# Products Liability Preemption: An Institutional Approach

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## *Introduction*

Preemption is the fiercest battle in products liability litigation today. The stakes are high in this recent manifestation of the collision between common-law tort and the modern administrative state.[1] In the legal academy, the conventional take on preemption frames the question theoretically as a pure matter of either statutory interpretation or congressional intent. To be sure, with the stroke of a pen Congress could definitively determine when its product regulations displace state common law.[2] Instead, Congress repeatedly punts, leaving unresolved the key question of the extent to which federal standards and regulations preempt state common-law remedies.

Products liability is a realm in which Congress typically either says everything—coupling broad preemption provisions that would seem to wipe out competing state tort claims with broad "savings clauses" that would seem to preserve those same actions[3]—or nothing at all.[4] Moreover, Congress tends to legislate in a decidedly piecemeal

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1 This clash has a historical pedigree dating back at least to the New Deal era, but it has certainly gathered momentum in contemporary times, largely due to the expansion in tort liability in the medical and products fields. *See, e.g.*, Richard A. Epstein & Michael S. Greve, *Conclusion: Preemption Doctrine and Its Limits*, *in* FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS 309, 324 (Richard A. Epstein & Michael S. Greve eds., 2007) ("Most statutes in this field were drafted before the explosion of product liability law in the 1970s . . . ."); *see also* Robert L. Rabin, *Keynote Paper: Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2052 (2000) (characterizing the late twentieth century as a "post-New Deal regulatory environment in which special competence means technical and scientific expertise, not just experience in hearing a great many similar cases").

2 Few would challenge Congress's ultimate constitutional authority under Article I to regulate products in the national economy. *See* U.S. CONST. art I, § 8, cl. 3 ("The Congress shall have power to . . . regulate Commerce . . . among the several States . . . ."). And of course, once enacted, "the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby . . . ." U.S. CONST. art. VI, cl. 2.

3 *See, e.g.*, *infra* notes 50–51, 59, 82, 90 and accompanying text.

4 What explains Congress's perpetual failure to weigh in definitively on this critical issue? According to James Henderson and Aaron Twerski, there is a simple political answer:

> Congress quite clearly has sought to placate both industry and consumers by speak-

fashion. Instead of comprehensive national products legislation, Congress regulates select product areas in which it typically focuses on the liability side, fashioning federal safety standards and requirements,[5] and all but ignores the remedial side, including private enforcement mechanisms.[6]

Products liability is a notably fraught area, where arguments for national uniform standards compete vigorously with arguments in

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> ing out of both sides of its mouth. And in the event that no one should understand how both [preemption and savings clauses] can work in tandem, that job is left to the United States Supreme Court, which does not have to face the wrath of political constituencies.

JAMES A. HENDERSON, JR. & AARON D. TWERSKI, PRODUCTS LIABILITY: PROBLEMS AND PROCESS 424 (5th ed. 2004). Roderick Hills offers a general theory of congressional gridlock or inertia to explain legislative inaction: namely, federal politicians may avoid legislating to "duck major policymaking responsibilities (which create political risk) and instead concentrate on the Personal Vote," i.e., securing reelection by placating local constituencies. *See* Roderick M. Hills, Jr., *Against Preemption: How Federalism Can Improve the National Legislative Process*, 82 N.Y.U. L. REV. 1, 16 (2007). While Hills's account might explain issues that fail to reach the congressional agenda, such as bills that die in committee, it has far less explanatory power in the situation—dominant in products liability preemption—where the issue is squarely before Congress (on a repeat basis no less) and Congress manages to speak out of both sides of its mouth. Instead, it seems more plausible that Congress affirmatively punts the issue to courts and/or agencies. *Cf.* Daryl J. Levinson, *Empire-Building Government in Constitutional Law*, 118 HARV. L. REV. 915, 928 (2005) (arguing that congressmen, in some cases, might "prefer to defer to some 'competing' institution, leaving their own diminished in scope and wealth"); Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 302 n.235 (2000) ("When members of Congress focus on a particular issue but fail to reach a collective decision about how to resolve it, they sometimes compromise by enacting intentionally ambiguous language that transfers the issue to the courts.").

5 For example, it regulates medical devices and drugs under the Federal Food Drug and Cosmetic Act, 21 U.S.C. §§ 301–399 (2000), motor vehicle safety under the Motor Vehicle Safety Act, 49 U.S.C. §§ 30101–30170 (2000), recreational boat safety under the Federal Boat Safety Act, 46 U.S.C. §§ 4301–4311 (2000), labeling of cigarettes under the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331–1341 (2000), and pesticide labeling under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136–136y (2000). None of these federal statutes contains an express private right of action; moreover, the Supreme Court has increasingly shied away from inferring implied rights of action. *See, e.g.*, Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 248–49 (2007).

6 Most of the relevant federal statutes do not include an express or implied private right of action. The exceptions are labor statutes like the Employee Retirement Income Security Act, Pub. L. No. 93-406, 88 Stat. 829 (1974) (codified in scattered sections of 26 & 29 U.S.C.), and the Labor Management Relations Act, Pub. L. No. 101, 61 Stat. 163 (1947) (codified at 29 U.S.C. §§ 141–144, 167–187 (2000)), which create express remedies, *see* 29 U.S.C. §§ 185, 1132(a) (2000), and environmental statutes like the Oil Pollution Act, Pub. L. No. 101-380, 104 Stat. 484 (1990) (codified in scattered sections of 33, 43 & 46 U.S.C.), and Clean Water Act, Pub. L. No. 95-217, 91 Stat. 1566 (1990) (codified at 33 U.S.C. §§ 1281a, 1294–1297 (2000)), which provide fairly elaborate remedial mechanisms through which their provisions are enforced, *see* 33 U.S.C. §§ 1311–1330, 2701–2720 (2000).

favor of more localized experimentation, particularly when it comes to performance standards as opposed to the design or labeling of products.[7] The difficulty, then, is how to discern the appropriate sphere for federal regulation, a difficulty only exacerbated by the modern world of dual state common-law and federal regulatory systems addressing similar problems.

A new approach to products liability preemption must highlight the issue's institutional dimension: when Congress punts, courts and federal agencies vie to fill the interpretive gap.[8] A modern take must also recognize that products liability preemption is multidimensional, involving layers of legal and policy issues—from the determination of the optimal regulatory sphere (national or state), to federalism issues, to the level of deference accorded agency determinations. Questions about the proposed preemptive effects of federal legislation above and beyond the customary and usually inconclusive inquiry into legislative intent must be posed (and answered). First, how should courts determine the extent to which their decisions must defer to, or advance, a federal regulatory policy due to interests such as promoting national uniformity or coordination among the states? Second, if such a federal policy exists, what is the optimal balance between common-law tort actions and federal regulation, considered in light of the comprehensiveness of the regulatory scheme?

With these animating principles in mind, I advance an "agency reference model" for judicial decisionmaking in products liability preemption cases: courts should look to agencies to supply the empirical data necessary to determine whether a uniform federal regulatory pol-

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7 Theorists have struggled to specify criteria for regulation at a centralized, national level in realms ranging from environmental to securities law. *See, e.g.*, Richard L. Revesz, *Federalism and Interstate Environmental Externalities*, 144 U. PA. L. REV. 2341, 2375 & n.123 (1996) (concluding that federal regulation is necessary to overcome negative externalities resulting from large-scale and complex environmental problems in which Coasean bargaining is unlikely because uncertainty about pollution's geographic impact bars transactions and because, depending on the source of pollution, the range of affected states will vary); Roberta Romano, *Is Regulatory Competition a Problem or Irrelevant for Corporate Governance?*, 21 OXFORD REV. ECON. POL'Y 212, 226 (2005) ("[N]o participants in that debate [on the theory of charter competition in corporate law] would contend that the federal government has no role in preventing negative externalities from jurisdictional spillovers.").

8 Of late, federal agencies have aggressively stepped in to fill this void. *See, e.g.*, Sharkey, *supra* note 5, at 229–42 (detailing forays into the preemption debate by the Consumer Product Safety Commission, National Highway Traffic Safety Administration ("NHTSA"), and Food and Drug Administration ("FDA")). Roderick Hills, by contrast, provocatively asserts that state law should fill this gap. *See* Hills, *supra* note 4, at 56 (advocating an approach that "enlists state governments to serve as the agents of Congress and empowers them to bring statutory ambiguities to the attention of Congress by enacting state legislation to fill . . . statutory gaps").

icy should exist—as agencies are in the best position to gather and evaluate data—and to make informed choices regarding the welfare of the American public. It may well be that the search for any global solution to the problem of the optimal regulatory level for products in an increasingly national (indeed international) market economy will be in vain. But a wealth of empirical evidence, furnished by federal regulatory agencies, can aid a more particularized search. Behind agency decisions to regulate or to refrain from regulating is a rich body of empirical cost-benefit (or increasingly risk-risk) analyses. These analyses made by the agency at the time of its action (or inaction), as well as the nature of the agency action and the contemporaneous reasons given by the agency to justify it, can guide courts' judgments regarding the need for, and equally significantly, the present feasibility of, uniform national regulatory standards.

This institutional approach departs from conventional preemption analysis with its focus on formal doctrinal categories and from the "presumption against preemption" interpretive canon, which directs courts to construe statutes not to preempt, absent a clear statement by Congress to the contrary.[9] Instead, it places federal agencies front and center in a realm in which they have often lurked just out of focus. The inquiry takes us into the heartland of administrative law, which is no surprise given that in our modern administrative state most statutory interpretation is left to agencies, not to the courts.[10] But my particular focus is the functional analysis that provides content to (or, at a minimum, complements) any interpretive exercise, whether by court or agency. My aim is to show that the agency reference model not only provides a better explanation for judicial outcomes, but also contains the seeds of a satisfying normative approach to products liability preemption jurisprudence.

Recent doctrinal developments—including controversial products liability preemption cases decided by the Supreme Court and applied by lower federal and state courts in litigation over allegedly defective medical devices and dangerous pharmaceuticals—cast doubt on the

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9 *See infra* Part I.A.

10 EINER ELHAUGE, STATUTORY DEFAULT RULES: HOW TO INTERPRET UNCLEAR LEGISLATION 79 (2008) ("Understanding the proper basis and limits of judicial deference to agency interpretations is vital for a simple reason: in the modern administrative state, most statutory interpretations are done by agencies."); *see also* Sharkey, *supra* note 5, at 227–28 (discussing the recent trend of federal agencies' issuance of preambles to regulations that purport to preempt conflicting or contrary state law).

conventional statutory interpretation approach and provide compelling support for the new agency reference model.[11]

## *I. Products Liability Preemption in the Supreme Court*

It is exceedingly difficult to demonstrate that any consistent principle or explanatory variable emerges from the Supreme Court's products liability preemption jurisprudence. Given Congress's track record in failing to address squarely the question of preemption in the products liability realm, interpretive canons should, at least in theory, take on added significance. But, as Jack Goldsmith has aptly summed up: "The [statutory interpretation] canons have an uncertain justification . . . and they probably conceal more than they enlighten about what drives the judicial decision to preempt or not."[12] Even the presumption against preemption—perhaps the leading contender to maintain consistency in the traditional state realm of torts—breaks down in the products liability realm, rearing its head with gusto in some cases, but oddly quiescent in others. Its subdued role, moreover, fits a wider empirical pattern, whereby for decades roughly fifty-fifty odds have prevailed in Supreme Court preemption decisions.[13] Indeed, the preemption rate actually *increases* to greater than sixty percent when considering preemption of state common-law tort claims[14]—a realm in which the putative anti-preemption presumption should be at its zenith, given the historic role of the states in matters of health and safety.

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11 The Supreme Court's products liability preemption jurisprudence is a small but expanding area that traces its beginnings to the early 1990s with *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and continues most recently through the 2008 decision of *Riegel v. Medtronic, Inc.*, No. 06-179, 2008 WL 440744 (U.S. Feb. 20, 2008). Two additional cases—*Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), *aff'd per curiam by an equally divided Court sub nom.* Warner-Lambert Co., LLC v. Kent, No. 06-1498, 2008 WL 552875 (U.S. Mar. 3, 2008), and *Levine v. Wyeth*, No. 2004-384, 2006 WL 3041078 (Vt. Oct. 27, 2006), *cert. granted*, 76 U.S.L.W. 3018 (U.S. Jan. 18, 2008) (No. 06-1249) (to be argued October Term 2008)—will add significantly to this budding jurisprudential line.

12 Jack Goldsmith, *Statutory Foreign Affairs Preemption*, 2000 SUP. CT. REV. 175, 200.

13 *See* Michael S. Greve & Jonathan Klick, *Preemption in the Rehnquist Court: A Preliminary Empirical Assessment*, 14 SUP. CT. ECON. REV. 43, 57 (2006) (finding that 52% of 105 preemption decisions from the Rehnquist Court era were decided in favor of preemption); Note, *New Evidence on the Presumption Against Preemption: An Empirical Study of Congressional Responses to Supreme Court Preemption Decisions*, 120 HARV. L. REV. 1604, 1612–13 (2007) ("Between the 1983 and 2003 Terms the Supreme Court decided 127 cases involving federal preemption of state law, finding state law preempted approximately half of the time.").

14 Greve & Klick, *supra* note 13, at 52 (finding 62.5% preemption rate in thirty-two cases involving preemption of state common-law tort claims from 1986 to 2004; the rate increases to 67.6% when cases are restricted to the "Second Rehnquist Court," beginning in 1994).

Failure on the part of the more formalist statutory canons would seem to open up more room for functional accounts. Particularly in the realm of implied preemption of state tort law, courts are called upon to fill the gap by engaging in interpretive lawmaking. Indeed, as Daniel Meltzer has noted (and even critics of the implied preemption doctrine have conceded), "the grist of implied preemption jurisprudence is supplied by cases in which the conflict between federal and state law is less stark and depends upon a judicial evaluation of statutory purpose."[15] Although it is possible to posit abstract principles such as spillover effects and economies of scale or scope to guide such a functional analysis, these, too, seem to disappoint when it comes to organizing, let alone predicting the course of, Supreme Court products liability preemption jurisprudence.

Strangely eluding detection to date, the influence of the relevant federal agency's position may be a better predictor of outcome. To be sure, the Supreme Court has been less than forthcoming about its reliance upon the views of the agency.[16] But a discernible trend toward agency deference emerges, at least in the products liability realm.

### *A. Conventional Approach: Congress and the Presumption Against Preemption*

The touchstone of conventional preemption analysis is congressional intent.[17] The standard textualist statutory interpretation approach, however, falls short even in the limited terrain of express preemption, given the contradictory language employed by Congress.[18] *Cipollone v. Liggett Group, Inc.*[19] is in some sense the high-water mark of express preemption in the products liability realm.[20]

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15 Daniel J. Meltzer, *The Supreme Court's Judicial Passivity*, 2002 SUP. CT. REV. 343, 364; *see also* John F. Manning, *Competing Presumptions About Statutory Coherence*, 74 FORDHAM L. REV. 2009, 2034 n.114 (2006) ("I should also note that the Court's approach to implied federal preemption of state law generally reflects premises more akin to those evident in its former purposivism." (citing Meltzer, *supra*, at 364–68)).

16 These views are sometimes put forward in official regulations, but more often simply in amicus briefs submitted by the Solicitor General, which may or may not get explicit mention by the Court. *See infra* Part I.C.

17 Cipollone v. Liggett Group, Inc., 505 U.S. 504, 530 n.27 (1992) (plurality opinion) ("[O]ur ambition here is not theoretical elegance, but rather a fair understanding of congressional purpose.").

18 *See supra* notes 3–4 and accompanying text.

19 Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992). For a discussion of *Cipollone*, see *infra* notes 37–47 and accompanying text.

20 *See* Cipollone, 505 U.S. at 523 (plurality opinion) (defending a narrow construction of an express preemption clause "in light of the strong presumption against pre-emption").

Since that time, the Court has expanded the domain of implied preemption,[21] where a textualist approach almost by definition fails. For here, even in the face of express statutory preemption or "savings" language, the Court has proceeded to consider whether state law should nonetheless be impliedly displaced.[22]

By way of divining congressional intent, the Court has wielded the presumption against preemption as an interpretive canon in areas traditionally occupied by the states.[23] Defenders of the presumption advert to its critical role in maintaining the enduring relevance of the "political safeguards of federalism";[24] they claim that Congress—as the sole constitutional body that effectively represents state interests—should exercise its powers to decide critical issues of policy, lest important federalism values fall by the wayside.[25] Seen in this light,

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21 Implied preemption takes two forms. First, "field preemption" occurs where the federal interest occupies, and thus dominates, an entire subject matter. Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 UCLA L. REV. 1353, 1366 n.40 (2006). Second, "conflict preemption" occurs where the federal interest conflicts with underlying state law, either in the narrow sense that an actor would find it impossible to comply with both commands or, in the broader sense, that compliance with the state law command would pose an obstacle to, or frustrate, federal regulatory purposes and objectives. *Id.*

22 *See, e.g.*, Geier v. Am. Honda Motor Co., 529 U.S. 861, 869 (2000) ("We now conclude that the savings clause (like the express preemption provision) does *not* bar the ordinary working of conflict pre-emption principles."); Freightliner Corp. v. Myrick, 514 U.S. 280, 288 (1995) ("The fact that an express definition of the pre-emptive reach of a statute "implies"—*i.e.*, supports a reasonable inference—that Congress did not intend to pre-empt other matters does not mean that the express clause entirely forecloses any possibility of implied pre-emption.").

23 *See, e.g.*, Wis. Pub. Intervenor v. Mortier, 501 U.S. 597, 605 (1991) ("'[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.'" (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947))).

24 *See generally* Larry D. Kramer, *Putting the Politics Back into the Political Safeguards of Federalism*, 100 COLUM. L. REV. 215 (2000); Herbert Wechsler, *The Political Safeguards of Federalism: The Role of the States in the Composition and Selection of the National Government*, 54 COLUM. L. REV. 543 (1954).

25 *See, e.g.*, Bradford R. Clark, *Separation of Powers as a Safeguard of Federalism*, 79 TEX. L. REV. 1321, 1427 (2001) ("Unless the Court is convinced that Congress actually considered—and proceeded to enact into law—a proposal that threatens state prerogatives, there is no guarantee that federal lawmaking procedures served to safeguard federalism.").

The vigorous dissent in *Geier*, penned by Justice John Paul Stevens and joined by Justices David Souter, Clarence Thomas, and Ruth Bader Ginsburg, in many respects echoed this view: "Unlike Congress, administrative agencies are clearly not designed to represent the interests of States, yet with relative ease they can promulgate comprehensive and detailed regulations that have broad pre-emption ramifications for state law." *Geier*, 529 U.S. at 908 (Stevens, J., dissenting).

It is not self-evident that Congress is a particularly effective representative of states' interests, at least those implicated by preemption determinations. Moreover, although beyond the scope of this Article, it is likewise not beyond the realm of possibility that robust participation by representatives of states' regulatory interests could open up the agency decisionmaking process.

the presumption against preemption is the modern reincarnation of the all-but-discredited nondelegation doctrine.[26] Such lines of argument can have a decided focus on constitutional structure;[27] alternatively, they have been defended on information-forcing (or what Einer Elhauge has termed "preference-eliciting") grounds, based on the fact that preemption-advocating interest groups may have a greater ability to lobby Congress for such a result.[28] Critics of the presumption, however, have been equally impassioned. Several leading commentators have called for the Court to abandon the presumption

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*See generally* Catherine M. Sharkey, *Agency Accountability*, 58 DEPAUL L. REV. (forthcoming 2009).

26 *Cf.* Cass R. Sunstein, *Nondelegation Canons*, 67 U. CHI. L. REV. 315, 337–43 (2000) (arguing for reconception of the nondelegation doctrine as a check on agency authority).

27 *See, e.g.*, Clark, *supra* note 25, at 1429 ("[T]he constitutional structure appears to favor a presumption against preemption because the Constitution gives states a role in selecting Congress and the President, but not federal courts.").

A more extreme position defends the presumption against preemption as a form of constitutional avoidance: if preemption implicates the Supremacy Clause in invalidating a state law, then courts should construe statutes not to preempt, absent a clear statement by Congress to the contrary. *See, e.g.*, Brief of the Center for State Enforcement of Antitrust and Consumer Protection Laws, Inc. as Amicus Curiae in Support of Petitioner at 9, Watters v. Wachovia Bank, N.A., 127 S. Ct. 1559 (2007) (No. 05-1342), 2006 WL 2570991, at *9 ("Because the power to displace state law through preemption likewise rests on a provision of the Constitution—the Supremacy Clause—and because from the States' perspective a judgment of preemption is tantamount to a finding of unconstitutionality, it is equally anomalous to say that federal courts must defer to reasonable agency determinations of preemption.").

28 *See, e.g.*, ELHAUGE, *supra* note 10, at 152 (defining preference-eliciting default rules as "designed to choose the interpretations that are most likely to elicit legislative reactions"); Hills, *supra* note 4, at 28 ("[C]ourt[s] ought to interpret the preemptive force of federal statutes to burden interest groups favoring preemption, on the assumption that these pro-preemption groups are more capable of promoting a vigorous debate in Congress than their opponents."). *But see* Adrian Vermeule, *The Judiciary Is a They, Not an It: Interpretive Theory and the Fallacy of Division*, 14 J. CONTEMP. LEGAL ISSUES 549, 566 (2005) ("Information-forcing or deliberation-forcing arguments assume that judges can and will coordinate on the relevant canons, doctrines and precepts. Such arguments thus ignore the inevitable heterogeneity and fluctuation of interpretive doctrine across courts over time.").

Interest group theory accounts of the federal legislative process drive two opposing views of statutory default rules in the preemption context. *Compare, e.g.*, Hills, *supra* note 4, at 28 (defending the anti-preemption rule of statutory construction on the basis of its benefits for the national lawmaking process), *with, e.g.*, Alan Schwartz, *Statutory Interpretation, Capture, and Tort Law: The Regulatory Compliance Defense*, 2 AM. L. & ECON. REV. 1, 7–8 (2000) (advocating a presumption in favor of preemption on the ground that Congress would find it easier to reverse erroneous judicial decisions that enforce preemption than the opposite). *But see* Note, *supra* note 13, at 1605 ("The data [analyzing Congress's responses to every Supreme Court preemption decision between the 1983 and 2003 Terms] show that Congress almost never responds to the Court's preemption decisions, so mistaken interpretations for or against preemption are unlikely to be corrected.").

and simply apply ordinary principles of preemption against a background of neutrality.[29]

Moreover, as an empirical matter, the presumption against preemption must cede explanatory ambitions in the products liability realm. Here, I join a veritable chorus of scholars pointing out the Court's haphazard application of the presumption.[30] In the realm of products liability preemption, the presumption does yeoman's work in some cases[31] while going AWOL altogether in others.[32] The present trend, paradoxically, is for the Court to apply the presumption when interpreting express preemption provisions,[33] but not when called upon to engage in implied preemption analysis.[34] And it is striking

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29 *See, e.g.*, Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2111–12 (2000); Goldsmith, *supra* note 12, at 177.

30 *See, e.g.*, Calvin Massey, *"Joltin' Joe Has Left and Gone Away": The Vanishing Presumption Against Preemption*, 66 ALB. L. REV. 759, 764 (2003) ("[T]he Court . . . continues to simultaneously repeat and ignore the presumption against preemption."); Nelson, *supra* note 4, at 298 ("The Court itself has applied the presumption only half-heartedly.").

31 *See, e.g.*, Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005) ("'[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.'" (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996))); *see also id*. ("Even if Dow had offered us a plausible alternative reading of [the express preemption provision]—indeed, even if its alternative were just as plausible as our reading of that text—we would nevertheless have a duty to accept the reading that disfavors pre-emption.").

32 *See, e.g.*, Riegel v. Medtronic, Inc., No. 06-179, 2008 WL 440744 (U.S. Feb. 20, 2008); Sprietsma v. Mercury Marine, 537 U.S. 51 (2002); Geier v. Am. Honda Motor Co., 529 U.S. 861, 906 (2000) (Stevens, J., dissenting) ("[T]he Court simply ignores the presumption . . . ."); Freightliner Corp. v. Myrick, 514 U.S. 280 (1995).

The dissent in *Geier*, which touted the presumption, inveighed against the majority's purposeful neglect thereof. *See* 529 U.S. at 888 (Stevens, J., dissenting) ("[T]he Court is quite wrong to characterize its rejection of the presumption against pre-emption, and its reliance on history and regulatory commentary rather than either statutory or regulatory text, as 'ordinary experience-proved principles of conflict pre-emption.'" (quoting *id.* at 874 (majority opinion))).

33 *Bates*, *Lohr*, and *Cipollone*, each of which relied on the presumption, *see supra* notes 20 & 31, were decided on express preemption grounds. *See Bates*, 544 U.S. at 452; Medtronic, Inc. v. Lohr, 518 U.S. 470, 484 (1996); Cipollone v. Liggett Group, Inc., 505 U.S. 504, 517 (1992). *But see Riegel*, 2008 WL 440744 (decided on express preemption grounds, but with no mention by the majority of the presumption against preemption).

34 The Court's seminal implied preemption cases, *Sprietsma* and *Geier*, eschew any reliance on the presumption. *See supra* note 32.

This trend is paradoxical because an interpretive default rule or "thumb on the scale" would seem warranted, if at all, where there is no express statutory language. Even critics of the presumption usually concede that it may have a role to play, given the expansive doctrine of implied preemption. *See, e.g.*, Nelson, *supra* note 4, at 290 ("By telling judges to approach federal statutes with 'the starting presumption that Congress does not intend to supplant state law,' the Supreme Court offsets its own expansive formulations of 'implied' preemption." (quoting N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 654 (1995))).

that in the single implied preemption case in which the presumption was invoked, it was for the purpose of disavowing it, given the primacy of the federal interest at stake.[35]

On either normative or empirical grounds alone, then, one might defend setting aside the presumption against preemption. The fall of this interpretive canon, moreover, would make way for alternative organizing principles.

### *B. Functional Approach: The Two Faces of Tort Law in the Supreme Court*

To our modern sensibilities, tort law wears (at least) two hats: victim-specific compensation and regulatory deterrence.[36] The Supreme Court's preemption jurisprudence reflects an incoherent, and at times internally inconsistent, conception of the tort-regulation pas-à-deux. In each of its products liability preemption cases, the Court has, in interpreting Congress's directives regarding preemption of state "requirements" or "safety standards," confronted the issue whether common-law damages actions exert a regulatory effect analogous to that of positive enactments of law. The Court has oscillated between competing conceptions of tort as either primarily regulatory or compensatory, with the regulatory view justifying preemptive results and the compensatory view compelling the opposite.

#### *1. Tort as Regulation*

*Cipollone* was a watershed case in products liability preemption jurisprudence. In that case, a plurality held that the Public Health Cigarette Smoking Act of 1969[37] expressly preempted certain com-

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35 *See* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347–48 (2001) (refusing to apply presumption given that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied'" and "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law" (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947))).

36 Additional roles of tort law include "educating the public about serious health risks and profit-driven efforts to conceal those risks," Rabin, *supra* note 1, at 2070, and information-updating, *see* Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L., Issue 1, Art. 4, at 45 (2006), http://www.bepress.com/jtl/vol1/iss1/art4 (follow "Download" hyperlink) (subscription required) ("[T]ort litigation triggers the compulsory mechanism of civil discovery by which plaintiffs may obtain industry-held information.").

37 Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331–1338 (2000)). The Act amended the Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, 79 Stat. 282, 15 U.S.C. §§ 1331–1341 (2000).

mon-law failure-to-warn claims.[38] Central to its determination was its construction of the statutory language, "No requirement or prohibition . . . shall be imposed under State law with respect to the advertising or promotion of any cigarettes,"[39] to include these common-law claims.[40] The plurality reasoned that "[t]he phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules."[41] More specifically, the plurality reasoned, "common-law damages actions of the sort raised by petitioner are premised on the existence of a legal duty, and it is difficult to say that such actions do not impose 'requirements or prohibitions.'"[42]

Writing for the plurality, Justice Stevens's reasoning went beyond the equation of common-law liability standards and positive enactments of law as "requirements." Its underlying conception of tort law as regulation extended to the remedial side as well: "'[State] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.'"[43]

The significance of this conception of tort law is brought into sharper relief by the contrasting view of the dissent, which emphasized two differences between tort and regulation. First, the dissent stressed that the regulatory effect of tort law is, at most, indirect, stating that "[t]he level of choice that a defendant retains in shaping its own behavior distinguishes the indirect regulatory effect of the common law from positive enactments such as statutes and administrative regulations."[44] This view emphasizes that defendants retain an "option" to

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38 Cipollone v. Liggett Group, Inc., 505 U.S. 504, 530–31 (1992) (plurality opinion).

39 15 U.S.C. § 1334(b).

40 *See Cipollone*, 505 U.S. at 521 (plurality opinion).

41 *Id.*; *see also id*. at 548–49 (Scalia, J., concurring in judgment in part, dissenting in part) ("I agree . . . that the phrase 'State law' as used in [§ 1334(b)] embraces state common law.").

42 *Id.* at 522 (plurality opinion) (citing WILLIAM PROSSER, LAW OF TORTS 4 (4th ed. 1971)); *see also id*. ("[I]t is the essence of the common law to enforce duties that are either affirmative *requirements* or negative *prohibitions*.").

43 *Id.* at 521 (quoting San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 247 (1959)). An earlier part of Justice Stevens's opinion, joined by six other Justices, however, includes a significant caveat: "[T]here is no general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of state common-law damages actions." *Id.* at 518 (majority opinion).

44 *Id.* at 536–37 (Blackmun, J., concurring in part, concurring in judgment in part, dissenting in part).

"pay as they go"—in other words, to pay tort damages instead of altering their conduct.[45] Second, the dissent underscored tort law's entirely separate ambition to compensate.[46] This focus on the compensatory role of tort law was coupled with a concern for leaving injured plaintiffs without a remedy.[47]

The majority in *Geier v. America Honda Motor Co.*[48] pushed the "tort as regulation" view even further. In passing the National Traffic and Motor Vehicle Safety Act of 1966 ("MVSA"),[49] Congress stated a clear intent to clear the field of rivals to federal regulations,[50] while at the same time adding a "savings clause" that assured that nothing

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45 *See id.* at 536 ("Although an award of damages by its very nature attaches additional consequences to the manufacturer's continued unlawful conduct, no particular course of action (*e.g.*, the adoption of a new warning label) is required.").

This dichotomy is less stark than the Court assumes. For, after all, defendants may equally disregard safety regulations and similarly "pay as they go." *See, e.g.*, Goodyear Atomic Corp. v. Miller, 486 U.S. 174, 185–86 (1988) ("Appellant may choose to disregard Ohio safety regulations and simply pay an additional workers' compensation award if an employee's injury is caused by a safety violation.").

46 *See Cipollone*, 505 U.S. at 537 (Blackmun, J., concurring in part, concurring in judgment in part, dissenting in part) (citing Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1540 (D.C. Cir. 1984)).

The dissent's compensatory focus places the plurality's reasoning in still sharper relief. Consider in this regard that Justice Stevens, having invoked the "presumption against preemption," *see id.* at 518 (majority opinion), could have insisted that the Court presume that Congress intended to preserve the states' historic police powers in this area—for example, the power to spread risk and the power to improve the welfare of injured accident victims through compensation. Instead, Justice Stevens took the view that, in this instance, the state was engaged only in regulation. *See id.* at 519. At that point, the plurality naturally characterized the tort system as enforcing regulatory "prohibitions and requirements." *See supra* notes 40–42 and accompanying text.

47 *See Cipollone*, 505 U.S. at 541 (Blackmun, J., concurring in part, concurring in judgment in part, dissenting in part) ("[T]here is absolutely no suggestion in the legislative history that Congress intended to leave plaintiffs who were injured as a result of cigarette manufacturers' unlawful conduct without any alternative remedies . . . . Unlike other federal statutes where Congress has eased the bite of pre-emption by establishing 'comprehensive' civil enforcement schemes, the Cigarette Labeling and Advertising Act is barren of alternative remedies.").

48 Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000).

49 National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. §§ 1381–1431 (1988) (current version at 49 U.S.C. §§ 30101–30170 (2000)).

50 The version of the MVSA in effect when the events leading to the *Geier* lawsuit transpired contained the following express preemption clause:

> [N]o State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not *identical* to the Federal standard.

*Id.* § 1392(d) (emphasis added) (current version at 49 U.S.C. § 30103(b)).

would alter the customary operation of tort law.[51] The issue in the case was whether the failure to install airbags, arguably the state-of-the-art safety technology at the time, could be the basis for liability.[52] In reaching its implied preemption conclusion foreclosing state tort liability, the majority referred to a verdict in a common-law tort suit as a "jury-imposed safety standard."[53] Moreover, its opinion tightened the grip against the "pay-as-you-go" distinction drawn by the *Cipollone* dissent.[54]

Once again, the dissent raised the specter of the forgotten remedial, compensatory role of tort, although this time, it was Justice Stevens—the author of the *Cipollone* plurality—who raised the concern: "This distinction [between legislative and administrative rulemaking, on one hand, and common-law liability, on the other] was certainly a rational one for Congress to draw in the Safety Act given that common-law liability—unlike most legislative or administrative rulemaking—necessarily performs an important remedial role in compensating accident victims."[55] The *Geier* majority, however, paid little heed to any such congressional determination regarding the importance of compensation in this realm. It evinced little desire to balance the states' interest in compensating victims of commercial behavior that transgresses local norms against the drawbacks associated with the existence of nonuniform tort law in a national automobile market.[56]

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51 *See id.* § 1397(k) ("Compliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law.") (current version at 49 U.S.C. § 30103(e)).

52 *See Geier*, 529 U.S. at 865.

53 *Id.* at 871. The dissent, this time led by Justice Stevens, challenged the interpretive point and chastised the majority for its "fundamental misconception of the nature of duties imposed by tort law." *Id.* at 902 n.18 (Stevens, J., dissenting); *see also id.* at 896 ("It is perfectly clear . . . that the term 'safety standard' . . . refers to an objective rule prescribed by a legislature or an administrative agency and does not encompass case-specific decisions by judges and juries that resolve common-law claims.").

54 *See id.* at 882 (majority opinion) ("[T]his Court's pre-emption cases ordinarily *assume* compliance with the state-law duty in question.").

55 *Id.* at 896 (Stevens, J., dissenting).

56 The Court did consider the fact that the inclusion of a savings clause reflected a congressional determination that providing compensation to victims sometimes outweighed the costs of nonuniformity. *See id.* at 871 (majority opinion). The Court noted that this "policy by itself disfavors pre-emption, at least some of the time," but then concluded that it could find nothing to suggest that Congress would favor a policy of compensation over its policy—expressed in the preemption clause—in favor of uniformity. *Id.*

*Buckman Co. v. Plaintiffs' Legal Committee*[57] likewise embraced a regulatory conception of state tort law. In *Buckman*, the Court held that the Medical Device Amendments of 1976 ("MDA")[58] to the Federal Food, Drug, and Cosmetic Act ("FDCA")[59] impliedly preempted plaintiffs' state-law "fraud-on-the-agency" claim against a manufacturer's regulatory consultant based on allegedly false statements made to the Food and Drug Administration ("FDA") in the course of seeking premarket notification approval for the manufacturer's medical device (orthopedic bone screws).[60]

The Solicitor General's amicus brief to the Court highlighted the need for consistency at the remedial, as well as the liability, end:

> Even if juries in different States applied the same substantive standards as FDA, it would not eliminate that conflict. As this Court has explained, "[a] multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law."[61]

The concept that "'remedies form an ingredient of any integrated scheme of regulation'"[62]—in other words, that remedies cannot be

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57 Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001).

58 Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

59 Federal Food, Drug, & Cosmetic Act, 21 U.S.C. §§ 301–399 (2000). Although *Buckman* was decided on implied preemption grounds, the MDA contains an express preemption clause, 21 U.S.C. § 360k(a)(1) ("[N]o State . . . may establish or continue in effect with respect to a device intended for human use any requirement [relating to the safety or effectiveness of the device] which is different from, or in addition to, any requirement applicable . . . to the device."), and no savings clause. But, as is par for the course for congressional products liability legislation, even though the MDA contains an express preemption clause, the status of common-law tort claims was left ambiguous. *See* Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 923–24 (1994) ("[W]e note that there is no absolutely dispositive language in the MDA regarding preemption and the common law. That is, nowhere in the amendments or in the legislative history of the amendments does Congress indicate that state common law tort claims are preempted or are not preempted.").

60 *See Buckman*, 531 U.S. at 348. The FDA approved the screws as a predicate device, but issued this approval based on representations that the screws were to be marketed for legs and arms, as opposed to spines. *See id.* at 346. Arguing that the FDA would not have approved the screws had petitioner not made the fraudulent representation, *id.* at 346–47, plaintiffs—who claimed injuries resulting from the use of the screws in their spines—sought damages under state tort law. *Id.* at 343. The suit claimed that the misrepresentations were the "but for" cause of injuries that plaintiffs sustained from the implantation of these devices. *Id.* at 343.

61 Brief for the United States as Amicus Curiae Supporting Petitioner at 23, Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001) (No. 98-1768), 2000 WL 1364441, at *23 [hereinafter U.S. *Buckman* Br.] (quoting Garner v. Teamsters, 346 U.S. 485, 490–91 (1953)).

62 *Id.* (quoting San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 247 (1959)).

blithely separated from substantive common-law requirements—is critical to this view.

In preempting the state-law cause of action, the Court forged a link between the remedial and liability side of tort law by seeking to protect the federal regulatory scheme from being adulterated by the tort system's incentives.[63] The Court analyzed the regulatory effects that state tort law would have on the medical device industry:

> As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants . . . . Would-be applicants may be discouraged from seeking . . . approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates . . . to unpredictable civil liability.[64]

*Riegel v. Medtronic, Inc.*[65] is the most recent Court pronouncement in the "tort as regulation" camp. In *Riegel*, a near-unanimous (eight Justice majority) Court held that the express preemption provision of the MDA[66] foreclosed state-law claims seeking damages for injuries caused by an allegedly defectively designed balloon catheter that received "rigorous" premarket approval from the FDA.[67] Re-

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63 By contrast, no attention was paid to the fact that, from the state's point of view, it was both enforcing federal law—thereby deterring firms from harming its citizens in the future—and providing a remedy to a citizen who had been injured, thereby correcting an imbalance of justice. Instead, the Court held that there was "clear evidence that Congress intended that the [statute] be enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 352.

64 *Id.* at 350. Arguably, the Court instead could have rested its decision exclusively on the ground that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied' . . . [;] [t]o the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

65 Riegel v. Medtronic, Inc., No. 06-179, 2008 WL 440744 (U.S. Feb. 20, 2008).

66 *See supra* note 59.

67 *Riegel*, 2008 WL 440744, at *7–10; *id.* at *11 (Stevens, J., concurring in part and concurring in the judgment). The Court held that all state-law claims alleging design defect or failure to warn were preempted, *see id.* at *7–10 (majority opinion); claims for manufacturing defect and negligence per se claims "premised on a violation of FDA requirements" would not be preempted, *id.* at *11 (Stevens, J., concurring in part and concurring in the judgment); *see also id.* at *12 (Ginsburg, J., dissenting).

The balloon catheter at issue in *Riegel* is a "Class III" medical device. *See id.* at *5. The FDCA categorizes medical devices into three classes based on the risk they pose to the public and the controls necessary to provide "reasonable assurance" of a device's "safety and effectiveness." *See* 21 U.S.C. § 360c(a)(1) (2000). "Class III" devices are the most dangerous and either are used to support or sustain human life or possess a potentially unreasonable risk of illness and injury. *See id.* § 360c(a)(1)(C). In general, before a Class III device can be introduced into the market, a manufacturer must obtain premarket approval ("PMA") from the FDA. *See id.*; *id.*

turning full circle to its *Cipollone* decision, the Court resolutely declared: "Absent other indication, reference to a State's 'requirements' includes its common-law duties."[68] Once again, bridging the remedial-liability divide, the Court reasoned that "while the common-law remedy is limited to damages, a liability award 'can be, indeed is designed to be, a potent method of governing conduct and controlling policy.'"[69] Indeed, the Court goes the furthest it has to date in terms of provocatively suggesting that jury-imposed liability decisions would wreak havoc upon the federal regulatory scheme ensconced in the MDA.[70]

The lone dissenter (Justice Ginsburg) made a plea for compensation on behalf of consumers injured by defective medical devices: "The MDA's failure to create any federal compensatory remedy for such consumers further suggests that Congress did not intend broadly to preempt state common-law suits . . . ."[71] But this lone plea was met with the majority's (per Justice Scalia) retort that "the solicitude for those injured by FDA-approved devices, which the dissent finds controlling, was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations."[72]

The pro-preemption Court rulings, then, follow a distinct pattern of emphasizing commonalities between tort and regulation in terms of

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§ 360e(d)(2) (setting forth premarket approval procedures). *But see infra* note 74 (describing an exception for less rigorous approval of Class III devices that are "substantially equivalent" to those already on the market).

68 *Riegel*, 2008 WL 440744, at *7.

69 *Id.* (quoting Cipollone v. Liggett Group, Inc., 505 U.S. 504, 521 (1992) (plurality opinion)).

70 *Id.* at *8 ("How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court."); *id.* at *8 ("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."). Justice Stevens dropped off the majority's train at this juncture. *See id.* at *11 (Stevens, J., concurring in part and concurring in the judgment).

71 *Id.* at *13 (Ginsburg, J., dissenting); *id.* ("It is 'difficult to believe that Congress would, without comment, remove all means of judicial recourse' for large numbers of consumers injured by defective medical devices." (quoting Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984))).

72 *Id.* at *8 (expounding this position, with the lead-in caveat: "It is not our job to speculate upon congressional motives. If we were to do so, however, the only indication available—the text of the statute—suggests . . . ."). Justice Stevens also declined to join this part of the Court's opinion. *Id.* at *11 (Stevens, J., concurring in part and concurring in the judgment) ("That is a policy argument advanced by the Court, not by Congress.").

governing conduct; moreover, they have a distinct deterrence-based flavor that would meld the remedial and liability sides of tort and contemplate the incentive-based effects of common-law damages. This conception basically inverts itself, however, with the alternative view of tort as compensation guiding the majority in the anti-preemption rulings.

*2. Tort as Compensation*

The Court does a seeming 180-degree turnabout in cases that stand for the proposition that the call for the uniformity of national regulation should not be taken so far as to justify the displacement of state common-law remedies for accident victims. *Medtronic, Inc. v. Lohr*[73] is an apt starting point for this contrasting view—if only because it presents the clearest foil to *Riegel*. The case involved fairly typical negligence and strict liability claims by a plaintiff who was injured by an allegedly defectively designed pacemaker that had been granted premarket notification approval by the FDA.[74]

Justice Stevens, writing for the plurality, attempted to retreat from the *Cipollone* position that tort law standards of care ought to be preempted under express preemption clauses because they are "requirements" every bit as regulatory as an administrative regulation or statute.[75] *Lohr* relied on *Silkwood v. Kerr-McGee Corp.*,[76] a case in which the Court held that a plaintiff could collect damages on a common-law strict liability cause of action notwithstanding the fact that

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73 Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

74 *See id.* at 480–81. The pacemaker at issue in *Lohr* was a Class III medical device, *see supra* note 67, but it was not subject to the rigorous PMA process at issue in *Riegel*. Manufacturers may distribute devices that are "substantially equivalent" to those on the market via a less comprehensive, and less burdensome, premarket notification process. *See Lohr*, 518 U.S. at 478–79; *see also* 21 U.S.C. § 360c(f)(4), 360e(b)(1)(B) (2000).

75 Justice Stevens, author of the plurality opinion in *Cipollone*, distinguished the case as follows:

> The Court in *Cipollone* held that the petitioner in that case was able to maintain some common-law actions using theories of the case that did not run afoul of the pre-emption statute. Here, however, Medtronic's sweeping interpretation of the statute would require far greater interference with state legal remedies, producing a serious intrusion into state sovereignty while simultaneously wiping out the possibility of remedy for the [plaintiffs'] alleged injuries.

*Lohr*, 518 U.S. at 488–89 (plurality opinion). Restated, this position would seem to advocate a new balancing approach (for which Justice Stevens did not garner five votes): where there is statutory ambiguity as to preemption, the Court, in deciding whether to preempt tort law liability standards, should balance the costs that preemption imposes upon state sovereignty against the extent to which the continued operation of state law would interfere with the federal government's balancing of safety risks against the benefits of innovation.

76 Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984).

the United States Nuclear Regulatory Commission had "exclusive authority to regulate safety matters."[77] The *Silkwood* Court emphasized tort law's compensatory role; in essence, according to the Court, Congress had split the atom of tort law's regulation-through-compensation nature, isolating and focusing on the compensatory function of tort law, thereby protecting it from preemption.[78] The *Lohr* plurality was equally skeptical of congressional intent to impede compensation.[79]

S*prietsma v. Mercury Marine*[80]—decided after *Cipollone*, *Geier*, and *Buckman*—nonetheless returned to the logic of *Lohr*'s narrow reading of "requirements." At issue in *Sprietsma* was the Federal Boat Safety Act of 1971 ("FBSA")[81]—yet another statute saddled with the ambiguity created by the combination of a broad preemption clause and a seemingly contradictory savings clause[82]—which is ad-

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77 *See id.* at 256. There is an unresolved tension in the case between the Commission's exclusive regulatory authority and the Court's view that Congress intended to engage in minimal regulation, and thus was willing to accept additional regulatory demands from state common law. *See id.*

78 *See id.* The Court reasoned that Congress sought to preserve the states' power to define standards of liability in light of its judgment that the importance of the states' power to award compensation to injured plaintiffs outweighs the costs, consisting of the added complications faced by nuclear power generation companies and the disincentives for nuclear projects that meet the stringent regulations of the Nuclear Regulatory Commission. *See id.* at 253–54.

Despite its focus on the compensatory nature of tort law, the Court did concede a regulatory role for the tort system:

> It may be that the award of damages based on the state law of negligence or strict liability is regulatory in the sense that a nuclear plant will be threatened with damages liability if it does not conform to state standards, but that regulatory consequence was something that Congress was quite willing to accept.

*Id.* at 256.

79 First, Justice Stevens suggested that preemption of state remedies would have the "perverse effect" of immunizing an industry that "in the judgment of Congress, needed more stringent regulation." *Lohr*, 518 U.S. at 487 (plurality opinion). Second, he noted that if Congress had intended such a radical transformation, "contemporary reviews of the legislation" would have made some reference to the change. *Id*. at 491 n.13. Finally, according to Justice Stevens, if Congress intended to preclude state-law damages, it chose an "odd" word to effect the change—suggesting that Congress, in fact, had no such intention. *See id.* at 487.

80 Sprietsma v. Mercury Marine, 537 U.S. 51 (2002).

81 Federal Boat Safety Act of 1971, 46 U.S.C. §§ 4301–4311 (2000).

82 The preemption clause in the FBSA reads: "[A] State . . . may not establish, continue in effect, or enforce a law or regulation establishing a recreational vessel or associated equipment performance or other safety standard or imposing a requirement for associated equipment . . . that is not *identical* to a regulation prescribed . . . under this title." *Id.* § 4306 (emphasis added). The accompanying "savings clause" provides: "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." *Id.* § 4311(g).

ministered by the Coast Guard, the federal agency charged with regulating recreational boat safety.[83]

The Court held that the FBSA neither expressly nor impliedly preempted the plaintiff's common-law tort claims stemming from the manufacturer's failure to install propeller guards on a boat engine.[84] In reaching this conclusion, the Court read the express preemption clause at issue—which applies to "a [state or local] law or regulation"[85]—not to encompass common-law tort claims.[86] The Court, moreover, thought that Congress could have reasonably believed that state tort-law claims should not be preempted by the FBSA because common-law claims "perform an important remedial role in compensating accident victims."[87]

Finally, we come to *Bates v. Dow Agrosciences LLC*.[88] At issue in *Bates* was the preemptive effect of federal labeling requirements under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").[89] Congress, as by now should seem familiar in the products liability realm, passed a statute preempting state "requirements,"

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83 The FBSA authorizes the Secretary of Transportation to prescribe regulations establishing "*minimum* safety standards" for recreational boats. *See id.* § 4302(a) (emphasis added). The Secretary, in turn, has delegated this power to the Coast Guard. *Sprietsma*, 537 U.S. at 57 (citing 49 C.F.R. § 1.46(n)(1) (1997)).

84 *See Sprietsma*, 537 U.S. at 54–55.

85 *See* 46 U.S.C. § 4306.

86 *Sprietsma*, 537 U.S. at 63. The Court gave two—to my mind unsatisfactory—reasons, relying on what I would call rigid, formalist statutory interpretation:

> First, the article "a" before "law or regulation" implies a discreteness . . . that is not present in the common law. Second, . . . the terms "law" and "regulation" used together in the pre-emption clause indicate that Congress pre-empted only positive enactments. If "law" were read broadly so as to include the common law, it might also be interpreted to include regulations, which would render the express reference to "regulation" in the pre-emption clause superfluous.

*Id.*

87 *Id.* at 64.

88 Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005).

89 Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y (2000). FIFRA, enacted in 1947, was primarily a licensing and labeling statute. *Bates*, 544 U.S. at 437. In 1972, Congress strengthened FIFRA's registration and labeling standards in response to environmental and safety concerns; in effect, Congress transformed FIFRA from a labeling law into a comprehensive regulatory statute. *Id.* The amendments established a detailed program for the Environmental Protection Agency ("EPA") to register pesticides for particular uses and to approve pesticide labels. *See, e.g.*, 7 U.S.C. § 136a(c)(5). In 1978, in response to complaints from the EPA that its obligation to evaluate efficacy claims in the registration process was diverting scarce resources needed to evaluate the health and environmental effects, Congress relieved the EPA of its efficacy review obligations. *Bates*, 544 U.S. at 440; *see* 7 U.S.C. § 136a(c)(5). Approval by the EPA, therefore, does not reflect any determination that the pesticide is efficacious. *Bates*, 544 U.S. at 440. Instead, manufacturers are required to develop and maintain efficacy data. *See* 40 C.F.R. § 158.640(b)(1) (2007).

without further specifying whether such requirements included common-law tort duties in addition to positive enactments of statutory or regulatory law.[90] Moreover, as is par for the course for national products legislation, by exclusively focusing on standards, FIFRA's preemption provisions failed to address the states' remedial schemes.[91]

The Court held that FIFRA could coexist with state common-law tort claims brought by Texas peanut farmers who alleged that their crops were severely damaged by a newly marketed pesticide.[92] In reaching this conclusion, the Court forged an unstable compromise. On the one hand, the Court reaffirmed that "the term 'requirements' . . . reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties."[93] On the other hand, the Court introduced a rather restricted definition of when a common-law duty rises to the level of a "requirement," holding that "[a]n occurrence that merely motivates an optional decision does not qualify as a requirement."[94] It repeatedly distinguished commands of positive en-

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90 FIFRA expressly provides that a 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." 7 U.S.C. § 136v(b) (emphasis added). At the same time, Congress reserved to the states powers to regulate the sale or use of any pesticide within its borders. *Id.* § 136v(a). The voluminous legislative history of the 1972 amendments to FIFRA—consisting of thousands of pages of hearings, reports, and floor debates—contains nary a word about preemption or the continuing viability of state tort-law remedies. *See* Brief Amicus Curiae for the United States in Support of Plaintiffs-Appellants at 22–31, Etcheverry v. Tri-Ag Serv., Inc., 993 P.2d 366 (Cal. 2000) (No. S072524) [hereinafter U.S. *Etcheverry* Br.]; Brief for the Western Peanut Growers Ass'n et al. in Support of Petitioners at 13–14, Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005) (No. 03-388), 2004 WL 2097414, at *13–14.

91 Instead, the sole remedy should a manufacturer fail to comply with the pesticide registration requirements is that the EPA is authorized to issue a stop sale or seize the offending product. *See* 7 U.S.C. § 136k(a)–(b).

92 *See Bates*, 544 U.S. at 447–48. The EPA had conditionally registered the pesticide "Strongarm," thereby authorizing its sale, and approved a label stating that Strongarm was recommended for use in all areas where peanuts are grown. *Id.* at 434–35. The farmers complained that Dow knew or should have known that Strongarm would stunt the growth of peanut crops in high pH level soil. *Id.* at 435. They alleged (i) defective design; (ii) defective manufacture; (iii) negligent testing; (iv) breach of express warranty; (v) violation of the Texas Deceptive Trade Practices Act; (vi) fraud; and (vii) negligent failure to warn. *Id.* at 442 n.15.

93 *Id.* at 443. Any ambiguity on this point has been put to rest by the Court in *Riegel*. *See supra* text accompanying note 68; Riegel v. Medtronic, Inc., No. 06-179, 2008 WL 440744, at *7 (U.S. Feb. 20, 2008) ("Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments.").

94 *Bates*, 544 U.S. at 443. Under the Court's analysis, the claims for defective design, negligent testing, and breach of express warranty did not amount to packaging or labeling requirements and, thus, were not preempted. *See id.* at 444. The claims for fraud and negligent failure to warn, by contrast, did amount to such "requirements." *Id.* at 446. The Court, however, remanded these claims to the lower court to determine whether or not they impose requirements "in addition to or different from" the federal regulation. *See id.* at 453.

actments of law from those induced by liability rules.[95] The Court buttressed this distinction by drawing a conceptual wedge between liability standards and remedies.[96]

Once again, Justice Stevens linked preservation of the compensation function of tort law with respect for state sovereignty.[97] First, the Court highlighted the relevance of the history of tort litigation against pesticide manufacturers.[98] Remedies had been available through common-law actions both before and after the appearance of federal regulation,[99] demonstrating the persistence of a state common-law presence in regulating pesticides. Moreover, "for at least a decade after [the 1972] amendments [to FIFRA], arguments that such tort suits were pre-empted . . . either were not advanced or were unsuccessful."[100] Second, in reaching its decision, the Court was clearly concerned by the fact that most farmers would be left with virtually no remedy whatsoever if state tort suits for misbranding or failure to

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95 *See id.* at 445 ("A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement."); *id.* at 443 ("The Court of Appeals was therefore quite wrong when it assumed that any event, such as a jury verdict, that might 'induce' a pesticide manufacturer to change its label should be viewed as a requirement.").

96 *Id.* at 448 ("To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*." (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 513 (1996) (O'Connor, J., concurring in part, dissenting in part))).

97 This, of course, harkened back to Justice Stevens's plurality opinion in *Lohr*, *see supra* note 79 and accompanying text; in *Bates*, he had a majority on board.

98 *See Bates*, 544 U.S. at 440–41.

99 *See id.* ("Courts entertained tort litigation against pesticide manufacturers since well before the passage of FIFRA in 1947, and such litigation was a common feature of the legal landscape at the time of the 1972 amendments."). In this regard, *Cipollone* might serve as a useful contrast; when the statutes involved in *Cipollone* were adopted, there had been almost no history of common-law failure-to-warn actions against cigarette manufacturers. *See* Robert L. Rabin, *A Sociolegal History of the Tobacco Tort Litigation*, 44 STAN. L. REV. 853, 857–64 (1992) (describing the "first wave" of tobacco litigation in 1954 as entirely unsuccessful and dying out in 1961 with the publication of RESTATEMENT (SECOND) OF TORTS (1965) sounding a "death knell" for early tobacco litigation).

100 *Bates*, 544 U.S. at 441. Previously, the United States advocated that FIFRA did not preempt state tort law, *see infra* note 250 and accompanying text, and argued that this legal landscape supported its anti-preemption position. *See* Brief Amicus Curiae for the United States in Support of Appellants at 7, Hart v. Bayer Corp., 199 F.3d 239 (5th Cir. 2000) (No. 98-60496), 1999 WL 33607265, at *7 [hereinafter U.S. *Hart* Br.] ("When Section 136v(b) was enacted in 1972, state law actions against pesticide manufacturers for failure to warn were a commonplace and uncontroversial feature of the legal landscape. No evidence from the text or legislative history of FIFRA suggests that Congress had any intent to extinguish those actions or that Congress even considered doing so."); U.S. *Etcheverry* Br., *supra* note 90, at 5 (same).

warn were entirely preempted.[101] Viewed from this remedial vantage point, *Bates* seems to settle comfortably within a wider pattern in the Court's general unwillingness, in the products liability realm, to leave injured citizens without any remedy whatsoever.[102]

But a tension emerges: although there is certainly a strong state interest in compensating victims, compensation likewise affects the administration of national regulatory regimes. Indeed, this tension is, in some sense, at the root of the Supreme Court's alternating conception of tort-as-regulation versus tort-as-compensation. Although such a functional approach may be a helpful guide to understanding why the Court has reached a particular result in a particular case, it falls short as a normative prescription for cases yet to be decided, as it does not explain when the compensatory role or the regulatory role of tort law should have primacy in any particular case. The functional approach explored in this Section thus begs the institutional question of who should decide the critical regulatory policy issues at the heart of the products liability preemption inquiry.

### *C. Behind the Scenes: Federal Agencies*

Because of the inattention to the role of agencies, thus far missing from the vast (and still growing) literature is the following simple, positive observation: from *Cipollone* in 1992 to *Riegel* in 2008, the Supreme Court's position in every products liability preemption case (save one—*Bates*) aligned with the relevant underlying federal agency's take on preemption.[103] Given the contentious territory of preemption, frequently summed up as "a muddle,"[104] this empirical fact is rather surprising. It is difficult to tell what stands behind such

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101 *See Bates*, 544 U.S. at 449. Again, the United States had previously endorsed this position. *See* U.S. *Hart* Br., *supra* note 100, at 7 ("Given that FIFRA establishes no private damages remedy for those injured by pesticides, it would be astonishing that, without any discussion, Congress could have intended to deprive injured persons of all means of relief."); U.S. *Etcheverry* Br., *supra* note 90, at 32 ("[I]t would make no sense to infer that Congress intended to close off all avenues of judicial relief for those injured by pesticides.").

102 The Court's concern regarding what I term a remedial or enforcement "void," *see infra* note 146 and accompanying text, contrasts with its general indifference to this concern in the implied right of action context. *See, e.g.*, Andrew M. Siegel, *The Court Against the Courts: Hostility to Litigation as an Organizing Theme in the Rehnquist Court's Jurisprudence*, 84 TEX. L. REV. 1097, 1118–24 (2006); *see also supra* note 5.

103 The Solicitor General filed briefs on behalf of the relevant agency in each of the following cases: the FDA in *Buckman*, *Lohr*, and *Riegel*; NHTSA in *Geier* and *Freightliner*; the Coast Guard in *Sprietsma*; and the EPA in *Bates*. *See supra* note 61; *infra* notes 109, 113, 121, 126, 138 & 244.

104 Nelson, *supra* note 4, at 232 ("Most commentators who write about preemption agree on at least one thing: Modern preemption jurisprudence is a muddle."); *see also* Goldsmith,

deference to agency views. Indeed, as I will explore below, the Court itself has been cryptic at best in characterizing its reliance upon agency views.[105]

### *1. Pro-Preemption*

It might seem natural that a federal agency would adopt a pro-preemption stance, accentuating its domain at the expense of the competing state sources of authority. And so I begin with *Geier*, a classic case in which the underlying statutory scheme could support almost any outcome.[106] The case posed both the possibility of state law overriding federal regulation and the complete preemption of state tort remedies. Each seemed a violation of the statutory mandate.[107]

Into the mix stepped the relevant federal agency, the National Highway Traffic Safety Administration ("NHTSA"),[108] which explained that its decision not to mandate a specific form of passive restraint was intended to stimulate industry experimentation, rather than to compel the industry upon pain of liability to settle upon one specific form of restraint.[109] Here, notwithstanding the express statutory directive for the agency to promulgate "minimum" safety standards[110] and the express savings clause, the Court held that the state-

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*supra* note 12, at 178 ("The Supreme Court's preemption jurisprudence is famous for its incoherence.").

105 Deference to agencies could be a position defensible on legal and policy principles. Alternatively, it might simply be a way to evade difficult issues or to sustain a status quo position amidst great contestation, or some combination of the two.

106 *See supra* notes 49–51 and accompanying text.

107 *Cf.* Issacharoff & Sharkey, *supra* note 21, at 1391 n.144 (discussing Peter Strauss's admirable, yet in the end unpersuasive, attempt to reconcile the seeming contradiction by suggesting that, in 1966, when the MVSA was enacted, Congress most likely only contemplated common-law liability based upon manufacturing (not design) defects) (citing Peter L. Strauss, *Courts or Tribunals? Federal Courts and the Common Law*, 53 ALA. L. REV. 891, 919–20 (2002)).

108 The Secretary of Transportation delegated the authority to carry out the MVSA to the Administrator of NHTSA. 49 C.F.R. § 1.50(a) (2007).

109 *See* Brief for the United States as Amicus Curiae Supporting Affirmance at 9, Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000) (No. 98-1811), 1999 WL 1045115, at *9 [hereinafter U.S. *Geier* Br.]; *see also* Brief for the United States as Amicus Curiae at 13, Wood v. Gen. Motors Corp., 865 F.2d 395 (1st Cir. 1988), *cert. denied*, 494 U.S. 1065 (1989) (No. 89-46) [hereinafter U.S. *Wood* Br.] (arguing that the allowance of tort action would interfere with federal policy because the "incentive effects" of state common law actions would be very powerful due to the sizeable damages in wrongful death and serious injury cases).

110 The MVSA required the Secretary of Transportation to establish "appropriate Federal motor vehicle safety standards." 15 U.S.C. § 1392(a) (1988) (current version at 49 U.S.C. § 30111(a) (2000)). The Act defined a safety standard as "a *minimum* standard for motor vehicle performance, or motor vehicle equipment performance . . . ." *Id.* § 1391(2) (emphasis added) (current version at 49 U.S.C. § 30102(a)(9)).

law claims were impliedly preempted.[111] In reaching its determination, the Court, per Justice Breyer, was explicit about its reliance upon the agency's views: "We place *some weight* upon [the agency's] interpretation of [its regulation]'s objectives and its conclusion, as set forth in the Government's brief, that a tort suit such as this one would '"stan[d] as an obstacle to the accomplishment and execution"' of those objectives."[112] In this case, the majority emphasized that "the agency's own views *should make a difference*."[113]

In similar fashion, *Buckman* might be characterized as another instance in which the Court deferred to a federal agency's—here the FDA's—turf-protecting impulse. Here again, the Court's ultimate determination tracked the position advocated by the agency, although it curiously made no mention of the FDA's position.

In an amicus brief submitted jointly on behalf of the Chief Counsel for the FDA, the Department of Justice, and itself, the Office of the Solicitor General took the position that state-law fraud-on-the-FDA claims were impliedly, but not expressly, preempted.[114] The FDA asserted its right to reign supreme, at least with respect to the federal domain of policing fraud against the FDA.[115] The Court not only embraced this argument[116] but also went further to incorporate, although without attribution or any acknowledgement whatsoever,[117] broader arguments advanced by the FDA, including that allowing fraud-on-the-FDA claims would distort the regulatory enforcement

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111 *See Geier*, 529 U.S. at 869.

112 *Id.* at 883 (emphasis added) (internal citations omitted).

113 *Id*. (emphasis added). The Court also noted the fact that the Department of Transportation had urged this same position before the Court in previous cases. *Id.* (citing Brief for the United States as Amicus Curiae Supporting Respondents at 28–29, Freightliner Corp. v. Myrick, 514 U.S. 280 (1995) (No. 94-286), 1994 WL 16012084, at *28–29 [hereinafter U.S. *Freightliner* Br.] and U.S. *Wood* Br., *supra* note 109, at 7, 11–16). For further discussion of the import of consistency of agency position, see *infra* Part II.B.2.b.

114 *See* U.S. *Buckman* Br., *supra* note 61, at 11–30.

115 *See id.* at 16–24.

116 Relying upon the characterization of policing fraud against the FDA as a decidedly federal function, the Court explicitly eschewed employing the presumption against preemption. *See* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347–48 (2001).

117 Unlike in *Geier*, *see supra* note 112 and accompanying text, the majority opinion does not explicitly cite or reference the Brief of the United States.

and penalty scheme,[118] and that permitting state-law fraud suits could distort the behavior of regulated entities.[119]

*Riegel* rounds out the pro-preemption trilogy with its protection of the federal statutory scheme for rigorous FDA premarket approval of medical devices from incursions by state tort law seeking to impose additional or different design or labeling requirements.[120] The Solicitor General, joined by the General Counsel of the Department of Heath and Human Services, urged this position before the Court.[121] More specifically, the government's brief admonished that "[p]ermitting a state jury to impose liability on the basis that a device FDA found to be safe and effective is *not* safe or effective would clearly interfere with the agency's ability to utilize the premarket approval process to balance the risks and benefits of Class III medical devices."[122] While acknowledging that "the FDA has supported the position taken by our opinion with regard to the meaning of the statute,"[123] the *Riegel* Court disclaimed explicit reliance upon the FDA's views.[124] The majority's opinion, nonetheless, bears the agency's conspicuous imprint.[125]

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118 *Compare* U.S. *Buckman* Br., *supra* note 61, at 23 ("[F]raud-on-the-FDA claims . . . conflict with the strong federal interest in permitting FDA to decide for itself whether it has been defrauded, and, if so, what statutorily authorized remedy to seek."), *with Buckman*, 531 U.S. at 350 ("State-law fraud-on-FDA-claims inevitably conflict with the FDA's responsibility to police fraud consistently with the [FDA]'s judgment and objectives.").

119 *Compare* U.S. *Buckman* Br., *supra* note 61, at 29–30 ("If a regulated entity knows that juries applying the tort law of any one of the 50 States will play a central role in interpreting the entity's duties to the federal government, that concern could cause it to alter its behavior in unpredictable ways that may well be inconsistent with the efficient administration of the federal regulatory scheme."), *with Buckman,* 531 U.S. at 351 ("[F]raud-on-the-FDA claims would . . . cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the [FDA], will later be judged insufficient in state court.").

120 *See* Riegel v. Medtronic, Inc., No. 06-179, 2008 WL 440744, at *7–10 (U.S. Feb. 20, 2008).

121 Brief for the United States as Amicus Curiae Supporting Respondent at 20–21, Riegel v. Medtronic, Inc., No. 06-179 (U.S. Oct. 19, 2007), 2007 WL 3231418, at *20–21 [hereinafter U.S. *Riegel* Br.]; *id.* at *20–32 ("The conclusion that the MDA preempts the claims at issue here is buttressed by the extent to which those claims would interfere with FDA's expert balancing of a device's health risks and benefits.").

122 *Id.* at 21.

123 *Riegel*, 2008 WL 440744, at *8.

124 *Id.* ("We have found it unnecessary to rely upon that agency view because we think the statute itself speaks clearly to the point at issue.").

125 *Compare id.* ("State tort law that requires a manufacturer's [medical devices] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme . . . ."), *and id.* ("Congress[ ] . . . [evinced] solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations."), *with* U.S. *Riegel* Br., *supra* note 121, at 22 (asserting that "Congress intended FDA to use its expert

### *2. Anti-Preemption*

Counterintuitively, federal agencies have been just as likely, if not more likely, to argue *against* preemption in the products liability realm. Indeed, the very same agencies from *Buckman* and *Riegel* (FDA) and *Geier* (NHTSA), operating under the very same statutes (MDA/FDCA and MVSA, respectively), urged anti-preemption positions that were adopted by the Court in two key products liability cases.

In *Lohr*, unlike in *Buckman* and *Riegel*, the FDA was averse to treading on state-law turf, ceding regulation of the design of medical devices to state common law, at least where FDA's involvement was limited to the premarket notification process.[126] Five Justices followed suit, affording "substantial weight" to FDA regulations interpreting the preemptive effect of the medical device requirements.[127] According to the Court, the FDA "is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the . . . execution of the full purposes and objective of Congress,' and, therefore, whether it should be pre-empted."[128] Justice Breyer elaborated in his separate concurrence:

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judgment concerning the appropriate warnings for a particular medical device, and not to permit that judgment to be second guessed by lay juries").

126 The FDA adopted a narrowly constricted view of its preemptive power, taking the position that "[n]either the FDCA nor the FDA's regulations prescribe criteria for the design of devices. The design of a device originates with its manufacturer." Brief for the United States as Amicus Curiae Supporting Respondents/Cross-Petitioners at 20, Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) (Nos. 95-754, 95-886), 1996 WL 118035, at *20 [hereinafter U.S. *Lohr* Br.]. Specifically, it argued that the FDA's premarket notification process, whereby it had approved petitioner's device as "substantially equivalent" to those on the market, did not preempt the plaintiff's design defect claim. *See id.*

127 *Lohr*, 518 U.S. at 496 ("The ambiguity in the statute . . . provide[s] a sound basis for giving *substantial weight* to the agency's view of the statute." (emphasis added) (internal quotation marks and citation omitted) (citing Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984))); *id.* at 495 ("The FDA regulations interpreting the scope of § 360k's pre-emptive effect support the [plaintiffs'] view, and our interpretation of the pre-emption statute is *substantially informed* by those regulations." (emphasis added)).

A fairly sharp distinction can be drawn with the Court's treatment of these same FDA regulations in *Riegel*. *See Riegel*, 2008 WL 440744, at *10 ("All in all, we think that [the FDA's regulation] can add nothing to our analysis but confusion."); *id*. at *9 (acknowledging that "[t]he agency's reading of its own rule is entitled to substantial deference," but finding "the agency's explanation less than compelling") (citing Auer v. Robbins, 519 U.S. 452, 461 (1997)).

128 *Lohr*, 518 U.S. at 496 (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)); *see also id.* at 506 (Breyer, J., concurring in part, concurring in judgment) (commenting that the FDA has a "special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether . . . state requirements may interfere with federal objectives.").

> [T]his Court has previously suggested that, in the absence of a clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect . . . . [Agencies] can communicate those intentions, for example, through statements in "regulations, preambles, interpretive statements, and responses to comments" . . . .[129]

Just as the FDA switched from an anti- to pro-preemption position before the Supreme Court between *Lohr* and *Buckman* and *Riegel*, so too did NHTSA in the progression from *Freightliner Corp. v. Myrick*[130] to *Geier*; in both cases, the Court followed suit. In *Freightliner*, decided five years before *Geier*, the Court held that common-law defective-design tort claims based upon the failure to install an antilock braking system ("ABS") in trucks were not preempted under Federal Motor Vehicle Safety Standard 121,[131] an implementing regulation of the MVSA.[132]

In an amicus brief to the Court, NHTSA offered its view that, since it had amended Standard 121 in August 1979 to remove trucks from its purview, there were no relevant federal regulations regarding ABS devices or stopping distances "in effect" at the time.[133] NHTSA explicitly argued that its views—based on its interpretation of its regulations—were entitled to substantial deference by the Court.[134] Although the Court did not mention NHTSA's position, the Court's holding squarely rested on the argument—pressed by NHTSA—that

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129 *Id.* at 505–06 (Breyer, J., concurring in part, concurring in judgment) (quoting Hillsborough County, Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 718 (1985)) (citations omitted).

130 Freightliner Corp. v. Myrick, 514 U.S. 280 (1995).

131 49 C.F.R. § 571.121 (2006).

132 *See Freightliner*, 514 U.S. at 282.

133 U.S. *Freightliner* Br., *supra* note 113, at 11–12. A prior 1971 regulation promulgated by NHTSA that effectively required an ABS to be installed in trucks, buses, and trailers, *see* Air Brake Systems; Trucks, Buses, and Trailers, 36 Fed. Reg. 3817, 3817 (Feb. 27, 1971), was rejected by the Ninth Circuit Court of Appeals, *see* Paccar v. NHTSA, 573 F.2d 632, 645 (9th Cir. 1978). In the wake of *Paccar*, NHTSA amended the regulation to exempt trucks and trailers from its purview. *See* Air Brake Systems; Interpretative Amendment, 44 Fed. Reg. 46,849, 46,849 (Aug. 9, 1979). But instead of completely repealing these provisions, NHTSA left them in place so that manufacturers would be "'aware of what the agency still considers to be reasonable standards for minimum acceptable performance.'" U.S. *Freightliner* Br., *supra* note 113, at 5–6 (quoting Air Brake Systems; Interpretative Amendment, 44 Fed. Reg. at 46,849).

134 U.S. *Freightliner* Br., *supra* note 113, at 29 n.17 ("NHTSA's construction of Standard 121, including that it confers no federally protected right to choose whether or not to install ABS devices that must in turn be free from the incidental effect of common law tort suits, is entitled to substantial deference.").

there was no relevant federal motor vehicle safety standard in effect.[135]

Perhaps the most surprising decision, certainly to a majority of commentators at the time, was the anti-preemption position taken by the Coast Guard and adopted by a unanimous Court in S*prietsma*. The Court took the position that "a Coast Guard decision not to regulate a particular aspect of boating safety is fully consistent with an intent to preserve state regulatory authority pending the adoption of specific federal standards."[136] Its holding rested firmly on the Coast Guard's decision not to promulgate a regulation requiring (or prohibiting) the use of propeller guards on motorboats.[137] The Court, moreover, explicitly distinguished its contrary holding in *Geier*, noting that here the Coast Guard, in contradistinction to the views of NHTSA in *Geier*, stated that it did not view its regulatory actions as having pre-emptive effect.[138] And, as in *Geier*, the Court was prepared to accord substantial weight to the agency's position.[139]

### *II. Agency Reference Model for Judicial Decisionmaking*

Out of the preemption muddle, then, a glimmer of clarity emerges at least with respect to the products liability cases—the Court's final decisions line up with the positions urged by the agency. In this Part, I put forth an agency reference model not only as the best explanatory fit, but also as a normative model for judicial decision-making in products liability preemption cases.

With respect to answering the key regulatory policy issue at the heart of the preemption query—namely, whether there in fact should be a uniform federal regulatory policy—federal agencies emerge as the institutional actor best equipped to provide the answer. As a the-

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135 *See Freightliner*, 514 U.S. at 286. The Court, moreover, was influenced by the fact that "the lack of federal regulation did not result from an affirmative decision of agency officials . . . . Rather, [it] stemmed from the decision of a federal court that the agency had not compiled sufficient evidence to justify its regulations." *Id.* at 286–87.

136 Sprietsma v. Mercury Marine, 537 U.S. 51, 65 (2002).

137 *See id*. at 64–68.

138 *See id.* at 67–68; *see also* Brief for the United States as Amicus Curiae Supporting Petitioner at 22, Sprietsma v. Mercury Marine, 537 U.S. 51 (2002) (No. 01-706), 2002 WL 500643, at *22 [hereinafter U.S. *Sprietsma* Br.] ("[T]he fact that the Coast Guard made a considered decision not to promulgate a federal propeller guard requirement is not, in and of itself, a sufficient basis for finding petitioner's state common-law claims to be preempted.").

139 *See Sprietsma*, 537 U.S at 68 ("In the case before us today, the Solicitor General, joined by counsel for the Coast Guard, has informed us that the agency does not view the 1990 refusal to regulate or any subsequent regulatory actions by the Coast Guard as having any pre-emptive effect. Our reasoning in *Geier* therefore provides strong support for petitioner's submission.").

oretical economic matter, the feasibility and desirability of uniform national rules are dependent upon factors such as the presence of significant interstate externalities, coordination problems, and economies of scale and scope. Conversely, state or local regulation might be preferred where there is substantial uncertainty about the correct regulatory strategy, suggesting the need for experimentation.

Debates in the economic literature on this issue are illuminating, but partial.[140] If, to quote Thomas Merrill, "[o]ne person's healthy regional diversity is another's interstate externality,"[141] what are courts to do? Particularly when it comes to products liability cases, it may well be that there is no general, "one size fits all" theoretical solution to the regulatory policy problem. Viable answers to the question of what constitutes optimal regulation are contingent upon extensive legislative findings of fact.

An institutional approach may provide the best guide. The preemption debate has focused on courts interpreting legislation as promoting greater or lesser exclusion of the common-law baseline, but has ignored critical actors: federal agencies.[142] The legal literature likewise abstracts from the role of agencies as the central determinants of not just the implementation of an administrative scheme, but also of the administrative reach of the statutes at issue.[143]

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140 *See infra* Part II.A.

141 Thomas W. Merrill, *Preemption in Environmental Law: Formalism, Federalism Theory, and Default Rules*, *in* FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS 166, 168 (Richard A. Epstein & Michael S. Greve eds., 2007).

142 An article by Keith Hylton provides a notable exception. *See infra* notes 157, 256. Moreover, of late, there has been a surge of attention, prompted by aggressive maneuvering by federal agencies to preempt state law and by a rash of regulatory preemption cases pending before the Supreme Court. *See, e.g.*, Sharkey, *supra* note 5, at 228; *infra* note 200; *see also Agency Preemption: Speak Softly But Carry a Big Stick?*, The Federalist Society for Law & Public Policy, 2006 National Lawyer's Convention (Nov. 18, 2006), published in 11 CHAP. L. REV. (Winter 2008) (forthcoming); Nina A. Mendelson, *A Presumption Against Agency Preemption*, *in* PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION (William Buzbee ed., forthcoming 2008); Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U.L. REV. (forthcoming 2008) (manuscript at 30), *available at* http://www.law.northwestern.edu/colloquium/constitutionallaw/Merrill.pdf.

143 This neglect of agencies in the preemption debate is a subset of a more widespread problem—what Adrian Vermeule terms "institutional blindness" in the realm of statutory interpretation. *See* ADRIAN VERMEULE, JUDGING UNDER UNCERTAINTY: AN INSTITUTIONAL THEORY OF LEGAL INTERPRETATION 16–18 (2006). Vermeule makes the case for a widespread *Chevron* deference approach, stressing that "relative to judges, agencies' institutional capacities make them superior interpreters on both originalist and dynamic views of statutory interpretation." *Id.* at 226; *id.* at 225 ("[A]gencies are best suited to function as common-law courts because of their superior information, superior capacities for policy analysis, and more direct pipeline to the changing political and public values that [William] Eskridge wants courts to incor-

Agencies can serve as a reference in determining the optimal regulatory strategy; specifically, agencies conduct context-specific cost-benefit (or risk-risk) analyses in deciding whether or not to pass regulations.[144] This information base, moreover, can provide an empirical basis for the Court's assessment as to whether a uniform federal regulatory policy should exist in a particular area.[145] The role played by an agency might be significant in two different respects. First, there is the degree of regulatory scrutiny employed by the agency in its review and approval of products and attendant risks. In addition, an agency often weighs in contemporaneously on factors that arguably determine the preemptive effect of its regulatory actions.

Second, an agency may assume a distinct interpretive role as administrator of the congressional legislation, and it has a variety of means at its disposal to express its position on preemption, from formal notice-and-comment rulemaking to less formal interpretive statements and preambles. Finally, an agency may share its views in amicus briefs before courts (including the Supreme Court) tasked with deciding preemption questions. Reliance upon federal agency interpretation at each of these three levels—issuance of regulations regarding preemptive scope, contemporaneous views interpreting regulatory action, and expressions of views in amicus briefs before courts—is contentious (and increasingly so, with the FDA's move away from formal regulations toward less formal interpretive positions).

A federal agency's determination that there is a relevant federal regulatory policy based upon uniformity or coordination demands should be the beginning—not the end—of the preemption analysis. Remedies and enforcement are key ingredients of integrated schemes of regulation, and any court's consideration of the comprehensiveness of a federal regulatory scheme must pay some attention to the reme-

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porate into statutory interpretation."); *see also* ELHAUGE, *supra* note 10, at 80–82 (concluding that, as compared with judges, agencies are significantly more connected to the political and policy preferences of the public, as they face extensive nominating processes as well as congressional and executive oversight, whereas judges serve life terms and are generally politically insulated).

144 *See infra* Part II.B.1.

145 *Cf.* Matthew C. Stephenson, *The Strategic Substitution Effect: Textual Plausibility, Procedural Formality, and Judicial Review of Agency Statutory Interpretations*, 120 HARV. L. REV. 528, 536 (2006) (building a statutory interpretation model based upon the "assum[ption] that an administrative agency wants to secure whatever interpretation would best advance its substantive policy agenda"). *But cf. id.* at 536 n.22 (noting that the impulse to interpret statutes in line with agency prerogatives may be tempered by agency employees, "particularly agency lawyers, [who] may feel some intrinsic obligation to respect the statutory text," as well as by the desire "to cultivate public support").

dial end. The Supreme Court has set a high bar to imputing a congressional intent to preempt when such an interpretation would create what I would call a remedial or enforcement "void."[146] A key question, of course, remains: does the appropriateness of certain remedies likewise fall within the policy expertise of agencies or, instead, do courts have a broader role to play?

### *A. Theoretical Considerations*

Two basic (sometimes overlapping) theoretical issues are implicated in the products liability preemption debate: first, determining the relative desirability of the common-law liability regime as opposed to safety regulation; and second, the level—state or federal—at which liability or regulation should be organized. Table 1 plots these two regulatory policy dimensions in a simple two-by-two matrix.

*Table 1. Products Liability Preemption: Theoretical Issues*

| Regulatory Mechanism (Institutional Actor) \ Substantive Law | Federal Law | State Law |
|---|---|---|
| Ex Ante Regulation (agencies) | X | |
| Ex Post Common Law Liability (courts) | Negligence per se | X |

This simple framework highlights the overlapping nature of these factors in the products liability realm. By and large, a decision to opt for ex ante regulation of products corresponds with a choice in favor of federal substantive law, whereas the ex post common law liability

146 The Court has repeatedly noted that only in the clearest of cases should a court find that Congress intended wholly to remove any and all remedies for injured citizens, let alone accept an agency's view that such was the intent of Congress. *See, e.g.*, Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005) ("If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly."); Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984) ("It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."); *see supra* notes 79, 101 and accompanying text.

route is associated with state law. But this is not necessarily the case, given the category of common-law negligence per se actions (noted in Table 1), premised upon violations of federal standards and regulations.

### *1. Common Law Liability Versus Safety Regulation*

Steven Shavell has focused attention on the first dimension (depicted along the vertical axis in Table 1), laying out four general determinants that govern the optimal mix of liability and regulation: (i) differences in information about costs and benefits of activity between private parties and regulators; (ii) ability of private parties to pay for the harms they cause; (iii) whether parties face the threat of suit for harms caused; and (iv) the respective administrative costs of the tort system and direct regulation.[147] According to Shavell, two factors—differential knowledge and administrative costs—favor liability,[148] whereas the remaining two—incapacity to pay and escaping suit—advantage regulation.[149] Shavell argues, as a theoretical matter, that "[a] complete solution to the problem of the control of risk evidently should involve the joint use of liability and regulation, with the balance between them reflecting the importance of the determinants."[150]

In practice, moreover, Shavell concludes that "the actual, observed use of the two methods of reducing risks may be viewed as socially desirable, or roughly so."[151] Further, Shavell rejects the regu-

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147 *See* Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. LEGAL STUD. 357, 358–64 (1984) [hereinafter Shavell, *Liability for Harm*]; *see also* Steven Shavell, *A Model of the Optimal Use of Liability and Safety Regulation*, 15 RAND J. ECON. 271, 271 (1984) ("According to the model, regulation does not result in the appropriate reduction of risk—because the regulator lacks perfect information—nor does liability result in that outcome—because the incentives it creates are diluted by the chance that parties would not be sued for harm done or would not be able to pay fully for it. Thus, neither liability nor regulation is necessarily better than the other . . . ."); Donald Wittman, *Prior Regulation Versus Post Liability: The Choice Between Input and Output Monitoring*, 6 J. LEGAL STUD. 193, 193 (1977) (discussing the necessity of considering "such factors as information, insurance and transaction costs" when deciding whether to use legal as opposed to market solutions to policy problems).

148 *See* Shavell, *Liability for Harm*, *supra* note 147, at 359–60, 363–64. *But see* RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 402 (5th ed. 1998) (identifying the fixed cost of lawsuits as a potential argument in favor of regulation).

149 *See* Shavell, *Liability for Harm*, *supra* note 147, at 360–63.

150 *Id.* at 365.

151 *Id.* at 358. For example, Shavell claims that "it is desirable that society resort to safety regulation where it generally does"—including "the production and sale of many foods and drugs." *Id.* at 368; *see also id.* at 369 ("[I]n dealing with many health-related and environmental risks, a regulatory agency may have better access to, or a superior ability to evaluate, relevant medical, epidemiological, and ecological knowledge."). In reality, FDA regulatory preemption in pharmaceutical cases has sharply divided the courts. *See infra* Part III.A.

latory compliance defense on the ground that "[a]s liability will induce many of these parties [who present above-average risk of doing harm] to take beneficial precautions beyond the required ones, its use as a supplement to regulation will be advantageous."[152] As a direct corollary, he suggests that "the statutory standard ought to be regarded as a minimum."[153]

Shavell is forthright, however, that "the fit between the theory presented here and reality is only approximate."[154] He adverts to two of the limitations inherent in his analysis. First, applying an economic method of analysis, Shavell does not consider compensation of injured plaintiffs as an independent factor.[155] Second, his account abstracts away from real-life considerations, such as interest-group theories of regulation.[156] But his analysis also misses an important dimension of the problem: the dual levels of regulation in our federal system and the fact that the choice between liability and regulation most often also entails a state versus federal, or localized versus centralized, dimension.[157]

### *2. State Versus Federal Regulation*

In previous collaborative works, Samuel Issacharoff and I offered a positive analytic account of the Rehnquist Court's preemption cases: in the interpretive room created by Congress's failure to set forth an express determination on preemption, the Court seemed to be influ-

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152 Shavell, *Liability for Harm*, *supra* note 147, at 365. Shavell includes the caveat that "just because this is true, regulatory requirements need not be as rigorous as if regulation were the sole means of controlling risks." *Id.*

153 *Id.* at 371 n.18.

154 *Id.* at 372.

155 *Id*. at 358 ("I have not counted compensation of injured parties as an independent factor on the grounds that first-party insurance (augmented if necessary by a public insurance program) can discharge the compensatory function no matter what the mix of liability and regulation.").

156 *See id.*; *cf., e.g.*, Edward L. Glaeser & Andrei Shleifer, *The Rise of the Regulatory State*, 41 J. ECON. LITERATURE 401, 401 (2003) (presenting an economic model of the interplay between litigation and regulation wherein "the crucial difference between liability and regulation as alternative mechanisms of controlling market behavior is their vulnerability to subversion by the potential violator").

157 In an impressive extension and application of Shavell's framework, Keith Hylton has placed emphasis on the role of federal agencies. Hylton identifies four factors that can be used to predict whether the courts will preempt products liability litigation: (i) agency expertise (which weighs in favor of preemption); (ii) local knowledge (which weighs against preemption); (iii) political distortion or agency capture (which weighs against); and (iv) predictability (which weighs in favor). *See* Keith N. Hylton, *Preemption and Products Liability: A Positive Theory* 7–8 (Boston Univ. Sch. of Law Working Paper Series, Working Paper No. 03-17), *available at* http://ssrn.com/abstract=433661; *infra* note 256.

enced by the functional considerations of promoting national uniformity and solving coordination problems among states that can externalize regulatory costs to other states.[158] These criteria—in economic parlance, economies of scope or scale and the existence of interstate externalities—tend to favor regulation at the national level.[159] Pro-federalization arguments for products liability law have also gained sway in the academy. As the late Gary Schwartz noted in 1996, a "time arrives for more mature and experienced decision making. After thirty years with products liability at the state level, that time has probably come."[160] In the products liability realm, Schwartz and others have argued that "[t]he value associated with federalism in allowing experimentation at the state level seems undercut by the practical inability of manufacturers distributing products at the national

158 *See* Issacharoff & Sharkey, *supra* note 21, at 1365–98; *see also* Samuel Issacharoff & Catherine M. Sharkey, *Supreme Court Preemption: The Contested Middle Ground of Products Liability*, *in* FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS 194, 195 (Richard A. Epstein & Michael S. Greve eds., 2007). Our aim was to fit this preemption jurisprudence into a wider pattern, depicting the Rehnquist Court as a willing collaborator with Congress in increasing federalization of substantive law and forum allocation. While we defended a functional approach to preemption as a descriptive matter, we stopped short of any normative take on the federalization trend, or, more specifically, how courts *should* decide these thorny preemption issues.

159 *See, e.g.*, Merrill, *supra* note 141, at 167 ("[U]niform national rules should prevail when state regulation would yield significant interstate externalities or would give rise to destructive interstate competition (races to the bottom or the top), or would interfere with important economies of scope or scale."); Gary T. Schwartz, *Considering the Proper Federal Role in American Tort Law*, 38 ARIZ. L. REV. 917, 926 (1996) ("[E]conomies of mass production necessitate that products sold nationwide have uniform designs and originate in uniform manufacturing processes."). As Larry Ribstein and Bruce Kobayashi point out, the issues are a bit more complicated:

> Inconsistent state laws can impose costs by, for example, exposing a manufacturer that sells its products nationally to many different product liability design standards or a business association to varying governance rules. Uniform state laws only partly solve these problems, however, since even a "uniform" law may result in several different enforcement standards.

Larry E. Ribstein & Bruce H. Kobayashi, *An Economic Analysis of Uniform State Laws*, 25 J. LEGAL STUD. 131, 138 (1996).

160 Schwartz, *supra* note 159, at 930. Schwartz argued that there was a high degree of variability between state products liability laws. *See id.* at 927–29 (discussing various state rules regarding what constitutes a "design defect"); *id.* at 929 (concluding that the differences in state products liability laws are "both more frequent and more significant than they are in other sectors of the common law of torts"). *But see* Stephen D. Sugarman, *Should Congress Engage in Tort Reform?*, 1 MICH. L. & POL'Y REV. 121, 127 (1996) ("[S]tate tort laws today are broadly the same in product injury cases.").

level to respond to whatever experiments state courts might undertake."[161]

But the ascendancy of the pro-federalization thesis—as a descriptive, but especially, as a normative matter—is by no means assured. Equally strong abstract factors tend to cut in the opposite direction, favoring state or more local regulation. These factors include democratic accountability based upon regional differences in policy preferences,[162] the benefits of experimentation,[163] and the comparative advantage of interstate competition yielding optimal policy outcomes.[164]

Not surprisingly, there is a vigorous debate regarding which way these factors cut in specific subject areas.[165] Given the indeterminacy as a theoretical matter, it is useful to turn to the oft-overlooked institutional dimension of regulatory policy.

### *B. Institutional Considerations*

In the products liability realm (as depicted in Table 1), the question of regulation versus liability maps, by and large, onto agencies and courts, respectively, as institutional actors. By bringing the institutional dimension of the regulatory policy issue into focus, I ask which actor is best suited to determine whether a uniform federal regulatory policy should exist.[166]

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161 Schwartz, *supra* note 159, at 950. Schwartz, however, remained skeptical of the negative externalities argument. *See id.* at 934.

162 *See, e.g.*, Ribstein & Kobayashi, *supra* note 159, at 141 (noting that states can produce local variations of laws that can account for idiosyncratic characteristics of a region so that they might be best served); *see also* Betsy J. Grey, *The New Federalism Jurisprudence and National Tort Reform*, 59 WASH. & LEE L. REV. 475, 517–18 (2002) (mentioning that voters play an important role in judicial lawmaking because if they do not like a common-law rule, they can vote for legislators that will overturn it).

163 *See, e.g.*, Schwartz, *supra* note 159, at 930 (identifying the wide variety of strict products liability rationales as evidence suggesting the vitality of decentralized decisionmaking).

164 *See, e.g.*, Harvey S. Perlman, *Products Liability Reform in Congress: An Issue of Federalism*, 48 OHIO ST. L.J. 503, 507 (1987) ("The choice between state authority and federal authority is the choice between competition and monopoly.").

165 For example, in the area of environmental law, see Revesz, *supra* note 7, at 2342 (arguing that allowing states to pass individual pollution standards results in "an undesirably large amount of pollution" crossing state lines) and Richard B. Stewart, *Pyramids of Sacrifice? Problems of Federalism in Mandating State Implementation of National Environmental Policy*, 86 YALE L.J. 1196, 1196–97 (1977) (describing the need for greater federal control of environmental regulatory enforcement).

166 Here, I home in on a slice of a broader debate about the comparative institutional competence of courts (and juries) and agencies. *See, e.g.*, Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 ROGER WILLIAMS U. L. REV. (forthcoming 2008) (manuscript at 6, on file with *The George Washington Law Review*) (highlighting

The agency reference model I propose directs attention to a repository of agency information—ideally reflecting a broad range of views, having been vetted by expert and public opinion—focusing on the precise nature of the agency's regulatory cost-benefit (or risk-risk) determinations as well the economic consequences of various determinations and the effects of state regulation on federal regulatory schemes.[167]

### *1. Comparative Advantage of Agencies*

The normative mooring here is an amalgam of the conventional "expertise" and "uniformity" rationales for reliance on, or deference to, agencies.[168] Not surprisingly, agency expertise is the leading rationale put forward by agencies themselves.[169] But it also finds voice in the Supreme Court, especially channeled via Justice Breyer. As he emphasized, writing for the *Geier* majority:

> Congress has delegated to [the Department of Transportation] authority to implement the statute; the subject matter is technical; and the relevant history and background are complex and extensive. The agency is likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements.[170]

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"certain structural features of the tort system . . .—particularly, its relative deficiencies in information-processing, learning, corrigibility, and accountability").

167 Note that the informational demands of the agency reference model all but require that courts forego making preemption decisions on motions to dismiss, but instead evaluate the merits of such claims at the summary judgment stage. I see this as an attractive feature of the model, however, for, in practice, it would mitigate decisions based upon statutory canons, such as the "presumption against preemption" or "*Chevron* deference" to agency determinations, in recognition of the centrality of legislative facts to the relevant regulatory policy questions at stake in the preemption inquiry. *See infra* Part III.B.

168 For arguments in favor of preemption, as well as the regulatory compliance defense, on the ground that it preserves uniformity and avoids undermining carefully calibrated federal standards set by administrative bodies with superior technical and procedural lawmaking capacities to that of courts, see, e.g., David R. Geiger & Mark D. Rosen, *Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Safety Standards*, 45 DEPAUL L. REV. 395, 397 (1996); Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167, 2173–76 (2000) (noting the need for national-scale risk-benefit balancing).

169 *See, e.g.*, *infra* notes 268, 294–297 and accompanying text.

170 Geier v. Am. Honda Motor Co., 529 U.S. 861, 883 (2000) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 496 (1996)); *see also* Bates v. Dow Agrosciences LLC, 544 U.S. 431, 455 (2005) (Breyer, J., concurring) ("[T]he federal agency charged with administering the statute is often better able than are courts to determine the extent to which state liability rules mirror or distort federal requirements."); *cf.* Credit Suisse Sec. (USA) LLC v. Billing, 127 S. Ct. 2383,

The conventional uniformity rationale, as ably explicated by Peter Strauss, stresses the advantage agency action holds over the geographically divided federal court system in promoting coherence and uniformity of standards in areas of national law.[171] Whereas Strauss's main concern is the coherence of agreed-upon national law, I posit that agency input is critical in determining an answer to the threshold question of whether it is optimal to regulate a product, or an aspect of a product, at the state or national level.

As mentioned above, agencies may act in distinct (though sometimes overlapping) regulatory as well as interpretive guises. A review of a few of the Supreme Court products liability cases provides some guidance. Take, for instance, *Lohr*. The FDA's actual regulatory review of the pacemaker in *Lohr* consisted solely of its determination that the device was "substantially equivalent" to a device that was on the market before 1976 (the effective date of the MDA).[172] Moreover, the FDA indicated at the time of its regulatory action—when it issued its "substantial equivalence" letter to the manufacturer—that its premarket approval did not amount to an endorsement of safety or efficacy.[173]

Turning to its interpretive role, the FDA had issued a formal regulation, subject to notice-and-comment rulemaking, construing the scope of the express preemption provision of the MDA; this regula-

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2394–95 (2007) (relying upon the Securities and Exchange Commission's expertise to draw a distinction between permitted and prohibited conduct under antitrust law).

171 *See* Peter Strauss, *One Hundred Fifty Cases per Year: Some Implications of the Supreme Court's Limited Resources for Judicial Review of Agency Action*, 87 COLUM. L. REV. 1093, 1121–22 (1987); *see also* VERMEULE, *supra* note 143, at 208 ("*Chevron* therefore works against balkanization of federal law. This idea [taken from Strauss's account], which justifies agency deference by emphasizing the Supreme Court's low capacity for coordinating the actions of the federal judiciary, fits snugly with [Vermeule's] account of judicial coordination problems . . . .").

172 *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 480 (1996). Known as the "premarket notification" process (or, alternatively, section 510(k) process), the FDA's review focuses narrowly on equivalence as opposed to safety and effectiveness. *See supra* note 74. Its review is a streamlined process, completed in an average of twenty hours, that allows manufacturers to avoid the more stringent PMA process as a kind of accommodation "to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market." *See Lohr*, 518 U.S. at 478–79 (citing 21 U.S.C. § 360e(b)(1)(B) (2000)). Although designed as a limited exception, in practice most new medical devices are approved via the premarket notification process. *See id.* at 479 ("[T]he House reported in 1990 that [eighty percent] of new Class III devices were being introduced to the market through the § 510(k) process and without PMA review."); Riegel v. Medtronic, Inc., No. 06-179, 2008 WL 440744, at *4 (U.S. Feb. 20, 2008) ("In 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices.").

173 *Lohr*, 518 U.S. at 480.

tion cabins the statute's preemptive force to instances where the FDA has established "specific counterpart regulations or . . . other specific requirements applicable to a particular device."[174] The regulation further provides that the MDA "does not preempt State or local requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to devices."[175]

In an amicus brief filed in the Supreme Court, the FDA adopted a narrowly constricted view of its preemptive power: "Neither the FDCA nor the FDA's regulations prescribe criteria for the design of devices. The design of a device originates with its manufacturer."[176] The FDA reasoned that its "substantially equivalent" determination, the end result of the premarket notification process, was in no way tantamount to its more rigorous premarket approval process, which requires "a showing of reasonable assurance" that the device is safe and effective.[177] For this reason, it would not make sense to conclude that the premarket notification process set up a uniform, national regulatory policy—at least not one based upon anything resembling optimal standards.[178] The Supreme Court's anti-preemption determination in *Lohr* was far removed from the precise statutory language in the FDCA and had more to do with the agency's explanation of its own review process and the level of rigor involved.[179]

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174 21 C.F.R. § 808.1(d) (2007).

175 *Id.* § 808.1(d)(1). The *Lohr* Court accorded the FDA regulation "substantial weight," in part because Congress delegated to the FDA authority to grant exemptions from preemption, an exercise that requires the FDA to assess the compatibility of state laws with the federal scheme. *See Lohr*, 518 U.S. at 496. Recall that, whereas the *Lohr* Court's statutory interpretation was "substantially informed" by the FDA regulations, the *Riegel* Court was much more equivocal, *see supra* note 127.

176 U.S. *Lohr* Br., *supra* note 126, at 20.

177 *See id.* at 19–20.

178 The FDA left open the issue of preemption following the more rigorous premarket approval process. *See id.* at 20 n.14 ("There is no occasion in this case to consider the extent to which the PMA process may result in requirements applicable to a device under the FDCA that would trigger preemption . . . ."). The agency took a pro-preemption position before the Court in *Riegel*, *see supra* note 121 and accompanying text, which decided that, unlike premarket notification, the PMA process leads to preemptive federal requirements under the MDA, *see* Riegel v. Medtronic, Inc., No. 06-179, 2008 WL 440744, at *7-10 (U.S. Feb. 20, 2008).

179 *Lohr*, 518 U.S. at 495–96 ("Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect."); *supra* notes 126–29 and accompanying text. Even in *Riegel*, where the Court was emphatic that the statutory language could resolve the preemption inquiry, *see Riegel*, 2008 WL 440744, at *8, its opinion was nonetheless guided by the degree of regulatory scrutiny employed by the FDA in its PMA approval process as well as the FDA's own view of the preemptive effect of its regulatory actions, *see id.* at *7 ("While § 510(k) is 'focused on *equivalence*, not safety,' premarket approval is focused on safety, not equivalence." (quoting *Lohr*, 518 U.S. at 493)); *id.* ("[The PMA process] *is* federal safety review.").

The Court's decision in *Geier* fits this pattern as well. The MVSA, the statute at issue in that case, was written in terms of "minimum" standards.[180] When the Court turned from express preemption to implied preemption, however, it widened its interpretive lens. NHTSA's statement of its own federal regulatory objectives, as well as its bottom-line conclusion that state tort law would interfere with the accomplishment of those objectives, played a key role in the Court's decision.[181] The federal regulation at issue, FMVSS 208[182]—promulgated after nearly fifteen years of analysis, full notice-and-comment rulemaking, and litigation[183]—gave automobile manufacturers a range of choices among different passive restraint devices that were to be gradually introduced over time.[184] In fact, the Department of Transportation had rejected a proposed regulation requiring airbags in all cars because of concerns about backlash and the desire to promote a national policy whereby vehicle manufacturers would be encouraged to offer the public a choice of either automatic seatbelts or airbag passive protection systems.[185] Among the reasons cited by the Secretary at the time was serious public concern regarding the safety of airbags.[186] Given that the agency had considered and rejected the airbag-only rule, state-law claims based upon the manufacturer's failure to install airbags were preempted.[187]

But perhaps the most persuasive example of how an agency reference model might work is illustrated in *Sprietsma*. Concerned about a rise in the number of recreational boating accidents in which passengers were struck by propellers, the Coast Guard asked the National Boating Safety Advisory Council to appoint a special Propeller Guard Subcommittee "to review the available data on the prevention of propeller-strike accidents and to study the various methods of shrouding propellers to prevent contact with a person in the water."[188] After an

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180 *See supra* note 110 and accompanying text.

181 *See supra* notes 112–13 and accompanying text.

182 Standard No. 208; Occupant Crash Protection, 49 C.F.R. § 571.208 (2004).

183 U.S. *Geier* Br., *supra* note 109, at 3.

184 Geier v. Am. Honda Motor Co, 529 U.S. 861, 874–75 (2000). FMVSS 208 required car manufacturers to install passive restraint devices in a rising percentage of their vehicles every year. *See* 49 C.F.R. § 571.208 S4.1.3 (2006).

185 *See* Federal Motor Vehicle Safety Standard; Occupant Crash Protection, 49 Fed. Reg. 28,962, 29,000–02 (July 17, 1984) (to be codified at 49 C.F.R. pt. 571).

186 *See id.* at 29,001 ("Some people have serious fears or concerns about airbags. If airbags were required in all cars, these fears, albeit unfounded, could lead to a backlash affecting the acceptability of airbags. This could lead to their being disarmed . . . .").

187 *See Geier*, 529 U.S. at 879–81.

188 Sprietsma v. Mercury Marine, 537 U.S. 51, 60–61 (2002) (quotation omitted).

extensive eighteen-month study, the Coast Guard concluded that the data were insufficient to warrant a federal regulation.[189] But, as the Coast Guard itself explained in an amicus brief to the Court,[190] *why* the Coast Guard chose not to regulate was important to the implied preemption analysis.

The Coast Guard explained that, at the time of its review, it did *not* conclude that such regulation would be economically inefficient or increase risks. Specifically, the Coast Guard stated that it never concluded (a) that propeller guards were "technologically infeasible, economically unjustified, and likely to increase safety hazards" or (b) that manufacturers should have "unfettered discretion" to decide whether or not to install propeller guards.[191] Instead, the Coast Guard had merely determined that "[a]vailable propeller guard accident data do not support imposition of a regulation requiring propeller guards on

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189 *Id.* at 61. The Subcommittee's findings at the time of its review, as summarized in the United States amicus brief, included:

> (i) "the incidence of injuries or fatalities caused by persons coming into contact with propellers was relatively small";
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> (ii) "propeller guards adversely affect the operation of boats at certain speeds";
>
> (iii) "[propeller guards] could create additional and more severe hazards"; and
>
> (iv) "[n]o simple universal [propeller guard] design suitable for all boats and motors in existence has been described or demonstrated to be technologically or economically feasible."

U.S. *Sprietsma* Br., *supra* note 138, at 5. The Advisory Council adopted the Subcommittee's recommendation that "[t]he U.S. Coast Guard should take no regulatory action to require propeller guards." *Id.* (quotation omitted).

190 Curiously, the United States waited until after the Supreme Court granted certiorari in the *Sprietsma* case to set forth its position. *See* Sprietsma v. Mercury Marine, 757 N.E.2d 75, 86 (Ill. 2001) ("[T]he Solicitor General has not presented his argument concerning the *Lewis* [*v. Brunswick*] case or the Sprietsma claim to this court."), *rev'd*, 537 U.S. 51 (2002).

Richard Epstein charges that the agency's position in *Sprietsma* was manipulated by political forces. *See* Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of* Chevron *Deference and a Response to Richard Nagareda*, 1 J. TORT L., Issue 1, Art. 5, at 18 (2006), http://www.bepress.com/jtl/vol1/iss1/art5 (follow "Download" hyperlink) (subscription required). But, ironically, *Sprietsma* is distinct from the other products liability cases as a counterexample to political flip-flop by agencies, for the Coast Guard maintained a consistent anti-preemption position, notwithstanding a change in administrations from Clinton to Bush. The same preemption question had been presented during the Clinton administration in *Lewis v. Brunswick Corp.*, 107 F.3d 1494 (11th Cir. 1996), *cert. granted*, 522 U.S. 978 (1997), *and cert. dismissed*, 523 U.S. 1113 (1998), *abrogated by* Sprietsma v. Mercury Marine, 537 U.S. 51 (2002). In that case, the United States took the same position that the Secretary's 1990 decision did not preempt a private tort suit based on a manufacture's failure to install a propeller guard. *See* Brief for the United States as Amicus Curiae Supporting Petitioners at 25, Lewis v. Brunswick Corp., 522 U.S. 978 (cert. dismissed Dec. 29, 1997) (No. 97-288). The writ of certiorari in *Lewis* was dismissed after oral argument pursuant to settlement. *See* Lewis v. Brunswick Corp., 523 U.S. 1113, 1114 (1998).

191 U.S. *Sprietsma* Br., *supra* note 138, at 26 (quotation omitted).

motorboats."[192] A critical finding supporting this determination was that "[n]o simple universal [propeller guard] design suitable for all boats and motors in existence has been described or demonstrated to be technologically or economically feasible."[193] And, as the Coast Guard urged the Court, common-law claims do not subvert agency policy when the agency "believe[s] that the available evidence is too inconclusive to warrant the imposition of a prescriptive standard" or "find[s] that . . . a workable prescriptive rule of general applicability cannot feasibly be adopted."[194] In this case, then, the Coast Guard concluded that state common-law tort claims would in no way "subvert any federal policy reflected in the agency's decision to forgo regulation."[195]

Here was a situation where—according to the agency that studied the matter—there was no presently suitable uniform federal regulation given the diversity inherent in boat designs. Given the "thousands of hull designs" and the vast range of "hull/propulsion unit combinations,"[196] the Coast Guard therefore decided to leave the question of whether propeller guards should be required to the machinery of the tort system, where liability would be decided on a case-by-case basis at a more localized level.[197] And the Supreme Court was persuaded that "[t]he Coast Guard's apparent focus was on the lack of any 'universally acceptable' propeller guard for 'all modes of boat operation.'"[198]

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192 *See id.* at 17–18.

193 *Id.* at 5.

194 *See id.* at 17.

195 *Id.* at 17–18 (quotation omitted). The Coast Guard, nonetheless, took the odd position that "unless and until the agency has promulgated a safety standard dealing with a particular matter, a state law or regulation establishing a safety standard addressing that same matter is preempted" even though state common-law actions would not be. *Id.* at 11. This is an odd position because drawing such a distinction between statutory requirements and tort actions would give juries more power to set safety standards than state officials who act through legislative or regulatory process. *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 504 (1996) (Breyer, J., concurring in part, concurring in judgment) ("To distinguish between [regulations and common law tort] for pre-emption purposes would grant greater power (to set state standards 'different from, or in addition to,' federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes."); *see also* Riegel v. Medtronic, Inc., No. 06-179, 2008 WL 440744, at *8 (U.S. Feb. 20, 2008) ("[O]ne would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of protection [than state regulatory law].").

196 *See* U.S. *Sprietsma* Br., *supra* note 138, at 5.

197 *See id.* at 27 (concluding that the Coast Guard's decision not to regulate at a federal level is consistent with "a determination that there is no justification for a uniform federal solution, but States may impose damages liability as they see fit").

198 Sprietsma v. Mercury Marine, 537 U.S. 51, 67 (2002); *see also* U.S. *Sprietsma* Br., *supra*

### *2. Keeping Agencies in Check*

There is good reason to be chary of agencies acting in their interpretive, as distinct from regulatory, guise. Most of the arguments in favor of agencies' comparative expertise speak to the rigor of the product review and approval process. While it is certainly the case that an agency might manipulate its regulatory record at the time of its product review or evaluation of attendant risks, that danger pales in comparison to the risk of an agency's post hoc rationalization of its actions in litigation briefs, or promulgation of interpretive rules and preambles. For this reason, it is worth considering checks on agency preemptive power.

#### *a.* Skidmore*, Not* Chevron*, Deference*

Having articulated an agency reference model for judicial decisionmaking in products liability preemption cases, it is necessary to explore one logical extension of the model: what level of deference courts should provide to administrative agency determinations of preemption. In the seminal case of *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*,[199] the Supreme Court held that courts must grant deference to agency interpretations of statutes they administer if (1) Congress has not directly spoken to the precise question at issue and (2) the interpretation is based on a permissible construction of the statute.[200] Where an interpretation is not accorded mandatory deference under *Chevron*, it may still be granted deference under *Skidmore v. Swift & Co.*[201] if its interpretation "persuades" the

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note 138, at 6 ("Regulatory action is . . . limited by the many questions about whether a universally acceptable propeller guard is available or technically feasible in all modes of boat operation.").

199 Chevron U.S.A. Inc. v. Natural Res. Def. Council, 467 U.S. 837, 842–43 (1984).

200 *Id.* The *Chevron* deference issue in regulatory preemption has garnered significant attention of late due to its implication in *Watters v. Wachovia Bank, N.A.*, a case decided last Term by the Supreme Court, which held that state attempts to regulate the operating subsidiaries of national banks are preempted by the National Bank Act ("NBA"). *See* 127 S. Ct. 1559, 1564–65 (2007). The Court had an opportunity to provide further guidance on the interplay between the presumption against preemption and *Chevron* deference, but the majority took the position that the deference issue was "beside the point, for under [its] interpretation of the statute, the level of deference owed to the [Office of Comptroller of the Currency ("OCC")] regulation is an academic question." *Id.* at 1572. *Compare id.* at 1572 n.13 ("Because we hold that the NBA itself—independent of OCC's regulation—preempts the application of the pertinent [state] laws to national bank operating subsidiaries, we need not consider the dissent's lengthy discourse on the dangers of vesting preemptive authority in administrative agencies."), *with id.* at 1585 (Stevens, J., dissenting) ("Whatever the Court says, this is a case about an administrative agency's power to preempt state laws.").

201 Skidmore v. Swift & Co., 323 U.S. 134 (1944).

court.[202] Here, I address aspects of the issue as to whether agency interpretations of preemption should be accorded *Chevron* or *Skidmore* deference that are directly implicated by the agency reference model.

First, the model claims a wider scope than that covered, at least under existing doctrine, by *Chevron*. As detailed above, the Court's reliance upon agency input has often been *sub silentio*.[203] The agency reference model would not only force this consideration out into the open but would in essence call upon courts to solicit the agency's views on whether a uniform federal regulatory policy exists with respect to various regulated products.[204] It would seem self-defeating, however, to limit this significant input to *Chevron*'s contested domain.[205] Moreover, courts should be more receptive to soliciting more informal agency views in a world of non-mandatory deference.

Second, the agency reference model would not seem to require *Chevron* deference; in fact, based upon my descriptive account of Supreme Court products liability preemption jurisprudence,[206] reliance upon agency input would seem more closely aligned in practice with

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202 *See id.* at 140 ("[R]ulings, interpretations and opinions of the [administrative agency], while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."); *see also* United States v. Mead Corp., 533 U.S. 218, 228 (2001) (outlining the factors relevant to *Skidmore* deference, including degree of agency expertise, persuasiveness, and consistency over time). For general background on modern *Skidmore* analysis, see Kristen E. Hickman & Matthew D. Kruger, *In Search of the Modern* Skidmore *Standard*, 107 COLUM. L. REV. 1235, 1286–88 (2007).

203 *See, e.g.*, *supra* text accompanying notes 117, 135.

204 I leave for another day how far to extend such a model of court solicitation of agency views. It would be radical, indeed, to suggest that courts do so in all cases of statutory ambiguity when no statement of a relevant agency's views exists. Given the central nature of the regulatory policy question at stake in products liability preemption questions, coupled with the existence of active agency regulation in at least some of these areas, requiring substantive input from the relative agency would seem to make sense.

205 Thomas Merrill, among others, has argued that *Chevron* deference applies only to issues as to which Congress has delegated an agency the authority to create legally binding rules, orders, or directives. *See, e.g.*, Thomas W. Merrill, *The* Mead *Doctrine: Rules and Standards, Meta-Rules and Meta-Standards*, 54 ADMIN. L. REV. 807, 809 (2002); William Funk, *Preemption by Federal Agency Action* (manuscript at 2), *in* PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION (William Buzbee ed., forthcoming 2008) ("[D]eference [to agency statements regarding preemption] should only be given when Congress has explicitly delegated preemptive authority to the agency.").

206 *See supra* Part I.C.

the weaker *Skidmore* deference.[207] In products liability cases, the Supreme Court has considered agency views on a regular basis with hardly any mention of the touchstone of deference jurisprudence. The strongest evidence that the Court has studiously avoided *Chevron* in this realm comes from dissenting Justices in closely divided preemption cases who have voiced sharp criticism in response to the Court's ambiguous reliance on agencies' views and interpretations of regulations in the cases discussed above.

Recall the *Lohr* Court's defense that its interpretation of the preemption statute was "*substantially informed* by [the FDA] regulations."[208] The Court also noted that the statute was "not entirely clear," and proceeded to cite *Chevron* without elaboration.[209] Justice Breyer's separate concurrence went further, suggesting that when Congress is not clear, agencies possess "a degree of leeway" in determining whether their actions have preemptive effect;[210] moreover, according to Justice Breyer, agencies can communicate their intentions through "'regulations, preambles, interpretive statements, and responses to comments.'"[211]

The ambiguity on the deference point prompted Justice O'Connor (joined by Chief Justice Rehnquist and Justices Scalia and Thomas) to rail against the majority in dissent:

> Apparently recognizing that *Chevron* deference is unwarranted here, the Court does not admit to deferring to these regulations, but merely permits them to "infor[m]" the Court's interpretation. It is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference, but one pertaining to the clear statute at issue here is surely not.[212]

The dissent's rancor over ambiguous deference to agency views is ratcheted up a notch when confronted with the majority opinion in

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207 Here, I expand an argument I made before in more limited context in Sharkey, *supra* note 5, at 243–44.

208 Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996) (emphasis added); *see supra* note 127 and accompanying text.

209 *See Lohr*, 518 U.S. at 495–96 (1996) (citing Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984)). The Court also cited *Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*, noting that the Court in that case "consider[ed] FDA understanding of pre-emptive effect of its regulations 'dispositive.'" *Id*. at 496 (citing Hillsborough County, Fla. v. Automated Med. Labs., Inc., 417 U.S. 707, 714 (1985)).

210 *Id.* at 505 (Breyer, J., concurring in part, concurring in judgment).

211 *Id.* at 506 (quoting Hillsborough County, Fla. v. Automated Med. Labs., Inc., 417 U.S. 707, 718 (1985)).

212 *Id.* at 512 (O'Connor, J., concurring in part, dissenting in part) (citations omitted).

*Geier*, per Justice Breyer. Again, recall that the majority placed "some weight" on the agency's conclusion that state law interfered with the federal regulatory scheme, emphasizing that "Congress has delegated to [the agency] authority to implement the statute; the subject matter is technical; and the relevant history and background are complex and extensive. . . . In these circumstances, the agency's own views should make a difference."[213] The dissent, per Justice Stevens (joined by Justices Souter, Thomas, and Ginsburg), made a point of highlighting the fact that the majority afforded the agency's view "lesser deference" than *Chevron* would have required.[214] According to the dissent, however, even this lesser deference was unwarranted.[215]

All of this bickering, moreover, makes the unanimous *Sprietsma* Court's opinion—written by Justice Stevens, no less—and its deferential nod to the agency's view perplexing. As the Court reasoned: "[T]he agency does not view the 1990 refusal to regulate or any subsequent regulatory actions by the Coast Guard as having any pre-emptive effect. Our reasoning in *Geier* therefore provides *strong support* for petitioner's submission."[216] And, while the Court likely remains divided over when to turn to agency views for interpretive guidance on preemption questions, dicta in *Riegel* would seem to suggest unanimous endorsement of the *Skidmore* deference standard.[217]

Third, and finally, the *Chevron* deference model may be normatively troublesome. Various concerns raised by agency skeptics relat-

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213 Geier v. Am. Honda Motor Co., 529 U.S. 861, 883 (2000); *see supra* notes 112–13 and accompanying text.

214 *See Geier*, 529 U.S. at 911 (Stevens, J., dissenting).

215 As the dissent elaborated:

> As to the [agency]'s litigating position, it is clear that "an interpretation contained in a [legal brief], not one arrived at after, for example, a formal adjudication or notice-and-comment rulemaking[,] . . . do[es] not warrant *Chevron*-style deference." . . . Requiring the [agency] to put its pre-emptive position through formal notice-and-comment rulemaking—whether contemporaneously with the promulgation of the allegedly pre-emptive regulation or at any later time that the need for pre-emption becomes apparent—respects both the federalism and nondelegation principles that underlie the presumption against pre-emption in the regulatory context and the APA's requirement of new rulemaking when an agency substantially modifies its interpretation of a regulation.

*Id.* at 911–12 (quoting Christensen v. Harris County, 529 U.S. 576, 587 (2000)).

216 Sprietsma v. Mercury Marine, 537 U.S. 51, 68 (2002) (emphasis added).

217 Riegel v. Medtronic, Inc., No. 06-179, 2008 WL 440744, at *8 (U.S. Feb. 20, 2008) ("We have found it unnecessary to rely upon that agency view because we think the statute itself speaks clearly to the point at issue. If, however, we had found the statute ambiguous and had accorded the agency's current position deference, [then] . . . mere *Skidmore* deference would seemingly be at issue . . . ."); *id.* at *14 n.8 (Ginsburg, J., dissenting) ("An amicus brief interpreting a statute is entitled, at most, to deference under [*Skidmore*].").

ing to the motives and capabilities of regulators include: (i) regulatory capture,[218] (ii) self-aggrandizing administrators,[219] (iii) tunnel vision,[220] (iv) ossification of standards,[221] and (v) a "race to the bottom" in regulatory standards.[222] Implicit in the agency reference model is a judgment that none of these concerns—few of which have been empirically justified in any rigorous fashion—outweighs the value ad-

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218 *See, e.g.*, Thomas W. Merrill, *Capture Theory and the Courts: 1967–1983*, 72 CHI.-KENT L. REV. 1039, 1064–67 (1997); Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1684–85 (1975). *But see* Matthew C. Stephenson, *Public Regulation of Private Enforcement: The Case for Expanding the Role of Administrative Agencies*, 91 VA. L. REV. 93, 130–32 (2005) (suggesting that claims of agency capture have been "wildly overstated"). There is a corresponding economic literature on the subject of regulatory capture. *See generally, e.g.*, Fred S. McChesney, *Rent Extraction and Rent Creation in the Economic Theory of Regulation*, 16 J. LEGAL STUD. 101 (1987); Sam Peltzman, *Toward a More General Theory of Regulation*, 19 J.L. & ECON. 211 (1976); Richard A. Posner, *Theories of Economic Regulation*, 5 BELL J. ECON. & MGMT. SCI. 335 (1974); George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3 (1971). As a counterpoint to agency capture, other scholars offer evidence of ideologically-driven voting by judges in agency review cases. *See generally, e.g.*, Thomas J. Miles & Cass R. Sunstein, *Do Judges Make Regulatory Policy? An Empirical Investigation of* Chevron, 73 U. CHI. L. REV. 823 (2006); Richard L. Revesz, *Environmental Regulation, Ideology, and the D.C. Circuit*, 83 VA. L. REV. 1717 (1997).

219 *See, e.g.*, WILLIAM A. NISKANEN, JR., BUREAUCRACY AND REPRESENTATIVE GOVERNMENT 36–42 (1971); Thomas W. Merrill, *supra* note 142, manuscript at 30 ("Agencies may be inclined to engage in empire building, or may resent the implicit competition from other sources of regulatory authority like states."). *But see* Levinson, *supra* note 4, at 932–34 (challenging the view that "administrative agencies will be inclined toward, and be able to get away with, engorging themselves at the public's expense" and arguing instead that agencies' "political overseers will have strong incentives to turn agencies to their own purposes, which will have nothing to do with aggrandizing bureaucracy").

220 *See, e.g.*, Hills, *supra* note 4, at 15 ("Bureaucrats . . . tend to resist or at least be indifferent to broad policy considerations or claims of abstract justice that do not fall squarely within their regulated specialty."); *id.* at 61 ("When Congress or a federal agency regulates, it often does not account for cost internalization, compensation, or insurance policy. Many regulatory agencies have no mechanism for, or expertise in, spreading the costs of accidents through damages, insurance, or other sorts of liability rules."); Merrill, *supra* note 142, manuscript at 29–30 ("Agencies know a great deal about one federal regulatory scheme, and they may know quite a bit about the pros and cons of making that particular scheme the exclusive source of legal obligation, as opposed to one that exists concurrently with state and local regulation. But they are unlikely to have much knowledge—or even care—about larger questions concerning the division of authority between the federal government and the states.").

221 *See, e.g.*, Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1387–96 (1992); Sharkey, *supra* note 5, at 230–33.

222 *See, e.g.*, Richard L. Revesz, *The Race to the Bottom and Federal Environmental Regulation: A Response to Critics*, 82 MINN. L. REV. 535, 538 (1997) ("The race-to-the-bottom rationale posits that states will try to induce geographically mobile firms to locate within their jurisdictions, in order to benefit from additional jobs and tax revenues, by offering them suboptimally lax environmental standards.").

ded by the agency in determining whether it is feasible to regulate by a uniform national standard.[223]

The seeds of my normative discontent with *Chevron* deference to agency preemption determinations can, nonetheless, be found in *Chevron*'s application in FDA prescription drug cases, discussed in Part III below.[224] Three aspects draw special concern. First, the FDA has proffered its view before courts in amicus briefs or in a preamble to a rule,[225] not only outside of the process of official notice-and-comment rulemaking,[226] but also, in some instances, taking expansive positions well beyond anything warranted by its contemporaneous risk-risk analyses.[227] *Chevron* deference would seem unwarranted, at least in most of these instances.

Doctrinally, while agency briefs and preambles arguably lack "the force of law" necessary to warrant mandatory *Chevron* deference under *United States v. Mead Corp.*,[228] enough confusion and uncertainty exists in the case law to warrant caution.[229] The doctrine on deference to agency preambles and amicus briefs—particularly in the realm of preemption—is far from pellucid. The confusion stems largely from the ad hoc handling of deference in the relevant Supreme Court products liability preemption precedents, which, as discussed above,[230] suggest an intermediate, if not uncertain, level of deference.[231] Moreover, although *Mead* would appear to preclude *Chevron*

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223 With all else equal, to the extent one is skeptical of agencies—for any of the reasons listed above—one would favor the weaker deference to agencies and reservation of authority with courts.

224 *See infra* Part III.A.

225 *See infra* note 267 and accompanying text.

226 Notice-and-comment rulemaking requires administrative agencies to solicit and incorporate the views of all "interested persons" before issuing a final noninterpretive rule. *See* 5 U.S.C. § 553 (2000).

227 *See infra* Part III.A.2.

228 *See* United States v. Mead Corp., 533 U.S. 218, 228 (2001) ("[A]dministrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the *force of law*, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.") (emphasis added).

229 It would, of course, take some wind out of the sail of my intimations regarding the dangers of the *Chevron* deference model if it were simply the case that courts are confused about the applicability of the *Chevron* framework.

230 *See supra* notes 206–17 and accompanying text.

231 When confronting the issue of deference to agency interpretation, some courts take the lead from the Supreme Court's preemption cases. *See, e.g.*, Horn v. Thoratec Corp., 376 F.3d 163, 177–79 (3d Cir. 2004) (citing *Lohr* and noting the FDA's amicus brief "reinforced" its conclusion); Scherz v. S.C. Ins. Co., 112 F. Supp. 2d 1000, 1009–10 (C.D. Cal. 2000) (citing *Geier* and giving "weight" to FEMA's view that state-law claims interfered with the regulatory scheme).

deference for both preambles and amicus briefs, the factors laid out by Justice Breyer in *Barnhart v. Walton*[232] may open the door to greater deference—even if courts are not willing to abandon traditional administrative law deference analysis and rely solely on preemption doctrine.[233] In the wake of *Mead*, courts have given mixed signals about the appropriateness of affording *Chevron* deference to regulatory preambles in the realm of preemption.[234]

Second, an argument for the weaker form of deference follows from a realization that agency input provides the answer to one—but not the sole—key question courts must face when making preemption decisions. An added dimension to the problem is the persistence of state tort law where the alternative is a complete remedial or enforcement void.[235] I have argued above that, as a general matter, agencies are better situated than courts to determine the extent to which state tort regimes, including the remedies they impose, interfere with federal regulatory interests. There is, nonetheless, a strong argument for

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Other courts focus on more traditional administrative law analysis. *See, e.g.*, Perry v. Novartis Pharm. Corp., 456 F. Supp. 2d 678, 683 (E.D. Pa. 2006) (citing *Mead* and *Skidmore* and noting that *Chevron* deference is only appropriate when agencies make rules carrying the force of law, and that when agencies lack "power to control," courts should respect their position only to the extent that it has the power to persuade).

232 *See* Barnhart v. Walton, 535 U.S. 212, 222 (2002) (noting that "the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time" may indicate that *Chevron* deference is appropriate).

233 There is much confusion, post-*Barnhart*, about the difference between the factors that trigger *Chevron* (versus *Skidmore*) deference. *See* Lisa Schultz Bressman, *How* Mead *Has Muddled Judicial Review of Agency Action*, 58 VAND. L. REV. 1443, 1457–74 (2005). An agency's expertise and the thoroughness of its consideration would certainly work in favor of gaining *Chevron* deference for decisions that its regulations supersede state tort law, but without notice-and-comment rulemaking, it would likely be an uphill battle. Preambles attached to rules that go through the notice-and-comment procedure may have the strongest argument under the *Mead-Barnhart* framework. *See, e.g.*, La. Envtl. Action Network v. EPA, 382 F.3d 575, 583 (5th Cir. 2004) (declining to afford *Chevron* deference to preamble containing "interpretations made *prior to notice-and-comment* rulemaking," but considering them "persuasive") (emphasis added).

234 *Compare* cases cited *infra* note 290, *with* cases cited *infra* note 304.

235 *See supra* Part I.B.2. A separate line of inquiry might ask whether, just as the mainstream view of tort law has evolved toward characterizing tort as regulation (notwithstanding the Supreme Court's deployment of alternating compensatory and regulatory guises), perhaps Congress's view of federal regulation should expand to focus on compensatory elements. For the time being, however, the Court's interpretation of congressional action is in the opposite direction. *See supra* note 102.

limiting agency deference at the outer edges where preemption would lead to a complete remedial or enforcement void.[236]

A weaker version of this rule would require simply that courts defer as long as the agency has fully and explicitly balanced the relevant interests at issue. Recall that in *Sprietsma*, for example, the Court implied that it might have deferred to an agency's determination that a tort compensation regime should give way: "*Absent a contrary decision by the Coast Guard*, the concern with uniformity does not justify the displacement of state common-law remedies."[237] Indeed, far from taking the view that tort liability and federal regulation were at odds, or were pure substitutes, the agency had argued that "the existence of potential common-law damages liability under state law may *complement* the agency's decision by creating an incentive for responsible parties in the private sector to address the problem through private research and innovation, in addition to affording compensation to individual injured parties in appropriate circumstances."[238]

Finally, and relatedly, the choice of granting *Skidmore* as opposed to *Chevron* deference would fuel the agency reference model by encouraging agencies to engage in formal notice-and-comment rulemaking processes that, arguably, vet the agency decisionmaking process and make the agency respond to substantive concerns raised by all affected parties.[239]

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236 The strong form of this argument is that when Congress is unclear about whether it wants to provide tort victims with a civil remedy, but legislates against a backdrop of relevant tort lawsuits, then Congress did not intend to preempt state common law. In other words, Congress simply would not have delegated such a consequential decision without being more explicit. This would, in effect, reinstate the "clear statement" rule, *see supra* note 27, but only for preemption decisions that preclude *all* remedial avenues for tort victims.

In a similar vein, Cass Sunstein has suggested that major questions can properly be, and in practice are, resolved at Step One of the *Chevron* inquiry, when courts decide whether Congress has directly spoken to the precise question at issue. *See* Cass R. Sunstein, Chevron *Step Zero*, 92 VA. L. REV. 187, 243 (2006); *see also supra* text accompanying note 200.

Rather than confronting congressional intent at Step One of the *Chevron* analysis, Thomas Merrill and Kristin Hickman have suggested that courts ought to evaluate the limits of an agency's authority at "Step Zero"; that is, at the stage in which the court decides whether to grant *Chevron* or *Skidmore* deference. *See* Thomas W. Merrill & Kristin E. Hickman, Chevron*'s Domain*, 89 GEO. L.J. 833, 912 (2001). According to Merrill and Hickman, those issues about which "Congress clearly would not want the courts to give mandatory deference to agency interpretations" would not be subject to *Chevron* deference. *See id.* at 912–13.

237 Sprietsma v. Mercury Marine, 537 U.S. 51, 70 (2002) (emphasis added).

238 U.S. *Sprietsma* Br., *supra* note 138, at 18 (emphasis added).

239 For this reason, I have proposed elsewhere that courts—should they conclude that *Chevron* deference is warranted in a particular case—might nonetheless condition deference to agency preamble statements on agencies' compliance with congressional and executive mandates

### *b. Consistency of Agency Position*

Invocation of *Skidmore* deference goes hand-in-hand with consideration of the consistency of the agency's position on preemption over time—which serves as an important check on agency overreaching in the preemption realm.[240] Specifically, when an agency's regulations conflict with its own prior interpretations, the level of deference courts should accord to the agency decreases.[241]

This consistency factor can also shed light on the explanatory power of the agency reference model to organize the Supreme Court's products liability preemption jurisprudence. As discussed above, when considered against the backdrop of the other products liability preemption cases before the Court, *Bates* stands in fairly sharp relief.[242] As an anti-preemption case, it shares company with *Freightliner*, *Lohr*, and *Sprietsma* in tempering the momentum toward federalization of products liability law.[243] But it also stands alone as a seeming outlier to the agency reference model, given that the government—representing the Environmental Protection Agency ("EPA")—argued rather emphatically *in favor* of preemption.

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designed to make agencies more accountable, such as consultation mandates, federalism impact statements, and notice-and-comment processes. *See* Sharkey, *supra* note 5, at 256–58.

240 *See* Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944) ("The weight of [an agency's position] in a particular case will depend upon [factors including] its consistency with earlier and later pronouncements . . . ."). In *National Cable & Telecommunications Ass'n v. Brand X Internet Services*, the Court held that agency inconsistency is *not* relevant to a court's decision whether to accord *Chevron* deference to an agency interpretation. 545 U.S. 967, 981 (2005). Three years prior, however, the Court in *Barnhart v. Walton* stated: "[T]he Agency's regulations reflect the Agency's own longstanding interpretation . . . [a]nd [thus] this Court will normally accord [it] particular deference . . . ." 535 U.S. 212, 219–20 (2002) (citations omitted). While the relevance of agency consistency as a factor in applying *Chevron* deference is therefore somewhat ambiguous, there is no doubt as to its relevance in applying the weaker "power to persuade" *Skidmore* deference.

241 *See* Riegel v. Medtronic, Inc., No. 06-179, 2008 WL 440744, at *8 (U.S. Feb. 20, 2008) ("If . . . we had found the statute ambiguous and had accorded the agency's current position deference, the dissent is correct, that—inasmuch as mere *Skidmore* deference would seemingly be at issue—the degree of deference might be reduced by the fact that the agency's earlier position was different." (citing *Skidmore*, 323 U.S. 134; United States v. Mead Corp., 533 U.S. 218 (2001); Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 417 (1993))). The Solicitor General explained the FDA's change in position in *Riegel* thusly: "[T]he United States' earlier position was based in part on proposed regulations that FDA has since withdrawn, and its prior position is inconsistent with FDA's current understanding and application of . . . risk-management principles . . . (e.g., the need to prevent over-warning)." U.S. *Riegel* Br., *supra* note 121, at 24; *id.* ("Neither FDA's reasoned change in position, nor the absence of a formal agency regulation addressing the specific question presented here, negates deference." (citing Auer v. Robbins, 519 U.S. 452, 461-62 (1997))).

242 *See supra* text accompanying note 103.

243 *See supra* Part I.C.2.

The Court held its anti-preemption ground, notwithstanding the emphatic pro-preemption case made to it by the EPA, the agency tasked to enforce FIFRA.[244] The Court not only rejected the EPA's interpretation in light of the allegedly "clear text" of the organic statute,[245] but it also resisted the agency's position on the disruptive effects of state tort claims.[246]

Arguably—and consistent with the agency reference model I have proposed—the EPA was the body best suited to decide whether it made more sense to regulate the chemical ingredients that go into pesticides at the state or national level.[247] By ignoring the agency's input, the Court failed to ask the relevant question.[248]

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244 *See* Brief for the United States as Amicus Curiae Supporting Respondent at 11, Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005) (No. 03-388), 2004 WL 2681684, at *11 [hereinafter U.S. *Bates* Br.] ("Section 136v(b) expressly preempts both state regulatory requirements and state common-law duties.").

245 *See Bates*, 544 U.S. at 448; *cf. Riegel*, 2008 WL 440794, at *8 ("[T]he statute itself [MDA] speaks clearly to the point at issue.").

246 *See Bates*, 544 U.S. at 451 ("Dow and the United States exaggerate the disruptive effects of using common-law suits to enforce the prohibition on misbranding."). The EPA argued that state tort regimes were inconsistent with the federal regulatory scheme, claiming that

> EPA administers FIFRA through centralized expert judgment, while the 50 States apply common-law standards through an adversarial process in which lay judges and juries can "reach different decisions on similar facts." . . . Pesticide manufacturers would be subject to multiple and inconsistent labeling regimes and would be forced to abandon or alter EPA-approved labels to avoid liability.

U.S. *Bates* Br., *supra* note 244, at 25–26.

247 Justice Breyer's concurring opinion came closest to endorsing this approach:

> As suggested by [*Lohr*], the federal agency charged with administering the statute is often better able than are courts to determine the extent to which state liability rules mirror or distort federal requirements. Thus, the EPA may prove better able than are courts to determine whether general state tort liability rules simply help to expose new dangers associated with pesticides.

*Bates*, 544 U.S. at 455 (Breyer, J., concurring) (quotation omitted).

248 Note the affinities here with the criticism of *Bates* offered by Thomas Merrill:

> Consider the question whether states should be permitted to regulate the chemical ingredients that go into pesticides. . . . The answer may depend on facts about the real world that can only be learned by investigating the way the industry operates. Are pesticides typically manufactured in central plants and then distributed to farm supply stores throughout the country? Or do pesticide manufacturers ship raw chemical ingredients to more localized assembly plants, where they are mixed in different combinations to accommodate local conditions? . . . The Supreme Court in [*Bates*] did not even ask.

Merrill, *supra* note 141, at 179–80. Merrill has advocated the development of default rules "drawn from [judicial and legislative] experience with how federalism values have played out in the past in particular areas." *Id.* at 169. To my mind, the institutional agency reference model provides a superior and far more comprehensive approach to discovering the relevant legislative facts necessary to determine the optimal level of regulation.

Nonetheless, two things might be said in an effort to fit *Bates* into an agency reference paradigm based upon *Skidmore* deference. First, Justice Breyer, in a separate concurrence, reiterated his view from *Lohr* that an agency "ha[s] the legal authority . . . to determine the pre-emptive effect of [its] rules in light of the agency's special understanding of 'whether (or the extent to which) state requirements may interfere with federal objectives.'"[249]

Second, the United States switched its position on the key question of whether FIFRA preempts common-law causes of action. On two prior occasions, the United States filed an amicus brief in a lower court that took the position that FIFRA does not preempt state common-law damages actions.[250] In an apparent attempt to downplay this shift in philosophy, the amicus brief submitted by the government in *Bates* simply states, without further elaboration: "The United States has properly reconsidered and disavowed its prior position that Section 136v(b) does not preempt state common-law duties."[251]

Thus, if a "consistency caveat" is added to the agency reference model—whereby, per *Skidmore*, an agency's interpretation of a regulation's preemptive power would be afforded less weight if the agency changes positions on the issue, particularly without reasoned justification—the model might then emerge undefeated, if slightly tainted.[252]

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249 *Bates*, 544 U.S. at 454 (Breyer, J., concurring) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 506 (1996) (Breyer, J., concurring in part, concurring in judgment)). Note, however, that with respect to the agency's regulatory action (as distinct from its interpretive sphere), the EPA did not engage in efficacy review of pesticides. *See supra* note 89; *see also* U.S. *Riegel* Br., *supra* note 121, at 26 (arguing that *Riegel* is "fundamentally different from *Bates* because, under FIFRA, the [EPA] did not evaluate either the product's efficacy or the accuracy of statements about efficacy in the proposed labeling").

250 *See* U.S. *Etcheverry* Br., *supra* note 90, at 8–33 ("FIFRA Does not Preempt State Common Law Damages Actions"); U.S. *Hart* Br., *supra* note 100, at 7 (arguing that the text, legislative history, and purposes of FIFRA demonstrate that Congress did not intend "requirements" in the preemption provision to extinguish state law damages actions). In one of those cases, the California Supreme Court rejected the United States's position. *See* Etcheverry v. Tri-Ag Serv., Inc., 993 P.2d 366, 368 (Cal. 2000).

251 U.S. *Bates* Br., *supra* note 244, at 20. The United States took a similar position in a previous amicus brief filed in response to a petition for certiorari. *See* Brief for the United States as Amicus Curiae at 17, Am. Cyanamid Co. v. Geye, 79 S.W.3d 21 (Tex. 2002), *cert. denied*, 539 U.S. 969 (2003) (02-367) ("The United States has reexamined the position that it urged in *Etcheverry* in light of the ruling by the California Supreme Court in that case, as well as the subsequent rulings by other courts.").

252 The Court has emphasized the need for agencies to provide adequate explanations of changes in position. *See, e.g.*, Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs., 545 U.S. 967, 981 (2005) ("Unexplained inconsistency is, at most, a reason for holding an interpretation to be an arbitrary and capricious change from agency practice under the Administrative Procedure Act."); Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29,

Support for this view can be gleaned from *Bates*: "The notion that FIFRA contains a nonambiguous command to pre-empt the types of tort claims that parallel FIFRA's misbranding requirements is particularly dubious given that just five years ago the United States advocated the interpretation that we adopt today."[253] Indeed, the Court further noted: "[F]or much of this period [the] EPA appears to have welcomed these tort suits."[254] Finally, it is noteworthy that—unlike in previous cases—the government did not argue explicitly that its views should be accorded deference by the Court.[255]

### *III. Institutional Model Applied: Pharmaceuticals*

Having laid out a generalized normative framework for products liability preemption cases, in this Part, I apply this approach to the specific context of prescription drug labeling—a vexing preemption issue that numerous state and federal courts now face and one that has sparked tremendous controversy.[256]

The typical pattern of congressional regulation of national products plays out in the realm of pharmaceuticals. Congress offered up little guidance to those committed to a formalist, statutory-interpretation approach, given its lack of attention to how regulation of prescription drugs would affect existing state law. In 1962, Congress enacted sweeping changes to the FDCA,[257] imposing requirements

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41-42 (1983) (holding that agency's changed position is entitled to deference so long as the agency provides a reasoned explanation for the change); *see also* 5 U.S.C. § 706(2)(A) (2000) ("The reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.").

253 *Bates*, 544 U.S. at 449.

254 *Id.* at 452.

255 *Cf., e.g.*, U.S. *Lohr* Br., *supra* note 126, at 26–27; U.S. *Freightliner* Br., *supra* note 113, at 29 n.17; U.S. *Geier* Br., *supra* note 109, at 26–27; *see also* U.S. *Riegel* Br., *supra* note 121, at 23, 28.

256 Keith Hylton has offered a "positive theory" of products liability preemption. *See generally* Hylton, *supra* note 157. With respect to failure-to-warn claims, Hylton concluded that the preemption determination turns on whether the agency overseeing product labeling examines the same issues as the court, noting that "[c]ongruence [between the federal regulatory standard and the common-law standard], under this framework, is a necessary condition for preemption of failure to warn claims." *Id.* at 15. But there are limitations to Hylton's study. First, the study cuts off in 2002, when the more aggressive maneuvering by federal agencies in the preemption realm was just beginning. Second, and relatedly, Hylton's classification of federal statutes by "congruence level" is debatable. The FDCA, for example, is given a low "congruence" rating on the ground that it is "understood" to impose generic minimum safety standards. *See id.* at 24. The center of the debate, at least today, is whether in fact the FDA imposes minimal or optimal standards. *See, e.g.*, *infra* note 295 and accompanying text.

257 Drug Amendments of 1962 (Harris-Kefauver Act), Pub. L. No. 87-781, 76 Stat. 780

that manufacturers establish that their drugs are both safe and effective as preconditions for FDA premarket approval.[258] Unlike the MDA, however, the prescription drug provisions contain no preemption provision;[259] the drug provisions do, on the other hand, include a qualified "savings clause."[260]

In enacting the drug provisions, Congress's full attention was devoted to addressing manufacturer liability; in the 1962 amendments, Congress neither provided a federal private right of action nor addressed remedies for consumers injured by dangerous drugs with inadequate warnings. To the extent courts have considered this aspect of the FDCA, they have varied greatly in deciding the relevance they should accord the lack of a statutory remedy when inferring congressional intent.[261] In my view, although existence of a remedial void

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(codified as amended in scattered sections of 21 U.S.C.). It has been widely asserted that 1962 marks the commencement of the "modern U.S. drug regulatory system." *E.g.*, Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1764 (1996).

258 *See* 21 U.S.C. § 355(d) (2000); *see also id.* § 393(b)(1), (b)(2)(B) (FDA's mission is to protect public from unsafe drugs and to promote public health by approving regulated products in timely manner). The FDA oversees the fairly extensive process of investigating new drugs and approving them for introduction into the U.S. market. Indeed, "the regulations imposed by the [FDA] are generally considered the world's most demanding." Joan E. Shreffler, Comment, *Bad Medicine: Good-Faith FDA Approval as a Recommended Bar to Punitive Damages in Pharmaceutical Products Liability Cases*, 84 N.C. L. REV. 737, 753 (2006) (citing MARK MATHIEU, NEW DRUG DEVELOPMENT: A REGULATORY OVERVIEW 1 (5th ed. 2000)). For a detailed description of the FDA drug approval process, see Lars Noah, *Premarket Approval and Postmarket Surveillance*, *Pharmaceutical Products*, *in* LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES AND MATERIALS 221–54 (2d ed. 2007).

259 *Cf. supra* note 59. Several cases—wrongly in my view—have inferred congressional intent to defer to state law from the absence of a preemption clause. *See, e.g.*, Witczak v. Pfizer, Inc., 377 F. Supp. 2d 726, 732 (D. Minn. 2005) ("If Congress intends to create a class of protected businesses, it has the means and ability to do so."); Cartwright v. Pfizer, Inc., 369 F. Supp. 2d 876, 884-85 (E.D. Tex. 2005).

260 Harris-Kefauver Act § 202, 76 Stat. at 793 ("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." (emphasis added)). Despite the existence of the savings clause, federal law may still preempt state law in the realm of drug liability when they conflict—and this arguably includes both the narrower "impossibility" variety as well as the broader "obstacle" or "frustration of purposes" variety. *See supra* note 21.

261 *Compare, e.g.*, *In re* Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig., No. M: 05-1699 CRB, 2006 WL 2374742, at *7 (N.D. Cal. Aug. 16, 2006) ("Congress's omission of a federal damages remedy in the FDCA is not a 'clear congressional command' of no preemption."), *with, e.g.*, *In re* Paxil Litig., No. CV 01-07937 MRP, 2002 WL 31375497, at *1 (C.D. Cal. Oct. 18, 2002) (reasoning that preemption of state common-law actions "vitiates, rather than advances, the FDCA's purpose of protecting the public" and would require "find[ing] that in enacting the FDCA for the purposes of protecting public health, Congress not only declined to provide for a private cause of action, but also eliminated the availability of common law state

should not lead inevitably to an anti-preemption position, it should take arguments for implied field preemption off the table.[262]

In what has emerged as a familiar pattern, the federal regulator—in this case the FDA—entered into the interpretive zone of implied conflict preemption facing the courts. It is debatable whether the FDA promulgates "minimal" or "optimal" safety standards in the drug approval process. On top of the legislative silence on this topic, there is an added layer of regulatory ambiguity. An FDA regulation allows manufacturers to "add or strengthen a contraindication, warning, precaution, or adverse reaction" in a drug's label without prior FDA approval,[263] suggesting that the FDA sets minimum standards that can and should be supplemented by manufacturers or by state law failure-to-warn claims that give manufacturers an added incentive to do so.[264] But other regulations require drug manufacturers to make a supplemental filing with the FDA when making any changes without prior approval;[265] moreover, the FDA must reject any such changes if the added information makes the labeling "false or misleading."[266]

First in amicus briefs to various lower courts, and most recently in a preamble to a 2006 prescription drug labeling rule, the FDA has put forth its view: "FDA believes that under existing preemption principles, FDA approval of labeling under the act . . . preempts conflicting

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claims. This position contravenes common sense . . . ."); *see also In re* Vioxx Prods. Liab. Litig., 501 F. Supp. 2d. 776, 788 (E.D. La. 2007) ("Because there are no federal remedies for individuals harmed by prescription drugs, a finding of implied preemption in these cases would abolish state-law remedies and would, in effect, render legally impotent those who sustain injuries from defective prescription drugs.").

262 Field preemption, *see supra* note 21, may also be taken off the table as a matter of statutory interpretation due to the savings clause included in the 1962 amendments to the FDCA. *See supra* note 260.

Numerous academic commentators, nonetheless, carry the flag for field preemption, arguing its desirability "[b]y virtue of the specificity and comprehensiveness of the [FDCA's] regulation of prescription drugs." *See, e.g.*, Geiger & Rosen, *supra* note 168, at 414–16. Richard Epstein perhaps waves the flag most consistently and most vigorously. *See, e.g.*, Epstein, *supra* note 190, at 23–29 (arguing for default rule of preemption in field of pharmaceuticals).

263 21 C.F.R. § 314.70(c)(6)(iii)(A) (2007).

264 Under the federal regulatory regime, a manufacturer is required to provide warnings in a drug's label "as soon as there is *reasonable evidence of an association* of a serious hazard with a drug." *Id.* § 201.80(e) (emphasis added). This regime has been characterized as a "safety valve" or a "device that lessens the risk of a conflict or an obstacle in a situation that could otherwise cause harm." *See* James T. O'Reilly, *A State of Extinction: Does Food and Drug Administration Approval of a Prescription Drug Label Extinguish State Claims for Inadequate Warning?*, 58 FOOD & DRUG L.J. 287, 293–94 (2003).

265 *See* 21 C.F.R. §§ 314.70, 601.12(f) (2007).

266 *See* 21 U.S.C. § 352 (2000).

or contrary State law."[267] The FDA has justified its position in the interests of uniformity, expertise and safety concerns:

> Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug.[268]

The FDA's position is buttressed by the recently-enacted FDA Amendments Act of 2007, which bolsters the FDA's authority during the post-approval period to monitor drug side effects and to impose larger fines on companies that do not conduct post-marketing studies.[269]

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267 Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006). Since 2000, the FDA has intervened in pharmaceutical cases, taking a consistent position that the Supremacy Clause bars state tort liability for failure to include a warning in a drug label that is in conflict with, or contrary to, warnings approved by the FDA. *See, e.g.*, Amicus Brief for the United States in Support of the Defendant-Appellee & Cross-Appellant, & in favor of Reversal of the District Court's Order Denying Partial Summary Judgment to Defendant-Appellee & Cross-Appellant at 15–16, Motus v. Pfizer Inc., (Roerig Div.), 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372, 02-55498), 2002 WL 32303084, at *15–16 [hereinafter U.S. *Motus* Br.]; Brief for Amicus Curiae The United States of America at 13, Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514 (E.D. Pa. 2006) (No. 05-CV-05500-MMB), *appeal docketed*, No. 06-3107 (3d Cir. June 21, 2006); Corrected Amicus Brief for the United States at 25–26, Kallas v. Pfizer, Inc., No. 2:04CV0998 PGC (D. Utah Sept. 29, 2005), 2005 WL 4030146; Brief of the United States of America at 4–5, *In re* Paxil Litig., 218 F.R.D. 242 (C.D. Cal. 2003) (No. CV 01-07937 MRP (CWx)), 2001 WL 34883537, at *4–5; Statement of Interest of the United States at 7, Bernhardt v. Pfizer, Inc., Nos. 00 Civ. 4042 (LMM), 00 Civ. 4379 (LMM), 2000 WL 1738645, at *7 (S.D.N.Y. Nov. 13, 2000) [hereinafter U.S. *Bernhardt* Statement of Interest]; Amicus Curiae Brief of the United States of America in Support of Defendants/Respondents SmithKline Beecham Consumer Healthcare LP, et al. at 21–22, Dowhal v. SmithKline Beecham Consumer Healthcare, 88 P.3d 1 (Cal. 2004) (No. S109306).

268 Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935. The FDA explains further that, unlike state regulators, the FDA's regulatory decisions are "characterized by centralized expert evaluation" and would avoid "defensive labeling" that would result from disparate state liability regimes. *See id.*

269 *See* Food & Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823; Sarah Rubenstein et al., *Congress Expands FDA's Oversight On Drug Safety*, WALL ST. J., Sept. 21, 2007, at A12 ("With its expanded clout, an FDA leadership motivated to flex its muscles could lean on the bill's provisions to require label changes and other measures—bolstered by civil monetary penalties for noncompliance—without having to secure cooperation through give-and-take with the industry."); *Bush Signs FDA Drug Safety Bill into Law*, REUTERS, Sept. 27, 2007 ("The agency will be able to require new warnings on marketed prescription drugs, order the completion of post-approval safety studies or limit a product's distribution. Companies that do not comply could be fined up to $10 million."). *But see* PETER BARTON

In pharmaceutical drug cases, courts have been called upon to evaluate the import of a variety of sources of agency preemptive authority including the FDA preamble, agency amicus briefs and letters filed in individual cases, and the FDA's pre- and post-market determinations about the content of labels.[270] Courts' approaches to the preemption question run the gamut between two extreme or absolutist positions. At one end (the staunch "anti-preemption" pole), courts wield the "presumption against preemption" statutory canon to fend off even the more compelling preemption arguments.[271] At the opposite "pro-preemption" pole, courts have accorded *Chevron* deference to the FDA's preamble position, cutting a wide preemptive path. This sets the stage for the middle course position I will defend, supported by the agency reference model, which embraces the view that a specific determination by the FDA that a particular warning is not based on reliable scientific evidence should foreclose common-law claims based upon a failure to include such a warning.

### *A. Current Approaches*

#### *1. Presumption Against Preemption*

The presumption against preemption has a chimerical quality to it. In terms of explanatory power, it makes a poor showing in the products liability preemption realm.[272] That said, where it rears its head, its effect is seemingly outcome determinative. This pattern is exemplified in the lower courts' prescription drug cases. Where the presumption is invoked by courts, an anti-preemption determination is close at hand.

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HUTT, THE STATE OF SCIENCE AT THE FOOD AND DRUG ADMINISTRATION, at B-5, *in* SUBCOMM. ON SCI. & TECH., FOOD AND DRUG ADMIN., FDA SCIENCE AND MISSION AT RISK app. B (2007), *available at* http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_00_index.html (criticizing Congress for enacting "an unfunded FDA omnibus statute . . . that demands substantial FDA scientific resources to analyze and implement . . . with no plans for additional appropriated funds or personnel to implement it").

270 The vast majority of controversial failure-to-warn claims stem from risks that come to light after the FDA's initial approval of a drug label. *See* Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 8 GEO. L.J. 2119, 2130 n.53 (2000); *see also* 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, 600–06 (2005).

271 *Cf.* Goldsmith, *supra* note 12, at 201 ("The presumption against preemption weighs the interpretive scales in favor of states at the beginning of the analysis, and biases the interpretive project from the outset.").

272 *See supra* Part I.A.

The Vermont Supreme Court decision in *Levine v. Wyeth*[273] represents this approach. The court invoked a broad, "constitutionally rooted" presumption against preemption to reject wholesale any argument that federal drug labeling regulations preempted common law products liability claims,[274] ruling that "[a]bsent clear congressional intent to supersede state law, including state common law duties, there is a presumption against preemption."[275] In the hands of the *Levine* Court, the presumption does most of the necessary work to resolve the case. It is as if the presumption casts a wide protective shadow against implied preemption; regardless of the precise risk regulated by the FDA or specific agency actions taken, the FDA is taken to impose minimum safety standards, ripe for supplementation by state tort law.[276]

The bottom line is that the *Levine* Court upheld common-law actions for negligence and failure-to-warn in the face of not one, but two, specific determinations by the FDA regarding the precise regulated risk. The FDA-approved label warned of the risk of harm that transpired in the case—namely, the plaintiff developed gangrene resulting in amputation of her forearm and hand after an injection of defendant's anti-nausea drug, Phernergan.[277] After initial approval, the manufacturer proposed a different warning to the FDA for another version of the drug and was told to "[r]etain verbiage in current label."[278] The opinion did not point to any additional risk information

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273 Levine v. Wyeth, No. 2004-384, 2006 WL 3041078 (Vt. Oct. 27, 2006), *cert. granted*, 76 U.S.L.W. 3018 (U.S. Jan. 18, 2008) (No. 06-1249) (to be argued October Term 2008).

274 *See id.* ¶ 28. Prominent commentators have rejected the constitutional nature of the presumption. *See, e.g.*, Nelson, *supra* note 4, at 293 ("[T]he Supremacy Clause is not silent on this subject at all. Its *non obstante* provision rejects a general presumption that federal law does not contradict state law."); *see also* ELHAUGE, *supra* note 10, at 232–33 (rejecting the argument that canons favoring states rely on particularities of the U. S. Constitution).

275 *Levine*, 2006 WL 3041078, ¶ 7 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)); *see also id.* ¶ 17 ("Plaintiff's negligence and product-liability claims fall squarely within the scope of traditional state regulation, so it is appropriate to apply the presumption against preemption here.").

276 *See id.* ¶ 28 (concluding that, in light of the presumption against preemption, "the FDCA provides a floor, not a ceiling, for state regulation").

277 *See id.* ¶¶ 1–2; *id.* ¶ 4 n.1 (reproducing the label in full). The label stated that "extreme care should be exercised" when injecting the drug in "close proximity of arteries" due to the likelihood of "gangrene requiring amputation." *Id.* ¶ 56 (Reiber, C.J., dissenting); *see also id.* ¶ 23 (majority opinion) (approved label stated that it was "preferable" to inject the drug "through the tubing of [a functioning] intravenous infusion set").

278 *See id.* ¶ 21. The *Levine* majority, in finding the proposed label different but not stronger, took a much narrower view of the risk in question, namely that the FDA had not weighed in specifically on the "IV-push" method of administering the drug intravenously:

> Defendant has provided a number of letters exchanged by the FDA and defendant

that had come to light at that time, i.e., the FDA's review entailed a reexamination of the same information the manufacturer and the FDA relied upon in devising the original label.[279] In sum, the FDA knew both of the risk and the seriousness of the risk at issue, specifically calibrated the warning with these two factors in mind, and then later affirmed its initial determination.[280]

But the *Levine* Court gave little heed to the FDA's actions; nor did it solicit the FDA's views in the case, as the agency reference model might demand.[281] Certainly, if the FDA rejected the drug manufacturer's proposed warning on the ground that a stronger warning regarding the precise risk was not warranted (pursuant to a risk-risk analysis), then, under an implied conflict preemption analysis, a common-law claim for failure to warn of that risk should not be allowed to proceed. The *Levine* Court's analysis, however, demonstrates the seemingly limitless discretion on the part of courts to counter this straightforward implied preemption analysis, especially if they may substitute speculation for actual agency determinations. Not to be hemmed in by the FDA's actual decisionmaking process, the court

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> regarding Phenergan's label, but these letters do not indicate the FDA's opinion of the value of IV-push administration. Neither the letters nor any other evidence presented to the jury indicated that the FDA wished to preserve the use of IV push as a method of administering Phenergan.

*Id.* ¶ 23. Applying both a narrow "impossibility" view of implied conflict preemption and a broader "obstacle" or "frustration of purposes" view, *see supra* note 21, the *Levine* majority rejected Wyeth's claim that "it was impossible to comply with both state and federal law because the FDA prohibited the use of a stronger warning with respect to IV-push administration of Phenergan," *id.* ¶ 21, as well as Wyeth's argument that "state common-law liability for its use of an FDA-approved label presents an obstacle to federal objectives," *id.* ¶ 24 (holding that the "plaintiff's claim does not interfere with any objective that can legitimately be ascribed to Congress").

279 *Cf.* Brief for the United States as Amicus Curiae at 14, Wyeth v. Levine, No. 06-1249 (U.S. Dec. 21, 2007), 2007 WL 4555760, at *14 [hereinafter U.S. *Wyeth* Br.] ("In this case, it does not appear that [plaintiff] relies on any material new information that was not available to FDA.").

280 To me, this appears to be a realization of the troublesome scenario that Richard Nagareda dismissed as "fanciful." *See* Nagareda, *supra* note 36, at 22 ("Tort liability would 'frustrate' the FDA's *initial* drug approval in the *Geier* sense only in the fanciful scenario of a tort suit that seeks what one might describe charitably as a 'do-over'—that seeks to impose liability, even though the corpus of information about the risks posed by the drug has undergone no material change in the meantime.").

281 *See supra* text accompanying note 204. In a recent Essay, I demonstrated that, in practice, state courts are much less likely than federal courts to seek the views of the FDA in pharmaceutical drug preemption cases; moreover, the FDA is also more likely to intervene on its own in federal cases. *See* Catherine M. Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 BROOK. J.L. & POL'Y 1013, 1037–40 (2007).

reasoned that "[t]he FDA could have rejected the new warning for any number of reasons, including clarity or technical accuracy, without implicitly prohibiting a stronger warning."[282]

*Levine* provides an especially vivid example of a court's use of the presumption against preemption to clear a wide berth of the terrain of implied conflict preemption in the products liability realm.[283] But the court is by no means alone.[284] In another recent case, *Desiano v. Warner-Lambert & Co.*,[285] the Second Circuit likewise invoked the presumption to preserve state-law claims against drug manufacturers. At issue in the case was whether the Court's decision in *Buckman*, which held that the FDCA generally preempts state-law fraud-on-the-agency claims,[286] likewise mandates preemption of state tort claims that require a court to determine, as a condition for imposing damages liability, whether a drug manufacturer perpetrated fraud on the FDA in securing approval for a new drug.[287] Notwithstanding the fact that the Supreme Court itself refused to apply any presumption against

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282 *Levine*, 2006 WL 3041078, ¶ 23. In line with its speculation, the court concluded that it was more likely than not that the FDA had rejected the alternative language for some reason other than that it provided a stronger warning. *See id.* In addition to the procedural flaw in relying upon speculation, as opposed to the actual decisions and views of the FDA, there is an additional substantive flaw in the court's reasoning: the court's explanation fails to explain why the FDA, if it did not believe the manufacturer's warning was sufficient, would not in turn propose a stronger warning correcting whatever flaw it identified in the proposed warning.

283 Here, the court also seemed particularly wary of avoiding the remedial void that might be left in the wake of federal preemption of state tort law. *See id.* ¶ 28 ("[E]liminating lawsuits like the one at issue here would leave consumers without recourse in the event the FDA cannot move quickly enough to require strengthened warnings when they are appropriate."). In my view, the specter of a remedial void warrants taking implied *field* preemption arguments off the table; but it should not be used to circumvent implied conflict preemption altogether. *See supra* note 262 and accompanying text.

284 *See, e.g.*, Jackson v. Pfizer, Inc., 432 F. Supp. 2d 964, 967 (D. Neb. 2006) ("'In the absence of Congress's express statement, defendant must overcome the presumption against implying Congressional preemptive intent. It has not done so. As a result, plaintiff's state law claims remain viable.'" (quoting Witczak v. Pfizer, Inc., 377 F. Supp. 2d 726, 732 (D. Minn. 2005))).

285 Desiano v. Warner-Lambert & Co., 467 F.3d 85 (2d Cir. 2006), *aff'd per curiam by an equally divided Court sub nom.* Warner-Lambert Co., LLC v. Kent, 2008 WL 552875 (U.S. Mar. 3, 2008) (No. 06-1498).

286 Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001).

287 *See Desiano*, 467 F.3d at 87–88; *see also* MICH. COMP. LAWS ANN. § 600.2946(5)(a) (West 2004) (permitting liability against a drug manufacturer who has complied with relevant federal requirements when the manufacturer "[i]ntentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act . . . and the drug would not have been approved . . . if the information were accurately submitted"). For an extended discussion of this issue, see Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 Nw. U.L. REV. (forthcoming 2008) (manuscript at 7–16), *available at* http://ssrn.com/abstract_id=1020722.

preemption in the realm of fraud-on-the-agency claims,[288] the Second Circuit forged ahead, wielding the presumption to fend off the preemption challenge.[289] The court intimated further that the presumption against preemption precludes deference to the FDA's views on the matter.[290]

In similar fashion, the federal district court in *McNellis ex rel. DeAngelis v. Pfizer, Inc.*[291] held that the FDA's preemption preamble did not provide a sufficient basis to overcome the presumption against preemption.[292] Nor was the informality of the FDA's position—embodied in a preamble as opposed to pursuant notice-and-comment rulemaking—the true sticking point. Instead, the court emphasized that it

> must be mindful that the Supreme Court has instructed that there is a presumption against conflict preemption, and that the Court should presume "that the historic police power of the States were not to be superseded by the Federal Acts unless that was the clear and manifest purpose of Congress."[293]

In other words, the court held that the presumption against preemption constitutes a bar to preemption of state-law claims, irrespective of federal agency intervention.

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288 *See Buckman*, 531 U.S. at 347 ("Policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,' such as to warrant a presumption against finding federal pre-emption of a state-law cause of action. To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947))).

289 *See Desiano*, 467 F.3d at 93–94.

290 The court instead would require a clear statement rule. *See id.* at 98 n.9 ("Because we find that a presumption against preemption applies in the instant case, we are bound also to conclude that, absent a clear statement from Congress, the common law claims preserved by Michigan's immunity exception cannot be preempted by federal law."). Several courts have followed *Desiano* on this point. *See, e.g.*, *In re* Zyprexa Prods. Liab. Litig., 489 F. Supp. 2d 230, 273 (E.D.N.Y. 2007) ("The FDA lacks the authority to supply the legislative intent required to overcome the presumption against preemption in this case, removing it from those agency interpretations that receive deference under *Chevron*." (citing *Desiano*, 467 F.3d at 97 n.9)); *In re* Vioxx Prods. Liab. Litig., 501 F. Supp. 2d. 776, 788–89 (E.D. La. 2007) (quoting *Desiano*, 467 F.3d at 97 n.9).

291 McNellis *ex rel.* DeAngelis v. Pfizer, Inc., No. Civ. 05-1286 JBS, 2005 WL 3752269 (D.N.J. Dec. 29, 2005), *motion to vacate denied*, *interlocutory appeal granted*, 2006 WL 2819046 (D.N.J. Sept. 29, 2006), *appeal docketed*, No. 06-5148 (3d Cir. 2006) (argued Dec. 10, 2007).

292 *See* McNellis *ex rel.* DeAngelis v. Pfizer, Inc., No. Civ. 05-1286 (JBS), 2006 WL 2819046, at *5 (D.N.J. Sept. 29, 2006).

293 *Id.* (quoting N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995)).

### *2. Deference to the FDA in Favor of Preemption*

In the preamble, the FDA put forth a number of arguments that attacked any role of tort law in federal drug-labeling regulation and forged a wide swath approach to preemption.[294] The FDA is emphatic that its standards are optimal ones.[295] It has stated that it "believes 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."[296] Finally, the FDA interprets its regulations to require that "the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's under the act."[297]

The FDA has pushed the view that its "misbranding" provisions[298] have even wider preemptive scope. First, the agency has called for the preemption of state-law claims even when the FDA has not made a specific determination prior to the litigation as to the particular risk at issue.[299] Second—and even more expansive of its powers—the FDA has argued that, absent any agency determination

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294 Throughout, the FDA highlighted the dangers of allowing state law to supplement federal regulations. It argued that state tort claims can create pressure on manufacturers to include in labeling speculative risks that "can cause meaningful risk information to lose its significance," Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) (quotations omitted), and concluded that "[s]tate-law attempts to impose additional warnings can lead to labeling that does not accurately portray a product's risks, thereby potentially discouraging safe and effective use of approved products or encouraging inappropriate use and undermining the objectives of the act." *Id.* Notwithstanding the potential breadth of its arguments, the FDA does not expressly conclude in the preamble, or elsewhere, that FDA approval of a drug label should preempt *all* state tort claims. That said, while the FDA has been fairly cryptic as to precisely what constitutes "conflicting or contrary" state law, many authorities have interpreted the agency's comments as supporting the position that state failure-to-warn claims, in general, conflict with FDA regulations and should therefore be preempted entirely. *See, e.g.*, *infra* notes 303–07 and accompanying text.

295 *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935 ("FDA interprets the act to establish both a 'floor' and a 'ceiling' . . . ."); *id.* at 3934 ("Another misunderstanding of the [FDCA] encouraged by State law actions is that FDA labeling requirements represent a minimum safety standard."). According to the FDA, "additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading." *Id.* at 3935.

296 *Id.*

297 *Id.* at 3934.

298 *See* 21 U.S.C. §§ 331, 352 (2000).

299 U.S. *Motus* Br., *supra* note 267, at 18–19 ("FDA does not have to state in advance that a particular warning would misbrand the product in order to make the placement of such a warning a violation of federal law. The manufacturer's inclusion of a false or misleading warning misbrands the product *per se*.").

before or after the injury, state-law claims based upon failure to warn of risks unknown at the time the FDA approved the drug should be preempted. According to the FDA, only in exceptional circumstances do drug manufacturers unilaterally supplement the warnings on an approved label without creating a serious risk of misbranding the drug.[300] Any unilateral revision potentially conflicts with the FDA's final say on warnings; as it argued to the court in a recent case: "Should the FDA determine that new warnings are appropriate with respect to [a drug], there exists the very real possibility that such warnings would differ from those requested by plaintiffs."[301] Most recently, the Solicitor General (joined by General Counsel of the Department of Health and Human Services) urged the Supreme Court (in the *Wyeth v. Levine* case pending for next Term) to adopt the broad position that "FDA's approval of a drug, including its labeling, generally preempts state law claims challenging the drug's safety, efficacy, or labeling."[302]

Some courts have been receptive to the FDA's misbranding arguments, despite their overbreadth. A few courts have adopted the FDA's misbranding argument without being explicit about according any particular deference to the FDA.[303] Others have expressly accorded *Chevron* deference, either to the FDA's amicus briefs or else its recently promulgated preemption preamble.[304] In the words of the

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300 *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934 ("[I]n practice, manufacturers typically consult with FDA prior to adding risk information to labeling."). According to former FDA General Counsel Daniel Troy, "[c]ourts and plaintiffs rely on § 314.70(c)(6)(iii)(A) to support their argument that a defendant manufacturer could have revised the risk information in its package insert without explicit permission from FDA; however, manufacturers seldom, if ever, add or revise risk information unilaterally, preferring to consult with the FDA first." Daniel E. Troy, *The Case for FDA Preemption*, *in* FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS 81, 107 n.17 (Richard A. Epstein & Michael S. Greve eds., 2007) (citing Richard M. Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 FOOD & DRUG L.J. 233, 238 (1986) and Thomas Scarlett, *The Relationship Among Adverse Drug Reaction Reporting, Drug Labeling, Product Liability, and Federal Preemption*, 46 FOOD & DRUG L.J. 31, 36 (1991)).

301 U.S. *Bernhardt* Statement of Interest, *supra* note 267, at 8.

302 *See* U.S. *Wyeth* Br., *supra* note 279, at 8.

303 *See, e.g.*, Ehlis v. Shire Richwood, Inc., 233 F. Supp. 2d 1189, 1198 (D.N.D. 2002) ("The FDA dictates the contents of the label for [the drug] and defendants were prohibited from changing it without prior approval from the FDA, except in limited circumstances for a limited period of time.").

304 *See, e.g.*, Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289, 316–17 (E.D. Pa. 2007); *In re* Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig., No. M: 05-1699 CRB, 2006 WL 2374742, at *6–9 (N.D. Cal. Aug. 16, 2006); Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 525–29 (E.D. Pa. 2006), *appeal docketed*, No. 06-3107 (3d Cir. June 21, 2006) (argued Dec. 10, 2007); Conte v. Wyeth, Inc., No. CGC-04-437382, 2006 WL 2692469, at *6 (Cal. Super. Ct. Sept.

federal district court in *Colacicco v. Apotex, Inc.*,[305] "it is abundantly clear that the FDA's position is entitled to significant deference."[306] Emphasizing the centrality of the FDA's view to its analysis, the court was prepared to accord *Chevron* deference to the FDA's preemption preamble "because Supreme Court precedent dictates that an agency's interpretation of the statute and regulations it administers is entitled to deference."[307]

These cases occupy the polar extreme position from those, discussed above, invoking the presumption against preemption. To the extent courts are inclined to give mandatory deference to the FDA, preemption may altogether wipe out state law failure-to-warn claims, which would be barred regardless of whether the FDA has made a determination as to the specific risk in question.

### *B. Agency Reference Approach*

The theme of my proposed middle course approach—between the extremes of applying a strong-form presumption against preemption and granting mandatory *Chevron* deference to the FDA—is fairly easy to state. State-law failure-to-warn claims based upon a risk for which the FDA has made a specific determination, either prior to or after approval, should be preempted. Conversely, state-law failure-to-warn claims should not be preempted when the FDA has not made a specific determination about a particular risk at the time the cause of action arises. In other words, the mere fact that the FDA does not

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14, 2006); Abramowitz v. Cephalon, Inc., No. BER-L-617-04, 2006 WL 560639, at *3–4 (N.J. Super. Ct. Law Div. Mar. 3, 2006).

Technically, *Chevron* deference is accorded to agency interpretations of statutory schemes, whereas *Auer* deference is accorded to agency interpretations of its own regulations. *See* Leslie C. Kendrick, *FDA's Regulation of Prescription Drug Labeling: A Role for Implied Preemption*, 62 FOOD & DRUG L.J. 227, 234 (2007); *see also* Auer v. Robbins, 519 U.S. 452, 461 (1997) (holding an agency's regulatory interpretation controlling unless "plainly erroneous or inconsistent with the regulation") (quotation omitted). In practice, courts meld the two standards. *Compare Sykes*, 484 F. Supp. 2d at 315 (citing the *Auer* standard), *and Bextra*, 2006 WL 2374742, at *8 (same), *with Sykes*, 484 F. Supp. 2d at 313–14 (citing the *Chevron* standard), *and Bextra*, 2006 WL 2374742, at *8 (same).

305 Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514 (E.D. Pa. 2006), *appeal docketed*, No. 06-3107 (3d Cir. June 21, 2006) (argued Dec. 10, 2007).

306 *Id.* at 529 (citing Geier v. Am. Honda Motor Co., 529 U.S. 861, 883 (2000) and Chevron U.S.A. Inc. v. Natural Res. Def. Council, 467 U.S. 837, 844 (1984)).

307 *Id.* at 525; *see also id.* at 529 ("[T]he Supreme Court has explicitly stated that *amicus* briefs are an appropriate form to express preemptive intent."). Arguably, the *Colacicco* Court has a strained reading of Supreme Court precedent, as *Geier* gave agency interpretations "some weight" (consistent with *Skidmore* deference) rather than full *Chevron* deference. *See* Geier v. Am. Honda Motor Co., 529 U.S. 861, 883 (2000); *see supra* notes 112-13 and accompanying text.

require a warning on a product label at the time of initial approval would not preempt failure-to-warn claims; but if the FDA takes some action and rejects a proposed warning, or reviews evidence and declines to require a change, then potential grounds for preemption exist.[308]

This approach depends upon the feasibility of the agency reference model, whereby courts are able to scrutinize the FDA review process and evaluate the reasons set forth by the agency. Courts should scrutinize the regulatory process itself, relying on the FDA as a source of relevant information regarding the precise contours of the risks that it has considered. Such an analysis would be required both where the FDA has taken an affirmative regulatory action as well as where it has declined to do so.[309]

Two federal district court cases, *Perry v. Novartis Pharmaceutical Corp.*[310] and *Dusek v. Pfizer Inc.*,[311] apply this preferred middle course

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308 Note that, under this framework, manufacturing defect claims would survive preemption, as would negligence per se claims, based upon violation of the federal standard. Indeed, the framework discussed throughout is premised upon negligence-based failure-to-warn claims, wherein the jury is asked to evaluate the same risk-risk tradeoffs as the FDA. Were the standard instead one of no-fault or strict liability, there would be a stronger argument that no implied conflict arises. In other words, a manufacturer could be required to pay out money damages for loss-spreading or other rationales (with the significant caveat that such costs be internalized within the relevant state) completely distinct from the regulatory policy ones that are the focus of this Article. That said, I am not aware of a single jurisdiction that employs such a standard for failure-to-warn claims in the pharmaceutical context.

309 Here, I join Richard Nagareda in rejecting the overly broad preemption position urged by the government with respect to its misbranding concern. Like Nagareda, I instead focus upon the underlying regulatory process conducted by the FDA in its drug approval process. *See* Nagareda, *supra* note 36, at 4–5. We part ways, however, with respect to the sharp distinction Nagareda would place between FDA action versus inaction in the regulatory sphere. *See id.* at 29 ("declining to require a given course of conduct by manufacturers is not necessarily the same as declining to permit such conduct"). Whereas for Nagareda regulatory inaction is all of one piece and failure to regulate should never lead to preemption, *see id.* at 40–53, I would continue down one layer further into the regulatory process and distinguish among situations of agency inaction—some of which might lead to preemption.

That said, I am cognizant of the fact that, in practice, it may be difficult to distinguish between different types of agency inaction—one purposive, the other by default—due to lack of resources and the like. Moreover, various forms of agency action and inaction will fall short of what could be termed formal determinations.

310 Perry v. Novartis Pharm. Corp., 456 F. Supp. 2d 678 (E.D. Pa. 2006). At issue was a motion to dismiss a failure-to-warn claim arising from the use of Elidel by a two-year-old infant who was diagnosed with lymphoblastic lymphoma six months after first being given Elidel to treat eczema. *See id.* at 679–81.

311 Dusek v. Pfizer Inc., No. Civ.A. H-02-3559, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004). *Dusek* involved a motion for summary judgment to defeat the plaintiff's tort claim for failure-to-warn of a causal link between Zoloft, an antidepressant medication manufactured by Pfizer, and suicidality. *See id.* at *1.

approach and together demonstrate the preemption-neutrality of its analysis. In *Perry*, the FDA's empirical analysis of the inherent risks of the drug was too inconclusive to warrant a definitive national federal regulatory policy. By contrast, in *Dusek*, the FDA came to a resolute determination, thus forestalling arguments in favor of experimentation or further development of information and establishing instead a preemptive uniform federal standard.

In *Perry*, the more recent of these cases, the court rejected two varieties of the stark pro-preemption position. First, in undertaking its implied preemption analysis, the court eschewed mandatory *Chevron* deference to the FDA preemption preamble.[312] Second, the court likewise rejected the FDA's overly broad misbranding argument, which, like mandatory deference to its preemption preamble, would wipe out all failure-to-warn claims regardless of whether the FDA had issued a finding about the precise risk at issue prior to the injury.[313] But, in holding that the failure-to-warn claim before it was not preempted, the court did not embrace the equally stark anti-preemption position. Instead, the court relied upon the fact that there had been no conclusive determination by the FDA, prior to the time when plaintiff's cause of action arose, based upon its analysis of the relevant risk-risk tradeoffs.[314]

More specifically, as explained in some detail by the FDA in a letter brief to the court, the FDA's Pediatric Advisory Subcommittee concluded that the available information was not sufficient to indicate whether or not the drug caused cancer; on the basis of this indeterminate evidence, the FDA did not take any position on the issue.[315] The court's rejection of preemption of state failure-to-warn claims in this context is thus consistent with the middle course approach, as the lack

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312 *Perry*, 456 F. Supp. 2d at 684 ("[T]he Preamble is not entitled to any special consideration in our analysis."). Indeed, the court follows the analysis I sketched above, suggesting that the FDA's position was entitled to *Skidmore*, not *Chevron*, deference. *See id.* at 683.

313 *See id*. at 685 ("Because the FDA must initiate an enforcement action in order to find a drug misbranded, it will often not be possible for a court to determine after the fact whether a particular warning would have resulted in such a finding." (citation omitted)).

314 *See id.* at 685–86.

315 *See* Letter by the FDA as Amicus Curiae at 6–7, Perry v. Novartis Pharm. Corp., 456 F. Supp. 2d 678 (E.D. Pa. 2006) (No. 05-5350). The Subcommittee, which was convened by the FDA to discuss the monitoring of cancer rates in pediatric patients treated with calcineurin inhibitors, consisted of FDA staff in addition to a number of consultants and experts in the field. *See id.* at 5–6. The meeting took place over a two-day period; at its conclusion, the Subcommittee made no recommendation to the FDA for either action or inaction. *See id.* at 6–7. Transcripts of the Oct. 29 and Oct. 30, 2003 meetings are available at http://www.fda.gov/OHRMS/DOCKETS/ac/cder03.html#Anti-Infective.

of a specific position on the issue by the FDA precluded any of its statements from having a preemptive effect on state law. Moreover, the court went to some pains to emphasize that a different result would obtain where "the FDA has made a conclusive determination, positive or negative, as to the existence of a link between the drug at issue and some adverse health consequence."[316]

*Dusek* represents how the middle course approach can point in the opposite, pro-preemption direction. In *Dusek*, the court focused its attention on the depth of the FDA's prior consideration of the risk at issue: whether Zoloft, an anti-depressant medication in the class of drugs known as Selective Seratonin Reuptake Inhibitors ("SSRIs"), was causally linked to suicidality.[317] While the plaintiff sought a warning that "Zoloft can and does cause suicide in some patients,"[318] the FDA had on at least four prior occasions, between 1991 and 1997, considered such a warning and, each time, had rejected it as unsubstantiated.[319] Although the *Dusek* Court ultimately dismissed the plaintiff's claim as preempted, it did not do so under a wide swath preemption theory,[320] but instead carved out a middle position:

> The Court does not hold that FDA drug approvals in general preempt failure to warn claims. The Court merely rules that permitting Plaintiffs' claim would be authorizing judicially what the FDA already has expressly disallowed. . . . In the face of numerous contentions from several different sources that SSRI antidepressants should contain a warning that they

316 *Perry*, 456 F. Supp. 2d at 685–86.

317 *See* Dusek v. Pfizer Inc., No. Civ.A. H-02-3559, 2004 WL 2191804, at *10 (S.D. Tex. Feb. 20, 2004).

318 *Id.* at *4.

319 The court pointed to three prior occasions—in 1991, 1992, and 1997—when members of the public petitioned the FDA to require a warning of suicidality on labels for other SSRI medications, such as Prozac; the FDA rejected each petition as unsubstantiated. *See id.* at *6. The court also pointed out that in 1991, the FDA's Psychopharmacological Drugs Advisory Committee met to review both expert testimony and relevant scientific studies as to whether a causal link existed between SSRIs and an increased risk of suicide; the committee ultimately concluded that "no credible evidence" existed to support such a conclusion. *Id.*

320 The court considered comments issued by the FDA in an amicus brief filed in a similar case, *Motus v. Pfizer Inc.*, 358 F.3d 659 (9th Cir. 2004); it declined, however, to accord *Chevron* deference to the FDA's stark pro-preemption position articulated in the brief. *See Dusek*, 2004 WL 2191804, at *5 & n.7. Simultaneously, the court also rejected the stark anti-preemption position that FDA regulations are only minimum standards that can be supplemented by state tort law. *See id.* at *9 ("The Court does not dispute Plaintiffs' proposition that FDA approval generally does not shield a drug manufacturer from tort liability. However, . . . [h]ere, the FDA explicitly has stated that the warning Plaintiffs advocate would be inappropriate and should not be given and would misbrand the drug. In such a scenario, the FDA's requirements clearly cease to become minimum requirements and become mandatory.").

> can cause suicide, the FDA has consistently determined no such explicit causation admonition is justified scientifically. . . . Therefore, on the specific facts of this case . . . , Plaintiffs' failure to warn claim is preempted because it is in direct, actual conflict with federal law.[321]

The key inquiry facing both of these courts was the extent to which the FDA had considered and issued a conclusive determination as to the risk at issue in the state tort claim. While there may well be disagreement surrounding what comprises a "conclusive determination," as well as the scope of the relevant "risk at issue," these two cases offer guidance for such an analysis.[322] In *Perry*, the court determined that the FDA's prior consideration of the warning at issue was *not* sufficient to warrant preemption because the meeting of the Pediatric Advisory Subcommittee "was inconclusive and generated no recommendation to the FDA."[323] Mere inaction on the part of the FDA did not suffice; as in *Dusek*, some type of affirmative agency rejection of a warning or a risk was required to justify a finding of preemption.[324] Under the circumstances, the court did not read the inaction on the part of the FDA—in not issuing a determination on potentially harmful effects of the drug at issue—to bar states from doing so

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321 *Id*. at *10. Although the court's preemption holding sounded under a misbranding theory, it was not the same broad misbranding argument pressed by the FDA, which sought to declare preempted *any* warning required by state tort law not otherwise required by the FDA's label-approval process. *See* U.S. *Motus* Br., *supra* note 267, at 15–24. In *Dusek*, the court held that the plaintiff's proposed warning would have misbranded Zoloft, not because the FDA did not require a warning of suicidality at the time of approval, but rather because it had previously considered and rejected the precise warning at issue. *See Dusek*, 2004 WL 2191804, at *10.

322 *See also supra* note 278 (discussing the disputed nature of the precise "risk at issue" that the FDA was called upon to assess in the *Wyeth v. Levine* case). For this reason, it is particularly important for a court to review the full agency record and solicit the agency's views, if they are not already before the court.

323 *See* Perry v. Novartis Pharm. Corp., 456 F. Supp. 2d 678, 687 & n.16 (E.D. Pa. 2006). The *Perry* Court reasoned that when prior FDA consideration of a risk is inconclusive, it "allows a manufacturer that is in possession of information not considered by FDA scientists, or one who desires to act in an abundance of caution, to take steps to include an additional warning pending the FDA's more conclusive determination." *Id.* at 687 n.16.

324 A key element distinguishing the *Perry* case from the *Dusek* case, I believe, was what prompted the prior FDA consideration. In *Dusek*, the court noted that members of the public had filed three petitions requesting the FDA to add a warning of suicidality to SSRI drug labels. *See supra* note 319. To answer these petitions, the FDA necessarily had to make a determination as to whether the warning sought was valid or invalid; each time, the FDA determined it was invalid and accordingly denied the petitions. *See id.* In *Perry*, on the other hand, the FDA's prior consideration was not prompted by petitions. The FDA simply met to discuss cancer rates among pediatric patients treated with calcineurin inhibitors. *See supra* note 315. A specific determination on the validity of a cancer warning neither would be the natural result of such a meeting nor would it be expected.

through tort actions. A close parallel can be drawn here to the *Sprietsma* case. Given the uncertainty and inconclusive findings, the FDA's decision not to require an additional warning in *Perry* is analogous to the Coast Guard's decision not to mandate propeller guards in *Sprietsma*.[325] In both cases, preemption was unwarranted where the relevant federal agency considered a particular risk but the findings were inconclusive and did not point toward adoption of any uniform federal requirement.[326]

The *Dusek* Court, on the other hand, held that the FDA's prior consideration *was* sufficient to preempt where the FDA had previously considered and rejected petitions submitted by members of the public advocating the very same warning.[327] Where the FDA had concluded that there was "no credible evidence" to support a purported risk, a state that nonetheless allowed for claims requiring warning of that risk on a drug label would be in conflict with the agency's action. *Dusek* thus suggests that preemption is warranted where there was a particular warning on the table, through public petition or manufacturer request, that the FDA specifically considered and ultimately rejected based on the information available at the time.[328]

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325 *Cf. supra* text accompanying notes 188–89.

326 *Cf. supra* notes 191–97 and accompanying text.

327 *See* Dusek v. Pfizer Inc., No. Civ.A. H-02-3559, 2004 WL 2191804, at *10 (S.D. Tex. Feb. 20, 2004).

328 Contrast the approach of the *Dusek* Court with that of the court in *Colacicco*, which involved a state tort claim for the failure to warn of the increased risk of suicide associated with Paxil and its generic equivalent. *See* Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 518 (E.D. Pa. 2006), *appeal docketed*, No. 06-3107 (3d Cir. June 21, 2006) (argued Dec. 10, 2007). Paxil, like Zoloft—the drug at issue in *Dusek*—is an SSRI antidepressant medication, so its association with suicide had been investigated in depth by the FDA on multiple occasions since 1991. *See supra* note 319. Although the *Colacicco* Court ultimately reached the same result as the *Dusek* Court—that is, the dismissal of the plaintiff's state tort claim based on a preemption theory—it did so under a wide swath approach, granting *Chevron* deference to the FDA's preemption position in the preamble and amicus brief. *See supra* notes 304–07 and accompanying text. Indeed, the court made clear that it would have dismissed plaintiff's claim regardless of the FDA's prior consideration of the risk at issue, stating that "based on deference alone, this Court would deem *any* state failure-to-warn claim impliedly preempted." *Colacicco*, 432 F. Supp. 2d at 532 (emphasis added).

The *Colacicco* Court could have reached the same preemptive result using *Dusek*'s narrower approach. Like the *Dusek* Court, it acknowledged the depth of the FDA's prior consideration of the risk at issue and the effect it could have on the preemption question, *see id.* at 526–27; the *Colacicco* Court, however, expressly demoted the importance of these facts in its analysis, focusing instead on the deference question by asserting that "*how* the FDA came to its conclusion is far less relevant than the fact that the FDA *did* conclude Plaintiff's claims are preempted. It is the latter to which we give deference . . . ." *Id.* at 526 n.10.

The middle course approach, then, shifts courts' focus from both the preemption preamble and the optimality of drug labeling—a standard that might be unobtainable in a realm as dynamic and ever-changing as drug regulation—to an analysis of whether the FDA has made a conclusive determination about the precise risk at issue. And while there may well be disagreement surrounding what precisely constitutes such a conclusive determination, the *Perry* and *Dusek* cases suggest that such nuanced line-drawing is in fact possible. The agency reference model, premised upon *Skidmore* deference, gives the courts leeway to conduct this type of analysis.

The middle course approach has an additional potential pro-enforcement advantage in that it takes into account the dynamic nature of FDA regulation of drugs by providing manufacturers with incentives to go to the FDA upon discovery of new risks.[329] Under the FDA's sweeping view of preemption, drug manufacturers have no stake in the speed with which an agency determines if a particular adverse risk necessitates additional warning.[330] By contrast, here, only a specific FDA determination that claims of danger are unsubstantiated would insulate a drug manufacturer from liability, thus providing drug companies with a tremendous incentive to ensure the FDA has whatever information it needs to make a cognizable determination. This rule further acknowledges the ability of manufacturers, in possession of information not considered by FDA scientists, to take steps consistent with the FDCA to include an additional warning pending a

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329 Here, I address the same criticism offered by Robert Rabin in the last iteration of this debate, in the context of the regulatory compliance defense in the late 1990s, of assuming a "static regulatory environment" rather than a more realistic situation. *See* Rabin, *supra* note 1, at 2076–77. Rabin, in fact, uses the specific example of the FDA's regulation of prescription drugs, noting that "prescription drugs have a dynamic and often unpredictable life *after* regulatory approval"—including unexpected post-approval side effects in untested populations and time lags between exposure and time effect. *See id.* at 2077.

330 Richard Nagareda has made this point forcefully. *See* Nagareda, *supra* note 36, at 48 ("At present, the pharmaceutical industry stands to reap nothing but benefit from FDA inaction, once the FDA has permitted a new device or drug to reach market."); *see also* 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, 95 (2006) ("If courts extended federal preemption to drug claims . . . manufacturers would have little incentive to conduct post-approval clinical studies to examine a drug's safety. The FDA also would lose one of its few bargaining chips in pressuring companies to amend labels to warn of newly discovered risks.").

The effort to structure preemption rules so as to maximize the information-forcing effects is an extension of the same idea developed in the context of the earlier debate over structuring the regulatory compliance defense. *See, e.g.*, Stewart, *supra* note 168, at 2186 ("[T]he [American Law Institute] study proposal's disclosure condition should help stimulate firms to disclose information about the risks of a product or process that arise after its initial regulatory approval.").

more conclusive determination by the FDA.[331] The middle course approach mitigates information disclosure concerns to the extent that manufacturers would not have the prospect of complete immunity based upon initial FDA approval and thus would no longer have the same incentive to oppose efforts by the FDA to build upon previously approved warnings.[332]

Indeed, drug manufacturers may have an added incentive to come forward with new information. The middle course approach carves out a role for state tort law without interfering with the FDA's increasingly broad understanding of the federal objectives implicated by the FDCA. Here, again, the *Perry* Court recognized this potential information-forcing effect, observing "that state law may require a manufacturer to at least seek FDA approval for the addition of a new warning where there has been no determination by the agency whether there is a link between the adverse health effect to be warned against and the use of the drug."[333] Although the court recognized that principles of federal preemption may preclude application of state law to compel a drug manufacturer to alter its labeling absent FDA approval,[334] there is no reason to bar states from enacting laws that merely require the drug companies to petition the agency in favor of a particular warning.

### *Conclusion*

The Supreme Court is well poised to fashion a new framework for preemption. With *Riegel v. Medtronic, Inc.*[335] and *Warner-Lambert Co., LLC v. Kent*[336] this Term and *Wyeth v. Levine*[337] pending for next

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331 *See* 21 C.F.R. § 314.70(c)(6)(iii)(A) (2007).

332 *Cf.* Globetti v. Sandoz Pharm. Corp., No. CV98-TMP-2649-S, 2001 WL 419160, at *2 n.1 (N.D. Ala. Mar. 5, 2001) ("[D]rug manufacturers could avoid liability simply by resting on the formerly approved package insert (regardless of how long ago the approval occurred and how much information about the drug had changed) and resist all efforts to change it. The FDA approval of the package insert becomes a complete bar to liability, regardless of how inadequate it may have become over time.").

333 Perry v. Novartis Pharm. Corp., 456 F. Supp. 2d 678, 685 (E.D. Pa. 2006).

334 *See id.* at 685 n.12 ("[A]lthough state law can require a manufacturer to seek FDA approval for a new warning, it cannot require the addition of the warning without approval if there is a reasonable risk that the addition would lead to an FDA determination of misbranding.").

335 Riegel v. Medtronic, Inc., No. 06-179, 2008 WL 440744 (U.S. Feb. 20, 2008).

336 Desiano v. Warner-Lambert & Co., 467 F.3d 85 (2d Cir. 2006), *aff'd per curiam by an equally divided Court sub nom.* Warner-Lambert Co., LLC v. Kent, 2008 WL 552875 (U.S. Mar. 3, 2008) (No. 06-1498).

337 Levine v. Wyeth, No. 2004-384, 2006 WL 3041078 (Vt. Oct. 27, 2006), *cert. granted*, 76

Term, the issue of products liability preemption has moved to the fore. The FDA has argued forcefully in favor of preemption in each case.[338]

Federal agencies have been the key players, often behind the scenes, in Supreme Court products liability preemption cases. The institutional approach advanced in this Article seeks to refine and organize their input on the question of whether a uniform federal regulatory policy should exist in a particular area. The agency reference model emerges as a satisfying descriptive and normative account of judicial decisionmaking in products liability preemption cases.

The Supreme Court (as well as lower federal and state judges) faced with the task of deciding whether state-law failure-to-warn claims are preempted in pharmaceutical drug cases might be guided by the model, which steers a middle course approach between two existing polar approaches taken by courts: the anti-preemption "presumption against preemption" tack and the pro-preemption approach that accords *Chevron* deference to the FDA's field preemptive misbranding position.

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U.S.L.W. 3018 (U.S. Jan. 18, 2008) (No. 06-1249) (to be argued October Term 2008). The Court granted certiorari on the following question presented:

> Whether the prescription drug labeling judgments imposed on manufacturers by the [FDA] pursuant to FDA's comprehensive safety and efficacy authority under the [FDCA] preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use.

http://www.supremecourtus.gov/qp/06-01249qp.pdf.

338 *See* U.S. *Riegel* Br., *supra* note 121; Brief for the United States as Amicus Curiae Supporting Petitioners, Warner-Lambert Co., LLC v. Kent, 2007 WL 4218889 (U.S. Nov. 28, 2007) (No. 06-1498); U.S. *Wyeth* Br., *supra* note 279.