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# THE MATURE PRODUCT PREEMPTION DOCTRINE: THE UNITARY STANDARD AND THE PARADOX OF CONSUMER PROTECTION

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## INTRODUCTION

The product preemption doctrine<sup>1</sup> is reaching maturity with all the awkwardness of a hundred-year-old adolescent.<sup>2</sup> The history of modern product preemption doctrine has been characterized by inconsistency and paradox,<sup>3</sup> and attorneys anticipate each new decision of the United States Supreme Court with a mixture of hope for a definitive test and preparedness for new battles in an increasingly confusing landscape.<sup>4</sup> To date, the Supreme Court's

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<sup>1</sup> I use the term "product preemption doctrine" to refer to the rules and processes of preemption set forth in a series of U.S. Supreme Court product liability cases. Non-product cases and non-tort cases also have informed the product preemption doctrine, and to that extent, I include discussion of those cases in this Article. This Article focuses primarily, though not exclusively, on the Court's jurisprudence addressing whether state-law product liability claims should be preempted by federal law.

<sup>2</sup> Although the U.S. Supreme Court has addressed preemption in its decisions for this length of time, product preemption is a newer adjunct to the traditional doctrine.

<sup>3</sup> See, e.g., DAVID G. OWEN, PRODUCTS LIABILITY LAW § 14.4, at 896 (2005) (stating that the preemption doctrine "continues to wallow in a state of utter chaos"); Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2085 (2000) (stating that "the Supreme Court's numerous preemption cases follow no predictable jurisprudential or analytical pattern"); Allison H. Eid, *Preemption and the Federalism Five*, 37 RUTGERS L.J. 1, 8 (2005) (observing that "the pro-federalism Justices in the New Federalism cases find themselves, more often than not, on the pro-preemption side in the preemption cases"); Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. REV. 559, 559-60 (1997) (stating that "there is no better illustration of the Court's schizophrenia than in the area of federal preemption of state tort remedies").

<sup>4</sup> See Martina Barash & Julie Steinberg, *Preemption Tops Key Litigation Issues Heading Into New Year*, 24 TOXICS L. REP. (BNA) 120, 120-21 (2009) (recognizing the unpredictability of the Supreme Court's next decision, in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009)).

product preemption jurisprudence has failed to produce an optimal level of certainty and predictability in an area of the law dedicated to consumer protection.

An important segment of the Court's product preemption jurisprudence has involved medical devices and drugs regulated under the Food, Drug, and Cosmetic Act (FDCA).<sup>5</sup> In fact, two of the Court's three important preemption decisions in 2008 and 2009 have involved aspects of regulation under the FDCA. Products generally, and medical devices and drugs in particular, involve a complex set of policies relating to public health and safety, areas traditionally within the police power of the states. Federal product regulation also overlaps with state common law. One has only to look at the recent Vioxx debacle to see the problems that can result when a resource-stressed Food and Drug Administration (FDA) is hindered in providing necessary product oversight.<sup>6</sup> In the thousands of lawsuits that alleged illness or death associated with Vioxx use, the manufacturer, Merck & Co., argued that the plaintiffs' tort claims were preempted because the FDA approved the drug for marketing.<sup>7</sup> The delicate balance between these kinds of product liability claims, which ultimately establish standards of conduct, and FDA regulation, which serves other goals as well,<sup>8</sup> presents a special challenge in preemption analysis. Focusing on cases involving the FDCA, therefore, provides insight into the most pressing problems raised by the Court's product preemption doctrine.

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<sup>5</sup> 21 U.S.C.A. §§ 301–395 (West 2009).

<sup>6</sup> See Jonathan V. O'Steen & Van O'Steen, *The FDA Defense: Vioxx and the Argument Against Federal Preemption of State Claims for Injuries Resulting from Defective Drugs*, 48 ARIZ. L. REV. 67, 67–68 (2006) (describing the FDA's failure to act on the dangers of Vioxx, despite the numerous warning signs of the drug's dangerous side effects).

<sup>7</sup> See, e.g., *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776, 788–89 (E.D. La. 2007) (holding that plaintiffs' product liability claims were not preempted); *McDarby v. Merck & Co.*, 949 A.2d 223, 251 (N.J. Super. Ct. App. Div.) (holding that plaintiffs' tort claims were not preempted), *cert. granted*, 960 A.2d 393 (N.J. 2008).

<sup>8</sup> The FDA defines its task as follows:

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

U.S. Food & Drug Administration, Mission Statement, [http://www.fda.gov/opacom/more\\_choices/mission.html](http://www.fda.gov/opacom/more_choices/mission.html) (last visited Sept. 23, 2009) [hereinafter FDA Mission Statement]. Thus, the FDA must balance consumer safety with speed in making needed therapeutic innovations available to the public.

Now that the product preemption doctrine is entering its maturity with the recent triad of Supreme Court decisions,<sup>9</sup> it is useful to reassess the doctrine. This Article undertakes that task and reaches some disappointing conclusions from the perspective of consumer safety. In an earlier article, I argued that the Court's product preemption doctrine embodies certain norms and rules, including the value of consumer protection.<sup>10</sup> As the doctrine has matured, however, there is a disconnect between those goals and the analytical process by which the Court reaches its decisions on preemption. The mature doctrine is not easily discernible from the collection of individual cases. Rather, it must be understood as a kind of gestalt, which presents itself as something other than the sum of its individual parts. Thus, even in cases in which the result reached by the Court on preemption advances consumer protection goals, the underlying process used by the Court may establish a precedent that will jeopardize those goals in future cases. The doctrine is a double-edged sword, wielded in the interest of consumer protection, but just as capable of mortally wounding that goal in a broad sweep.

Part I of this Article begins by briefly reviewing some of the decisions that defined the Supreme Court's product preemption doctrine prior to 2008. This section focuses primarily on the often irreconcilable inconsistencies among the cases and the resulting confusion over the standards they embody. Part II considers the overriding concerns of product safety and consumer protection that form the basis of most of product law, both in regulation and in the common law. Particular attention is given to the challenges faced by the FDA in making accurate decisions on the safety and effectiveness of drugs and medical devices as the agency struggles with insufficient resources and increasing demands. Part III of this Article presents a critical analysis of the triad of product preemption cases that the Court decided in 2008 and 2009, and demonstrates what these decisions add to the development of the doctrine. Armed with this new information, I argue in Part IV that the mature product preemption doctrine has become a unitary standard, merging previously discrete analytical elements into a single process. Finally, Part V argues that the unitary standard poses a threat to the health and

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<sup>9</sup> See *Wyeth v. Levine*, 129 S. Ct. 1187 (2009); *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008); *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008). The Court had an opportunity to decide another product preemption case, but the case resulted in a 4-to-4 tie. See *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168, 1168 (2008) (per curiam) (letting stand a Second Circuit decision that federal drug law does not preempt the fraud exception to a state statute immunizing prescription drug manufacturers from lawsuits).

<sup>10</sup> See Jean Macchiaroli Eggen, *The Normalization of Product Preemption Doctrine*, 57 ALA. L. REV. 725, 752-54 (2006) [hereinafter Eggen, *Normalization of Product Preemption*].

safety goals of product liability law, particularly in an era when the FDA is unable to fully and effectively execute its role in product safety. This Article concludes that although consumer interests may have been served in many of the Court's preemption cases, the potential for arbitrary and policy-laden decisions is great.

### I. THE DEVELOPMENT OF THE PRODUCT PREEMPTION DOCTRINE: CASES AND CONFUSION

Prior to 2008, the United States Supreme Court issued a number of important decisions on the product preemption doctrine. I do not intend to survey these decisions in any detail, as they have been thoroughly surveyed in the past.<sup>11</sup> Rather, in this section I identify and elucidate the concepts that are significant in the mature doctrine and demonstrate how the confusion over the analytical standards has arisen. The doctrine of preemption is derived from the Supremacy Clause<sup>12</sup> of the United States Constitution.<sup>13</sup> The United States Supreme Court has consistently recognized several types of preemption, which have fallen into the two broad categories of express preemption and implied preemption. Express preemption of state laws may arise when the federal statute or a regulation promulgated by a federal agency within its statutory authority<sup>14</sup> contains a preemption provision that sets forth the circumstances under which state rules will be barred.<sup>15</sup> Implied preemption may occur in several ways. First, Congress may have intended a particular

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<sup>11</sup> See, e.g., Richard C. Ausness, *Preemption of State Tort Law by Federal Safety Statutes: Supreme Court Preemption Jurisprudence Since Cipollone*, 92 KY. L.J. 913, 940–66 (2004); Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967, 974–1012 (2002); Eggen, *Normalization of Product Preemption*, *supra* note 10, at 728–50; Jean Macchiaroli Eggen, *Shedding Light on the Preemption Doctrine in Product Liability Actions: Defining the Scope of Buckman and Sprietsma*, 6 DEL. L. REV. 143, 144–62, 168–73 (2003) [hereinafter Eggen, *Shedding Light*]; Jean Macchiaroli Eggen, *Sense or Sensibility?: Toxic Product Liability Under State Law After Cipollone and Medtronic*, 2 WIDENER L. SYMP. J. 1, 6–11 (1997) [hereinafter Eggen, *Sense or Sensibility*]; M. Stuart Madden, *Federal Preemption of Inconsistent State Safety Obligations*, 21 PACE L. REV. 103, 111–57 (2000); David G. Owen, *Federal Preemption of Products Liability Claims*, 55 S.C. L. REV. 411, 422–37 (2003).

<sup>12</sup> U.S. CONST. art. VI, cl. 2.

<sup>13</sup> See, e.g., *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 663 (1993) (“Where a state statute conflicts with, or frustrates, federal law, the former must give way.”); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (“[I]t has been settled that state law that conflicts with federal law is ‘without effect.’”); *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981) (discussing the Supremacy Clause and asserting that “[i]t is basic to this constitutional command that all conflicting state provisions be without effect”).

<sup>14</sup> See *Fidelity Fed. Sav. & Loan Ass’n v. De La Cuesta*, 458 U.S. 141, 153 (1982) (“Federal regulations have no less pre-emptive effect than federal statutes.”).

<sup>15</sup> See *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (“[W]hen Congress has ‘unmistakably . . . ordained’ that its enactments alone are to regulate a part of commerce, state laws regulating that aspect of commerce must fall.” (citation omitted)).

statutory scheme to “occupy the field” on the subject in question. If so, “[t]he scheme of federal regulation may be so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.”<sup>16</sup> Second, state laws may be preempted because there is an actual conflict between them and the federal statute in one of two ways.<sup>17</sup> Conflict preemption may occur when it is impossible to comply with both the federal statute or regulation and the state-law rules<sup>18</sup> or when state law is an obstacle to the achievement of the goals of the federal scheme.<sup>19</sup>

Another fixture in the preemption landscape has been the so-called presumption against preemption. This presumption, which derives from the Supremacy Clause, holds that “the historic police powers of the States [are] not to be superseded by the Federal Act unless that [is] the clear and manifest purpose of Congress.”<sup>20</sup> This definition of the presumption against preemption is particularly apt in the context of products involving health and safety issues. What has not been clear from the Supreme Court’s jurisprudence, however, is why the presumption is rejected—or ignored—in some cases where it would otherwise seem applicable.<sup>21</sup>

The perceived dichotomy between express preemption and implied preemption—and the notions that they are invoked under different circumstances and involve different analytical processes—has driven much of the legal system’s understanding of product preemption. To be sure, the Supreme Court has typically dealt with express preemption and implied preemption as separate processes. But these

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<sup>16</sup> *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Field preemption is rarely a factor and is usually not discussed in the product preemption cases, except to indicate that comprehensiveness of regulations does not necessarily mean that Congress meant to occupy the field. *See Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 717 (1985) (stating that the Court is reluctant to infer field preemption from comprehensive federal statutory provisions or administrative regulations). This Article does not treat field preemption because that type of implied preemption has not been an issue in the Court’s product preemption doctrine. *Cf. Sprietsma v. Mercury Marine*, 537 U.S. 51, 68–69 (2002) (conducting one of the only analyses in the product preemption line of cases that address whether the statutory scheme was intended to occupy the field and concluding that it was not).

<sup>17</sup> *See Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm’n*, 461 U.S. 190, 204 (1983).

<sup>18</sup> *See Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963) (“A holding of federal exclusion of state law is inescapable . . . where compliance with both federal and state regulations is a physical impossibility . . .”).

<sup>19</sup> *See Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (stating that the Court’s primary function in preemption analysis is to determine whether state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress”).

<sup>20</sup> *Rice*, 331 U.S. at 230.

<sup>21</sup> *Compare Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 870–71 (2000) (refusing to apply the presumption against preemption), *with Altria Group, Inc. v. Good*, 129 S. Ct. 538, 543 (2008) (recognizing that the presumption against preemption applies in both the express and implied preemption contexts).

processes have often seemed at cross purposes, and the rules the Court has followed have appeared inconsistent. In particular, the relationship between express preemption and implied preemption, and the extent to which either or both are involved in a given case, have often flummoxed Court observers and confounded courts attempting to apply the doctrines.

Comparing several Supreme Court cases demonstrates the breadth of this problem. In *Cipollone v. Liggett Group, Inc.*,<sup>22</sup> the Court was called upon to interpret the language in the express preemption provisions of two federal cigarette labeling statutes establishing mandatory health warnings on cigarette packages and elsewhere.<sup>23</sup> The underlying action was a product liability suit brought by the estate of a smoker.<sup>24</sup> The *Cipollone* Court conducted a detailed examination of the scope of the preemption provisions in the two statutes. The Court first held that the language in the 1965 preemption provision was not intended to preempt state common-law suits, and then further held that Congress intended the provision in the 1969 Act to preempt at least some state tort claims.<sup>25</sup> The Court's analysis centered around the intent of Congress in changing the language of the 1969 provision to bar state-law "requirements" based upon the advertising and promotion of cigarettes.<sup>26</sup> The Court held that Congress intended the term "requirements" to include at least some common-law claims.<sup>27</sup> In a plurality opinion written by Justice Stevens—a frequent author of subsequent product preemption decisions for the Court—the Court ultimately held that the failure-to-warn claims were preempted, but that the breach of express warranty claim and the misrepresentation claims based upon a general duty not to deceive under state law were not preempted.<sup>28</sup>

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<sup>22</sup> 505 U.S. 504 (1992).

<sup>23</sup> Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, 79 Stat. 282 (codified as amended at 15 U.S.C. §§ 1331-1340 (2006)); Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. § 1340 (2006)).

<sup>24</sup> *Cipollone*, 505 U.S. at 512 (plurality opinion) (listing the claims relevant to the Court's decision as failure to warn, breach of express warranty, fraudulent misrepresentation, and conspiracy to defraud).

<sup>25</sup> *Id.* at 522. The focus of the Court's analysis was the change in language from a prohibition of any "statement relating to smoking and health," as stated in the 1965 preemption provision, to preemption of any "requirement or prohibition based on smoking and health," as stated in the 1969 provision. *Id.* at 514-15 (discussing the Federal Cigarette Labeling and Advertising Act of 1965, § 5(a), and the Public Health Cigarette Smoking Act of 1969, § 5(b)).

<sup>26</sup> *Id.* at 520-23. The claims held not preempted were deemed to be requirements that were (1) not "imposed under State law," (2) not "with respect to the advertising or promotion" of cigarettes, or (3) not "based on smoking and health," all of which the preemption provision required. *Id.* at 525-30.

<sup>27</sup> *Id.* at 524-29.

<sup>28</sup> *Id.*

The *Cipollone* Court suggested that because the cigarette labeling acts contained express preemption provisions, only express preemption analysis was appropriate. Thus, the Court stated: “In our opinion, the pre-emptive scope of the 1965 Act and the 1969 Act is governed entirely by the express language” therein.<sup>29</sup> Furthermore, the Court reasoned that when an express preemption provision “provides a ‘reliable indicium of congressional intent with respect to state authority’”—in other words, where Congress clearly indicated what kinds of state rules were barred—the provision absolutely governs on matters of preemption.<sup>30</sup>

In 1996, in *Medtronic, Inc. v. Lohr*,<sup>31</sup> the Court closely followed the approach outlined in *Cipollone* for preemption analysis in cases in which the federal statute contains an express preemption provision.<sup>32</sup> *Lohr* involved a different statute, one encompassing major health and safety decisions impacting most members of the general public.<sup>33</sup> The claims asserted in the case involved an allegedly defective cardiac pacemaker lead, a Class III medical device<sup>34</sup> that had been granted

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<sup>29</sup> *Id.* at 517; *cf.* *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 98 (1992) (stating, in a non-product liability case, that “[a]bsent explicit pre-emptive language,” an implied preemption analysis would be appropriate). *Cipollone* appeared to be a compromise decision in that the Court held that some, but not all, of the plaintiff’s claims were preempted. The decision thus spawned two partial dissents, one from Justice Scalia and one from Justice Blackmun. Both partial dissents assumed that the plurality’s position was that express preemption was the only analysis to be conducted when the statute contains a preemption provision. Calling this point one of the “new rules” he thought the plurality was announcing on preemption, Justice Scalia observed with disapproval: “Once there is an express pre-emption provision, in other words, all doctrines of implied pre-emption are eliminated.” *Cipollone*, 505 U.S. at 547 (Scalia, J., concurring in part and dissenting in part). Justice Blackmun, however, approved of the plurality’s apparent position, stating: “We resort to principles of implied pre-emption . . . only when Congress has been silent with respect to pre-emption.” *Id.* at 532 (Blackmun, J., concurring in part and dissenting in part). Thus, the position of a majority of the Court appeared to be that the existence of an express preemption provision circumscribed the preemption analysis and foreclosed implied preemption. This, of course, proved not to be the case.

<sup>30</sup> *Cipollone*, 505 U.S. at 517 (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 505 (1978)).

<sup>31</sup> 518 U.S. 470 (1996).

<sup>32</sup> *See Eggen, Sense or Sensibility*, *supra* note 11, at 27–28.

<sup>33</sup> When it enacted the first cigarette labeling act, Congress stated: “It is the policy of the Congress, and the purpose of this Act, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health . . . .” Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, § 2, 79 Stat. 282, 282 (codified as amended at 15 U.S.C. § 1331 (2006)). The purpose of the legislation, however, was information communication. Its safety concerns were limited to communication of warnings to the general public in the form of packaging and advertising. Furthermore, Congress clearly stated that the act was intended to protect the economic interests of the tobacco industry. *See id.* § 2(2)(A) (stating that a goal of the act was to ensure that “commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy”). The FDCA, as amended, which was invoked in *Lohr*, was instead largely concerned with health and safety determinations in the first instance.

<sup>34</sup> *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c(a)(1)(C) (2006). Class III devices are those used for “supporting or sustaining human life or . . . preventing impairment of



marketing approval pursuant to section 510k of the Medical Device Amendments<sup>35</sup> (MDA) of the FDCA. Section 510k permitted the FDA to allow marketing of a Class III device upon a finding that the device was the “substantial equivalent” of a device on the market prior to the enactment of the MDA.<sup>36</sup>

The Court applied the preemption provision in the MDA, which states that “no State . . . may establish or continue in effect with respect to a device intended for human use any requirement . . . which is different from, or in addition to, any requirement applicable under [the FDCA] to the device, and . . . which relates to the safety or effectiveness of the device . . . .”<sup>37</sup> In addition to the statutory language, the Court relied upon an FDA regulation interpreting the preemption provision.<sup>38</sup> The Court remained very close to the text of the MDA’s preemption provision in its analysis, ultimately concluding, for a variety of reasons, that none of the plaintiffs’ product liability claims were preempted.<sup>39</sup> The Court did not proceed to conduct an implied preemption analysis, which was also consistent with *Cipollone*.

More than a decade after *Cipollone*, the Court, in *Bates v. Dow Agrosciences L.L.C.*,<sup>40</sup> seemed to reaffirm the same approach. *Bates* involved the Federal Insecticide, Fungicide, and Rodenticide Act

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human health,” or those that “present[] a potential unreasonable risk of illness or injury.” *Id.* § 360c(a)(1)(C)(ii). Thus, they present the greatest risk to human safety and health.

<sup>35</sup> *Id.* § 360k (originally enacted as the Act of Oct. 10, 1962, Pub. L. No. 87-78, Title III, § 302, 76 Stat. 794, and amended by the Medical Device Amendments of 1976, Pub. L. No. 94-295, § 4, 90 Stat. 539, 579).

<sup>36</sup> *See id.* § 360c(i).

<sup>37</sup> *Id.* § 360k(a).

<sup>38</sup> The regulation states, in pertinent part:

State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements.

21 C.F.R. § 808.1(d) (2009). The Court followed the regulation closely in determining whether the MDA and its regulations constituted “requirements,” whether they established “counterpart regulations” that were specific to the device in question, whether any state requirements were “different from or in addition to” any federal requirements, and whether the state-law claims were “requirements applicable to the device.” The Court answered most of those questions in the negative. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) (stating that the FDA did not “require” the product to be designed in any particular way); *id.* at 495 (holding that any claims alleging violation of state requirements that paralleled federal requirements were not preempted); *id.* at 501 (holding that the federal manufacturing and labeling requirements were generic in nature and not specific to particular devices); *id.* (stating that state common-law duties of general applicability are not “requirements applicable to the device”).

<sup>39</sup> *Lohr*, 518 U.S. at 493–502.

<sup>40</sup> 544 U.S. 431 (2005).

(FIFRA),<sup>41</sup> which also contains a preemption provision.<sup>42</sup> Dow, the manufacturer of the pesticide Strongarm, had brought a declaratory judgment action against farmers complaining of crop damage to determine whether the doctrine of preemption barred any claims for property damage that the farmers might bring.<sup>43</sup> The farmers counterclaimed for their damages, asserting claims for strict liability, negligence, fraud, breach of warranty, and violation of a state consumer protection statute.<sup>44</sup> Employing only an express preemption analysis, the Court held that most of the petitioner-farmers' claims were not preempted.<sup>45</sup> The Court once again remained silent on implied preemption. More to the point, all nine Justices appeared to accept the proposition that, at least in that case, it was inappropriate to consider anything but express preemption. Justice Thomas, joined by Justice Scalia, wrote in partial dissent: "Because we need only determine the ordinary meaning of [the preemption provision], the majority rightly declines to address respondent's argument that petitioners' claims are subject to other types of pre-emption."<sup>46</sup> Moreover, Justice Thomas opined that the approach taken by the majority "comports with this Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied preemption."<sup>47</sup>

A brief look at some of the product preemption decisions intervening between *Cipollone* and *Bates* suggests that Justice Thomas's assessment was not quite accurate. In *Freightliner Corp. v. Myrick*, Justice Thomas himself wrote for the Court and applied first an express preemption analysis and then implied preemption principles to hold that the plaintiffs' claims were not preempted.<sup>48</sup>

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<sup>41</sup> 7 U.S.C. § 136v (2006).

<sup>42</sup> *Id.* § 136v(a)–(b). The preemption provision states:

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter. . . . Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

*Id.*

<sup>43</sup> *Bates*, 544 U.S. at 435.

<sup>44</sup> *Id.* at 435–36.

<sup>45</sup> *See id.* at 444–45. The Court held that the claims for defective design and manufacture, negligent testing, and breach of express warranty were not preempted. *Id.* at 444. The Court also held that the failure-to-warn claims were not preempted to the extent that they claimed violation of state standards that were parallel to those imposed under FIFRA. *Id.* at 447 (remanding to the Fifth Circuit the question whether Texas's common-law duties are equivalent to FIFRA's misbranding standards).

<sup>46</sup> *Id.* at 458 (Thomas, J., concurring in part and dissenting in part).

<sup>47</sup> *Id.* at 459.

<sup>48</sup> 514 U.S. 280 (1995) (considering allegations that the absence of an antilock braking

The case involved the National Traffic and Motor Vehicle Safety Act of 1966,<sup>49</sup> which contained both a preemption provision and a saving clause that recognized the continued validity of state law. The saving clause provided that “[c]ompliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law.”<sup>50</sup> The Court first determined that the express preemption provision, which barred state law “[w]henver a Federal motor vehicle safety standard . . . is in effect” with respect to “the same aspect of performance,”<sup>51</sup> did not preempt the plaintiffs’ product liability claims because no federal standard existed at the time of the plaintiffs’ accidents.<sup>52</sup>

The inquiry did not end there, for the Court went on to apply principles of implied preemption. Justice Thomas stated:

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. . . . Our subsequent decisions have not read *Cipollone* to obviate the need for analysis of an individual statute’s pre-emptive effects. . . . At best, *Cipollone* supports an inference that an express pre-emption clause forecloses implied pre-emption; it does not establish a rule.<sup>53</sup>

At least eight Justices concurred in this view.<sup>54</sup> The Court’s implied preemption analysis in *Myrick* was less than probing, with the Court ultimately rejecting preemption.<sup>55</sup> The Court never took up the question of the role of the saving clause because it rejected preemption for other reasons.<sup>56</sup> In all, the process used by the Court in conducting its preemption analyses in *Myrick* raised questions about the circumstances under which the “inference” that a preemption

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system in tractor-trailers constituted a negligent design defect).

<sup>49</sup> 15 U.S.C. §§ 1391–1431 (1988) (repealed 1994).

<sup>50</sup> *Id.* § 1397(k) (repealed 1994).

<sup>51</sup> *Id.* § 1392(d) (repealed 1994).

<sup>52</sup> *Myrick*, 514 U.S. at 286 (noting that the suspension of truck and trailer braking standards created an absence of regulation in that area).

<sup>53</sup> *Id.* at 288–89 (citations omitted).

<sup>54</sup> The judgment was unanimous. Justice Scalia concurred without a written opinion, so he did not offer a detailed view on this point. *Id.* at 290 (Scalia, J., concurring in judgment).

<sup>55</sup> *See id.* at 289–90.

<sup>56</sup> *See id.* at 287 n.3.

provision “forecloses implied preemption” may in fact yield to an implied preemption analysis.

A more puzzling departure from *Cipollone* and *Lohr* occurred in 2000. When the Supreme Court decided *Geier v. American Honda Motor Co.*,<sup>57</sup> the continued vitality of *Cipollone* and *Lohr* was questioned. The confusion surrounding *Geier* arose primarily from two analytical points. First, even though the relevant federal statute contained an express preemption provision and a saving clause—and the Court determined that the plaintiff’s personal injury claims were not expressly preempted<sup>58</sup>—the Court held that the claims were impliedly preempted because state tort law created an actual conflict with the federal standard.<sup>59</sup> In *Myrick*, the Court had determined that the plaintiffs’ claims were not impliedly preempted; but in *Geier*, the Court conducted a full-blown implied preemption analysis and held the claims preempted. Second, the Court refused to apply the presumption against preemption,<sup>60</sup> leaving unclear—and in jeopardy—the role of the presumption in implied preemption cases. In the immediate aftermath of *Geier*, commentators criticized the decision as being bereft of any clear analytical principles.<sup>61</sup>

*Geier* arose from a motor vehicle accident that raised the question whether the car was defective because it had not been equipped with a driver’s-side airbag. The plaintiffs’ product liability claims alleged negligent and defective design of the automobile. The relevant federal regulation, Federal Motor Vehicle Safety Standard 208,<sup>62</sup> established a gradual phase-in scheme for passive restraints, but did not require automobile manufacturers to install particular passive restraints, such

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<sup>57</sup> 529 U.S. 861 (2000).

<sup>58</sup> *Id.* at 868 (finding “no convincing indication that Congress wanted to preempt, not only state statutes and regulations, but also common-law tort actions”).

<sup>59</sup> *Id.* at 874 (holding that the common-law “no airbag” action conflicts with the federal standard, FMVSS 208).

<sup>60</sup> *See id.* at 870 (finding “nothing in the natural reading of the two provisions that would favor one set of policies over the other”). Justice Breyer’s statements about the presumption against preemption were far from clear. *See Eggen, Normalization of Product Preemption, supra* note 10, at 757.

<sup>61</sup> *See, e.g., 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, 2 (2002); Stacey Allen Carroll, Note, *Federal Preemption of State Products Liability Claims: Adding Clarity and Respect for State Sovereignty to the Analysis of Federal Preemption Defenses*, 36 *GA. L. REV.* 797, 819–28 (2002); Alexander K. Haas, Note, *Chipping Away at State Tort Remedies Through Pre-Emption Jurisprudence: Geier v. American Honda Motor Co.*, 89 *CAL. L. REV.* 1927, 1943–47 (2001).

<sup>62</sup> 49 C.F.R. § 571.208 (2009). This standard was promulgated pursuant to the National Traffic and Motor Vehicle Safety Act of 1966, Pub. L. No. 89-563, 80 Stat. 718 (codified as amended at 49 U.S.C. §§ 30101–30169 (2000)). The Act was the same statute involved in *Myrick*.

as airbags, in their vehicles.<sup>63</sup> The authorizing statute contained both an express preemption provision and a saving clause. After determining that the express preemption provision did not preempt the plaintiffs' claims,<sup>64</sup> the *Geier* Court proceeded to consider whether the claims were impliedly preempted. Stating that "[n]othing in the language of the saving clause suggests an intent to save state-law tort actions that conflict with federal regulations,"<sup>65</sup> the Court held that conflict preemption barred the plaintiffs' claims.<sup>66</sup>

*Geier* was also significant because the Court directly addressed the role of the saving clause in the preemption analysis. The Court insisted that it had assumed in earlier preemption cases that principles of conflict preemption may still apply when the relevant statute contains a saving clause.<sup>67</sup> The circumstances that would cause a court to relegate the saving clause to an advisory, rather than mandatory, status would occur when state law "would upset the careful regulatory scheme established by federal law."<sup>68</sup> In this case, the Court determined that such a situation existed and held the plaintiff's claims preempted<sup>69</sup> notwithstanding the saving clause.

The Court followed *Geier*'s approach in *Buckman Co. v. Plaintiffs' Legal Committee*,<sup>70</sup> another case involving the MDA. This time, however, the Court largely ignored the MDA's preemption provision, which had been so focal in the *Lohr* decision. In *Buckman*, the plaintiffs' claims took the form of allegations that the manufacturer of the section 510k "substantially equivalent" medical device involved in the case—a bone screw that had been used in spinal surgery—had

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<sup>63</sup> 49 C.F.R. § 571.208 (2009). The Department of Transportation (DOT) had rejected a provision that would have required manufacturers to equip their vehicles with airbags. Instead, the standard gave manufacturers a choice among the types of passive restraints available. The DOT's goal was to phase in the passive-restraint requirement over a period of several years. See *Geier*, 529 U.S. at 878–79. The standard contained a non-mandatory incentive to install airbags. *Id.* at 879–80.

<sup>64</sup> *Geier*, 529 U.S. at 868 (stating that there was "no convincing indication that Congress wanted to pre-empt, not only state statutes and regulations, but also common-law tort actions").

<sup>65</sup> *Id.* at 869.

<sup>66</sup> *Id.* at 886.

<sup>67</sup> See *id.* at 870. Justice Breyer, writing for the Court, stated:

Neither do we believe that the pre-emption provision, the saving provision, or both together, create some kind of "special burden" beyond that inherent in ordinary pre-emption principles—which "special burden" would specially disfavor pre-emption here. The two provisions, read together, reflect a neutral policy, not a specially favorable or unfavorable policy, toward the application of ordinary conflict pre-emption principles.

*Id.* at 870–71 (citation omitted).

<sup>68</sup> *Id.* at 870 (quoting *United States v. Locke*, 529 U.S. 89, 106 (2000)).

<sup>69</sup> *Id.* at 873.

<sup>70</sup> 531 U.S. 341 (2001).

committed fraud on the FDA in its application for 510k marketing approval.<sup>71</sup> The Court held that principles of implied preemption barred the claims because the FDCA contained a unique federal scheme for addressing fraudulent practices perpetrated against the FDA. The federal scheme for policing fraud on the FDA,<sup>72</sup> the Court reasoned, embodied substantial federal interests in its comprehensive set of regulations and reflected the uniquely federal nature of the relationship between the manufacturer and the FDA.<sup>73</sup> In its analysis, the Court completely ignored express preemption, notwithstanding the provision contained in the MDA.<sup>74</sup> In so doing, the Court seemed to view the claims—and policies—involved in *Buckman* as distinct from those involved in *Lohr* in some way that justified different treatment. But beyond that, little could be discerned of the Court's preemption doctrine.

If *Geier* and *Buckman* were not confounding enough, the Court decided *Sprietsma v. Mercury Marine*<sup>75</sup> in 2002. *Sprietsma* added nothing but further confusion to the general understanding in the legal community about the parameters and process of the product preemption doctrine. The Court was called upon to determine whether a plaintiff's product liability claims, arising from a motor boat accident in which the plaintiff's decedent was struck by a propeller, were preempted.<sup>76</sup> The plaintiff claimed that the boat should have been equipped with a propeller guard, notwithstanding that the manufacturer was in compliance with the Federal Boat Safety Act of 1971 (FBSA).<sup>77</sup> The authority to promulgate boat safety regulations fell upon the United States Coast Guard, which had declined to require propeller guards on motor boats.<sup>78</sup> The FBSA contained both an express preemption provision<sup>79</sup> and a saving clause.<sup>80</sup> The Court

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<sup>71</sup> *Id.* at 347 (claiming that "petitioner and AcroMed made fraudulent representations to the FDA as to the intended use of the bone screws and that, as a result, the devices were improperly given market clearance").

<sup>72</sup> See, e.g., 18 U.S.C. § 1001 (2006) (criminal penalties for material false statements to the government); 21 U.S.C. § 332 (2006) (authorizing injunctive relief); *id.* § 333(a) (authorizing criminal sanctions); *id.* § 333(g) (authorizing civil penalties); *id.* § 372 (granting the FDA the power to investigate fraudulent practices).

<sup>73</sup> *Buckman*, 531 U.S. at 347–48. Much of the *Buckman* opinion discussed the "delicate balance of statutory objectives" in the MDA in which Congress envisioned a clear role for the federal agency in policing fraud. *Id.* at 348. For further discussion of this point, see Eggen, *Shedding Light*, *supra* note 11, at 157–59.

<sup>74</sup> The Court made a single direct reference to the provision in a footnote, stating: "In light of [our] conclusion, we express no view on whether these claims are subject to express pre-emption under 21 U.S.C. § 360k." *Buckman*, 531 U.S. at 348 n.2.

<sup>75</sup> 537 U.S. 51 (2002).

<sup>76</sup> *Id.* at 54.

<sup>77</sup> 46 U.S.C. § 4301–4311 (2006).

<sup>78</sup> *Sprietsma*, 537 U.S. at 62.

<sup>79</sup> 46 U.S.C. § 4306 ("Unless permitted by the Secretary . . . a State or political

conducted an express preemption analysis and determined that the plaintiff's claims were not preempted because Congress did not intend state common-law actions to fall within the provision.<sup>81</sup> The Court then proceeded to conduct an implied preemption analysis, concluding that the claims were not impliedly preempted either.<sup>82</sup>

If the ultimate holdings in *Buckman* and *Sprietsma* made some sense, the Court's approach to preemption in those cases did nothing to clear up the confusion over the operation of the doctrine; the result was a serious lack of predictability and a perception that no set standards applied.<sup>83</sup> One could reasonably wonder what had become of the statement in *Cipollone*, followed to the letter in *Lohr*, that when the federal statute contains an express preemption provision, the preemption analysis is "governed entirely by the express language" of the provision.<sup>84</sup> Further confounding the effort to understand the process was the appearance of *Bates*<sup>85</sup> in 2005, which reverted to the *Cipollone-Lohr* express preemption principles.<sup>86</sup>

As the decisions have demonstrated, other contradictory matters have further complicated efforts to apply the doctrine with any consistency. For example, the Court has explicitly applied a presumption against preemption in some circumstances,<sup>87</sup> but firmly rejected its application in others.<sup>88</sup> The lack of clear parameters on the application of the presumption against preemption has amplified the

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subdivision of a State may not establish . . . a law or regulation . . . that is not identical to a regulation prescribed under section 4302 of this title.").

<sup>80</sup> *Id.* § 4311(g) ("Compliance with this chapter or standards, regulations, or orders prescribed under this chapter does not relieve a person from liability at common law or under State law.").

<sup>81</sup> *Sprietsma*, 537 U.S. at 63–64.

<sup>82</sup> *Id.* at 67–70. The Court included a field preemption analysis, but rejected preemption on that ground. *See id.* at 68–69.

<sup>83</sup> *See* sources cited *supra* note 3.

<sup>84</sup> *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992).

<sup>85</sup> *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431 (2005).

<sup>86</sup> *See supra* notes 22–39 and accompanying text.

<sup>87</sup> *See, e.g., Cipollone*, 505 U.S. at 518 (stating that the express preemption provisions in the cigarette labeling acts must be construed "in light of the presumption against the pre-emption of state police power regulations"); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (acknowledging "the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that [is] the clear and manifest purpose of Congress").

<sup>88</sup> *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347–48 (2001) (rejecting application of the presumption against preemption in the context of the unique and inherently federal interest in policing fraud against the FDA). In *Geier v. American Honda Motor Co.*, Justice Breyer's language rejecting "some kind of 'special burden'" disfavoring preemption, 529 U.S. 861, 870 (2000), has been broadly read as rejecting the presumption against preemption. *But cf. Eggen, Normalization of Product Preemption*, *supra* note 10, at 758 (arguing that Justice Breyer's concurrence in *Lohr* indicated his adherence to the presumption against preemption and that the language in *Geier* should be read narrowly).

confusion.<sup>89</sup> Furthermore, the role of a saving clause in the preemption analysis has not been fully explored in the cases. In a separate, but equally relevant issue, the Court has sometimes expressly acknowledged the value of state tort actions in the federal regulatory context, even while preempting them,<sup>90</sup> but at other times has disparaged them.<sup>91</sup> In this climate of uncertainty, the product preemption decisions of 2008 and 2009 were eagerly anticipated.

## II. ADVANCING CONSUMER SAFETY THROUGH FEDERAL REGULATION AND STATE TORT LAW

Most of modern product law involves the health and safety of consumers.<sup>92</sup> A moral imperative is therefore often at the basis of product decisions. As Professor David G. Owen has stated: “By choosing to expose product users and others to certain types and degrees of risk, manufacturers appropriate to themselves certain interests in safety and bodily integrity that may belong to those other persons. . . . At bottom, product accidents are moral—not technological—events.”<sup>93</sup> This fact distinguishes product regulation from many other kinds of regulation, which may focus on a variety of other social goals.<sup>94</sup> The product preemption doctrine must be viewed in this broader public health context, even when other goals enter into the mix.<sup>95</sup>

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<sup>89</sup> For a discussion of the presumption against preemption and an analysis of the Court’s approach up to and including *Bates*, see Eggen, *Normalization of Product Preemption*, *supra* note 10, at 754–63 (arguing that the presumption against preemption has had continued vitality notwithstanding the Court’s refusal to apply it in some cases). For a discussion of how the Court has once again proclaimed the importance of the presumption, see *infra* text accompanying note 201. *But see generally* Davis, *supra* note 11, at 1013–16 (arguing that *Geier* and the earlier cases demonstrated that the Court has abandoned the presumption against preemption).

<sup>90</sup> See *Geier*, 529 U.S. at 870 (discussing the saving clause and stating that it “preserves those actions that seek to establish greater safety than the minimum safety achieved by a federal regulation intended to provide a floor”).

<sup>91</sup> See *Buckman*, 531 U.S. at 350 (expressing concern that allowing state tort actions for fraud on the FDA would deter companies from developing potentially beneficial medical devices).

<sup>92</sup> See DAN. B. DOBBS, *THE LAW OF TORTS* § 352, at 970 (2000) (stating that “[t]he focus [of product liability law] has been on products that do not meet safety standards or expectations”).

<sup>93</sup> OWEN, *supra* note 3, § 1.1, at 7.

<sup>94</sup> For example, the Endangered Species Act focuses on an entirely different set of priorities—“to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved.” 16 U.S.C. § 1531(b) (2006). *Cf.* Oliver A. Houck, *Of Bats, Birds and B-A-T: The Convergent Evolution of Environmental Law*, 63 *MISS. L.J.* 403 (1994) (arguing that successful environmental regulation takes into account various alternative approaches).

<sup>95</sup> The FDA must balance the need to make drugs and medical devices available to the public as speedily as possible with the safety and health of the consuming public. See FDA Mission Statement, *supra* note 8.



A complex interaction between federal law and state law is pervasive in the area of product safety.<sup>96</sup> Matters relating to the health and safety of the general public are traditionally within the province of the states.<sup>97</sup> Thus, state product liability law evolved<sup>98</sup> to advance these goals in the absence of regulation and, later, to supplement regulation. Most consumer products involve risks as well as benefits.<sup>99</sup> The choice made by a manufacturer and a regulating agency to market a particular product in a particular condition represents a complex analysis of its risks and benefits.<sup>100</sup> Nevertheless, some products marketed to consumers are defective and unreasonably dangerous in design or manufacture, or because they contain inadequate warnings.<sup>101</sup>

A related matter is the role of tort litigation in accomplishing the health and safety goals that are woven into the fabric of federal product regulations. The tort system has come under criticism in recent years, and the topic has been hotly debated.<sup>102</sup> Much of the anecdotal information about the excesses of the tort system has been shown to be exaggerated, but some concerns have merit.<sup>103</sup> Still, the United States Supreme Court's product preemption cases are replete with statements acknowledging the value of state tort actions.<sup>104</sup> The

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<sup>96</sup> See generally Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 225–26 (2000) (“The extent to which a federal statute displaces (or ‘preempts’) state law affects both the substantive legal rules under which we live and the distribution of authority between the states and the federal government.” (footnote omitted)).

<sup>97</sup> See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996).

<sup>98</sup> The New York Court of Appeals case *MacPherson v. Buick Motor Co.*, 111 N.E. 1050 (N.Y. 1916), is generally viewed as the first true product liability case in tort. See OWEN, *supra* note 3, § 1.2, at 22 (stating that *MacPherson* “in many respects began the modern era of products liability law”).

<sup>99</sup> This is particularly true of many prescription drugs and medical devices, which have therapeutic value, but which may also have substantial side effects or other negative risks associated with them.

<sup>100</sup> See, e.g., Michael D. Green, *Safety as an Element of Pharmaceutical Quality: The Respective Roles of Regulation and Tort Law*, 42 ST. LOUIS U. L.J. 163, 167 (1998) (discussing the risk-benefit analysis conducted in the FDA drug approval context); Richard A. Merrill, *Risk-Benefit Decisionmaking by the Food and Drug Administration*, 45 GEO. WASH. L. REV. 994, 996 (1977) (“‘Risk-benefit analysis’ . . . includes any technique for making choices that explicitly or implicitly attempts to measure the potential adverse consequences of an activity and to predict its benefits.”).

<sup>101</sup> See generally RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998) [hereinafter THIRD RESTATEMENT] (providing a basic statement of product liability claims for defective design and manufacture and for failure to warn).

<sup>102</sup> See DAN B. DOBBS, PAUL T. HAYDEN & ELLEN M. BUBLICK, *TORTS AND COMPENSATION* 816–18 (6th ed. 2009).

<sup>103</sup> It is beyond the scope of this Article to discuss the tort reform movement. For a reasoned discussion of the issues, see generally Marc Galanter, *Real World Torts: An Antidote to Anecdote*, 55 MD. L. REV. 1093 (1996) (examining the validity of assertions made by critics of the tort system).

<sup>104</sup> See *infra* notes 293–97 and accompanying text.

tort system serves an intricate set of policy goals, such as corrective justice, compensation of injured persons, and deterrence. In the area of product development, the tort system has the ability to influence product research and development by exerting pressure on manufacturers to optimize safety in the design and manufacture of their products, and in the communication to consumers of risks associated with the products.<sup>105</sup>

The federal agencies entrusted with the job of assuring the safety and health of the American public have a monumental task. In an era of economic uncertainty and substantial demand for government services, the major questions are whether the agencies can accurately and completely collect the information necessary to their decision making processes and whether the agencies have sufficient resources to carry out their charges to protect public health and safety. Many of the United States Supreme Court's product preemption decisions involve matters related to drugs and medical devices.<sup>106</sup> Therefore, an examination of the ability of the FDA to achieve its goals is particularly illustrative.

The FDA's role does not end upon approval of a drug or medical device for marketing. Many safety problems arise after the drug or device is on the market, and many problems take a substantial time to appear. Premarket clinical trials collect information on safety and effectiveness from a tiny segment of the population. The postmarket phase is critical in determining the full scope of any risks posed by the drug or device.<sup>107</sup> Manufacturers may be less than willing to provide the FDA with complete data on the postmarket risks of their products because of their financial investment in them.<sup>108</sup> In this light,

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<sup>105</sup> See Green, *supra* note 100, at 184 ("The best prophylactic available to a drug manufacturer with liability concerns is to include information about all risks that emerge as promptly as possible.").

<sup>106</sup> Cf. David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-To-Warn Claims*, 96 GEO. L.J. 461, 484 (2008) (stating that products regulated by the FDA currently constitute one-quarter of American consumer spending).

<sup>107</sup> See *Should FDA Drug and Medical Device Regulation Bar State Liability Claims?: Hearing Before the H. Comm. on Oversight and Government Reform*, 111th Cong. 37-38 (2008) [hereinafter *2008 House Oversight Hearing*] (statement of David A. Kessler, M.D., former Comm'r of FDA) (noting that in studies involving only a few thousand patients, serious and life-threatening side effects with an occurrence of 1 in 10,000 or less are unlikely to become apparent until after the drug goes to market), available at <http://oversight.house.gov/documents/20080523115742.pdf>. See generally Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L. & ETHICS 587, 594-606 (2005) (discussing the role of postmarketing surveillance and its deficiencies).

<sup>108</sup> See *2008 House Oversight Hearing*, *supra* note 107, at 32-33 (statement of Aaron Kesselheim, M.D., Dep't of Pharmacoepidemiology, Brigham Women's Hospital, Boston) (noting the inherent conflict of interest between the need to disclose safety problems and a manufacturer's financial interest).

the FDA's ability to follow up on drugs and devices in the postmarket phase is critical, but its effectiveness has been compromised by limited resources.

A 2007 report of the Institutes of Medicine (IOM) of the National Academies of Science unqualifiedly stated: "The Food and Drug Administration (FDA) lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future."<sup>109</sup> The IOM report characterized the FDA as "seriously underfunded" for the tasks it must accomplish, particularly those related to postmarketing surveillance of drugs granted marketing approval.<sup>110</sup> In fact, a 2006 report commissioned by the FDA itself reached similar conclusions regarding the lack of institutional resources for appropriate postmarket surveillance of prescription drugs.<sup>111</sup> This report also identified procedural failings within the FDA that prevented effective decision making, including lack of appropriate oversight over a complex process with unclear criteria.<sup>112</sup>

In an age in which health and safety regulations abound, it is paradoxical that the government is increasingly less capable of amassing and utilizing the critical information necessary to make the judgments authorized by federal regulations. Scholars have noted the effects of such "debilitating limitations on information that reduce the competence and accountability of agency regulators."<sup>113</sup> Even efforts to correct systemic agency deficiencies in the wake of regulatory failures, such as the FDA's response to Vioxx, are insufficient to eliminate the agency's problems in the absence of supporting resources.<sup>114</sup> Crucial regulation lags, even when the need for more stringent standards has been identified by Congress. The Government Accountability Office has noted that most of the riskiest medical

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<sup>109</sup> INST. OF MED. OF THE NAT'L ACADS., *THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC* 193 (Alma Baciú et al. eds., 2006) [hereinafter IOM REPORT].

<sup>110</sup> *Id.* at 193–94.

<sup>111</sup> See U.S. GOV'T ACCOUNTABILITY OFFICE, *DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS* 24–29 (2006), <http://www.gao.gov/new.items/d06402.pdf> (discussing the data constraints faced by the FDA that increase the difficulty of postmarket safety decisions).

<sup>112</sup> See *id.* at 18–23.

<sup>113</sup> Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 GEO. L.J. 693, 695 (2007); see also Kessler & Vladeck, *supra* note 106, at 465 (stating that "the FDA does not have the resources to perform the Herculean task of monitoring comprehensively the performance of every drug on the market" and citing recent regulatory failures, such as the FDA's failure to adequately respond to the Vioxx crisis).

<sup>114</sup> See Kessler & Vladeck, *supra* note 106, at 467 (noting that the creation of the Drug Safety Oversight Board (DSOB) in 2005 was not accompanied by sufficient supporting resources).

devices still attain marketing approval through the “substantial equivalency” grandfathering provision<sup>115</sup> in the FDCA,<sup>116</sup> even though Congress directed the FDA nearly two decades ago to promulgate more stringent, safety-conscious regulations for that entire group of devices.<sup>117</sup> Thus, reliance on regulation—supplemented with voluntary steps taken by manufacturers—to achieve public health and safety goals will result in incomplete benefits. Tort litigation is capable of filling the gap between deficient government regulation and the needed goals.<sup>118</sup>

The IOM report predicted dire consequences if the FDA fails to improve information collection and maximize resources at the agency level:

Continued resource shortages will impede the agency’s ability to use new and future scientific and technological advances in drug research across the lifecycle. In particular, the limited resources could impede the agency’s ability to detect risks of new drugs in a timely fashion, analyze emerging drug safety data, and effectively communicate that information to the public in the ways envisioned in the committee’s report.<sup>119</sup>

Former FDA Commissioner David A. Kessler has expressed the opinion that, even with substantial increases in funding, the FDA would remain unable to meet its many safety obligations.<sup>120</sup> The

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<sup>115</sup> See 21 U.S.C. § 360c(i) (2006) (“substantial equivalency” devices).

<sup>116</sup> See U.S. GOV’T ACCOUNTABILITY OFFICE, MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS 27–28 (2009), <http://www.gao.gov/new.items/d09190.pdf>.

<sup>117</sup> See Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (codified as amended at 21 U.S.C. § 360i (2006)) (directing FDA to promulgate safety regulations on each type of device it continued to classify as Class III).

<sup>118</sup> For example, tort litigation may unearth information regarding products that cause a detriment to the public health and safety in cases where entities subject to regulation withhold necessary information about their products’ adverse effects. See Wagner, *supra* note 113, at 711 (referencing product liability cases involving asbestos, tobacco, tampons, and the Dalkon Shield intrauterine birth control device). Professor Wagner has argued further that even tort litigation that has been seriously criticized for condemning products that scientific evidence has since exonerated may have substantial health and safety benefits. *Id.* at 714 (discussing silicone gel breast implant litigation).

<sup>119</sup> IOM REPORT, *supra* note 109, at 194.

<sup>120</sup> See 2008 House Oversight Hearing, *supra* note 107, at 38–39 (statement of David A. Kessler, M.D., former FDA Comm’r). Another witness before the House Committee’s hearing discussed the example of Guidant’s implantable defibrillator device, noting that even though the FDA conducted multiple inspections of the manufacturing plant following incidents of device defects, the FDA still was not able to determine the problem. *Id.* at 62 (testimony of William H. Maisel, M.D., Director, Medical Device Safety Institute, Dep’t of Medicine, Beth Israel Deaconess Medical Center).

logical inference drawn from these concerns is that state tort law is needed to take a greater role in drug and medical device safety.

In matters related to defective products, all of the information necessary for evaluation of the health and safety aspects of the products is in the hands of the manufacturers.<sup>121</sup> There is no guarantee that all critical information will be made available to the regulating agency. Sometimes important information is withheld, whether intentionally or inadvertently.<sup>122</sup> The playing field simply is not level. Furthermore, products are becoming increasingly technological and complex, making ever greater demands on regulatory agencies. Many product defects do not emerge until after the product is on the market, lending urgency to the need for agency intervention in the postmarket phase.<sup>123</sup> The FDA in particular lacks the personnel and other resources to collect all the information it needs to conduct a full balance of risks and benefits and follow through on the health and safety issues during postmarket surveillance. It must trust the manufacturers to disclose all relevant information.

Tort litigation provides an incentive to manufacturers to conduct substantial safety follow-ups on their products on the market. Kessler, the former FDA Commissioner, testified before Congress that in the period from 1998 to 2000, fewer than eighty percent of the postmarket studies required of drug and medical device manufacturers were actually completed.<sup>124</sup> Tort litigation also serves an important role in encouraging manufacturers to make full disclosure of the risks of their products at all stages, instead of waiting for the litigation discovery process. In the case of Vioxx, certain safety studies did not come to light until the time of litigation because the manufacturer had chosen to interpret the data in a way that minimized the risks.<sup>125</sup> Experts have suggested that without tort

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<sup>121</sup> See *id.* at 32 (statement of Aaron S. Kesselheim, M.D., Dep't of Pharmacoepidemiology, Brigham Women's Hospital, Boston) (recognizing the control of the manufacturer over information relating to its products); *id.* at 38 (statement of David A. Kessler, M.D., former FDA Comm'r) (recognizing that the balance of information is on the side of the manufacturers).

<sup>122</sup> For example, a bioengineer in the medical device industry testifying before the House Committee on Oversight and Government Reform observed that while fraud is rare, lack of care is generally the result of poor understanding of the importance of the information. *Id.* at 112 (statement of Christine Ruther, Pres. & Chief Engineer, C & R Engineering, Inc.).

<sup>123</sup> See Kessler & Vladeck, *supra* note 106, at 469.

<sup>124</sup> 2008 *House Oversight Hearing*, *supra* note 107, at 92 (testimony of David A. Kessler, M.D., former FDA Comm'r).

<sup>125</sup> See *id.* at 74-75 (testimony of Aaron Kesselheim, M.D., Dep't of Pharmacoepidemiology, Brigham Women's Hospital, Boston). *But see id.* at 122 (statement of John E. Calfee of American Enterprise Institute) (stating that Vioxx litigation did not improve public information about the drug). Gregory Curfman, Executive Editor of the *New England Journal of Medicine*, also testified at the hearing regarding a Vioxx clinical study conducted by

litigation, manufacturers have a reverse incentive—to withhold information that is relevant to the safety of the product.<sup>126</sup> In addition to manufacturer deterrence, litigation serves a role in revealing information that may assist physicians in their prescribing decisions.<sup>127</sup>

These issues provide an important backdrop to the Supreme Court's evolving doctrine of product preemption. As time goes on, and products become increasingly complex, one can anticipate more regulation. But more regulation does not necessarily mean either better regulation or safer products. It is with these issues in mind that this Article turns to the triad of new Supreme Court cases.

### III. REACHING MATURITY IN A NEW TRIAD OF DECISIONS

In 2008, the United States Supreme Court decided two major product preemption cases that focused on the issue of express preemption. In early 2009, the Court decided a third case, which involved the doctrine of implied preemption. This triad of cases provides a unique opportunity to reevaluate the Court's product preemption doctrine, and the picture of the dynamics of the doctrine that emerges is revealing. On the one hand, the Court has developed a firm approach to certain procedural aspects of preemption analysis, particularly express preemption, which is useful to judges and attorneys. On the other hand, this triad of cases is troubling when viewed in the light of the health and safety role of product liability law. I first provide a brief critical analysis of each case in the triad. Thereafter, this Article demonstrates that the Court has moved toward a unitary standard of preemption analysis that merges—even blurs—the distinctions between express preemption and implied preemption.

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the manufacturer and published in the Journal in 2000. *See id.* at 106 (statement of Gregory Curfman). The reported results focused on the purpose of the study to examine the relationship between gastrointestinal bleeding and ingestion of Vioxx; the results were very favorable for the manufacturer. *Id.* at 106–07. The manufacturer failed to reveal, however, that the study revealed certain adverse cardiovascular incidents. *Id.* at 107. Eventually, the cardiac incidents came to light, but the label was not revised until 2002. *Id.* When the product was removed from the market in 2004, the deterrence value of litigation played a role. *Id.*

<sup>126</sup> *See id.* at 75 (testimony of Aaron Kesselheim, M.D., Dep't of Pharmacoepidemiology, Brigham Women's Hospital, Boston).

<sup>127</sup> *Id.* at 34 (testimony of Aaron Kesselheim, M.D., Dep't of Pharmacoepidemiology, Brigham Women's Hospital, Boston).

A. *Riegel v. Medtronic, Inc.*

In *Riegel v. Medtronic, Inc.*,<sup>128</sup> the Court employed language that extended beyond the scope of the issues presented and articulated legal principles that have far-reaching consequences. *Riegel*, like *Lohr*, involved the MDA and its preemption provision, as well as the role of the FDA.<sup>129</sup> *Riegel* differed factually from *Lohr* in that the cardiac catheter at issue in the case was a Class III medical device that had received approval by the FDA pursuant to the premarket approval process (“PMA process”).<sup>130</sup> In contrast, *Lohr* involved a device that had been marketed pursuant to the MDA’s section 510k provisions for approval upon a showing that the device was “substantially equivalent” to a device previously marketed.<sup>131</sup> The cardiac device alleged to be defective in *Riegel* was a balloon catheter that had received premarket approval by the FDA pursuant to the full PMA process in 1994, with supplemental labeling approval in 1995 and 1996.<sup>132</sup> Upon inflation, the catheter ruptured, resulting in a blockage and necessitating coronary bypass surgery.<sup>133</sup>

The *Riegel* Court found a sufficient distinction between 510k “substantial equivalency” and approval under the PMA process to hold that the claims raised by the plaintiff in *Riegel* were preempted.<sup>134</sup> The Court addressed the same issues as those raised in *Lohr*, based upon the requirements of the same MDA preemption provision. First, the Court determined that the federal government had “established or continued in effect” requirements “with respect to” the catheter in question. Keeping close to the analysis in *Lohr*, the Court examined the provisions of the FDA regulation, which interpreted the preemption provision as applicable “only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular

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<sup>128</sup> 128 S. Ct. 999 (2008).

<sup>129</sup> See *supra* notes 31–39 and accompanying text.

<sup>130</sup> *Riegel*, 128 S. Ct. at 1004–05 (discussing the premarket approval process under 21 U.S.C. § 360e).

<sup>131</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 480 (1996).

<sup>132</sup> *Riegel*, 128 S. Ct. at 1005.

<sup>133</sup> *Id.* The district court held that virtually all of the plaintiff’s personal injury claims against the manufacturer were preempted. *Id.* at 1005–06. The claims were based upon strict product liability and negligence in testing, design, and manufacture of the catheter, labeling, and all aspects of sale and distribution. The claims also included breach of express and implied warranty. *Id.* at 1006. The district court held all of the claims preempted except for breach of express warranty and negligent manufacture to the extent that it was based upon duties parallel to the duties established under federal law. *Id.* Later, the district court granted summary judgment to Medtronic on those claims. *Id.* at 1006 n.2. The Second Circuit affirmed. *Id.* at 1006.

<sup>134</sup> *Id.* at 1007.

device . . . .”<sup>135</sup> In *Lohr*, the Court had held that the MDA’s labeling and manufacturing regulations were not device-specific in any sense that triggered the preemption provision.<sup>136</sup> The *Riegel* Court found that the “[p]remarket approval, in contrast, imposes ‘requirements’ under the MDA as [it] interpreted it in *Lohr*,”<sup>137</sup> and held that the claims were expressly preempted. The Court reasoned as follows:

[T]he FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness. And while the FDA does not “require” that a device allowed to enter the market as a substantial equivalent “take any particular form for any particular reason,” the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.<sup>138</sup>

Thus, the Court paradoxically held that the premarket approval process per se imposes device-specific requirements, even though no such requirements appear in the regulations. In this respect, the Court’s analysis was at odds with *Lohr*.

Similarly, and again in conflict with *Lohr*, the *Riegel* Court held that although state common law applies generally, and not only to the medical device at issue in the case, the MDA preemption provision nevertheless barred the claims. Focusing on the statutory language, the Court stated that “[n]othing in the statutory text suggests that the pre-empted state requirement must apply *only* to the relevant device, or only to medical devices and not to all products and all actions in general.”<sup>139</sup> The plaintiffs had relied upon the same FDA explanatory regulation that the Court had found instructive in *Lohr*. The *Riegel* Court, however, found the regulation unpersuasive<sup>140</sup> and reached a different result.

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<sup>135</sup> *Id.* at 1006 (quoting 21 C.F.R. § 808.1(d) (2003)) (alteration in original).

<sup>136</sup> *Lohr*, 518 U.S. at 501.

<sup>137</sup> *Riegel*, 128 S. Ct. at 1007.

<sup>138</sup> *Id.* (citations omitted).

<sup>139</sup> *Id.* at 1010.

<sup>140</sup> *Id.* The Court’s skepticism of the regulation apparently was based upon statements made by the FDA in its amicus brief:

Even assuming that this regulation could play a role in defining the MDA’s pre-emptive scope, it does not provide unambiguous support for the Riegels’ position. The agency’s reading of its own rule is entitled to substantial deference, . . . and the FDA’s view put forward in this case is that the regulation does not refer to



Further, the Court determined that state tort law applicable to the case imposes requirements that are “different from, or in addition to” the requirements of the PMA process relative to the balloon catheter and that such requirements “relate to the safety or effectiveness of the device.”<sup>141</sup> The Court focused on the meaning of the term “requirements imposed under state law” set forth in the MDA express preemption provision.<sup>142</sup> Taking its cue from *Lohr*, the Court made a sweeping pronouncement regarding the meaning of “requirements” in the preemption provision of any statute. After noting that a majority of the Justices in *Lohr* held the position that common-law tort claims may impose “requirements” within the meaning of the MDA preemption provision,<sup>143</sup> the Court extended that definition to the same language appearing in any preemption provision in any federal statute. The Court stated: “Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State’s ‘requirements’ includes its common-law duties.”<sup>144</sup> Thus, the Court placed the burden squarely on Congress in the first instance to exclude state common-law claims from the meaning of “requirements” in a federal preemption provision or to use some other, more explicit, terminology.

In determining that the common-law duties were “different from or in addition to” the duties imposed by federal law, the Court reasoned that jury verdicts are not the result of the same risk-benefit balancing as that conducted by the FDA. Juries, the Court stated, are concerned

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general tort duties of care, such as those underlying the claims in this case that a device was designed, labeled, or manufactured in an unsafe or ineffective manner.

*Id.* (citing Brief for United States as Amicus Curiae Supporting Respondent, at 27–28, *Riegel*, 128 S. Ct. 999 (No. 06-179)) (other citation omitted). In *Lohr*, by contrast, the Court adopted the explanation of the preemption provision contained in the regulation itself. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 498–99 (1996).

<sup>141</sup> *Riegel*, 128 S. Ct. at 1007–11.

<sup>142</sup> *Id.* at 1006–07.

<sup>143</sup> *Id.* at 1008 (“In *Lohr*, five Justices concluded that common-law causes of action for negligence and strict liability do impose ‘requirement[s]’ and would be pre-empted by federal requirements specific to a medical device.” (alteration in original)). This majority was comprised of four Justices who concurred in part and dissented in part, as well as Justice Breyer. See *Lohr*, 518 U.S. at 509 (O’Connor, J., concurring in part and dissenting in part); *id.* at 503 (Breyer, J., concurring in part and concurring in judgment).

<sup>144</sup> *Riegel*, 128 S. Ct. at 1008. The Court seemed to suggest that the inclusion of common-law tort judgments within the meaning of “requirements” is a rebuttable presumption. The Court defended its definition in this particular case, stating that “excluding common-law duties from the scope of pre-emption would make little sense. State tort law that requires a manufacturer’s catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.” *Id.*

only with the risks of a product, not with balancing those risks against the benefits the product offers.<sup>145</sup> The FDA, by contrast, is concerned with the full range of costs and benefits associated with the product in deciding whether to grant premarket approval.<sup>146</sup>

On the surface, *Riegel* appears to follow closely the fundamentals of express preemption set forth in the earlier line of cases. *Riegel*'s formulation of express preemption is generally consistent with the analysis in *Lohr*, and thereby follows the line of cases from *Cipollone* to *Bates*. In the process, the Court standardized the definition of the term "requirements" when that term appears in a general express preemption provision. Whether this is warranted or not, there is at least a presumption that "requirements" includes state common-law judgments.

But the devil is in the details, and there are many in *Riegel*. First, *Riegel* is not entirely consistent with *Lohr*, its closest Supreme Court relative. For one thing, the Court refused to hold, consistent with *Lohr*, that common-law duties of general applicability were not "requirements" for the purpose of preemption under the MDA because they lacked device specificity.<sup>147</sup> In its refusal, the Court in effect embraced the FDA's new position favoring blanket preemption in product cases.<sup>148</sup> The FDA had advanced this position for several years in amicus briefs<sup>149</sup> and placed it in the 2006 preamble to FDCA amendments.<sup>150</sup> This new position in favor of broad preemption was a reversal of the position held by the FDA for decades, which recognized that state tort law coexists with FDA regulation.<sup>151</sup> The *Riegel* Court decided not to address the full legal implications of the 2006 preamble.<sup>152</sup> Instead, the Court simply reinterpreted the regulation the *Lohr* Court had relied on and, with a different

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<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> *Id.* at 1009–10.

<sup>148</sup> *Id.* at 1010 ("Even assuming that [the earlier] regulation could play a role in defining the MDA's pre-emptive scope, it does not provide unambiguous support for the Riegels' position."). The Court noted that the FDA's position on preemption in product liability cases had recently changed, as embodied in the amicus brief for the United States. *Id.* (citing Brief for United States as Amicus Curiae Supporting Respondent, at 27–28, *Riegel*, 128 S. Ct. 999 (No. 06-179)).

<sup>149</sup> See *Wyeth v. Levine*, 129 S. Ct. 1187, 1201–03 (2009) (discussing the FDA's new position favoring preemption); cf. *Riegel*, 128 S. Ct. at 1010 (relying on amicus brief of United States for interpretation of the earlier regulation explaining the preemption provision).

<sup>150</sup> 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601).

<sup>151</sup> See *Levine*, 129 S. Ct. at 1201–02 (noting that the preamble "reverses the FDA's longstanding position" regarding the interaction between state law and the FDA's own regulations).

<sup>152</sup> In *Levine*, the Court did take on the legal effect of the 2006 preamble, and rejected its application. See *id.* at 1201; *infra* notes 226–230 and accompanying text.

interpretation, reached a different result. The Court held that state common-law duties of general applicability do, in fact, fit within the regulation's description of those rules that may be preempted under the MDA.<sup>153</sup>

Second, the *Riegel* decision lacks the full contextual analysis of the statute and regulations invoked in the case, an analysis that the Court had embraced repeatedly in earlier cases, including in *Lohr*. In *Riegel*, Justice Ginsburg made the argument for this larger contextual analysis in her dissent. At the outset, Justice Ginsburg stated: "Contextual examination of the [MDA] convinces me that § 360k(a)'s inclusion of the term 'requirement' should not prompt a sweeping preemption of mine-run claims for relief under state tort law."<sup>154</sup> Discussing the legislative history of the MDA, she argued that blanket preemption of claims based upon devices that had undergone the PMA process is inconsistent with Congress's professed goal to provide regulation for an industry greatly in need of it.<sup>155</sup> Moreover, Justice Ginsburg demonstrated that the impetus for the inclusion of the MDA's preemption provision in the first instance had been state premarket approval regulatory schemes that had developed over the years in the absence of federal oversight, "not any design to suppress tort suits."<sup>156</sup>

Third, the Court's disparagement of lay juries as arbiters of the risks and benefits of products is a weak argument and runs counter to the value the Court has placed on tort judgments in other cases. State product liability law takes accounts of both the risks and benefits of the product at issue in a particular case. Jurisdictions recognizing versions of product liability law in accordance with the Second<sup>157</sup> or Third Restatement of Torts<sup>158</sup> ask jurors to apply a risk-utility balancing test in defective design cases. A related analysis applies to most failure to warn cases as well. For example, under New York law—the applicable substantive law in the *Riegel* case—the common law has definitively included risk-utility balancing for many years. As early as 1983, the New York Court of Appeals held with respect to design defect claims that the jury was to consider "whether it is a

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<sup>153</sup> *Riegel*, 128 S. Ct. at 1010. The Court was dismissive of the FDA's earlier explanation of its own rule, saying that it was "less than compelling." *Id.*

<sup>154</sup> *Id.* at 1014 (Ginsburg, J., dissenting).

<sup>155</sup> *Id.* at 1016 (stating that the majority's position has the "perverse effect" of relieving medical device sellers of liability under tort law).

<sup>156</sup> *Id.* at 1018.

<sup>157</sup> RESTATEMENT (SECOND) OF TORTS § 402A (1965). The Second Restatement employed a consumer expectations test, but used an explicit risk-benefit analysis for design defects in the category of unavoidably unsafe products. *See id.* cmt. k.

<sup>158</sup> THIRD RESTATEMENT, *supra* note 101, § 2.

product which, if the design defect were known at the time of manufacture, a reasonable person would conclude that the utility of the product did not outweigh the risk inherent in marketing a product designed in that manner.”<sup>159</sup> Reiterating this standard in 1995, the Court of Appeals further explained that it was founded in

a recognition that there are both risks and benefits associated with many products and that there are instances in which a product’s inherent dangers cannot be eliminated without simultaneously compromising or completely nullifying its benefits. In such circumstances, a weighing of the product’s benefits against its risks is an appropriate and necessary component of the liability assessment under the policy-based principles associated with tort law.<sup>160</sup>

Indeed, this same principle underlies the *Carroll Towing* formula as a mechanism for determining whether a defendant has breached a duty in a negligence case.<sup>161</sup>

Thus, a jury deliberating whether a product is defective is typically asked to weigh the benefits against the risks of the product in deciding whether it is unreasonably dangerous.<sup>162</sup> As Justice Stevens indicated in his concurring opinion in *Riegel*, juries merely apply the

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<sup>159</sup> *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 208 (N.Y. 1983). The court listed various factors to be considered by the jury in its risk-utility analysis. *Id.* at 208–09.

<sup>160</sup> *Denny v. Ford Motor Co.*, 662 N.E.2d 703, 735 (N.Y. 1995) (citation omitted). Applying the risk-utility balancing test to a case involving tobacco products, a New York appellate court in 2003 cited to the Third Restatement’s risk-utility test in support of its holding. *See Miele v. Am. Tobacco Co.*, 770 N.Y.S.2d 386, 391 (N.Y. App. Div. 2003) (citing RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2, cmt. g (1998)).

<sup>161</sup> *See United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947) (suggesting that a defendant fails to meet the appropriate standard of care if the burden of taking adequate precautions is less than the probability that harm will occur multiplied by the gravity of the resulting injury).

<sup>162</sup> A typical jury instruction on risk-utility balancing in a product liability case states, in part:

You may find that the product at issue in this case is unreasonably dangerous if you find that (1) a condition of the product was the proximate cause of the plaintiff’s injuries; and that (2) on balance, the benefits of the product’s design did not outweigh the risks of danger inherent in the design.

The defendant has the burden of proving that the benefits of the product’s design outweighed the risks of danger inherent in the design.

3-100 Illinois Forms of Jury Instruction § 100.05B (2008). The instruction follows with factors for the jury to consider in conducting the balancing test, including, but not limited to, the usefulness of the product, the likelihood that it would cause injury, the magnitude of the injury that could result, the availability of alternatives, and whether the manufacturer could have eliminated or reduced the risk through reasonable care and without impairing the utility of the product. *Id.*

law; they do not make the law.<sup>163</sup> This distinction is relevant to *Riegel* and all other cases involving statutes in which Congress has preempted state “requirements” of any sort. It also implies that jury verdicts, per se, do not have the power to force a defendant to alter its conduct. Rather, that is a choice left entirely to the defendant, weighing all the circumstances, including payments of judgments based upon findings that their products were defective. Regardless of the legitimacy of this argument, however, the *Riegel* Court ruled that the term “requirements” in any preemption provision will be presumed to include common-law verdicts.<sup>164</sup>

*Riegel* is counterintuitive in an additional way: there is no guarantee that medical devices marketed pursuant to the PMA process will fare much better in the postmarket phase than devices falling within the section 510k “substantial equivalency” designation. The Court emphasized that the FDA conducts approximately 1,200 hours of review for each PMA application, far more time than is spent on a finding of substantial equivalency.<sup>165</sup> While extensive review of a manufacturer’s PMA application may be a *prediction* of the safety and effectiveness of the product—based only on testing in controlled situations on very few persons—adverse events can occur in the postmarket phase.<sup>166</sup> Some of those adverse events could be due to inherent defects in the product or negligence of the manufacturer. Moreover, the fact that the FDA’s effectiveness in following through on postmarket surveillance has been seriously compromised by insufficient resources<sup>167</sup> means that the same safety crisis applies to any device on the market, regardless of how it got there. Thus, the basis for the Court’s distinction between *Riegel* and *Lohr* dissolves in the postmarket phase.

### B. Altria Group, Inc. v. Good

In late 2008, the United States Supreme Court decided a follow-up case to *Cipollone*. *Altria Group, Inc. v. Good*<sup>168</sup> reaffirmed the importance of *Cipollone* in the larger scope of the Court’s product preemption doctrine. Although *Good* did not directly raise the

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<sup>163</sup> *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1012 n.1 (2008) (Stevens, J., concurring in part and concurring in judgment).

<sup>164</sup> *Id.* at 1009–10 (majority opinion).

<sup>165</sup> *Id.* at 1004.

<sup>166</sup> See *supra* notes 107–27 and accompanying text.

<sup>167</sup> See David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 101 (2005) (“The FDA is perhaps the most capable federal safety agency, but it cannot exert sufficient discipline on the marketplace to ensure an adequate margin of safety for the devices on the market, a fact that the agency, at least until recently, itself acknowledged.”).

<sup>168</sup> 129 S. Ct. 538 (2008).

question of preemption of common-law tort claims, the case involved the same statute, and the same express preemption provision, as *Cipollone*. Moreover, the Court's approach offers a window into the mature product preemption doctrine. While the Court's procedural approach was consistent with the line of express preemption cases from *Cipollone* to *Bates*, and now *Riegel*, lurking beneath the surface of the opinion were some continuing unresolved issues.

The *Good* respondent-plaintiffs had brought an action claiming that the defendant cigarette manufacturer had deceived them about the health hazards of their so-called "light" cigarettes in violation of a state deceptive practices statute.<sup>169</sup> Philip Morris—whose parent company was petitioner Altria<sup>170</sup>—had marketed certain of its cigarettes as containing lower tar and nicotine than regular cigarettes, based upon test results acquired by the Cambridge Testing Method.<sup>171</sup> The plaintiffs alleged that Philip Morris's marketing of certain brands as "light" fraudulently represented the cigarettes as safer for human consumption than regular cigarettes. The plaintiffs further alleged that Philip Morris knew that smokers engaged in various compensatory smoking behaviors that enabled them to take in the same amount of nicotine, or more, as with regular cigarettes.<sup>172</sup> They also claimed that Philip Morris knew that the smoke emitted from its "light" cigarettes was in fact more harmful in chemical content than smoke from regular cigarettes.<sup>173</sup> Philip Morris's actions in marketing the "light" cigarettes, in the plaintiffs' opinion, constituted fraud in violation of Maine's deceptive practices statute.<sup>174</sup>

The *Good* Court agreed with the First Circuit that the claims were not preempted.<sup>175</sup> In a five-to-four decision written by Justice Stevens,

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<sup>169</sup> *Id.* at 541 (citing ME. REV. STAT. ANN. tit. 5, § 207 (Supp. 2008)).

<sup>170</sup> See PhilipMorrisUSA, About Philip Morris USA, [http://www.philipmorrisusa.com/en/cms/Company/Corporate\\_Structure/default.aspx](http://www.philipmorrisusa.com/en/cms/Company/Corporate_Structure/default.aspx) (last visited September 19, 2009).

<sup>171</sup> See *Good*, 129 S. Ct. at 541 & n.2 (discussing the Cambridge Testing Method and noting that the Federal Trade Commission indicated in 1966 that the process was an acceptable method for measuring tar and nicotine).

<sup>172</sup> *Id.* at 541. These behaviors included covering ventilation holes, inhaling more frequently or in larger amounts, and holding the smoke in their lungs for longer periods of time. *Id.*

<sup>173</sup> As the Court characterized it, "'Light' cigarettes are in fact more harmful because the increased ventilation that results from their unique design features produces smoke that is more mutagenic per milligram of tar than the smoke of regular cigarettes." *Id.* at 542.

<sup>174</sup> *Id.* at 541.

<sup>175</sup> *Id.* at 551. The district court had granted Altria's summary judgment motion on the ground that the claims were expressly preempted by the cigarette labeling act. *Id.* at 542. In doing so, the court characterized the fraud claim as a warning neutralization claim, similar to the fraud claim held preempted in *Cipollone*. *Id.*; see also *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 527 (1992). The *Cipollone* Court distinguished between fraud claims asserting that the cigarette manufacturer had neutralized the mandatory packaging warning through its advertising—which were held preempted—and fraud claims based upon a general state-law

the author of the Court's decisions in both *Cipollone* and *Lohr*, the Court re-emphasized the basic principles of express preemption underlying those two decisions. First, the Court stated that the intent of Congress is the "ultimate touchstone" of any express preemption decision.<sup>176</sup> Second, the Court again articulated the presumption against preemption: "[W]e begin our analysis 'with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'"<sup>177</sup> Citing its earlier decisions,<sup>178</sup> the Court reaffirmed the need to leave matters of historical state interest—particularly state police power—in the hands of the states.<sup>179</sup> Of particular interest was the fact that the Court stated the presumption rule broadly. Thus, not only does it have continuing vitality, but it applies in matters of both express and implied preemption.<sup>180</sup>

The Court acknowledged that the cigarette labeling act's requirements, coupled with the express preemption provision, prohibit states from creating their own cigarette warnings different from those established in the statute. But that prohibition in no way prevents the states from enforcing their deceptive practices laws in matters related to cigarettes labeled in conformity with the labeling acts. Moreover, the Court stated that the purposes of the labeling act "would [not] be served by limiting the States' authority to prohibit deceptive statements in cigarette advertising."<sup>181</sup> Still, the Court emphasized, the

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duty not to deceive—which were not preempted. *Cipollone*, 505 U.S. at 527–29. In *Good*, the First Circuit reversed, however, finding that the fraud claim was more akin to the fraud claim in *Cipollone* that was held not preempted. *Good*, 129 S. Ct. at 542.

<sup>176</sup> *Good*, 129 S. Ct. at 543 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

<sup>177</sup> *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)) (alteration in original).

<sup>178</sup> Another preemption case the Court relied upon was *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001), which also invoked the preemption provisions of the Federal Cigarette Labeling and Advertising Act (FCLAA). In *Reilly*, tobacco product manufacturers and retailers brought suit seeking to have certain Massachusetts deceptive practices regulations governing the advertising and sale of cigarettes, smokeless tobacco, and cigars declared preempted by federal law. *See id.* (addressing 940 MASS. CODE REGS. 21.01–07, 22.01–09 (2000)). The state regulations primarily imposed limitations on the sale and advertising of tobacco products to underage youths. *Id.* at 533–34. The Supreme Court conducted an express preemption analysis and held that the regulations relating to cigarettes were preempted by the FCLAA. *Id.* at 550–51. With regard to the regulations relating to smokeless tobacco products and cigars, the Court noted that the FCLAA was inapplicable. *Id.* at 565. The Court then held that certain of the advertising regulations violated the First Amendment as impermissible restraints on commercial speech. *Id.* at 565–66.

<sup>179</sup> *See Good*, 129 S. Ct. at 543.

<sup>180</sup> The Court referenced both *Lohr*, 518 U.S. at 485, and *Reilly*, 533 U.S. at 541–42.

<sup>181</sup> *Good*, 129 S. Ct. at 544.

touchstone of the analysis is the intent of Congress within the language of the express preemption provision.<sup>182</sup>

The main value of *Good* is in reinforcing the Court's approach to express preemption; the case adds little to the substance of the product preemption doctrine. As in *Riegel*, the *Good* Court reaffirmed its internal process of conducting an express preemption analysis. In *Good*, however, the Court, after finding no express preemption, proceeded to conduct an implied preemption analysis in response to the petitioners' argument that the Maine regulations constituted an obstacle to the achievement of Federal Trade Commission policies advancing the development and promotion of low tar cigarettes.<sup>183</sup> The Court decided that no such obstacle existed.<sup>184</sup> But its brief engagement in the process of implied preemption raised the same confusing set of questions as prior product preemption decisions. The Court could have decided, consistent with *Cipollone*, that moving to an implied preemption analysis was inappropriate—that the issue was encompassed fully by the express preemption provision—but the Court did not do so, opting instead to conduct an implied preemption analysis for reasons that remain unclear.

### C. Wyeth v. Levine

The United States Supreme Court took the opportunity to circumscribe the limits of implied preemption in *Wyeth v. Levine*,<sup>185</sup> a case that originated in the Vermont state court system. Although the case specifically involved the new drug provisions of the FDCA,<sup>186</sup> it has far-reaching implications for all other product cases raising implied preemption arguments. In holding that the respondent-plaintiff's failure-to-warn claims were not impliedly preempted, the Court upheld the decision of the Supreme Court of Vermont.<sup>187</sup>

The claims arose from the administration of the defendant's drug Phenergan by the "IV push" method, during which the drug was accidentally injected into an artery. The resulting arterial damage ultimately led to amputation of the plaintiff's forearm.<sup>188</sup> The plaintiff

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<sup>182</sup> *Id.* at 543.

<sup>183</sup> *Id.* at 549.

<sup>184</sup> *Id.* at 551.

<sup>185</sup> 129 S. Ct. 1187 (2009).

<sup>186</sup> 21 U.S.C. § 355 (2006), as amended by Pub. L. No. 110-379, 122 Stat. 4075 (2008); 21 C.F.R. § 314.105(b) (2009) (explaining the application approval process and labeling procedures).

<sup>187</sup> *Levine*, 129 S. Ct. 1187.

<sup>188</sup> *Levine v. Wyeth*, 944 A.2d 179, 182 (Vt. 2006), *aff'd*, 129 S. Ct. 1187 (2009).



brought an action for inadequate warnings based upon negligence and product liability.<sup>189</sup> Wyeth sought dismissal of the claims on a summary judgment motion on the ground that the labeling procedures in effect pursuant to the FDCA—with which Wyeth had complied—preempted the claims based upon inadequacy of the warning.<sup>190</sup> The trial court denied Wyeth's summary judgment motion, and the case went to trial, resulting in a jury verdict for the plaintiff on both the negligence and product liability claims.<sup>191</sup>

The Phenergan label contained a warning about the potential dangers of the drug to the patient's arteries if administered by IV push, rather than IV drip. The warning stated in part that "extreme care should be exercised to avoid . . . inadvertent intra-arterial injection."<sup>192</sup> Wyeth had submitted a revised warning to the FDA in 1988, which strengthened the language relating to inadvertent arterial injection. The FDA did not directly address the proposed language or respond to Wyeth's submission.<sup>193</sup> No new label activity occurred until 1996, when the FDA reviewed the existing label and told Wyeth to retain the language of the label then in use, giving no reason.<sup>194</sup>

The FDCA contains no express preemption provision applicable to drugs. Accordingly, Wyeth argued that the plaintiff's common-law claims conflicted with the FDA's approval of the original warning label and with its subsequent failure to approve the stronger warning submitted in 1988.<sup>195</sup> Wyeth therefore asserted that the trial court should have held that the plaintiff's claims were impliedly preempted.<sup>196</sup> The company followed two lines of argument. In the first, Wyeth said that complying with both the label required by the FDA and any common-law duties imposed by tort law would be impossible.<sup>197</sup> In the second, Wyeth argued that state tort damages for personal injuries allegedly caused by defective drugs effectively constituted a penalty for compliance with FDA labeling regulations. Thus, the argument continued, allowing tort claims would create an obstacle to accomplishing the purpose of the federal labeling

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<sup>189</sup> *Id.*

<sup>190</sup> *Id.* at 183.

<sup>191</sup> *Id.* at 182. The court similarly denied Wyeth's motion for judgment as a matter of law after the verdict on the same ground. *Id.* at 183.

<sup>192</sup> *Id.* at 183 n.1.

<sup>193</sup> See *Wyeth v. Levine*, 129 S. Ct. 1187, 1192 (2009).

<sup>194</sup> *Id.* The Court derived its information regarding the interaction between Wyeth and the FDA on the matter of the Phenergan label from the trial record. *Id.*

<sup>195</sup> *Id.* at 1193.

<sup>196</sup> *Id.*

<sup>197</sup> *Id.*

regulations<sup>198</sup> because the expert decisions of the FDA in approving drugs for market would be second-guessed by lay juries.<sup>199</sup>

The Vermont Supreme Court rejected both implied preemption arguments, and the United States Supreme Court affirmed. The Court began by restating the “two cornerstones” of the preemption doctrine,<sup>200</sup> relying on the principles set forth in *Lohr* and other decisions. What is especially striking is that the Court’s analysis in this implied preemption decision tracks its express preemption analysis to a large extent. First, the Court restated that “the purpose of Congress is the ultimate touchstone in every pre-emption case.”<sup>201</sup> Furthermore, the Court again emphasized the need for deference to the police powers of the States unless “the clear and manifest purpose of Congress” was to preempt state law.<sup>202</sup> Thus, the Court applied the presumption against preemption, which seemed to end the debate over whether the presumption may apply in cases of implied preemption.

In discerning the purpose of Congress, the Court fully examined the context of the relevant statutory provisions. The Court deemed significant several events in the history of the FDCA. The Court noted that when Congress enacted the Federal Food and Drugs Act in 1906<sup>203</sup>—the predecessor to the FDCA—it intended the Act to supplement pre-existing state regulations and common law.<sup>204</sup> Subsequently, Congress continued to have concern for the safety of drugs marketed to the public and enacted the FDCA in 1938,<sup>205</sup> which included provisions for new drug applications requiring FDA approval.<sup>206</sup>

The Act has been amended several times, but the Court was especially interested in the 1962 amendments. At that time, Congress amended the FDCA in two ways that the Court found relevant to its decision in *Levine*. First, the amendments placed the burden of proving the safety of a drug that was the subject of a new drug application on the shoulders of the manufacturer.<sup>207</sup> Prior to the amendment, the FDA was responsible for demonstrating that the drug

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<sup>198</sup> *Id.*

<sup>199</sup> *Id.* at 1194.

<sup>200</sup> *Id.* at 1194–95.

<sup>201</sup> *Id.* at 1194 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

<sup>202</sup> *Id.* at 1194–95.

<sup>203</sup> Federal Food and Drugs Act, ch. 3915, 34 Stat. 768 (1906).

<sup>204</sup> *Levine*, 129 S. Ct. at 1195.

<sup>205</sup> Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C.A. §§ 301–395 (West 2009)).

<sup>206</sup> 21 U.S.C.A. § 355(c).

<sup>207</sup> See Drug Amendments of 1962, Pub. L. No. 87-781, §§ 102(d), 104(b), 76 Stat. 780, 781–82, 784.

was harmful to prevent it from being released into the consumer market.<sup>208</sup> Second, the 1962 amendments contained a saving clause, which provided: “Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law . . . unless there is a direct and positive conflict between such amendments and such provision of State law.”<sup>209</sup> The Court also noted that in 1976 Congress enacted the Medical Device Amendments<sup>210</sup> to the FDCA, which included an express preemption provision, but has never included such a provision for drugs subject to the Act.<sup>211</sup> Finally, the Court examined the 2007 amendments to the FDCA,<sup>212</sup> which strengthened the FDA’s ability to require drug label changes after the drug has been approved for marketing, but which still allowed the manufacturer to make appropriate label changes without FDA prior approval.<sup>213</sup>

With reference to these congressional enactments, the Court first addressed Wyeth’s argument that it could not comply with both the FDCA and the obligations imposed under state tort law through money judgments. Wyeth had interpreted the FDA’s indifference to its proposed label modification as an absolute prohibition against either providing a stronger warning label or eliminating IV push as an acceptable method for drug delivery.<sup>214</sup> A state tort judgment, Wyeth argued, would effectively require the manufacturer to modify the label in one of these ways. The Court rejected this argument because Wyeth could have provided a stronger warning about the IV-push method without prior FDA approval and without falling afoul of federal laws on misbranded drugs.<sup>215</sup> Examining the trial record, the Court concluded that nothing in the record suggested that the FDA had made any safety judgment about Wyeth’s proposed label modification, or that the FDA’s indifference bore any substantive meaning. Thus, Wyeth could have provided a warning that comported with state-law tort duties without violating federal law.<sup>216</sup>

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<sup>208</sup> *Levine*, 129 S. Ct. at 1195.

<sup>209</sup> Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793.

<sup>210</sup> Medical Device Amendments of 1976, Pub. L. No. 94-295, § 521, 90 Stat. 539, 574 (codified as amended at 21 U.S.C. § 360k (2006)).

<sup>211</sup> *Levine*, 129 S. Ct. at 1196.

<sup>212</sup> Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823.

<sup>213</sup> See *Levine*, 129 S. Ct. at 1196 (citing rule of construction at 121 Stat. 925–26).

<sup>214</sup> See *Levine v. Wyeth*, 944 A.2d 179, 188 (Vt. 2006), *aff’d*, 129 S. Ct. 1187 (2009).

<sup>215</sup> Wyeth argued, among other things, that if it had strengthened the Phenergan warning without prior FDA approval, it would have either become subject to the “new drug” rules once again (on the theory that Phenergan with a new label would thereby become a new drug) or be marketing a “misbranded” drug. See *Levine*, 129 S. Ct. at 1196–98. The Court rejected these arguments as both unfaithful to Congress’ meaning and counterintuitive. See *id.* at 1196–97.

<sup>216</sup> *Id.* at 1198–99.

The Court next addressed Wyeth's argument that state tort-law judgments constituted an obstacle to the proper and effective administration of the federal drug labeling requirements.<sup>217</sup> Wyeth essentially argued that, based upon its expertise, the FDA is the only entity that Congress has allowed to render decisions about drug labels, through a complex process of risk-utility analysis.<sup>218</sup> Accordingly, in Wyeth's view, allowing state tort claims against a drug manufacturer would inappropriately supplant the FDA's expertise with lay jury judgments and prevent the FDA from effectively doing its job.<sup>219</sup> The Court rejected this argument as "an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law."<sup>220</sup> The Court stated that every prior action of Congress vis-à-vis the safety of prescription drugs led to the conclusion that Congress assumed all along that state common law would provide remedies for injured consumers.<sup>221</sup> In reaching this conclusion, the Court relied on both Congress's actions and its silence. Thus, the Court emphasized that Congress has never included an express preemption provision in the FDCA, with the exception of the MDA, and stated: "Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."<sup>222</sup>

The Court's examination of the entire history of the FDCA in relation to coexisting common-law actions is not new. In the 1984 case of *Silkwood v. Kerr-McGee Corp.*,<sup>223</sup> the Court held that the plaintiff's decedent's claim for punitive damages was not impliedly preempted because Congress intended the federal statute in question

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<sup>217</sup> See *id.* at 1199.

<sup>218</sup> See *id.*

<sup>219</sup> See *id.* at 1194, 1199.

<sup>220</sup> *Id.* at 1199.

<sup>221</sup> See *id.*

<sup>222</sup> *Id.* at 1200. The Court quoted from a unanimous 1989 preemption decision: "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." *Id.* (alteration in original) (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989)) (internal quotation marks omitted).

<sup>223</sup> 464 U.S. 238 (1984). *Silkwood* involved the question whether the exclusivity of the state workers' compensation statute barred the plaintiff from bringing his decedent's claim for punitive damages in court. See *Silkwood v. Kerr-McGee Corp.*, 667 F.2d 908, 912, 915-20 (10th Cir. 1981), *rev'd*, 464 U.S. 238 (1984). The preemption question arose because the federal Atomic Energy Act purported to occupy the field in matters of nuclear safety. See *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 212 (1983).

to preempt only state regulation and not state common-law verdicts.<sup>224</sup> The Court stated:

[T]here is no indication that Congress even seriously considered precluding the use of such remedies either when it enacted the Atomic Energy Act in 1954 or when it amended it in 1959. This silence takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.<sup>225</sup>

In *Levine*, the Court employed a similar approach. The Court examined, as it had in *Silkwood*, the long history of the relationship between common-law actions and the federal statute and Congress's failure to supplant state actions with a federal remedial scheme. Additionally, the Court noted the existence of the saving clause and the acquiescence of the FDA in the complementary role of state common law during most of the long history of the Act.

The Court reasoned that all these factors substantially outweighed the FDA's sudden and recent change of view on preemption, as set forth in the 2006 preamble to an FDA regulation amending the drug labeling requirements.<sup>226</sup> The *Levine* Court strongly rejected any application of the 2006 preamble to the issues in the case. In the preamble,<sup>227</sup> the FDA curiously stated that its position favoring preemption of drug and medical device tort claims "represents the government's long standing views on preemption."<sup>228</sup> The agency took the position that "[s]tate law actions can rely on and propagate

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<sup>224</sup> See *Silkwood*, 464 U.S. at 255–56.

<sup>225</sup> *Id.* at 251.

<sup>226</sup> See *Levine*, 129 S. Ct. at 1200–04; see also Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601).

<sup>227</sup> The statement appeared in the "Supplementary Information" section of certain amendments to the labeling requirements, in a section designated "Comments on Product Liability Implications of the Proposed Rule." Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3933–36. The FDA relied on arguments submitted on its behalf by the Department of Justice in various amicus briefs in earlier product liability cases, *id.* at 3934–35, concluding that "State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated." *Id.* at 3935.

<sup>228</sup> *Id.* at 3934. Apparently, the views had been expressed in a number of government amicus briefs for several years prior to the appearance of the 2006 preamble. See *id.* ("FDA believes that under existing preemption principles, FDA approval of labeling under the act . . . preempts conflicting or contrary State law. Indeed, the Department of Justice (DOJ), on behalf of FDA, has filed a number of amicus briefs making this very point.").

interpretations of the act and FDA regulations that conflict with the agency's own interpretations and frustrate the agency's implementation of its statutory mandate."<sup>229</sup> The FDA further stated:

State law actions also threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs. State actions . . . encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public—the central role of FDA—sometimes on behalf of a single individual or group of individuals. That individualized reevaluation of the benefits and risks of a product can result in relief—including the threat of significant damage awards or penalties—that creates pressure on manufacturers to attempt to add warnings that FDA has neither approved nor found to be scientifically required.<sup>230</sup>

These statements reversed the position that the FDA had been following in seventy years of jurisprudence under the FDCA.

The Court granted no deference to the FDA's statements for several reasons. First, interested parties had not been granted an opportunity for comment, thus rendering the statements on state law "inherently suspect in light of this procedural failure."<sup>231</sup> Second, the views set forth in the regulation's preamble conflicted with a much longer-standing position of the FDA.<sup>232</sup> Moreover, the Court stated, prior to its "dramatic change" in position in 2006, the FDA had accepted state tort law as providing remedial and deterrent value in ways that federal regulation was unable to achieve.<sup>233</sup>

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<sup>229</sup> *Id.*

<sup>230</sup> *Id.* at 3935.

<sup>231</sup> *Levine*, 129 S. Ct. at 1201.

<sup>232</sup> *Id.* at 1201–02 ("[I]t appears that the FDA traditionally regarded state law as a complementary form of drug regulation.")

<sup>233</sup> *Id.* The Vermont Supreme Court had taken a different, but related, tack in refusing to grant deference to the statements made in the 2006 preamble. The court focused on the principles of *Chevron* deference and determined that they had not been met. The court stated: "Under *Chevron*, deference to an agency's interpretation is appropriate only when a statute is 'silent or ambiguous with respect to the specific issue' the agency has considered; otherwise, 'the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'" *Levine v. Wyeth*, 944 A.2d 179, 192 (Vt. 2006), *aff'd*, 129 S. Ct. 1187 (2009) (quoting *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984)). This standard was not met in *Levine*, the court said, because the FDCA was not "silent or ambiguous with respect to the specific issue" in the case. *Id.* Accordingly, the court stated, "[n]othing in the FDA's new statement alters our conclusion that it would be possible for defendant to comply with both its federal obligations and the obligations of state common law." *Id.* at 193.

Justice Alito, in his dissent in *Levine*, argued that “[a] faithful application of this Court’s conflict pre-emption cases compels the conclusion that the FDA’s 40-year-long effort to regulate the safety and efficacy of Phenergan pre-empts respondent’s tort suit.”<sup>234</sup> Rather than examining the full history of Supreme Court product preemption jurisprudence, however, Justice Alito relied almost exclusively on *Geier*, a case that has only limited relevance.<sup>235</sup> The *Levine* dissent recognized that the FDCA authorizes the FDA to make safety determinations about new drugs,<sup>236</sup> but ignored the fact that the necessary safety determination was not made in this case. Instead, the dissent criticized the majority on policy grounds, stating: “[The majority] ignores the antecedent question of who—the FDA or a jury in Vermont—has the authority and responsibility for determining the ‘adequacy’ of Phenergan’s warnings.”<sup>237</sup> The dissent argued that Congress intended only for the FDA to make health and safety determinations about prescription drugs, and that a decision by the FDA to allow a new drug to be marketed, as a matter of law, conflicted with state tort law.<sup>238</sup> A large portion of the dissenting opinion argued that the facts in the record should have been interpreted differently to support the position that the FDA had conducted a full risk-benefit analysis of Wyeth’s label.<sup>239</sup> The dissent then applied *Geier* broadly to conclude that state tort law should have been preempted.<sup>240</sup> These arguments render meaningless the saving clause in the FDCA and suggest that it should be ignored for the purpose of implied preemption analysis.<sup>241</sup>

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<sup>234</sup> *Levine*, 129 S. Ct. at 1220 (Alito, J., dissenting). Chief Justice Roberts and Justice Scalia joined Justice Alito in dissent.

<sup>235</sup> See *infra* notes 259–273 and accompanying text.

<sup>236</sup> *Levine*, 129 S. Ct. at 1218 (Alito, J., dissenting).

<sup>237</sup> *Id.* at 1217.

<sup>238</sup> See *id.* at 1220 (“Where the FDA determines, in accordance with its statutory mandate, that a drug is on balance ‘safe,’ our conflict pre-emption cases prohibit any State from countermmanding that determination.”).

<sup>239</sup> See *id.* at 1222–26.

<sup>240</sup> *Id.* at 1220, 1229. The dissent argued that “*Geier* does not countenance the use of state tort suits to second-guess the FDA’s labeling decisions.” *Id.* at 1229.

<sup>241</sup> The dissent stated the following about the FDCA saving clause: “But a provision that simply recognizes the background principles of conflict pre-emption is not a traditional ‘saving clause,’ and even if it were, it would not displace our conflict-pre-emption analysis.” *Id.* at 1221 n.4 (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000)).

#### IV. THE UNITARY PRODUCT PREEMPTION DOCTRINE

##### *A. Toward a Unitary Standard*

The recent triad of Supreme Court product preemption cases—*Riegel*, *Good*, and *Levine*—taken together demonstrate a distinct movement in the Court toward a unitary product preemption doctrine. This unitary doctrine has the effect of merging the concepts of express preemption and implied preemption into a single, interrelated process. The earlier Supreme Court cases, upon closer examination, foreshadowed this development, and indeed the Court has been moving toward a unitary standard for some time. Much of the confusion that has emerged from the fluctuating standards that appeared to characterize the product preemption doctrine over the past two decades was a result of assumptions made by attorneys and scholars as to the fixed nature of that doctrine. In turn, the Court fed these assumptions with its statements about the doctrine, many of which separated express preemption analysis from implied preemption analysis, leaving the impression that discrete rules should apply to each. As its latest opinions demonstrate, however, the Court has instead merged the standards.

In the cases prior to 2008, the Court felt free to apply express or implied preemption as it saw appropriate. In *Lohr* and *Bates*, the Court conducted an express preemption analysis, which ended the inquiry. In *Buckman*, however—which involved the same federal statute as *Lohr*—the Court barely acknowledged express preemption and did not conduct an express preemption analysis in holding the claims preempted under an implied preemption analysis.<sup>242</sup> In *Geier*, the Court conducted an express preemption analysis and, after concluding that the claims were not preempted thereunder, proceeded to hold the claims preempted under an implied preemption theory.<sup>243</sup> In all of this muddle, the presumption against preemption appeared sporadically and inconsistently.

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<sup>242</sup> *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). The *Buckman* Court's entire discussion of express preemption was as follows:

Respondent also suggests that we should be reluctant to find a pre-emptive conflict here because Congress included an express pre-emption provision in the MDA. . . . To the extent respondent posits that anything other than our ordinary pre-emption principles apply under these circumstances, that contention must fail in light of our conclusion last Term in *Geier v. American Honda Motor Co.* . . . that neither an express pre-emption provision nor a saving clause "bar[s] the ordinary working of conflict pre-emption principles."

*Id.* at 352 (alteration in original) (citations omitted).

<sup>243</sup> See *Geier*, 529 U.S. at 881.



With these persistent problems in mind, I posit a simple theory: What if all of these inconsistencies could be explained by a unitary standard that does not pigeonhole courts into categories of preemption or mandatory application of the presumption against preemption? Arguably, what is left is a loose rule of policy and discretion in the service of shifting notions of federalism. Before examining the merits—and demerits—of such an approach, it is worthwhile to examine the ways in which the new triad of cases has moved the Supreme Court in the direction of a unitary standard.

Throughout much of its product preemption jurisprudence, the Court has treated the express preemption and implied preemption analyses not as two distinct processes, but as parts of a single integrated process containing multiple factors. In its most recent decision on implied preemption, *Wyeth v. Levine*,<sup>244</sup> this approach is evident. The *Levine* Court placed implied preemption into the analytical line defined by the major recent express preemption cases of *Cipollone*, *Lohr*, *Riegel*, and *Good*. In so doing, the Court also marginalized *Geier*.<sup>245</sup> Although *Levine* did not involve an express preemption provision, the Court's choice to embrace the analytical line of express preemption cases, instead of *Geier*, to resolve the conflict preemption issues indicates that it views the preemption doctrine in a unitary fashion.

In both *Riegel* and *Good*, the Court closely followed the express preemption principles it had articulated in earlier cases, such as *Cipollone* and *Lohr*, and which it subsequently embraced in *Levine*. In *Riegel*, the Court directly contrasted the premarket approval process with the 510k “substantial equivalency” process in *Lohr*, saying that although the 510k process did not establish federal requirements for safety or effectiveness in *Lohr*, the PMA process at issue in *Riegel* did establish such requirements.<sup>246</sup> Based largely upon this distinction, *Riegel* and *Lohr* yielded different preemption results, but the analytical process was the same.

Similarly, in its express preemption analysis in *Good*, the Court stayed close to the interpretation of the express preemption provision as previously outlined in *Cipollone* and another cigarette labeling act case, *Lorillard Tobacco Co. v. Reilly*.<sup>247</sup> Although *Reilly* had involved

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<sup>244</sup> 129 S. Ct. 1187 (2009).

<sup>245</sup> See *infra* notes 259–273 and accompanying text (illustrating the *Levine* Court's marginalization of *Geier*).

<sup>246</sup> *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1007 (2008). In *Lohr*, the Court had distinguished the PMA process from the 510k process, without ruling on whether the former constituted federal regulations that could conflict with state tort judgments. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477–79 (1996).

<sup>247</sup> 533 U.S. 525 (2001); see also *supra* note 178 (discussing *Reilly*).

Massachusetts deceptive practices regulations, which the Court held were preempted by the cigarette labeling act, the *Good* Court distinguished the Maine regulations at issue from those in *Reilly*. The Maine regulations were not directed exclusively at tobacco products, nor did they reference the relationship between smoking and health.<sup>248</sup> Rather, the Court held, the regulations were based upon the state duty not to deceive.<sup>249</sup> As such, the Court treated the Maine regulations as requirements analogous to the common-law fraud rule that it had upheld against the preemption challenge in *Cipollone*.<sup>250</sup> Once again, the Court followed an internal express preemption analysis in a consistent manner.

But that is where consistency dissipates. In *Cipollone* and *Reilly*, the Court's analysis ended with express preemption. Because the Court held the claims expressly preempted in *Reilly*, there was no need to proceed further. In *Cipollone*, the Court held some, but not all, claims expressly preempted, yet chose not to conduct an implied preemption analysis.<sup>251</sup> In *Good*, the Court proceeded to conduct an implied preemption analysis after fully resolving the issues on express preemption grounds.<sup>252</sup> As previously stated, the Court had a choice to end the inquiry in *Good* with its express preemption analysis, but opted not to do so. What may account for these divergent approaches is the unitary standard, by which the Court chooses among a menu of analytical factors in reaching its result. The mix of factors would then vary from case to case.

The unitary standard may also account for the inconsistencies in application of the presumption against preemption. In *Good*, the Court expressly stated that the presumption against preemption applies to both express preemption and implied preemption,<sup>253</sup> and in *Levine*, the Court applied the presumption.<sup>254</sup> Elsewhere, the Court has either rejected or ignored it.

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<sup>248</sup> See *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 545–47 (2008).

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

<sup>250</sup> *Id.* at 549 (“[W]e conclude now, as the plurality did in *Cipollone*, that ‘the phrase ‘based on smoking and health’ fairly but narrowly construed does not encompass the more general duty not to make fraudulent statements.”); see also *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 529 (1992).

<sup>251</sup> The Court firmly rejected the implied preemption analysis that had been employed by the Third Circuit below. See *Cipollone*, 505 U.S. at 516–17. Although Justice Stevens used some language that seemed to fit with implied preemption, the analysis was clearly an express preemption analysis. See *id.* at 518 (stating that “there is no general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of state common-law damages actions”).

<sup>252</sup> See *Good*, 129 S. Ct. at 549–51.

<sup>253</sup> *Id.* at 543.

<sup>254</sup> See *Wyeth v. Levine*, 129 S. Ct. 1187 (2009).

Another sign that the Court follows a unitary standard is the lack of consistency of standards when analyzing a particular type of implied preemption. For example, the Court has from time to time shifted its formulation of the applicable standard for deciding whether it was impossible for a defendant to comply with both the federal requirements and state law.<sup>255</sup> The Court has also on occasion articulated the types of conflict preemption as a single standard. In *Geier*, the Court refused to nit-pick among “types” of conflict preemption. The Court stated:

We see no grounds, then, for attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case. That kind of analysis, moreover, would engender legal uncertainty with its inevitable systemwide costs (*e.g.*, conflicts, delay, and expense) as courts tried sensibly to distinguish among varieties of “conflict” (which often shade, one into the other) when applying this complicated rule to the many federal statutes that contain some form of an express pre-emption provision, a saving provision, or as here, both. Nothing in the statute suggests Congress wanted to complicate ordinary experience-proved principles of conflict pre-emption with an added “special burden.”<sup>256</sup>

In all the fuss and bother of the aftermath of *Geier*, this simple statement of a unitary standard has been largely ignored.

In contrast, in *Levine* the Court did indeed distinguish among the types of conflict preemption. The Court conducted separate and distinct analyses of Wyeth’s argument that it was impossible to comply with both the FDA requirements and tort-law judgments and its argument that state tort law stands as an obstacle to the effective achievement of the goals of the FDCA drug provisions. It appears, then, that the Court feels comfortable choosing to deal separately with the types of conflict preemption when it deems it appropriate, but equally comfortable collapsing the analysis into a single process in other cases.

The notion of a unitary standard was raised—albeit obliquely—by Justice Thomas in his concurring opinion in *Levine*, in which he

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<sup>255</sup> See *id.* at 1208–09 (Thomas, J., concurring in judgment) (listing several cases applying different formulations of the standard).

<sup>256</sup> *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 874 (2000); see also *id.* at 873 (“The Court has not previously driven a legal wedge—only a terminological one—between ‘conflicts’ that prevent or frustrate the accomplishment of a federal objective and ‘conflicts’ that make it ‘impossible’ for private parties to comply with both state and federal law.”).

concurring in the judgment but rejected a broad role for implied preemption. Justice Thomas rejected the “purposes and objectives” analysis conducted by the Court in determining whether state law stood as an obstacle to accomplishing federal goals. He pointed to the tendency of the Court to “embark[] on its own freeranging speculation about what the purposes of the federal law must have been.”<sup>257</sup> In rejecting this approach, he essentially rejected wholesale a role for obstacle preemption. Apparently, he was willing to consider the purposes and objectives of Congress in determining whether express preemption applied, as in *Myrick*,<sup>258</sup> but saw no role for that analysis when no express preemption provision existed. Justice Thomas’s criticism of obstacle preemption suggests that the Court believes these purposes and objectives do have a role in preemption analysis in a way that collapses express preemption and implied preemption into a single standard.

### B. *The Marginalization of Geier*

Every product preemption decision from the Court since *Geier* has cited that case for one principle or another. It is the Rorschach inkblot in which everyone sees something different. Nearly a decade after it was decided, the picture has finally become clearer. *Geier* stands for one proposition: When a court conducts an express preemption analysis and determines that the provision does not preempt the plaintiff’s claims, nothing prohibits the court from holding the claims preempted under a theory of implied preemption. This may apply even when the federal statute contains a saving clause that recognizes the continued vitality of state law. But *Geier* also has been misleading. The case seemed to suggest that a saving clause, especially when coupled with an express preemption provision, may always be ignored. As a result, *Geier* has engendered more confusion in the product preemption area than any other case. It has taken nearly a decade for the Supreme Court to offer some clarity on *Geier*. What emerges from the cases decided in 2008 and 2009 is a better understanding of *Geier*’s narrow applicability.

In *Geier*, the Court devoted a substantial portion of its discussion to the role of the saving clause in the preemption analysis. In particular, the Court rejected the notion that a saving clause could

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<sup>257</sup> *Levine*, 129 S. Ct. at 1212 (Thomas, J., concurring in judgment) (discussing *Hines v. Davidowitz*, 312 U.S. 52 (1941)).

<sup>258</sup> *Freightliner Corp. v. Myrick*, 514 U.S. 280, 283–87 (1995) (holding, in a majority opinion written by Justice Thomas, that plaintiffs’ state common law claims for negligent design of antilock brakes were neither expressly nor impliedly preempted by federal law).

prevent conflict preemption where an actual conflict exists between the federal statute or regulation and the state laws involved—in this case, state common law. The Court stated: “[W]e conclude that the saving clause foresees—it does not foreclose—the possibility that a federal safety standard will pre-empt a state common-law tort action with which it conflicts.”<sup>259</sup> In so stating, the Court denied the saving clause the status of a talisman and seemed to suggest that the saving clause could freely be ignored. One question that remained was whether saving clauses serve any purpose at all in a preemption analysis. Congress must have thought they did; it has included them in many statutes in areas of the law in which state law has operated by way of regulation or common law.<sup>260</sup>

An examination of one of the cases on which *Geier* relies to support a diminished role for the saving clause demonstrates that *Geier* does not—indeed, cannot—offer an absolute answer in such a complex area of the law. In *United States v. Locke*,<sup>261</sup> a decision issued only a few months before *Geier*, the Court stated that the saving clauses in the federal Oil Pollution Act of 1990<sup>262</sup> must be read in the context of both their textual idiosyncrasies and the historical relationship between the federal government and the states on matters related to interstate navigation.<sup>263</sup> The Court stated:

Limiting the saving clauses as we have determined respects the established federal-state balance in matters of maritime commerce between the subjects as to which the States retain concurrent powers and those over which the federal authority displaces state control. . . . We think it quite unlikely that Congress would use a means so indirect as the saving clauses . . . to upset the settled division of authority by allowing States to impose additional unique substantive regulation on the at-sea conduct of vessels. We decline to give broad effect

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<sup>259</sup> *Geier*, 529 U.S. at 870.

<sup>260</sup> *See, e.g.*, 42 U.S.C. § 9659(h) (2006) (stating that the section of the Comprehensive Environmental Response, Compensation and Liability Act providing for citizens suits to remedy violations of the Act “does not affect or otherwise impair the rights of any person under Federal, State, or common law”).

<sup>261</sup> 529 U.S. 89 (2000). *Locke* was an action for declaratory and injunctive relief brought by a trade association of tanker operators against state and local officials seeking to enforce certain Washington state regulations regarding oil tankers. *See id.* at 97. The Supreme Court held that at least some of the state rules were preempted by the federal regulatory scheme. *See id.* at 109–10.

<sup>262</sup> Oil Pollution Act of 1990 (OPA), 33 U.S.C. §§ 2701–2762 (2006). The federal interest in interstate navigation is longstanding, and the Court reviewed the history of federal involvement in these matters, beginning with the Federalist Papers. *See Locke*, 529 U.S. at 99–103.

<sup>263</sup> *See Locke*, 529 U.S. at 105–06.

to saving clauses where doing so would upset the careful regulatory scheme established by federal law.<sup>264</sup>

Thus, the Court did not allow state regulations to alter the longstanding and evolving relationship between the federal government and the states, in which federal interests dominated in the matters relevant to the case.

Conversely, logic dictates that “respect[ing] the established federal-state balance” would apply equally when the “settled division of authority” between the states and the federal government assumes the existence and utility of state tort actions in the same area of the law. In other words, the entire context of the statute and the saving clause must be given full effect in the preemption analysis. *Geier* found support in *Locke*, but a fair reading of both *Locke* and *Geier* is that interpreting the saving clause is not a one-way street. There will be circumstances in which the saving clause should apply broadly to allow state regulation and/or common law.

Turning again to *Geier*, the federal standard at issue there established a scheme of gradual phased-in passive restraints, with a menu of options that made no single passive restraint mandatory.<sup>265</sup> The specificity of the standard, and the context of the way in which it implemented the goals of the Federal Motor Vehicle Safety Act, drove the result. There was further language in *Geier* indicating that the Court continued to respect the role of state common law in product safety. The Court stated:

[T]he saving clause reflects a congressional determination that occasional nonuniformity is a small price to pay for a system in which juries not only create, but also enforce, safety standards, while simultaneously providing necessary compensation to victims. That policy by itself disfavors pre-emption, at least some of the time. But we can find nothing in any natural reading of the two provisions that would favor one set of policies over the other where a jury-imposed safety standard *actually conflicts* with a federal safety standard.<sup>266</sup>

Notwithstanding this respect for state common law, the Court held that an actual conflict existed because a tort judgment concluding that the product was defective for lack of an airbag directly conflicted

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<sup>264</sup> *Id.* at 106 (citation omitted).

<sup>265</sup> See *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 878–81 (2000).

<sup>266</sup> *Id.* at 871 (emphasis added).

with both the letter (airbag not required) and the purpose (gradual phase-in) of the federal law. Viewed as another cog in the wheel of the unitary standard, *Geier*'s result reflected a contextual analysis of a unique and very narrow statute. *Geier* does not mandate identical results when other statutes, claims, and policies are involved. Nor does it mandate an implied preemption analysis in every case in which an express preemption provision does not bar the claims.

In *Levine*, the majority recognized these points and put *Geier* in its proper place. Refusing to adopt *Geier* wholesale, the Court recognized, among other things,<sup>267</sup> that the mix of federal interests and goals involved in *Geier* was different from that in *Levine* in ways that rendered *Geier* largely inapplicable to the case. The *Levine* Court stated: "Indeed, the 'complex and extensive' regulatory history and background relevant to this case . . . undercut the FDA's recent pronouncements of pre-emption [in the 2006 preamble], as they reveal the longstanding coexistence of state and federal law and the FDA's traditional recognition of state-law remedies . . ."<sup>268</sup> Further, the Court distinguished the agency inaction in *Levine* from the government's specific action in developing the unique set of federal passive-restraint standards applicable in *Geier*. The Court noted that the FDA had not determined that Wyeth's existing label was adequate or set any kind of safety standard relevant to Wyeth's proposed label.<sup>269</sup> Accordingly, the "longstanding coexistence of state and federal law" in the area of drug safety took precedence.

The *Levine* dissent relied heavily on an interpretation of *Geier* that was patently overbroad. In referencing *Geier*, the dissent noted that the Court had examined the underlying purpose of the passive-restraint standard, which was to provide a menu of options to manufacturers that were deemed safe in a phase-in period. Installation of airbags in all vehicles was one such option, but the other sanctioned options were deemed safe as well. For those reasons, the *Levine* dissent argued, the *Geier* Court had held that "the doctrine of conflict pre-emption barred *Geier*'s efforts to deem some of those federally approved alternatives 'unsafe' under state tort law."<sup>270</sup> The dissent then declared that *Levine* presented an identical issue, and

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<sup>267</sup> The main reason given by the Court was its refusal to grant deference to the regulation for procedural flaws related to the FDA's failure to provide an opportunity for comment on the broad preemption pronouncements included in the preamble. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1201 (2009) ("The agency's views on state law are inherently suspect in light of this procedural failure.").

<sup>268</sup> *Id.* at 1203 (noting that at all times applicable to the case, the FDA's position was its "traditional recognition of state-law remedies" (citation omitted)).

<sup>269</sup> See *id.* at 1203–04 n.14.

<sup>270</sup> *Id.* at 1221 (Alito, J., dissenting).

therefore the claims should have been preempted.<sup>271</sup> The dissent stated: “Through Phenergan’s label, the FDA offered medical professionals a menu of federally approved, ‘safe’ and ‘effective’ alternatives—including IV push—for administering the drug. Through a state tort suit, respondent attempted to deem IV push ‘unsafe’ and ‘ineffective.’”<sup>272</sup>

The dissent misapprehends an important point. While one might say that the Phenergan label offered a sort of “menu” for health care providers, the IV-push alternative was not safe in the way that the Secretary of Transportation deemed the items on the passive-restraint menu safe for purposes of the automobile phase-in. Indeed, the IV-push delivery system presented significant safety concerns. Further, prescription drug warnings for consumer safety implicate an entirely different set of policies from the issues contemplated by the Department of Transportation in establishing a plan to phase in passive restraints over time.

What, then, remains of *Geier*’s force? *Geier* remains an important, if not exactly original,<sup>273</sup> linchpin between express and implied preemption in the unitary doctrine. But the analytical process used by the Court and the conclusions reached were peculiar to the facts of the case. The *Levine* Court demonstrated the importance of marginalizing *Geier* to avoid elevating the result over the process. The *Levine* dissent, on the other hand, demonstrated that preemption under the unitary standard can be a slippery slope.

## V. THE UNITARY STANDARD AND THE THREATENED EROSION OF THE HEALTH AND SAFETY GOALS OF PRODUCT LIABILITY LAW

### A. Does Unitary Mean Standardless?

Justice Thomas, concurring in the judgment in *Levine*, expressed the concern that the Court is on a slippery slope in its preemption analysis. In commentary that focused on federalism, he stated: “[T]his brand of the Court’s pre-emption jurisprudence facilitates freewheeling, extratextual, and broad evaluations of the ‘purposes and

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<sup>271</sup> See *id.* (“The same rationale [as in *Geier*] applies here.”).

<sup>272</sup> *Id.*

<sup>273</sup> In *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287–89 (1995), the U.S. Supreme Court conducted an implied preemption analysis after determining that the express preemption provision in the National Traffic and Motor Vehicle Safety Act of 1966 did not bar the plaintiff’s personal injury claims. The Court then held, with little analysis, that implied preemption did not bar the claims. *Id.* at 289; see also discussion *supra* notes 48–56 and accompanying text. In *Geier*, by contrast, a specific federal standard existed, one that embodied a particular federal policy—to phase in passive restraints by offering a menu of options to motor vehicle manufacturers. *Geier v. Am. Honda Motor Co.* 529 U.S. 861, 878–81 (2000).



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 . . . .<sup>274</sup> Justice Thomas opined that the no-preemption result reached by the Court in *Levine* was fully supported by the text of the FDCA and that the Court did not need to speculate on the relevance and meaning of matters outside the text, such as Congress's decision not to include a preemption provision applicable to drugs when it amended the statute.<sup>275</sup>

Justice Thomas has long denounced this "purposes and objectives" approach to preemption and has been generally critical of implied preemption, particularly the "obstacle" type. While he has agreed with the Court when it has taken a restrained approach to the use of implied preemption,<sup>276</sup> he has voiced concern that the Court's preemption analysis is overly expansive, as evidenced by *Geier*.<sup>277</sup> In his concurrence in *Bates*, Justice Thomas raised a similar concern. While praising the Court for declining to conduct an implied preemption analysis after determining that the preemption provision did not bar the claims, he expressed displeasure with the application of implied preemption generally because, in his view, it could become "[a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives."<sup>278</sup> Justice Kennedy has also expressed concern that the Court's preemption analysis has replaced the intent of Congress with a "freewheeling judicial inquiry."<sup>279</sup> In the same context, Justice Kennedy has stated the importance of the presumption against preemption.<sup>280</sup> Clearly, both Justices were concerned that the Court would go too far in holding that federal statutes preempt state rules, including common-law tort rules.

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<sup>274</sup> *Levine*, 129 S. Ct. at 1217 (Thomas, J., concurring in judgment).

<sup>275</sup> *See id.* at 1216.

<sup>276</sup> *See, e.g., Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 458 (2005) (Thomas, J., concurring in part and dissenting in part) ("Because we need only determine the ordinary meaning of [the preemption provision], the majority rightly declines to address respondent's argument that petitioners' claims are subject to other types of pre-emption.")

<sup>277</sup> *See, e.g., Levine*, 129 S. Ct. at 1214 (Thomas, J., concurring in judgment) ("The Court's decision in *Geier* to apply 'purposes and objectives' pre-emption based on agency comments, regulatory history, and agency litigating positions was especially flawed, given that it conflicted with the plain statutory text of the saving clause within the Safety Act, which explicitly preserved state common-law actions . . .").

<sup>278</sup> *Bates*, 544 U.S. at 459 (Thomas, J., concurring in part and dissenting in part) (quoting *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and dissenting in part)) (alteration in original).

<sup>279</sup> *See Gade*, 505 U.S. at 111 (Kennedy, J., concurring in part and dissenting in part).

<sup>280</sup> *Id.* at 111–12 ("[W]e will not infer pre-emption of the States' historic police powers absent a clear statement of intent by Congress." (citations omitted)).

It is difficult, however, to imagine a preemption decision that does not examine, at least to some degree, the broader purposes and goals of the federal statute. Even in express preemption, the Court has held that “Congress’ intent must be divined from the language, structure, and purposes of the statute as a whole.”<sup>281</sup> Where Congress has not explicitly articulated those purposes, a multiplicity of factors may provide the necessary information. *United States v. Locke*,<sup>282</sup> which involved a long statutory history, a complex federal-state relationship, and textually unclear preemption provisions, is a perfect example.<sup>283</sup> Under the unitary standard, the Court examines these factors when deemed necessary using express preemption analysis, implied preemption analysis, or both. But the approach encourages arbitrariness. Will the Court apply the presumption against preemption? If not, why not? Will the Court consider the saving clause, or simply ignore it? If the Court considers it, how will it be interpreted? Will the Court even conduct an express preemption analysis or move directly to an implied preemption analysis?

In a particular case, the Court’s approach to preemption may make sense. For example, in *Buckman*, the Court all but ignored the preemption provision, choosing instead to analyze the case only under implied preemption. The Court held the plaintiff’s fraud-on-the-FDA claims preempted under implied conflict preemption because the FDCA contained a detailed federal scheme<sup>284</sup> for addressing fraudulent practices perpetrated against the FDA.<sup>285</sup> The Court declined to conduct an express preemption analysis, despite the existence of the preemption provision in the MDA. Rather, Chief Justice Rehnquist stated: “In light of this conclusion [that implied preemption bars the claims], we express no view on whether these claims are subject to express pre-emption under 21 U.S.C. § 360k.”<sup>286</sup> This approach suggests that the *Buckman* Court was following an ad hoc unitary standard, according to which the high federal interest in a federal agency policing itself allowed the Court to essentially choose to resolve the case according to implied preemption and ignore the express preemption provision.<sup>287</sup> Using a loosely phrased conflict preemption label, the Court merely said that allowing the state-law fraud claims would disturb the “somewhat delicate balance of

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<sup>281</sup> *Id.* at 112 (citing *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 138 (1990); *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51 (1987)).

<sup>282</sup> 529 U.S. 89 (2000).

<sup>283</sup> See *supra* notes 261–64 and accompanying text.

<sup>284</sup> See *supra* notes 72–73 and accompanying text.

<sup>285</sup> *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347–48 (2001).

<sup>286</sup> *Id.* at 348 n.2.

<sup>287</sup> See Eggen, *Shedding Light*, *supra* note 11, at 162–63.

statutory objectives” in the FDCA and the MDA.<sup>288</sup> This approach made substantial sense in the narrow world of that case, considering the extraordinarily high federal interest in the FDA’s power to police the entities that come before it for approval of medical devices and drugs. As precedent, however, *Buckman* is more problematic.

The Court’s unitary standard is a broad federalism approach that attempts to strike the “delicate balance of statutory objectives” referenced by the Court in *Buckman*. The risks of this approach are substantial, as it turns each decision into an ad hoc federalism analysis open to over-reliance on policy judgments and broad judicial discretion. The Court respects certain important values, but discards them just as easily when it serves its purpose. In *Levine*, Justice Thomas objected that the Court has substituted “judicially manufactured policies” for reasoned textual analysis.<sup>289</sup> I would argue that the Court is doing both, with inconsistent results. This approach begs the question how far the product preemption doctrine has come from its roots in the Supremacy Clause.<sup>290</sup>

Despite these issues, the Court’s approach to preemption is not standardless. Far from it. It is instead suffering from a surfeit of conflicting standards that are not applied in a uniform manner from case to case. Thus, although the Court has standardized its approach to express preemption to a large extent,<sup>291</sup> circling around that hub of certainty is a lack of predictability in individual cases. The more troubling issue is that after decades of product preemption decisions from the Supreme Court, the resulting unitary standard allows the Court to choose the factors that it deems relevant in a manner that could be handled arbitrarily and may vary depending on the individual views of the Justice writing the opinion.<sup>292</sup>

In cases involving consumer health and safety, the Court has often used the unitary standard to reach decisions that have been in the best interests of the consumer. But there is no guarantee of that result in future cases, even those involving the same federal statute. Trial

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<sup>288</sup> *Buckman*, 531 U.S. at 348.

<sup>289</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1217 (2009) (Thomas, J., concurring in judgment).

<sup>290</sup> Cf. Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 808 (1994) (arguing that preemption has nothing to do with the Supremacy Clause as a matter of constitutional law and stating that preemption is “nothing more nor less than an instance of ordinary legislative power”).

<sup>291</sup> See Eggen, *Normalization of Product Preemption*, *supra* note 10, at 769–74 (discussing the standardization of express preemption analysis in product preemption cases through *Bates*).

<sup>292</sup> Compare *Levine*, 129 S. Ct. at 1202 (Stevens, J.) (discussing the benefits of tort litigation), with *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008) (Scalia, J.) (arguing that juries are incapable of performing an adequate risk-benefit analysis of a product).

courts are left with a confusing collection of rules, and consumers may find the tort system unavailable for unpredictable reasons.

*B. The Threat to the Role of Tort Law in Consumer Health and Safety*

The Court has repeatedly stated its respect for the role of tort litigation in the balance of health and safety objectives advanced by federal law and state law. In so doing, the Court has emphasized some of the important policies underlying tort law generally and product liability law in particular. In *CSX Transportation, Inc. v. Easterwood*,<sup>293</sup> a non-product negligence case involving an accident at a railroad crossing, the Court stated: “[T]he scheme of negligence liability could just as easily complement these regulations by encouraging railroads . . . to provide current and complete information to the state agency responsible for determining priorities for improvement projects . . . .”<sup>294</sup> In *Bates*, the Court stressed “the importance of providing an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items.”<sup>295</sup> And in *Geier*, the Court observed that “occasional nonuniformity is a small price to pay for a system in which juries not only create, but also enforce, safety standards, while simultaneously providing necessary compensation to victims. That policy by itself disfavors pre-emption, at least some of the time.”<sup>296</sup> In *Levine*, the Court continued to recognize the deterrent value of state product liability actions. Justice Stevens acknowledged the FDA’s information vacuum, stating:

The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly.<sup>297</sup>

Accordingly, the Court refused to grant deference to the FDA’s 2006 preamble, which rejected a safety role for tort actions.<sup>298</sup>

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<sup>293</sup> 507 U.S. 658 (1993), *superseded on other grounds by statute*, Implementing Recommendations of the 9/11 Commission Act of 2007, Pub. L. No. 110-53, 121 Stat. 266 (2007)).

<sup>294</sup> *Id.* at 668.

<sup>295</sup> *Bates v. Dow Agrosiences L.L.C.*, 544 U.S. 431, 450 (2005).

<sup>296</sup> *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 871 (2000).

<sup>297</sup> *Levine*, 129 S. Ct. at 1202 (footnote omitted).

<sup>298</sup> *Id.*

As some scholars have noted, it is counterintuitive that the FDA now takes the position that the deterrence role of state product liability actions impairs the agency's work rather than assists it.<sup>299</sup> The explanation is likely political: the pro-business policy of the Bush administration favored barring drug and medical device lawsuits. The policy was based, in part, on the argument that strong warnings would reduce consumer use of beneficial products,<sup>300</sup> which would be detrimental to the industry. Mirroring this view, Chief Justice Rehnquist, writing for the Court in *Buckman*, warned that "unpredictable civil liability" could deter manufacturers from developing and seeking FDA approval of new medical devices.<sup>301</sup> One would instead expect the federal agency entrusted with marketing approval decisions for drugs and medical devices to appreciate and benefit from the role of the states in bringing to light information regarding the safety and effectiveness of the products.<sup>302</sup> On a fundamental level, tort litigation reflects the democratic ideal of participation in the system, both by litigants as adversaries and by the jury as the ultimate decision maker.<sup>303</sup> By contrast, the FDA, in the 2006 preamble, has taken an elitist and arbitrary position in rejecting any beneficial role for product liability suits.<sup>304</sup> The FDA's position represents a broad and standardless approach to implied preemption.

The Court also has repeatedly acknowledged the remedial nature of tort law in providing compensation to injured persons in areas of federal regulation. A quarter century ago, in *Silkwood v. Kerr-McGee Corp.*, the Court stated: "It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."<sup>305</sup> Two decades later, in *Bates*, the Court

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<sup>299</sup> See O'Steen & O'Steen, *supra* note 6, at 93–94.

<sup>300</sup> See Robert Pear, *In a Shift, Bush Moves to Block Medical Suits*, N.Y. TIMES, July 25, 2004, at A1.

<sup>301</sup> *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

<sup>302</sup> See Wagner, *supra* note 113, at 695 n.4 ("When regulatory decisions are made based primarily on the politics of the executive branch, the tort system also offers an important mechanism for outsiders to advance their preferred regulatory ends.")

<sup>303</sup> See Allan Kanner, *The Politics of Toxic Tort Law*, 2 WIDENER L. SYMP. J. 163, 163–64 (1997) ("As a group, toxic tort cases demonstrate how legal norms governing responsibility for the consequences of 'synthetic living' and technological failures reflect, in part, the conflict between the democratic and elitist ideals extant in our legal system." (footnotes omitted)); Christopher J. Peters, *Persuasion: A Model of Majoritarianism as Adjudication*, 96 NW. U. L. REV. 1, 20–22 (2001) (arguing that participation is "central to democratic legitimacy"). Kanner demonstrates that much of the tension in toxic tort litigation over the standards for scientific evidence, preemption, appropriate case management, and information gathering and dissemination may be explained by the tension between democratic and elitist ideals. Kanner, *supra*, at 178–83.

<sup>304</sup> This position is embodied in the 2006 preamble. See 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601).

<sup>305</sup> *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

echoed that statement and cautioned that “[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.”<sup>306</sup> In *Sprietsma*, the Court said that “the concern with uniformity does not justify the displacement of state common-law remedies that compensate accident victims and their families and that serve the Act’s more prominent objective . . . of promoting . . . safety.”<sup>307</sup>

The information vacuum in drug and medical device regulatory matters is an urgent problem,<sup>308</sup> but solutions have been slow to come. In the meantime, and for the foreseeable future,<sup>309</sup> the FDA will be hamstrung by insufficient resources, sluggish regulatory implementation, and institutional inadequacies. The inability of the FDA to conduct a meaningful risk-utility balancing process for drugs and devices on the market, as well as new applications, is seriously impaired. The product preemption doctrine must not ignore this reality in the way that it was ignored in *Riegel*.

The Court has recognized that tort law serves several valuable purposes in our federalist system. Preemption rules shielding manufacturers from lawsuits, in whole or in substantial part,<sup>310</sup> countermand the health and safety role of tort law. Such rules defeat the short-term goals of tort law by discouraging manufacturers from altering or withdrawing unsafe products and by eliminating incentives to make safety a priority in the development of new products. They also inhibit the long-term goals by removing the incentive for vigilance in the postmarket phase and eliminating compensation to persons injured by defective products. Broadly shielding product manufacturers from civil liability also prevents optimal information gathering for the regulatory agency, physicians, and ultimately consumers. Because the adversarial and deliberative process in court is different from the process by which regulatory agencies collect and consider information,<sup>311</sup> the tort system is a beneficial adjunct in the product arena. Proponents of extreme tort reform measures ignore the necessary role of the tort system or are willing to trade it for a host of

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<sup>306</sup> *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 449 (2005).

<sup>307</sup> *Sprietsma v. Mercury Marine*, 537 U.S. 51, 70 (2002).

<sup>308</sup> See *supra* notes 107–27 and accompanying text.

<sup>309</sup> See *supra* notes 113–20 and accompanying text.

<sup>310</sup> Of course, Congress has sometimes enacted a blanket shield of an entire industry. See, e.g., Protection of Lawful Commerce in Arms Act, 15 U.S.C. §§ 7901–7903 (2006) (granting gun industry immunity from most tort lawsuits).

<sup>311</sup> See Richard L. Abel, *Questioning the Counter-Majoritarian Thesis: The Case of Torts*, 49 DEPAUL L. REV. 533, 533 (2000) (“[C]ourts tend to be populist and deliberative, whereas legislatures tend to be captured by special interests, secretive, hasty, and unwilling or unable to offer reasons for their actions.”).

other goals. Indeed, the zeal of the tort reformers reflects a deep-seated distrust of the judicial system.<sup>312</sup> This distrust has placed all the cards in the hands of the legislature—both Congress and state legislatures—and has all too often resulted in no benefit to the public.<sup>313</sup>

How does this debate impact the product preemption doctrine? The unitary standard gives courts latitude to apply the doctrines of preemption to achieve a result that reflects a certain predetermined predilection.<sup>314</sup> There is nothing to ensure a truly balanced approach between consumer safety and the protection, or elevation, of business interests. This configuration of the product preemption doctrine is not optimal. One might argue that in *Levine* the Court achieved the “right” result for consumers, applying the unitary standard. Or one might point to *Bates*, in which the Court recognized that tort law plays a useful role supplementary to certain legislative schemes, stating: “FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products’ performance in diverse settings.”<sup>315</sup> The Court contemplated the role of product liability actions in providing the necessary information.<sup>316</sup> But the reality is that a doctrine of product preemption with insufficient predictability could just as well lead to elimination of consumer rights in future cases.

### C. Considerations for the Future

The evolution of the product preemption doctrine has moved slowly, and it is disappointing to have to conclude that little certainty and predictability have found their way into the mature doctrine. This Article has viewed the mature product preemption doctrine from the point of view of consumer health and safety. The mature doctrine jeopardizes consumer health and safety by permitting courts to employ the implied preemption doctrine using a loose collection of factors. In this sub-part, I identify some considerations that should

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<sup>312</sup> See Jean Macchiaroli Eggen & John G. Culhane, *Public Nuisance Claims Against Gun Sellers: New Insights and Challenges*, 38 U. MICH. J.L. REFORM 1, 54 (2004).

<sup>313</sup> See John G. Culhane, *Tort, Compensation, and Two Kinds of Justice*, 55 RUTGERS L. REV. 1027, 1084 (2003) (arguing that legislative enactments shielding entire industries result in “plaintiffs [being] forced to give up rights that seem required by . . . principles of corrective justice, and they gain nothing in return”).

<sup>314</sup> See Eggen, *Sense or Sensibility*, *supra* note 11, at 37 (discussing *Lohr*’s analytical process and stating that “the entire process is informed with policy decisions from start to finish”).

<sup>315</sup> *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 451 (2005).

<sup>316</sup> *Id.* (stating that “[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA”).

direct the application of the doctrine in the future to make it more predictable and to adequately reflect the health and safety concerns of product law.

First, the presumption against preemption should guide the analytical process in the courts, particularly when the state rule in question is a common-law claim invoking the historic police powers of the state. While the United States Supreme Court has discarded the presumption in some cases in which it has concluded the federal interest was high,<sup>317</sup> in product liability cases the presumption should receive primary consideration, whether the analysis is one of express preemption or implied preemption. It sometimes seems that the Court views the presumption against preemption as an absolute barrier to preemption and resists its application for that reason. Perhaps this resistance is because the Court has framed it as an “assumption,” rather than a rebuttable presumption. In *Rice v. Santa Fe Elevator Co.*, in an often-quoted statement of the presumption, the Court framed it as follows: “[W]e 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>318</sup> Rather than simply rejecting the “assumption,” the Court should treat it as a source of guidance in which the degree of its relevance in a particular case depends upon many factors, such as the extent of federal interest in the subject matter of the case or the historical relationship between state and federal law in the matters subject to federal regulation. Enhanced respect for the presumption against preemption, by mandating that courts address its applicability rather than discard it without substantial discussion, would restore the presumption to its role as the starting point for the preemption analysis.

A second matter for future consideration is the role of the saving clause, which has fluctuated throughout the Court’s product preemption jurisprudence. A saving clause can only be accurately interpreted within the broader context of the federal statute—including a preemption provision if it contains one—and Congress’s purpose in establishing the federal scheme. This is exactly the analysis conducted by the Court in *Levine*. After noting that the 1962 amendments to the FDCA added a saving clause,<sup>319</sup> the Court discerned congressional intent from the circumstances surrounding the long history of the FDCA against the background of state tort

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<sup>317</sup> See *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347–48 (2001); *United States v. Locke*, 529 U.S. 89, 108 (2000).

<sup>318</sup> *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (citations omitted).

<sup>319</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1195–96 (2009).



litigation.<sup>320</sup> The Court also deemed significant the fact that Congress declined both to create a federal remedy for consumers and to add a preemption provision to the statute.<sup>321</sup> The aggregate, the Court concluded, “is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.”<sup>322</sup> A saving clause must be interpreted in this comprehensive manner, where, as is typically the case, Congress has not offered a full explanation of its intent in the text of the statute. Even where the statutory text embodies a particular congressional agenda, the harsh realities of the operation of the agency may render that agenda impossible to achieve. The example of the FDA demonstrates this point. Preemption under those circumstances places consumers in double jeopardy.

Third, courts should shrink the role of implied preemption. Implied preemption should be the exception, not the rule, in matters traditionally relegated to the states. Justice Thomas has legitimate federalism concerns with the use of implied preemption, concerns that he articulated fully in his concurring opinion in *Levine*. As he argued, federalism problems arise when courts “expand federal statutes beyond their terms through doctrines of implied pre-emption.”<sup>323</sup> In his view, such evidence as “Congressional and agency musings” does not satisfy the requirements under the Supremacy Clause for preemption.<sup>324</sup> Rather, evidence in the “text and structure” of the federal statute must be the focus.<sup>325</sup> While the ability to accurately and comprehensively understand the meaning of the text and structure of the federal statute may require an examination of its broader

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<sup>320</sup> *Id.* at 1199–1200.

<sup>321</sup> *Id.*

<sup>322</sup> *Id.* at 1200. I have addressed this point in some detail elsewhere, stating in part:

The saving clause presents a classic issue of checks and balances. When Congress, using broad plain language, chooses to exempt common law claims from the preemption clause, the common law may occasionally be in conflict with the requirements and purposes of the federal statutory scheme. The doctrine of preemption allows the courts to determine the extent to which nonconforming state standards will be tolerated. That process will involve examining the unique characteristics of the federal statute, as well as the relationship of the state standard to the federal scheme.

Eggen, *Normalization of Product Preemption*, *supra* note 10, at 776.

<sup>323</sup> *Levine*, 129 S. Ct. at 1207 (Thomas, J., concurring in judgment) (quoting *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 459 (2005) (Thomas, J., concurring in part and dissenting in part)).

<sup>324</sup> *Id.*

<sup>325</sup> *Id.* at 1207–08 (stating that “[e]vidence of pre-emptive purpose [must be] sought in the text and structure of the [p]rovision at issue” (alterations in original) (quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993))).

context, efforts to limit an expansive use of implied preemption are warranted.

Finally, there is a lesson in all this for Congress. In *Riegel*, the Court stated: “Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State’s ‘requirements’ includes its common-law duties.”<sup>326</sup> This is, in fact, the opposite of the way it should be. Rather, Congress should provide the courts with a clear meaning of the terms it regularly uses in its enactments, thus avoiding judicial speculation. In reality, we do not know whether Congress intends the term “requirements” to have the same meaning in preemption provisions in statutes as diverse as those applicable to medical devices and motor vehicles. Without clear direction from Congress, it is all too easy for the courts to make errors. Going forward, Congress must pay attention to these details and provide some measure of clarity. Retrospectively, Congress may find it advisable to revisit some of its enactments in light of the Court’s interpretation and correct errors where necessary.<sup>327</sup>

#### CONCLUSION

The United States Supreme Court’s product preemption doctrine has moved into its maturity with a triad of cases decided in 2008 and 2009. Product law holds consumer health and safety as a primary goal. The Supreme Court has stated: “[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action.”<sup>328</sup> Product liability actions serve several goals, including providing an incentive to manufacturers to produce safe products and to remain vigilant of new risks that may arise after the product is approved for marketing. It is particularly important in the area of medical devices and drugs that preemption not bar state tort actions, as the FDA has been hindered by insufficient resources, particularly in postmarket surveillance.

The new triad of decisions from the Supreme Court is a double-edged sword. While the decisions provide some certainty, particularly in the analytical process of express preemption, they move the Court further in the direction of a unitary standard that lacks a clear distinction between express and implied preemption and

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<sup>326</sup> *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008).

<sup>327</sup> *See, e.g.*, Medical Device Safety Act of 2009, H.R. 1346, 111th Cong. (2009) (proposing legislation to retroactively reverse the result in *Riegel*).

<sup>328</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

invites broad judicial discretion. The unitary standard runs the risk of becoming a loose policy-laden analysis in which vague concepts of conflict preemption are applied randomly, offering little predictability. From the perspective of consumer protection in the product arena, the unitary standard could be applied in a sweeping fashion to eliminate many state product liability actions. Agency failures, such as those experienced by the FDA due to underfunding and other resource deficiencies, further place consumers in jeopardy. Congress and the Supreme Court should take account of these concerns to provide safety for consumers and predictability for manufacturers, judges, and attorneys.