement (Second) of Torts* provides, “[c]ompliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions.”<sup>215</sup> The *Restatement (Third) of Torts: Products Liability* states that:

[A] product’s compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.<sup>216</sup>

As to the relation between regulatory compliance and preemption, the *Restatement (Third) of Torts: Products Liability* offers the following clarification about the difference between regulatory compliance and preemption:

[Regulatory compliance] addresses the question of whether and to what extent, as a matter of state tort law, compliance with product safety statutes or administrative regulations affects liability for product defectiveness. When a court concludes that a defendant is not liable by reason of having complied with a safety design or warnings statute or regulation, it is deciding that the product in question is not defective as a matter of the law of that state. The safety statute or regulation may be a federal provision, but the decision to give it determinative effect is a state-law determination. In contrast, in federal preemption, the court decides as a matter of federal law that the relevant federal statute or regulation reflects, expressly or impliedly, the intent of Congress to displace state law, including state tort law, with the federal statute or regulation. The question of preemption is thus a question of federal law, and a determination that there is preemption nullifies otherwise operational state law. The complex set of rules and standards for resolving questions of federal preemption are beyond the scope of this Restatement. However, when federal preemption is found, the legal effect is clear.<sup>217</sup>

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emption has gained any traction whatsoever in state courts, which by and large have previously rejected any absolute regulatory compliance defense.”); see also Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049 (2004) (explaining the differences between regulatory compliance and regulatory preemption); Alan Schwartz, *Statutory Interpretation, Capture, and Tort Law: The Regulatory Compliance Defense*, 2 AM. L. & ECON. REV. 1 (2000) (discussing the proper role of regulatory compliance in light of regulatory preemption).

215 RESTATEMENT (SECOND) OF TORTS § 288C (1965).

216 RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 4(b) (1998).

217 *Id.* § 4 cmt. e.

The result of a court finding preemption and a jury granting dispositive weight to a defendant's regulatory compliance is the same—the plaintiff cannot recover. In fact, the fundamental question underlying each doctrine is the same: When should courts defer to regulatory agencies to set standards of care as a matter of law and when should courts adopt common law standards to determine liability? But presented with the same underlying question, courts answering it through the doctrine of preemption and through the doctrine of regulatory compliance resolve the question differently. Preemption cases—as demonstrated in the discussion above—come to different results even when courts are applying the same or similar statutory and regulatory frameworks.<sup>218</sup> The regulatory compliance defense, however, is a blanket grant of statutory immunity, a sweeping doctrine that, partly on account of its potential breadth, has rarely been recognized by courts, enacted by legislatures, or endorsed by the *Restatements*.<sup>219</sup>

This is because federal preemption, as usually understood, is about the *vertical* relationship between the federal and state governments, while the regulatory compliance defense is about the *horizontal* relationship among the judicial, legislative, and executive branches. Part of the problem in the preemption debate is that courts are forced to conduct a “vertical” federalism analysis when a “horizontal” doctrine such as regulatory compliance might better resolve the issues posed by the case, particularly where consideration of regulatory compliance might better govern the relationship between state tort law and regulatory agencies than the murky doctrine of implied preemption. But the regulatory compliance defense in its usual formulation is too blunt an instrument, as signaled by the *Third Restatement's* reluctance to endorse it. A better approach that has the benefits of a “horizontal” comparative competence approach without sacrificing case-by-case judicial examination of the underlying interests protected by the statutory or regulatory regime is provided by inverse negligence per se analysis.

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218 Compare *Wyeth v. Levine*, 555 U.S. 555, 581 (2009) (holding the plaintiff's claims were not preempted); *Medtronic v. Lohr*, 518 U.S. 470, 494 (1996) (same) with *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324–25 (2008) (holding the plaintiff's claim were preempted); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 874 (2000) (same).

219 Richard C. Ausness, *The Case for a “Strong” Regulatory Compliance Defense*, 55 MD. L. REV. 1210, 1239 (1996) (“Unfortunately, in its present form, the regulatory compliance defense is too weak to provide much of a safe harbor to product sellers.”).

## CONCLUSION

The most convinced proponents and opponents of federal preemption will reject my argument here. Those who, for example, understand state tort claims as a benign complement to regulatory safety standards will resist the use of safety standards as a floor and ceiling. Such views regard safety regulations as merely a floor, above which defendants should go in order to assure optimal safety and avoid liability. But the Supreme Court has held more or less consistently that federal safety regulations can, in at least some cases, establish a ceiling above which defendants do not need to (and, as in *Mensing*, cannot) take additional precautions—indeed, that is what a case upholding federal preemption entails. In cases of inverse negligence per se, the statute or regulation establishes a floor of reasonable care below which a defendant’s conduct may not fall but also a ceiling above which the manufacturer need not take additional precautions, while in cases rejecting the preemption defense the court is recognizing that the federal floor can and should be exceeded.<sup>220</sup>

One implication of my argument is that proposals advocating clear statement rules for preemption demand too much of legislatures and agencies, for such clear statement rules have not traditionally been required in negligence per se doctrine.<sup>221</sup> Just as we have serviceable canons of statutory interpretation in negligence per se cases, so we can apply these interpretive methods “in reverse” to preemption. Preemption as inverse negligence per se is, however, consistent with and complementary to other proposals in the preemption literature. Catherine Sharkey’s agency-reference model, for example, argues that courts have (descriptively) and should (normatively) look to the agency’s relevant expertise, the care with which a preemption determination was made, and the overall regulatory framework.<sup>222</sup> My argument here is that many of Sharkey’s objectives are met by the traditional categories of negligence per se analysis, including an examination of whether the purportedly preemptive regulation was intended to cover a class of persons including the plaintiff and the risk that caused the plaintiff’s injury, though I sidestep some of the inconclusive debates in administrative law about agency deference.

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220 See William W. Buzbee, *Federal Floors, Ceilings, and the Benefits of Federalism’s Institutional Diversity*, in PREEMPTION CHOICE 98 (William W. Buzbee ed., 2009).

221 See generally Hills, *supra* note 98 (arguing that an anti-preemption rule of statutory construction would benefit the federal law-making process by promoting visible, vigorous debate in Congress).

222 Catherine M. Sharkey, *Federalism Accountability: “Agency-Forcing” Measures*, 58 DUKE L.J. 2125 (2009); Sharkey, *supra* note 6.

More broadly, preemption as inverse negligence per se has implications for topics in tort theory, including the interplay between statutes and the common law and the private law aspects of tort law. Different areas of preemption would, of course, require different analysis, just as different types of tort and products liability claims—failure to warn, design defect, and manufacturing defect claims—would require analysis specific to those claims. Much of the revival of interest in private law aspects of tort law has focused on the elements of negligence and showing how features of negligence—the causation requirement, for example—are difficult to account for in a functionalist perspective. But those who would buck the tide of functionalism should engage the breadth of tort law, and few features of contemporary tort law are as controversial as federal preemption. If my argument is correct, then at least some of that controversy is on account of a misunderstanding about central aspects of federal preemption, namely the failure to attend to the specific tort aspects of federal preemption of state tort claims and a rush to embrace constitutional and administrative law approaches to preemption at the expense of more precise, historically sound, and well-developed common law doctrines such as negligence per se.

