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**FEDERALISM IN ACTION:  
FDA REGULATORY PREEMPTION IN  
PHARMACEUTICAL CASES  
IN STATE VERSUS FEDERAL COURTS**

*Catherine M. Sharkey*\*

INTRODUCTION

Federal preemption of state tort law unequivocally alters the balance between federal and state power. In this hotly contested field, all would agree that “[t]he extent to which a federal statute displaces (or preempts) state law affects both the substantive legal rules under which we live and the distribution of authority between the states and the federal government.”<sup>1</sup> Courts and academics have, accordingly, widely discussed and debated the federalism implications of preemption.<sup>2</sup> But the discussion has,

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\* Professor of Law, New York University School of Law. For helpful suggestions and comments, I thank Michael Dorf, Samuel Issacharoff, Gillian Metzger, Burt Neuborne, Gil Seinfeld, Cass Sunstein, and Amanda Tyler. Jaime Sneider provided superb research assistance.

<sup>1</sup> Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 225-26 (2000); Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2117 (2000) (characterizing the Supreme Court’s preemption analysis as an effort to redefine “the proper balance of legislative powers between Congress and the states”).

<sup>2</sup> For a sampling of the rich academic literature, see Richard H. Fallon, Jr., *The “Conservative” Paths of the Rehnquist Court’s Federalism Decisions*, 69 U. CHI. L. REV. 429, 471 (2002) (“Whereas one might expect pro-federalism Justices to disfavor claims of federal preemption of state law, substantive conservatism may help to explain why the Court has so frequently upheld preemption claims in recent years.”); Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 U.C.L.A. L. REV. 1353, 1357

to date, overlooked what I shall term “federalism in action”: whether, and why, state and federal judges adopt divergent approaches to the same interpretive exercise.<sup>3</sup>

Federal preemption of state tort law in the products liability realm is a particularly suitable context for this exploration because state and federal judges are routinely called upon to interpret the same federal statute and products liability trials that take place roughly equally in state and federal courts.<sup>4</sup> The

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(2006) (“Rather than standing as an ally of state autonomy against the encroachments of the federal behemoth . . . the Court appears to be a willing partner of Congress in providing federal oversight to state interference with the national market.”); Calvin Massey, *Federalism and the Rehnquist Court*, 53 HASTINGS L.J. 431, 508 (2002) (“[T]he failure of the Court to apply preemption doctrine sparingly, and with real attention both to Congress’s intent and the values of federalism, will in the long run prove disastrous to . . . the very real values . . . inherent in federalism.”); Daniel J. Meltzer, *The Supreme Court’s Judicial Passivity*, 2002 S. CT. REV. 343, 368-69 (remarking upon the “contrast . . . between the approach taken by individual Justices in preemption cases and the approach that the same Justices take to issues of constitutional federalism”); and Ernest A. Young, *The Rehnquist Court’s Two Federalisms*, 83 TEX. L. REV. 1, 131 (2004) (“Doctrines limiting federal preemption of state law thus go straight to the heart of the reasons why we care about federalism in the first place.”).

<sup>3</sup> A notable recent exception is Anthony J. Bellia, Jr., *State Courts and the Interpretation of Federal Statutes*, 59 VAND. L. REV. 1501 (2006), which emphasizes that “how courts ought to interpret federal statutes is not only a ‘horizontal’ question of the separation of powers between federal courts and Congress, but also a ‘vertical’ question of the proper relationship between Congress and state courts—in other words, a federalism question.” *Id.* at 1503; *id.* (“State courts play an important, often independent, role in the interpretation of federal statutes. Accordingly, the question of how they ought to interpret federal statutes should figure prominently in federal statutory interpretation debates.”).

<sup>4</sup> While a mere 9 percent of tort jury trials are litigated in federal district courts, “[a]lmost half of product liability trials (46 percent) that reached a verdict in 1992, 1996, and 2001 were handled by the federal courts.” Thomas C. Cohen, *Do Federal and State Courts Differ in How They Handle Civil Trial Litigation: A Portrait of Civil Trials in State and Federal District Courts* 17 (unpublished manuscript, available at <http://ssrn.com/abstract=912691>) [hereinafter Cohen, *Civil Trial Litigation*]. Moreover, “[i]n comparison to the state courts, products liability jury trials occurred more frequently in the federal courts.” *Id.* at 8 (reporting that roughly 22

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alleged parity between state and federal courts has been vigorously debated in the context of the enforcement of federal constitutional rights.<sup>5</sup> Thus far, however, the realm of federal

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percent of federal tort jury trials involved products liability issues as compared to less than 5 percent of state tort trials). Defendants are active in seeking removal in products cases. According to Cohen, in his sample of 584 non-asbestos products liability trials in federal district court, 35 percent originated in state court and were removed to federal court. Email from Thomas Cohen, Statistician, Bureau of Justice Statistics, to Catherine M. Sharkey, Professor of Law, Columbia Law School (Apr. 16, 2007) (on file with author). *See also* Theodore Eisenberg & Trevor Morrison, *Overlooked in the Tort Reform Debate: The Growth of Erroneous Removal*, 2 J. EMPIRICAL LEG. STUD. 551 (2005) (depicting an increasing trend of defendants removing diversity cases from state to federal court).

<sup>5</sup> *See, e.g.*, Burt Neuborne, *The Myth of Parity*, 90 HARV. L. REV. 1105, 1119-20 (1977) (arguing that “given the institutional differences between the two benches, state trial judges are less likely to resolve arguable issues in favor of protecting federal constitutional rights than are their federal brethren”); Burt Neuborne, *Parity Revisited: The Uses of a Judicial Forum of Excellence*, 44 DEPAUL L. REV. 797, 799 (1995) (“I continue to believe that a relative institutional advantage for the plaintiff exists in federal court; an advantage resulting from a mix of political insulation, tradition, better resources and superior professional competence.”); Michael Wells, *Behind the Parity Debate: The Decline of the Legal Process Tradition in the Law of Federal Courts*, 71 B.U. L. REV. 609, 644 (1991) (citing a “systematic disparity between federal and state court judges”).

Empirical studies have attempted to reassert the parity claim and debunk the competing disparity one. *See, e.g.*, Michael E. Solimine, *Rethinking Exclusive Federal Jurisdiction*, 52 U. PITT. L. REV. 383 (1991) (concluding, based upon review of 114 Section 1983 cases, that federal and state courts provide substantially the same likelihood of relief and evidence a comparable comprehension of federal law); Michael E. Solimine & James L. Walker, *Constitutional Litigation in Federal and State Courts: An Empirical Analysis*, 10 HASTINGS CONST. L.Q. 213 (1983) (concluding that sample of more than 1,000 federal district court and state appellate court decisions evidences parity in the treatment of First Amendment, Fourth Amendment, and equal protection claims). *See also* William B. Rubenstein, *The Myth of Superiority*, 16 CONST. COMMENT 599, 599 (1999) (challenging parity and Neuborne’s thesis in concluding based on personal experience as a civil liberties litigator that “gay litigants seeking to establish and vindicate civil rights have generally fared better in state courts than they have in federal courts”). Not only have the methodology and conclusions of these individual studies been assailed, *see, e.g.*, Susan N. Herman, *Why Parity Matters*, 71 B.U. L. REV.

statutory interpretation has evaded similar scrutiny.<sup>6</sup>

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651 (1991), but the entire empirical enterprise has come under withering attack as either politically manipulable given the lack of objective measures or else entirely beside the point, *see, e.g.*, Erwin Chemerinsky, *Ending the Parity Debate*, 71 B.U. L. REV. 593 (1991) (proposing a litigation choice model whereby plaintiffs have the choice of a state or federal forum); Martin H. Redish, *Judicial Parity, Litigant Choice, and Democratic Theory: A Comment on Federal Jurisdiction and Constitutional Rights*, 36 U.C.L.A. L. REV. 329 (1988) (defending an abstention doctrine that puts the onus on Congress to determine when federal jurisdiction is desirable and appropriate). *See also* Michael E. Solimine & James L. Walker, *State Court Protection of Federal Constitutional Rights*, 12 HARV. J.L. PUB. POL'Y 127 (1989) (responding to criticisms of their original empirical study).

<sup>6</sup> This Essay, then, merely scratches the surface of what may prove a fertile area of comprehensive study. Indeed, a cursory review of recent preemption cases before the U.S. Supreme Court provides anecdotal support for the existence of a more widespread preemption disparity thesis. Take, for example, the case that reached the U.S. Supreme Court in 2005 as *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005). The federal circuits were virtually unanimous in holding that FIFRA preempted state tort claims, while a few outlier state courts had rejected preemption. *Compare, e.g.*, *King v. E.I. Dupont De Nemours & Co.*, 996 F.2d 1346 (1st Cir. 1993); *Hawkins v. Leslie's Pool Mart, Inc.*, 184 F.3d 244, 246 (3d Cir. 1999); *Worm v. Am. Cyanamid Co.*, 5 F.3d 744, 748 (4th Cir. 1993); *Dow Agrosciences LLC v. Bates*, 332 F.3d 323 (5th Cir. 2003); *Kuiper v. Am. Cyanamid Co.*, 960 F. Supp. 1378 (7th Cir. 1997); *Hardlin v. BASF Corp.*, 397 F.3d 1082 (8th Cir. 2005); *Natham Kimmel, Inc. v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 981 F.2d 1177, 1179 (10th Cir.1993); *Oken v. Monsanto Co.*, 371 F.3d 1312, 1314-15 (11th Cir. 2004), *with e.g.*, *Ciba-Geigy Corp. v. Alter*, 834 S.W.2d 136, 141 (Ark. 1992) (“[S]tate common law tort claims for inadequate labeling are neither expressly nor impliedly preempted by FIFRA.”); *Dow Chemical Co. v. Ebling ex rel. Ebling* 753 N.E.2d 633, 636 (Ind. 2001) (“FIFRA does not preempt the plaintiffs’ failure to warn claims . . . .”); *Sleath v. West Mont Home Health Services, Inc.*, 16 P.3d 1042, 1053 (Mont. 2000) (same); *Brown v. Chas. H. Lilly Co.*, 985 P.2d 846, 853 (Or. App. 1999) (same). *See also* *Geier v. American Honda Motor Co.*, 529 U.S. 861, 866 (2000) (“All of the Federal Circuit Courts that have considered the question . . . have found pre-emption[.]” whereas “[s]everal state courts have held to the contrary.”); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 508-09 & n. 2-3 (1992) (noting split in authority between several federal courts of appeals, which had held that federal cigarette labeling statutes preempted state law claims, and two state supreme courts,

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In this Essay, I focus on the divergent approaches of state and federal courts in deciding whether the Federal Food Drug and Cosmetic Act (FDCA),<sup>7</sup> and accompanying regulations promulgated by the Food and Drug Administration (FDA), preempt state failure to warn claims brought against pharmaceutical companies. Intuitively, one might expect state court judges to be comparatively hostile to claims of federal incursions onto their state law turf. In fact, a recent empirical study of nearly 300 products liability preemption cases revealed that “federal courts are considerably more likely to find preemption than are state courts.”<sup>8</sup> This result fits the

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which held to the contrary that the federal statutes did not preempt similar common law claims).

In similar fashion, the Court’s certiorari grant in *Watters v. Wachovia Bank, N.A.*, 127 S. Ct. 1559 (2007), a regulatory preemption case last Term, took many by surprise, given the consensus for preemption in the lower federal courts. 431 F.3d 556, 560-63 (6th Cir. 2005) (case below) (holding that state attempts to regulate the operating subsidiaries of national banks are preempted by the National Bank Act and Office of the Comptroller of the Currency regulations). See *National City Bank of Indiana v. Turnbaugh*, 463 F.3d 325, 331-34 (4th Cir. 2006); *Wachovia Bank, N.A. v. Burke*, 414 F.3d 305, 315-16 (2d Cir. 2005); *Wells Fargo Bank N.A. v. Boutris*, 419 F.3d 949, 962-67 (9th Cir. 2005). Moreover, all but one state signed onto a brief in opposition to preemption of the claims in *Watters*. Brief of the States of New York et al. as Amicus Curiae in Support of the Petitioner, *Watters v. Wachovia Bank, N.A.*, No. 05-1342 (Sept. 1, 2006), 2006 WL 2570992.

<sup>7</sup> Pub. L. No. 75-171, 52 Stat. 1040 (1938); Pub. L. No. 87-781, 76 Stat. 781 (1962) (Kefauver-Harris Amendment); Food and Drug Administration Modernization Act of 1997, Pub. L. 105-115.

<sup>8</sup> Keith N. Hylton, *Preemption and Products Liability: A Positive Theory* 20 (Aug. 2006) (unpublished manuscript, available at <http://ssrn.com/abstract=433661>). Hylton reports that “[o]f the total claims, federal courts found 61 percent preempted while state courts found 42 percent preempted.” *Id.* The comparative statistics are even more dramatic in the subset of failure to warn claims. *Id.* (“For failure to warn claims, federal court preemption rate is 74 percent, while the state court preemption rate is 53 percent, which is statistically significant at the conventional five percent level.”).

In making any comparisons of preemption rates across state and federal courts, however, one must be cognizant of potential selection bias—namely, that products cases are not distributed randomly between state and federal

“widespread perception among attorneys, litigants, and policymakers that defendants are provided with more favorable forums than plaintiffs in the federal courts,”<sup>9</sup> and the corresponding observation that “much of the complex personal injury and commercial litigation arising under state law is routed into the federal courts by the corporate bar desirous of obtaining the technical advantages which federal trial courts are perceived to enjoy over their state counterparts.”<sup>10</sup>

This conventional explanation of the state-federal disparity overlooks two salient factors, which are at the heart of the FDA drug labeling preemption debate and the main focus of this Essay. First, the recurrent debate—in the academy and the courts—regarding the interplay between federal regulations and state common law tort actions has, in less than a decade, radically shifted from regulatory compliance to federal preemption. If state courts have an institutional interest in

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courts and may therefore differ in kind.

<sup>9</sup> Cohen, *supra* note 4, at 2. Subjecting this widely held perception to empirical analysis, Cohen’s study finds that “[o]verall, the rates in which plaintiffs won at trial were nearly equal in both the state and federal court systems.” *Id.* at 9. A marked disparity does, however, emerge in the realm of products liability: “In state courts, plaintiffs prevailed in 38 percent of product liability jury trials and in federal courts, the plaintiff success rate was 30 percent.” *Id.* at 10.

<sup>10</sup> Neuborne, *The Myth of Parity*, *supra* note 5, at 1130 n.88. *See also* Stephen Burbank, *Vanishing Trials and Summary Judgment in Federal Civil Cases: Drifting Toward Bethlehem or Gomorrah?*, 1 J. EMPIRICAL LEG. STUD. 591 (2004) (suggesting pro-defendant bias in that federal courts are more likely than state courts to grant summary judgment or to dismiss a case); Eisenberg & Morrison, *supra* note 4 (demonstrating increasing trend of defendants’ efforts to remove cases from state to federal court). A further pro-defendant bias operating at the federal appellate level is discussed in Kevin Clermont & Theodore Eisenberg, *Anti Plaintiff Bias in the Federal Appellate Courts*, 84 JUDICATURE 128 (2001-02) and Theodore Eisenberg, *Appeal Rates and Outcomes in Tried and Nontried Cases: Further Exploration of Anti-Plaintiff Appellate Outcomes*, 1 J. EMPIRICAL LEG. STUD. 659 (2004). For a critical take on this research, see Harry T. Edwards & Linda Elliott, *Beware of Numbers (And Unsupported Claims of Judicial Bias)*, 80 WASH. U. L.Q. 723 (2002) (characterizing Eisenberg’s conclusion as “specious,” his reasoning as “flawed,” and his empirical research as “deficient”).

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preserving the autonomy of state common law from broad federal overrides, then presumably one should expect the same resistance to claims of outright preemption. Perhaps most striking, then, is not the fact that federal courts' enthusiasm for preemption outpaces state courts, but the fact that preemption has gained any traction whatsoever in state courts, which by and large have previously rejected any absolute regulatory compliance defense. If state courts are now willing to entertain preemption arguments, even if not at the same level as federal courts' affinity for such claims, then the simple turf-guarding story has to be treated with some suspicion.

Second, a myopic institutional focus on the courts alone misses the critical role and influence of federal agencies. In our modern regulatory state, federal agencies have assumed a dominant role in statutory interpretation.<sup>11</sup> For instance, in 2006, the FDA promulgated a regulation governing the format and content of prescription drug labels.<sup>12</sup> In a preamble to the regulation, the FDA set forth its belief that the federal regulation trumped competing state regulatory and common law.<sup>13</sup> Such aggressive maneuvering by the FDA (and other federal agencies) on the preemption front has sparked considerable debate.<sup>14</sup> In the post-preamble world, state and federal courts have been faced with vexing questions raised by the clash of two competing canons of interpretation: the presumption against preemption in areas of traditional state purview and the mandatory *Chevron* deference accorded to agency interpretations

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<sup>11</sup> See EINER ELHAUGE, STATUTORY DEFAULT RULES at 153 (book manuscript) (forthcoming 2007) (“[M]ost statutory interpretations today are administrative ones . . .”).

<sup>12</sup> Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (effective date June 30, 2006).

<sup>13</sup> *Id.* at 3934 (“[U]nder existing pre-emption principles, FDA approval of labeling under the act . . . preempts conflicting or contrary State law.”).

<sup>14</sup> See, e.g., Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007) (characterizing the trend of federal agencies' issuance of preambles into their regulations that purport to preempt conflicting or contrary state law as a form of backdoor federalization of products liability).



of ambiguous statutes.<sup>15</sup> What has thus far been overlooked is the extent to which federal agencies' role and influence may be a driving force behind the state-federal disparity in preemption determinations. In the realm of FDA prescription drug preemption, not only are federal courts more likely to defer to federal agencies, but—equally important in terms of explaining the decision-making process of courts—federal courts are more likely than state courts to solicit the views of the FDA and the FDA is more apt to intervene on its own in federal court cases.

This Essay proceeds in three parts. The first two explore what I have identified as two salient features that might explain divergent approaches of state and federal courts to the FDA drug labeling preemption analysis: (1) the radical shift in the debate from regulatory compliance to preemption; and (2) the role and influence of the FDA. I conclude with some thoughts regarding the federalism implications of state-federal court differences in approach to the preemption inquiry.

#### I. THE SHIFT FROM REGULATORY COMPLIANCE DEFENSE TO FEDERAL PREEMPTION

In 2000, the *Georgetown Law Journal* published a seminal symposium issue on the regulatory compliance defense.<sup>16</sup> The volume was a culmination of the fervent interest in the

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<sup>15</sup> The U.S. Supreme Court had an opportunity last Term to provide some further guidance on the interplay between the presumption against preemption and *Chevron* deference in the *Watters* case. *See supra* note 6. The majority, however, took the position that the deference issue was “beside the point, for under our interpretation of the statute, the level of deference owed to the regulation is an academic question.” 127 S. Ct. 1559, 1572 (2007). *Compare id.* n.13 (“Because we hold that the [National Banking Act] itself— independent of OCC’s regulation—preempts the application of 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.”).

<sup>16</sup> Symposium, *Regulatory Compliance as a Defense to Products Liability*, 88 GEO. L.J. 2049 (2000).

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regulatory compliance defense on the part of academics, policymakers, courts and legislatures over the last quarter of the 20th century. In the early 1990s, the American Law Institute, as part of its Reporter's Study on *Enterprise Responsibility for Personal Injury*, weighed in with a regulatory compliance proposal based on the principle that supplementing administrative regulation with tort produces unreasonably high transaction costs in manufacturing and inconsistent risk-benefit analysis.<sup>17</sup> Notwithstanding the ALI's endorsement, the regulatory compliance defense ultimately amounted to a conceptual broadside that failed to take root in the case law.

Now, federal preemption of state tort liability has replaced regulatory compliance as a dominant issue for the 21<sup>st</sup> century. Preemption's grip on scholars is evinced by the recent series of law review symposia convened on the subject.<sup>18</sup> A prominent conservative think-tank, the American Enterprise Institute in Washington, D.C., has deemed regulatory preemption a central theme of its "Federalism Project."<sup>19</sup> Aggressive agency

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<sup>17</sup> See, e.g., 2 AMERICAN LAW INSTITUTE, REPORTER'S STUDY, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY (1991) (proposing a limited regulatory compliance defense on the grounds that supplementing administrative regulation with tort produces unreasonably high transaction costs in manufacturing and inconsistent risk-benefit analysis).

<sup>18</sup> Symposium, *Ordering State-Federal Relations Through Federal Preemption Doctrine*, 101 NW. U. L. REV. (forthcoming 2007); Symposium, *Federal Preemption of State Tort Law: The Problem of Medical Drugs and Devices*, 33 PEPP. L. REV. 1 (2005). See also Richard Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L. (2006), available at <http://www.bepress.com/jtl>; 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. (2006), available at <http://www.bepress.com/jtl>.

<sup>19</sup> American Enterprise Institute, *Federal Preemption: Law, Economics, Politics*, available at <http://www.federalismproject.org/preemption> ("The AEI Federalism Project conducts and sponsors original research on American federalism, with particular emphasis on federal and state business regulation, legal developments and the role of the courts, and the prospects for rehabilitating a constitutional federalism that puts states in competition for productive citizens and businesses."). Scholarly papers generated from the conference hosted by AEI were published in *FEDERAL PREEMPTION: STATES'*

maneuvers, like the FDA's issuance of its preemption preamble, has stoked even further interest in the subject.<sup>20</sup>

The shift from regulatory compliance to federal preemption is, at first glance, somewhat perplexing given that the latter is, in essence, a blunter instrument than the former, which on the whole failed to gain traction in jurisdictions across the country. Certainly the United States Supreme Court has played an influential role here. In the watershed 1992 case of *Cipollone v. Liggett Group*,<sup>21</sup> a divided Court signaled a willingness to set aside state common law in the name of federal objectives, leading to an upsurge in the use of preemption as a defense in products cases.<sup>22</sup> In this section, I propose that state court judges, influenced by legislative and common law hostility toward the regulatory compliance defense, would tend to be more predisposed against preemption arguments than federal court judges, conditioned to see the last decade or so of the U.S. Supreme Court's products liability preemption through a wider preemption jurisprudence lens.

#### A. *Regulatory Compliance Defense in State Courts*

It is hardly an exaggeration to claim that the push for a strong regulatory compliance defense to tort liability—in the

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POWERS, NATIONAL INTERESTS (Richard A. Epstein & Michael S. Greve eds.) (2007).

<sup>20</sup> See, e.g., Sharkey, *supra* note 14, at 229-42 (discussing recent spate of preemption preambles issued by FDA, NHTSA, and CPSC). The Department of Homeland Security is one of the latest agencies to announce a rule indicating its belief that agency regulations impliedly preempt state law. See 71 Fed. Reg. 78276 (Dec. 28, 2006) (“The Department is particularly concerned that a conflict or potential conflict between an approved Site Security Plan and state regulatory efforts could create ambiguity that would delay or compromise implementation of security measures at a facility.”).

<sup>21</sup> 505 U.S. 504 (1992).

<sup>22</sup> Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 WM. & MARY L. REV. 903, 904 (1996) (“The Supreme Court's decision in [*Cipollone*] . . . triggered a notable upsurge in the successful use of preemption as a defense to products liability lawsuits.”).

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pharmaceutical context, immunizing drug manufacturers from liability where they have met or exceeded federal standards—advocated by a host of scholars and policymakers has been an abject failure.<sup>23</sup> Today, Michigan stands alone in having adopted, by statute, blanket immunity based upon federal regulatory compliance.<sup>24</sup> Several additional states (Colorado, Indiana, Kansas, Kentucky, New Jersey, Tennessee, Texas, and Utah) provide weaker protection in the form of a rebuttable presumption that FDA-approved warnings are adequate in the

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<sup>23</sup> See, e.g., Richard C. Ausness, *The Case For a “Strong” Regulatory Compliance Defense*, 55 MD. L. REV. 1210, 1212 (1996) (“[M]ost courts allow juries to take compliance with regulatory standards into account, but steadfastly refuse to treat federal safety standards as anything more than minimum standards.”); James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 320 (1990) (“[F]or reasons that we find difficult to understand, courts have not deferred to the determinations of product safety agencies. . . . The analysis usually begins and ends with the statement that agency standards are minimum, not maximum, standards and that courts are therefore free to disregard them.”).

<sup>24</sup> MICH. COMP. LAWS ANN. § 600.2946(5) (2007) (“In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration’s approval at the time the drug left the control of the manufacturer or seller.”). Michigan’s immunity provision, moreover, is under attack. See, e.g., Michelle Miron, *Local Leaders Fear Change to Drug-suit Law*, KALAMAZOO GAZETTE (March 2, 2007) (describing “proposed changes in a law [passed by the Michigan House and headed for the Senate] that makes it nearly impossible for Michigan citizens to sue drug companies when prescription drugs cause death or injury”), available at <http://www.mlive.com/news/kzgazette/index.ssf?base/news22/1172852630246550.xml&coll=7>. Several states (Arizona, Colorado, New Jersey, Ohio, Oregon, and Utah) provide more limited immunity from punitive damages where the FDA has approved warnings. ARIZ. REV. STAT. ANN. § 12-701 (2003); COLO. REV. STAT. § 13-64-302.5(5)(a) (2004); N.J. STAT. ANN. § 2A:58C-5(c) (West 2000); OHIO REV. CODE ANN. § 2307.80(c)(1) (2005); OR. REV. STAT. § 30.927(1)(a) (2003); UTAH CODE ANN. § 78-18-2(1) (2002).

face of failure to warn claims.<sup>25</sup> But a strong super-majority of state jurisdictions stands opposed to the regulatory compliance defense; the conventional view is that regulatory compliance is simply one factor to be taken into account in tort actions.<sup>26</sup>

Debate over the regulatory compliance defense—in general, and as applied specifically to pharmaceuticals—has occupied scholars for the better part of the last quarter century. Some deplore courts' rejection of the defense and sustained use of common law remedies even in areas where specific conduct is regulated—especially with respect to failure to warn claims.<sup>27</sup> As

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<sup>25</sup> See COLO. REV. STAT. § 13-21-403(1) (2004); IND. CODE ANN. § 34-20-5-1 (2004); KAN. STAT. ANN. § 60-3304(a) (1995 & Supp. 2004); KY. REV. STAT. ANN. § 411.310(2) (West 2004); TENN. CODE ANN. § 29-28-104; UTAH CODE ANN. § 78-15-6(3). For statutory provisions targeted specifically at FDA-approved warnings, see also COLO. REV. STAT. § 13-21-403(1)(b) (2004); N.J. STAT. ANN. § 2A:58C-4 (West 2000); TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 (Vernon 2005).

<sup>26</sup> See, e.g., *Carlin v. Superior Court*, 920 P.2d 1347, 1365 (Cal. 1996) (“The manufacturer’s compliance with product safety statutes or regulations such as those of the FDA would also be relevant, but not necessarily controlling.”); *Brooks v. Beech Aircraft Corp.*, 902 P.2d 54, 63 (N.M. 1995) (“[E]vidence of compliance with applicable regulations, is relevant to whether the manufacturer was negligent or whether the product poses an unreasonable risk of injury, but that such evidence should not conclusively demonstrate whether the manufacturer was negligent or the product was defective.”). See generally JAMES A. HENDERSON & AARON D. TWERSKI, *PRODUCTS LIABILITY: PROBLEMS AND PROCESS* 293 (5th ed. 2004) (“Several states treat compliance with statute as a presumption of non-defectiveness. . . . However, decisions have indicated a judicial unwillingness to apply these presumptions with any bite.”).

Some states go beyond rejecting the regulatory compliance defense by cabining defendants’ ability to make a state of the art defense. See, e.g., *Feldman v. Lederele Labs.*, 479 A.2d 374, 388 (N.J. 1984) (“[T]he defendant should properly bear the burden of proving that the information was not reasonably available or obtainable and that it therefore lacked actual or constructive knowledge of the defect.”). As James Henderson and Aaron Twerski observed, “[g]iven that defendants are unlikely to carry the burden of proving a negative, the modified New Jersey rule may be the functional equivalent of true strict liability.” Henderson & Twerski, *supra* note 23, at 275.

<sup>27</sup> See, e.g., Richard A. Epstein, *Legal Liability for Medical Innovation*,

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one commentator notes, “a defendant often will have printed on the label of its product the exact words of a warning mandated by statute and in the particular size and manner statutorily required for the specific type of product sold.”<sup>28</sup> That “courts have freely imposed common law tort liability on defendants in compliance with the relevant [warning] statute” is all the “more troubling” in the related context of design defect.<sup>29</sup>

The troubling aspects are (at least) twofold. One set of objections, highlighted by David Geiger and Mark Rosen, contends that tort liability, subsequent to FDA drug approval, constitutes “retrospective jury nullification” of FDA regulations and “is contrary to public policy.”<sup>30</sup> A separate line of attack advocated by Kip Viscusi (among others), is that tort liability is, at best, useless and, at worst, counterproductive in terms of ensuring safer drugs.<sup>31</sup>

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8 CARDOZO L. REV. 1139, 1151 (1987) (“What is needed . . . is a rule that provides that certain warnings approved by, say, the FDA shall be *conclusively* regarded as adequate in any subsequent lawsuit.”); James A. Henderson, Jr., *Manufacturers’ Liability for Defective Product Design: A Proposed Statutory Reform*, 56 N.C. L. REV. 625, 639 (1978); Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277 (1985).

<sup>28</sup> Paul Dueffert, Note, *The Role of Regulatory Compliance in Tort Actions*, 26 HARV. J. ON LEGIS. 175, 200 (1989).

<sup>29</sup> *Id.*

<sup>30</sup> 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).

<sup>31</sup> W. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1480 (1994) (“Tort law in the pharmaceutical context has proven to be an extraordinarily expensive regime that suffers from institutional constraints limiting its accuracy. . . . [W]here the manufacturer has complied with the FDCA and its implementing regulations, tort law does not appear to have significant ability to generate safer drugs.”); W. Kip Viscusi, *Toward a Diminished Role for Tort Liability: Social Insurance, Government Regulation, and Contemporary Risks to Health and Safety*, 6 YALE J. ON REG. 65 (1989). *See also* Epstein, *supra* note 18 (“What possible reason is there not to preempt [pharmaceutical] litigation which on balance is worse than useless?”).

Others extol the virtues of common law liability even in the face of regulatory compliance.<sup>32</sup> Robert Rabin, for example, upholds as “counterweights to a regulatory expertise model . . . claims for respecting state autonomy, for attending the nonefficiency goals such as compensation, for acknowledging dynamic social utility goals such as monitoring the ethics of business practices, and for recognizing the often unanticipated circumstances under which risks come to fruition.”<sup>33</sup> According to Rabin, two key features of the tort system—its role “as an information-generating mechanism and as a compensatory system”—“suggest its complementary characteristics to regulation.”<sup>34</sup> The crux of the debate boils down to whether agencies, such as the FDA, promulgate minimum or optimal safety standards.<sup>35</sup> As Rabin remarks, “no serious commentator would argue for a regulatory compliance defense in circumstances where the agency regulations are regarded as minimum safety standards rather than optimal standards.”<sup>36</sup>

FDA-approved drugs may provide one of the strongest cases for the regulatory compliance defense,<sup>37</sup> given that the FDA sets

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<sup>32</sup> See, e.g., Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L.J. 2119, 2123 (2000) (“[A] regulatory compliance defense for pharmaceuticals is not nearly as scalpel-sharp as some, who ignore the details, have led us to believe.”).

<sup>33</sup> Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2084 (2000).

<sup>34</sup> *Id.* at 2061.

<sup>35</sup> See, e.g., *Wilson v. Piper Aircraft Corp.*, 577 P.2d 1322, 1333 (Or. 1978) (Linde, J., concurring) (“The role of such [regulatory] compliance should logically depend on whether the goal to be achieved by the particular government standards, the balance struck between safety and its costs, has been set higher or lower than that set by the rules governing the producer’s civil liability. It may well be that when government intervenes in the product market to set safety standards, it often confines itself to demanding only minimum safeguards against the most flagrant hazards, well below the contemporary standards for civil liability. But that . . . is not necessarily so for all products today.”), *reh’g denied*, 579 P.2d 1287 (Or. 1978).

<sup>36</sup> Rabin, *supra* note 33, at 2074.

<sup>37</sup> This point is conceded even by those who argue against the regulatory compliance defense. See, e.g., *id.* (“[M]any scholars have regarded FDA licensure of new prescription drugs as the strong case for the regulatory

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optimal standards, employs scientific experts, and regulates products highly valued in the market.<sup>38</sup> Nonetheless, courts and commentators continue to refer to the new drug application process as minimum standards setting. And this view has held particular sway in the state courts. As soon as one appreciates the centrality of the minimum standards view to courts' rejection of the regulatory compliance defense,<sup>39</sup> hostility toward federal preemption by force of such a minimum regulatory standard of common law failure to warn claims seems foretold.<sup>40</sup>

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compliance defense for a number of reasons.”); Green & Schultz, *supra* note 32, at 2122 (“[T]he FDA sets optimal standards—or at least better than any other entity that exists.”).

<sup>38</sup> Given the stringency of its *ex ante* regulation, the FDA might merit a greater degree of deference than other agencies. *Cf.* Cass R. Sunstein, *Beyond Marbury: The Executive's Power to Say What the Law Is*, 115 *YALE L.J.* 2580, 2596 (2006) (“Perhaps some institutions (the SEC? the White House itself?) deserve more respect than others (the Federal Energy Regulatory Commission? the Bureau of Immigration Affairs?); the real world of judicial review undoubtedly reflects different levels of deference to different agencies.”).

<sup>39</sup> *See, e.g.*, *Edwards v. Basel Pharm.*, 933 P.2d 298, 302 (Okla. 1997) (“It is the widely held view that the FDA sets minimum standards for drug manufacturers as to design and warnings. We conclude that compliance with these minimum standards does not necessarily complete the manufacturer’s duty.”); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 931 (Kan. 1990) (“[R]egulations imposed by the FDA are minimal standards. A drug company is not prohibited from providing additional warnings and additional information that is not required by the FDA.”); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973) (“[M]ere compliance with regulations or directives as to warnings, such as those issued by the United States Food and Drug Administration here, may not be sufficient to immunize the manufacturer or supplier of the drug from liability.”).

<sup>40</sup> *See, e.g.*, *Bell v. Lollar*, 791 N.E.2d 849, 855 (Ind. App. 2003) (“The FDA’s requirement that a generic drug have the same labeling as the pioneer drug is a minimum standard.”); *Levine v. Wyeth*, \_\_\_ A.2d \_\_\_, 2006 WL 3041078, at ¶61 (Vt. Oct. 27, 2006) (Reiber, C.J., dissenting) (“[T]he majority in the instant case . . . viewed the federal regulation as setting a minimum safety standard that states were free to supplement or strengthen.”); *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 874 (Wis. App. 2004) (“[T]his Court is right to interpret the FDA standards as minimum ones . . .”).



*B. Products Liability Preemption in the Supreme Court*

Torts cases are not what come to mind when one contemplates the jurisprudence of the U.S. Supreme Court, particularly on the superheated topic of federalism. But there is a burgeoning coterie of products liability preemption cases of fairly recent vintage that has captured the Court's attention.<sup>41</sup> The 1992 *Cipollone* case marks the genesis of these cases, with its key holding that the threat of tort liability and damages, as much as statutory or regulatory standards, governs primary conduct.<sup>42</sup> *Geier v. America Honda Motor Co.*,<sup>43</sup> the next seminal case regarding federal preemption of state tort law, stands for the proposition that Congress' inclusion of a "savings clause" in a statute, preserving common law liability, does not thwart the operation of the principles of implied conflict preemption.<sup>44</sup>

Keep in mind that, prior to *Cipollone*, defendants rarely pressed preemption arguments in products cases<sup>45</sup> and that, at the time of the *Georgetown Law Journal* symposium issue on the regulatory compliance defense, *Geier* was yet to be decided. The point is that there have been significant developments in the

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<sup>41</sup> See, e.g., Samuel Issacharoff & Catherine M. Sharkey, *Supreme Court Preemption: The Contested Middle Ground of Products Liability*, in FEDERAL PREEMPTION, *supra* note 19, at 194-216.

<sup>42</sup> See, e.g., Noah, *supra* note 22, at 906 ("In the decade before *Cipollone*, the Court expressed a marked reluctance to find preemption of common-law tort claims, but its decisions from the last several Terms suggest a significant reversal in this attitude.").

<sup>43</sup> 529 U.S. 861 (2000).

<sup>44</sup> *Id.* at 869 ("We . . . conclude that the savings clause (like the express pre-emption provision) does *not* bar the ordinary working of conflict pre-emption principles. Nothing in the language of the savings clause suggests an intent to save state-law tort actions that conflict with federal regulations.").

<sup>45</sup> DAVID OWEN ET AL., PRODUCTS LIABILITY AND SAFETY 383 (4<sup>th</sup> ed. 2004) ("Until the early 1990s, manufacturers had virtually abandoned the preemption argument, for it had been routinely rejected by most courts in most contexts for many years. . . . [T]he Supreme Court in 1992 infused the preemption doctrine with new power, and it is now a frequent issue in modern products liability litigation.").

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Court's preemption jurisprudence in the recent past that may go a long way toward explaining the radical shift in the debate from regulatory compliance to preemption. I want to suggest, perhaps provocatively, that these developments may have affected federal and state court judges in subtly different ways. To be clear, I am not intimating that state court judges act in defiance of federal law, nor indeed that they are incapable of understanding or applying federal preemption jurisprudence. The difference is far more nuanced.

I want to draw upon Burt Neuborne's classic arguments in *The Myth of Parity* for state versus federal differences in constitutional litigation. Neuborne pressed the view that "[w]hen the mandates of the Federal Constitution are clear, most state court judges respect the supremacy clause and enforce them. Constitutional litigation, however, is rarely about clear law."<sup>46</sup> The same admonition applies in spades to preemption jurisprudence—notoriously described as a "muddle."<sup>47</sup> Here, as in the realm of constitutional litigation, "federal courts are more responsive than state courts to Supreme Court commands."<sup>48</sup> As Neuborne stated,

federal judges often display an enhanced sense of bureaucratic receptivity to the pronouncements of the Supreme Court. State judges, of course, almost always recognize that they too are bound not to disregard the Supreme Court's interpretation of the Federal Constitution. Their bureaucratic relationship with the Supreme Court is, however, more attenuated than that of a district court judge.<sup>49</sup>

Moreover, and perhaps even more striking in the statutory realm of preemption,

federal judges appear to recognize an affirmative

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<sup>46</sup> Neuborne, *The Myth of Parity*, *supra* note 5, at 1119.

<sup>47</sup> Nelson, *supra* note 1, at 232; *see also* Dinh, *supra* note 1, at 2085 ("[T]he Supreme Court's numerous preemption cases follow no predictable jurisprudential or analytical pattern.").

<sup>48</sup> Neuborne, *The Myth of Parity*, *supra* note 5, at 1121 n.59.

<sup>49</sup> *Id.* at 1124.

obligation to carry out and even anticipate the direction of the Supreme Court. Many state judges, on the other hand, appear to acknowledge only an obligation not to disobey clearly established law.<sup>50</sup>

Given these similarities, Neuborne's disparity thesis might have traction in the realm of preemption, or statutory interpretation more generally.

It would not be too far of a stretch to suggest that state courts, by hewing closely to prior precedents rejecting the regulatory compliance defense, steer clear of flouting any "clearly established" Supreme Court law. State court judges, as creatures of state government, moreover, may be subtly predisposed to rely on state law.<sup>51</sup> Indeed, this predilection is

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<sup>50</sup> *Id.* at 1124-25; *see also* Bellia, *supra* note 3, at 1553 (criticizing federal courts' creative interpretation of statutes, arguing that "for inferior federal courts strategically to make federal law in forward-looking ways in statutory interpretation would deny the law so made the characteristic of being 'the supreme Law of the Land.' The Supremacy Clause's characterization of federal law as the 'supreme Law of the Land,' fairly implies that at an appropriate level of generality federal law should have a uniform meaning in any state or federal court."); *id.* at 1556 ("[N]one of this is to deny the reality that different courts give different interpretations to the same statute in materially similar contexts.").

<sup>51</sup> *See, e.g.,* Helen Hershkoff, *State Courts and the 'Passive Virtues': Rethinking The Judicial Function*, 114 HARV. L. REV. 1833, 1901 (2001) ("[State judges] frequently have had legislative experience, participate to some degree in the lawmaking process, and in some states, stand for election"); Hans A. Linde, *The State and the Federal Courts in Governance: Vive La Différence!*, 46 WM. & MARY L. REV. 1273, 1286 (2005) ("Elective state courts are, however, more likely to have some members with prior legislative experience than the Supreme Court . . . . In the smaller state capitals, if not in California or New York, judges and legislators are more likely to meet informally as well as in official collaborations on law reforms."). *See also* THE COUNCIL OF STATE GOVERNMENTS, 38 BOOK OF THE STATES 253 (2006) (indicating that the state legislatures are vested with the power to appoint state judges in South Carolina and Virginia).

The dynamic is surely more complicated, however, than a familiarity and loyalty towards state law. Electoral politics may play a large role in influencing partisan-elected judges. *See, e.g.,* Anthony Champagne, *Tort Reform and Judicial Selection*, 38 LOY. L.A. L. REV. 1483 (2005) (demonstrating ongoing battle, especially in partisan election states, for

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borne out in the sample of state court decisions involving the preemptive effect of FDA labeling. The state court decisions rely predominantly (and sometimes exclusively) on prior state law precedents (mostly involving rejection of the regulatory compliance defense).<sup>52</sup>

Furthermore, while the U.S. Supreme Court's jurisprudence on implied preemption in the products realm is far from pellucid, a majority of the state court cases fail to cite the relevant precedents (such as *Geier* or *Sprietsma v. Mercury Maine*<sup>53</sup>).<sup>54</sup> The difference between the paradigmatic state court approach and that of some federal courts, which read the pro-preemption directional force of Supreme Court precedents as in *Geier* as support for a highly deferential view toward regulatory preemption, is unmistakable.<sup>55</sup>

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control of state supreme courts). In particular, the relative strengths of the plaintiffs' bar versus the pharmaceutical lobby may affect elected state court judges' preemption proclivities.

<sup>52</sup> See, e.g., *Abramowitz v. Cephalon, Inc.*, 2006 WL 560639, at \*4 (N.J. Super Ct. Law Div. Mar. 3, 2006) (citing *R.F. v. Abbott Labs.*, 745 A.2d 1174 (N.J. 2000)); *Bell v. Lollar*, 791 N.E.2d 849, 852 (Ind. Ct. App. 2003) (citing *Rogers ex rel. Rogers v. Cosco, Inc.*, 737 N.E.2d 1158 (Ind. Ct. App. 2000)); *Coutu v. Tracy*, 2006 WL 1314261, at \*2 (R.I. Super. May 11, 2006) (citing *Verizon New England, Inc. v. R.I. Pub. Utilities Comm'n*, 822 A.2d 187, 192 (R.I. 2003)); *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 875 (Wis. Ct. App. 2004) (citing *Feldman v. Lederle Labs.*, 592 A.2d 1176 (N.J. 1991)).

<sup>53</sup> 537 U.S. 51 (2002).

<sup>54</sup> See *Abramowitz*, 2006 WL 560639; *Bell*, 91 N.E.2d 849; *Coutu*, 2006 WL 1314261; *Kurer*, 679 N.W.2d 867.

<sup>55</sup> E.g., *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 518 (E.D. Pa. 2006) ("Fundamentally, a series of Supreme Court decisions point this Court in the direction of deference, and require dismissal of this case."); *id.* at 524 ("*Geier* is the most recent in a consistent, long line of cases that articulate the Supreme Court's principles on implied preemption."), *appeal docketed*, No. 06-3107 (3d Cir. 2006). See also *In re Bextra and Celebrex Marketing Sales Practices and Prod. Liab. Litig.*, 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006); *Dusek v. Pfizer Inc.*, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004); *Needleman v. Pfizer Inc.*, 2004 WL 1773697 (N.D. Tex. Aug. 6, 2004).

## II. THE KEY INFLUENCE OF FEDERAL AGENCIES

FDA influence in prescription drug labeling cases reached a high-water mark in 2006. In a preamble to a new rule governing the form and content of prescription drug labels, the FDA stated its view that the new regulations preempt competing state law regulatory or common law claims. The FDA was emphatic that state law decisions that reject the preemptive authority of FDA labeling “rely on and propagate interpretations of the Act and FDA regulations that conflict with the agency’s own interpretations and frustrate the agency’s implementation of its statutory mandate.”<sup>56</sup> It remains to be seen whether the 2006 preamble, which represents a formal statement by the expert federal agency charged with regulating prescription drug labels<sup>57</sup> as to the preemptive effect of its determinations, will alter the general reluctance on the part of courts—both state and federal—to find wholesale preemption of personal injury claims in drug cases.<sup>58</sup>

Here, I focus on a slightly different issue, namely whether we should expect state and federal courts to differ in their respective responses to the FDA’s influence and role. My prediction is that federal courts will continue to be more likely to solicit the views of the FDA in the cases before them, and that the FDA will be more likely to intervene on its own in

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<sup>56</sup> Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 n.7 (Jan. 24, 2006) (effective date June 30, 2006).

<sup>57</sup> 21 U.S.C. § 393(b)(2)(B).

<sup>58</sup> As I have explained in more detail elsewhere,

[c]ourts’ approaches to the preemption question run the gamut between what I would call 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. At the opposite “pro-preemption” pole, courts have accorded *Chevron* deference to the FDA’s preamble position, cutting a wide preemptive path.

Catherine M. Sharkey, Products Liability Preemption: An Institutional Approach 37 (2007) (unpublished manuscript) (on file with author).

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federal cases. Each of these developments, in turn, should lead to greater deference on the part of federal courts toward the agency's view.

Already, a sense of a stark disparity between federal and state court approaches to the preemptive effect of the FDA preamble emerges from the early cases. Consider, as one example, *Colacicco v. Apotex*,<sup>59</sup> the first federal court decision to grapple with the preemptive effect of the FDA preamble. In *Colacicco*, the husband of a woman who committed suicide after having taken a generic form of the anti-depressant drug Paxil (one of the class of drugs known as SSRIs, or selective serotonin reuptake inhibitors), sued the generic drug manufacturer (Apotex) and the manufacturer of Paxil (GlaxoSmithKline) for failure to warn of an increased risk of suicide.<sup>60</sup>

The court called upon the FDA to file an amicus brief to explain the legal effect of the recently promulgated preemption preamble.<sup>61</sup> Answering the court's call,<sup>62</sup> the FDA filed an

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<sup>59</sup> 432 F. Supp. 2d 514 (E.D. Pa. 2006), *appeal docketed*, No. 06-3107 (3d Cir. 2006).

<sup>60</sup> *Id.* at 519-20.

<sup>61</sup> *Id.* at 519.

<sup>62</sup> Brief of Amicus Curiae The United States of America, *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) (No. 05-CV-05500-MMB) [hereinafter U.S. *Colacicco Br.*].

The FDA (via the Department of Justice) submitted amicus briefs in three prior (pre-preamble) SSRI cases. *See* Corrected Amicus Brief for the United States, *Kallas v. Pfizer*, No. 04-00998 (D. Utah Sept. 29, 2005) [hereinafter U.S. *Kallas Br.*]; Amicus Brief for the United States in Support of Defendant-Appellee and Cross-Appellant, and in Favor of Reversal of the District Court's Order Denying Partial Summary Judgment to Defendant-Appellee and Cross-Appellant, *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372, 02-55498) [hereinafter U.S. *Motus Br.*]; Brief of the United States of America, *In re Paxil Litig.*, 218 F.R.D. 242 (C.D. Cal. 2003) (No. CV 01-07937 MRP) [hereinafter U.S. *Paxil Br.*]. *Kallas* was settled soon after the FDA filed its amicus brief in the case. Notice of Settlement, *Kallas v. Pfizer, Inc.*, No. 2:04-cv-998 (D. Utah filed Oct. 13, 2005). In *Motus*, the Ninth Circuit Court of Appeals affirmed the district court's grant of summary judgment on causation grounds, without reaching the merits of the preemption defense. *Motus*, 358 F.3d 659, 660 (9th Cir. 2004).

amicus brief to elaborate upon the preamble, which “sets out [the] FDA’s current understanding of the way in which state tort judgment can interfere with the FDA’s implementation of federal law.”<sup>63</sup>

The FDA emphasized that its requirements for prescription drug labels set both the “ceiling and a floor.” In other words, according to the FDA, it sets optimal, as opposed to minimal, safety standards.<sup>64</sup> To justify its stance, the FDA further explained that “[i]n considering the agency’s views on drug labeling, it is critical to understand, where warnings are concerned, more is not always better.”<sup>65</sup> According to the FDA, in the context of prescription drugs, overwarning is a risk every bit as serious as underwarning. To address the precise regulatory issue before the court, the FDA explained that it had considered and rejected adding warnings discussing the potential between suicide and the use of SSRIs.<sup>66</sup> Having weighed in on the precise risk of suicide, the FDA urged that “it would stymie the regulatory scheme established by Congress to hold as a matter of state law that the defendants are liable for failing to provide” a warning that had been rejected by the FDA.<sup>67</sup>

The views espoused by the FDA in its amicus brief proved central to the federal district court’s holding that the FDCA and

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<sup>63</sup> U.S. *Colacicco Br.*, *supra* note 62, at 18.

<sup>64</sup> Specifically, the FDA’s aim is “to encourage the optimal level of use in light of reasonable safety concerns, by requiring scientific evidence of an association between a drug and a particular hazard before warning of that association on a drug’s labeling.” *Id.* at 14.

<sup>65</sup> *Id.* at 13. *See also* U.S. *Kallas Br.*, *supra* note 62, at 28.

<sup>66</sup> U.S. *Colacicco Br.*, *supra* note 62, at 7-11.

<sup>67</sup> *Id.* at 16. *See also* U.S. *Kallas Br.*, *supra* note 62, at 39-40 (“FDA’s accomplishment of its responsibilities would be disrupted and undermined if, driven in part by concerns about later state law tort liability, drug manufacturers were to engage in their own labeling determinations by adding warnings that, in FDA’s judgment, were not based on reasonable scientific evidence of an association or causation.”); U.S. *Motus Br.*, *supra* note 62, at 14-15 (“[I]mposition of liability on the basis of a failure to warn would thwart the FDCA’s objectives of ensuring a drug’s optimal use by requiring that the manufacturers disseminate only truthful information as to its effects.”).

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FDA regulation preempted the plaintiff's state tort failure to warn claims against both the generic and brand name drug companies.<sup>68</sup> Indeed, the court specifically acknowledged that "the FDA's view is critical to this Court's analysis because Supreme Court precedent dictates that an agency's interpretation of the statute and regulations it administers is entitled to deference."<sup>69</sup> Moreover, the court continued, "it is not the function of this Court, or for a jury empanelled to decide this case, to substitute its judgment for the FDA's about these medical issues."<sup>70</sup>

If the *Colacicco* court represents one endpoint on the spectrum of respect and deference accorded the FDA preemption preamble, at the opposite pole one finds this state court's view:

The preamble, as I see it, is a political statement by the FDA. The primary purpose of it is to criticize state courts and to set forth the FDA's position that—not to criticize state courts so much as to set forth the FDA's position that they believe there should be federal preemption of all tort actions. . . . What the preamble is saying is the FDA should be the final word.<sup>71</sup>

Suffice it to say that here, New Jersey Superior Court Judge Carol E. Higbee, in a hearing in a Vioxx case pending before her, not only rejected the preemption defense, but eschewed any

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<sup>68</sup> *Colacicco v. Apotex*, 432 F. Supp. 2d 574, 536 (E.D. Pa. 2006).

<sup>69</sup> *Id.* at 525 (citing *Chevron U.S.A., Inc. v. Nat'l Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984)). The court was emphatic that "pre-emptive intent may properly be communicated in amicus briefs, preambles, and interpretive statements." *Id.* at 530. The court's view that the FDA's preamble warrants *Chevron* deference is controversial. *See infra* notes 92-96 and accompanying text.

<sup>70</sup> *Colacicco*, 432 F. Supp. 2d at 530.

<sup>71</sup> *Doherty v. Merck & Co., Inc.*, No. ATL-L-638-05-MT (N.J. Super. June 9, 2006). The case ended with a defense verdict in July 2006. *Id.* (July 13, 2006). The Vioxx cases in New Jersey state court were coordinated before the Honorable Carol E. Higbee. Recently, in another of these Vioxx cases before Judge Higbee, plaintiff won a jury verdict, awarding \$20 million in compensatory damages and \$27.5 million in punitive damages. *Humeston v. Merck & Co., Inc.*, No. ATL-L-2272-03 (N.J. Super. March 12, 2007).



reliance whatsoever on the FDA preamble by defendant Merck.

Nor is Judge Higbee's position anomalous. In *Levine v. Wyeth*,<sup>72</sup> the Vermont Supreme Court embraced the same emphatic view that "the FDA's statement deserves no deference."<sup>73</sup> And, in direct contravention of the FDA's expressed view, the court held that the FDCA established a floor, not a ceiling, for safety standards. According to the court, in the context of prescription drugs, common law tort standards always complement federal regulation. Almost by definition, then, state tort liability would not frustrate federal objectives or conflict with federal law.<sup>74</sup>

While federal and state court decisions run the gamut from pro- to anti-preemption in the prescription drug context, the type of hostility towards the FDA embodied in these state court opinions finds no parallel in the federal court decisions. For a variety of reasons, state courts may be less deferential towards federal agencies. First, the nearly wholesale rejection of the regulatory compliance defense by state courts (discussed above) may "reflect a populist faith in laypersons and an accompanying distrust of distant federal bureaucracies."<sup>75</sup> Second, state courts' attitude towards federal agencies might bear some relationship to their attitude towards state agencies (and state agencies' interpretations of state law).<sup>76</sup>

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<sup>72</sup> \_ A.2d \_, 2006 WL 3041078 (Vt. Oct. 27, 2006).

<sup>73</sup> *Id.* at ¶32 ("Nothing in the FDA's new statement alters our conclusion that it would be possible for defendant to comply with both its federal obligations and the obligations of state common law."). Nor did the court countenance any of the FDA's previously filed amicus briefs, *see supra* note 62.

<sup>74</sup> 2006 WL 3041078, at ¶6.

<sup>75</sup> Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2153 (2000).

<sup>76</sup> But this is an open question, as scholars have found it difficult, if not impossible, to identify any overarching pattern of state courts' deference to state agencies' interpretation of state law. *See* William R. Anderson, *Chevron in the States: An Assessment and a Proposal*, 58 ADMIN. L. REV. 1017, 1018 (2006) (describing the "problems of indeterminacy and confusion" of deference principles at the state level "because of the variety and diversity of state development of the pertinent doctrinal considerations"); Sunstein, *supra*

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*A. Agency Involvement*

On the whole, the FDA is far more active in the federal courts than in the state courts. Federal courts have actively requested the participation of the FDA in several key cases. Before issuance of the preamble, the FDA obliged the federal courts' requests in *Bernhardt v. Pfizer, Inc.*<sup>77</sup> (a New York federal district court), *In re Paxil Litigation*<sup>78</sup> (a California federal district court), and *Kallas v. Pfizer, Inc.*<sup>79</sup> (a Utah federal district court). In addition, the FDA intervened on its own initiative by filing an amicus brief in *Motus v. Pfizer, Inc.*<sup>80</sup> (the Ninth Circuit Court of Appeals).<sup>81</sup> Post-preamble, federal

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note 38, at 2597 n.79 (noting “[t]he difference between the *Chevron* approach and the contrasting approach of several state courts”).

A further complication is state courts' treatment of federal agencies and their interpretations of federal law. Even state courts that generally accord deference to *state* agencies might nonetheless resist the idea of *Chevron* deference to *federal* agencies on separation of powers grounds. *But see infra* note 101 (noting the converse situation, whereby state courts that, as a general matter, reject deference to state agencies' interpretation of state law, nonetheless accord *Chevron* deference to at least one federal agency, the FDA).

<sup>77</sup> Statement of Interest of the United States, *Bernhardt v. Pfizer, Inc.*, 2000 WL 1738645 (S.D.N.Y. Nov. 22, 2000) (Nos. 00-Civ-4042 LMM, 00-Civ.-4379 LMM). The FDA's statement of interest contended, “[B]oth modifications to approved product labeling and the issuance of labeling in the form of warning letters—intrudes upon the FDA's role and is preempted.” *Id.* at 2. The court ultimately avoided the question of preemption, on the ground that the FDA had primary jurisdiction. *Id.* at 1.

<sup>78</sup> 218 F.R.D. 242 (C.D. Cal. 2003) (No. CV 01-07937 MRP). The FDA filed a statement of interest arguing that “courts . . . should regard FDA's actions as preemptive of state law.” U.S. *Paxil Br.*, *supra* note 62, at 6; *id.* (“[T]he Court should consider Plaintiffs' purportedly state-law based injunctive request preempted by federal law.”).

<sup>79</sup> No. 2:04CV0998 (D. Utah Sept. 29, 2005).

<sup>80</sup> 358 F.3d 659 (9th Cir. 2004) (Nos. 02-cv-55372, 02-civ-55498).

<sup>81</sup> Agencies may submit amicus briefs to either federal or state courts when the United States has a “substantial interest” in the proceedings. 28 U.S.C. § 517 (2007) (“The Solicitor General, or any officer of the Department of Justice, may be sent by the Attorney General to any State or district in the United States to attend to the interests of the United States in a

courts have asked for the FDA's views in *Colacicco v. Apotex*<sup>82</sup> (discussed above) and *Perry v. Novartis Pharmaceutical Corp.*<sup>83</sup> (both Pennsylvania federal district court, the former now pending in the Third Circuit Court of Appeals). In all, the FDA has been directly involved in roughly one quarter of the federal court decisions since 2000.<sup>84</sup> In sharp contrast, no state court has asked the FDA to submit its views in a pending case.<sup>85</sup> The FDA intervened, on its own initiative, in a single state case in a California appellate court, *Dowhal v. SmithKline Beecham Consumer Healthcare L.P.*<sup>86</sup>

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suit pending in a court of the United States, or in a court of a State, or to attend to any other interest of the United States.”).

<sup>82</sup> 432 F. Supp. 2d 514 (E.D. Pa. 2006), *appeal docketed*, No. 06-3107 (3d Cir. 2006).

<sup>83</sup> 456 F. Supp. 2d 678 (E.D. Pa. 2006). At the court's request, the FDA submitted a letter brief that equivocated on the ultimate preemption question. Letter of the United States to Judge Dalzell, *Perry*, 456 F. Supp. 2d 678 (filed Oct. 12, 2006) (“[I]t is not possible to decide as a matter of law whether liability on the plaintiffs' failure-to-warn claim would prevent the accomplishment of federal regulatory objectives.”).

<sup>84</sup> The sample of state and federal cases (listed in the Appendix) is drawn from Westlaw searches of litigated cases, supplemented with a few settled cases mentioned in the briefs of litigated cases and unpublished orders from an electronic case notification service. The sample includes 22 federal cases that have considered the preemptive effect of drug labeling regulations.

<sup>85</sup> Here, state courts have neither acted *sua sponte*, nor on prompting by the parties. *See, e.g.*, Motion for Reargument Defendant-Appellant at 1, 11, *Levine v. Wyeth*, 2006 WL 3041078 (Vt. Oct. 27, 2006) (No. 670-12-01) (“The Court should seek FDA's views on its own regulation”), *reh'g denied*, No. 2004-384 (filed Dec. 11, 2006) (“Insofar as appellant has failed to demonstrate that the Court overlooked or misapprehended points of law or fact that would have affected the result, the motion is denied.”).

<sup>86</sup> 122 Cal. Rptr. 2d 246 (Cal. Ct. App. 2002) (No. A094460), *rev'd*, 88 P.3d 1 (2004). The FDA's intervention in *Dowhal* might be explained by the fact that, prior to the litigation, the California Attorney General had solicited the FDA's opinion in order to decide whether to initiate an enforcement action against the drug manufacturer. *See* Amicus Curiae Brief of the United States of America in Support of Defendants/Respondents Smithkline Beecham Consumer Healthcare LP, et al. at 15-16, *Dowhal*, 88 P.3d 1 (No. S109306).

In the sample of cases (listed in the Appendix), there have been seven state cases concerning the preemptive effect of drug labeling, so all told, the

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Moreover, this difference in the frequency with which the FDA files amicus briefs in federal versus state court litigation is a very conservative measure of the disparity in agency influence for the simple reason that federal courts are also more likely than state courts to rely on FDA amicus briefs filed in prior cases. For example, in three federal cases involving products liability claims associated with the use of anti-depressant SSRIs, the courts explicitly relied upon amicus briefs filed by the FDA in earlier cases, urging preemption of claims relating to the same class of drugs.<sup>87</sup> In *Weiss v. Fujisawa Pharmaceutical Co.*,<sup>88</sup> another recent case involving a failure to warn claim against the manufacturer of the drug Elidel, the federal district court relied explicitly on the letter brief the FDA had previously submitted in *Perry v. Novartis*—again, because the same drug was at issue.<sup>89</sup> Taking into account reliance on previously submitted FDA briefs, federal courts explicitly consider the FDA’s views in nearly one of every two cases.<sup>90</sup>

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FDA is roughly twice as likely to participate in federal (versus state) litigation.

<sup>87</sup> *Ackermann v. Wyeth Pharms.*, 2006 WL 2591078, at \*5 (E.D. Tex. Sept. 8, 2006) (“Wyeth has also provided recent decisions, as well as briefs submitted by the FDA, which clearly demonstrate that at least the FDA views its labeling requirements as preemptive to any other state rule or regulation.”) (magistrate report and recommendation), *withdrawn*, 2006 WL 3780913 (E.D. Tex. Dec. 20, 2006); *Dusek v. Pfizer, Inc.*, 2004 WL 2191804, at \*4 (S.D. Tex. Feb. 20, 2004) (referencing the *Motus* brief, the court held, “Supreme Court precedent dictates that the FDA’s position as stated in its *amicus* brief is entitled to some deference”); *Needleman v. Pfizer, Inc.*, 2004 WL 1773697, at \*4 (N.D. Tex. Aug. 6, 2004) (“More compelling is the *amicus* brief submitted by the government in *Motus*. There, the United States plainly concluded that ‘any warning, no matter how worded, that could reasonably have been read as describing or alluding to such a relation [between Zolofit and suicide] would have been false or misleading, and therefore in conflict with federal law because there was no (and still is not) scientific support for such a warning.’”).

<sup>88</sup> 464 F. Supp. 2d 666, 674 (E.D. Ky. 2006).

<sup>89</sup> *Id.* at 674 (“[T]his Court finds that the approach taken by the District Court for the Eastern District of Pennsylvania [in *Perry v. Novartis Pharm.*] is persuasive.”).

<sup>90</sup> There is no similar reliance phenomenon in the state court decisions.

FDA intervention in individual cases is by no means a perfectly accurate measure of agency influence. Two caveats bear mentioning. First, it is important to keep in mind that the preemption preamble was part of a strategy aimed at relieving the burden on the FDA to intervene in individual cases.<sup>91</sup> The preemption preamble, in other words, may, at least in part, substitute for direct agency involvement case by case. Second, agency involvement is by no means tantamount to influence. It is necessary, but by no means sufficient, for a court to be apprised of the FDA's position before it can be swayed by it. We turn next to examine deference to agency position—whether embodied in an amicus brief or else the newly promulgated preemption preamble.

### *B. Deference to Agency Position*

Judicial deference to the FDA's position on preemption has been controversial since the FDA first articulated that position in 2000. The recent preemption preamble has simply ratcheted up the debate. Technically, the preamble is a regulatory advisory opinion.<sup>92</sup> The nub of the controversy is whether it is appropriate to defer to an agency statement in a preamble. Those in the affirmative camp draw support from Justice Stephen Breyer's concurrence in *Medtronic, Inc. v. Lohr*,<sup>93</sup> which cast a wide net for relevant sources of preemptive intent: "'regulations, preambles, interpretive statements, and responses to comments,' as well as through the exercise of its explicitly designed power

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A couple caveats are relevant here. First, none of the state cases involved SSRIs or Elidel, which could partially explain the nonreliance. Second, roughly half of the state cases (four out of seven) were decided after passage of the FDA preemption preamble, which might be taken by courts as a sufficient exposition of the FDA's view.

<sup>91</sup> Daniel E. Troy, *The Case for FDA Preemption*, in FEDERAL PREEMPTION, *supra* note 19, at 81, 100 ("One advantage of the explicit preemption statement in the Physician Labeling Rule is that it may reduce the need for FDA to submit *amicus* briefs in the myriad of cases around the country.").

<sup>92</sup> 21 C.F.R. § 10.85 (d) (1) (2006).

<sup>93</sup> 518 U.S. 470 (1996).

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to exempt state requirements from preemption.”<sup>94</sup> In this vein, the *Colacicco* federal district court emphasized that “the Court has made clear that such preemptive intent may properly be communicated in *amicus* briefs as well as in ‘regulations, preambles, interpretive statements and responses to comments.’”<sup>95</sup> This position, however, has been countered on administrative law grounds by courts that take the position that *amicus* briefs and preambles lack the requisite “force of law” to merit *Chevron* deference.<sup>96</sup>

*Colacicco* is an exemplar of deference to the agency position on preemption. *Colacicco* followed the path set by two earlier (pre-preamble) Texas federal district court cases (*Needleman v. Pfizer*<sup>97</sup> and *Dusek v. Pfizer*<sup>98</sup>), which deferred to the FDA’s

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<sup>94</sup> *Id.* at 506 (Breyer, J., concurring in part and concurring in the judgment) (citing *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 718 (1985)).

<sup>95</sup> *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 525 (E.D. Pa. 2006), *appeal docketed*, No. 06-3107 (3d Cir. 2006).

<sup>96</sup> *See, e.g., Weiss v. Fujisawa Pharm. Co.*, 464 F. Supp.2d 666, 673 (E.D. Ky. 2006) (“[T]he preamble . . . is not entitled to *Chevron* deference,” because advisory opinions—which include “any portion of a Federal Register notice other than the text of a proposed or final regulation”—lack the force of law). As I have remarked elsewhere:

The confusion stems largely from the ad hoc handling of deference in the relevant Supreme Court products liability preemption precedents, which . . . suggests some intermediate, if uncertain level of deference. . . . [A]lthough [*United States v. Mead Corp.*, 533 U.S. 218 (2001)] would appear to preclude *Chevron* deference for both preambles and *amicus* briefs because they lack force of law, Justice Breyer’s [*Barnhart v. Walton*, 535 U.S. 212 (2002)] factors may open the door to greater deference, even if courts are not willing to abandon traditional deference analysis and rely solely on preemption doctrine.

Sharkey, *supra* note 58, at 43.

<sup>97</sup> 2004 WL 1773697, at \*4 (N.D. Tex. Aug. 6, 2004) (“[T]he Court places weight on the FDA’s unambiguous statement that it would view any statement describing a relationship between Zolofit use and suicide as ‘false and misleading,’ and it would deem any state warning requirement preempted.”).

<sup>98</sup> 2004 WL 2191804, at \*5 (S.D. Tex. Feb. 20, 2004) (“The Court concludes that the FDA’s position as stated in the *amicus* brief that any label

position on the ground that “Supreme Court precedent dictates that the FDA’s position as stated in its *amicus* brief is entitled to some deference.”<sup>99</sup> Recall that the *Colacicco* court termed the FDA’s view—as embodied in the preamble as well as *amicus* brief—“critical” to the court’s analysis “because Supreme Court precedent dictates that an agency’s interpretation of the statute and regulations it administers is entitled to deference.”<sup>100</sup>

In the post-preamble period, a California federal district court (*In re: Bextra and Celebrex*) staked out an equally accommodating stance, setting a fairly low “reasonableness” bar for deference to agency view:

[T]he FDA’s view of the preemptive effect of its own regulations is not “plainly erroneous or inconsistent with the regulation.” Its preemption position is premised on its assertion “the determination whether labeling revisions are necessary is, in the end, squarely and solely the FDA’s under the act.”<sup>101</sup>

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suggesting that Zolofit can cause suicide would be false or misleading provides support for preemption.”).

<sup>99</sup> *Id.*

<sup>100</sup> *Colacicco*, 432 F. Supp. 2d at 525 (citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984)).

<sup>101</sup> *In re: Bextra and Celebrex Marketing Sales Practices and Prod. Liab. Litig.*, 2006 WL 2374742, at \*8 (N.D. Cal. Aug. 16, 2006) (citations omitted). The court elaborated further: “The FDA explains that while a manufacturer can distribute a unilaterally strengthened label after giving the FDA prior notice, the FDA retains authority to disapprove the label. The FDA’s opinion is reasonable.” *Id.*

A California state court followed suit, relying heavily on the federal court’s reasoning. *See Conte v. Wyeth*, 2006 WL 2692469, at \*6 (Cal. App. Dep’t Super. Ct. Sept. 14, 2006) (“The circumstances of this case are sufficiently similar to those in *Bextra* and also *Colacicco v. Apotex Inc.* to warrant granting summary judgment. The cases are similar insofar as their resolution turns on whether the recently promulgated FDA Preamble preempts State law ‘failure to warn’ claims. Since the Court finds the reasoning of the two cases very persuasive, and in light of *Dowhal v. SmithKline Beecham Consumer Healthcare* [88 P.3d 1, 929-30 (Cal. 2004), which deferred to the FDA’s views “[b]ecause of the FDA’s scientific expertise and long administrative experience”], the Court grants summary judgment . . .”). A second post-preamble state court case likewise placed

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This highly deferential view stands in marked contrast to that of the state courts in *Doherty v. Merck* and *Levine v. Wyeth*, each of which refused to pay any heed whatsoever to the FDA's pro-preemption view as embodied in the preamble.

Another striking distinction between federal and state courts is the way each has viewed the extent to which the FDA has changed its preemption position over time. In *In re: Bextra and Celebrex*, the California federal district court adopted an accommodating stance:

While the FDA's current view of the preemptive effect of its labeling regulations is a 180-degree reversal of its prior position, the Supreme Court has recognized that an agency's view of the preemptive effect of its regulations may change over time as the agency gains more experience with the interrelationship between its regulations and state laws.<sup>102</sup>

A Rhode Island state court in *Coutu v. Tracy* was far less forgiving, and held it against the FDA that its "interpretation of its role squarely conflicts with the FDA's previous stance" on the ground that "[t]he United States Supreme Court has articulated its preference to discount federal agencies'

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heavy reliance on deference to the FDA. *See* *Abramowitz v. Cephalon, Inc.*, 2006 WL 560639, at \*3 (N.J. Super. Mar. 3, 2006) ("[I]t is the court's opinion that pursuant to the newly released federal regulation, the FDA's decision to approve the defendant's label for Actiq would preempt a state claim for failure to warn.").

As a first cut in this Essay I treat state courts as if they are all of a piece; it might, however, be fruitful to investigate state by state differences. For example, California or New Jersey state courts may prove themselves to be especially inclined toward the pro-preemption view. If so, an interesting further puzzle emerges, because these states reject the notion of deference to state agencies in the context of interpreting state law. *See, e.g.*, Sunstein, *supra* note 38, at 2597 ("California courts reject the notion that agencies have been delegated authority to interpret statutes. Similarly, the New Jersey Supreme Court notes that 'courts are in no way bound by the agency's interpretation of a statute or its determination of a strictly legal issue.'").

<sup>102</sup> 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006), at \*8 (citing *Hillsborough* and *Chevron*).



interpretations of their regulations where said interpretations ‘contradict the agenc[ies]’ own previous construction that [the] Court [has] adopted as authoritative.’”<sup>103</sup>

Finally, it is worth keeping in mind that deference to agency position does not necessarily yield (at least in this context) a pro-preemption outcome. In the *Perry* case, the FDA advised in its letter brief (also relied upon by the court in *Weiss*), that “it is not possible to decide as a matter of law whether liability on the plaintiffs’ failure-to-warn claim would prevent the accomplishment of federal regulatory objectives.”<sup>104</sup> Nor is it by any means the case that federal district courts have consistently deferred to the FDA’s position.<sup>105</sup> Some have, like the *Coutu* state court case above, denigrated the FDA’s recent position as too inconsistent to warrant deference.<sup>106</sup>

Another key point of contention, emphasized by the Nebraska federal district court in *Jackson v. Pfizer, Inc.*,<sup>107</sup> focuses on the procedural infirmities of the promulgation of the preamble: “The FDA failed to comply with its requirements to

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<sup>103</sup> *Coutu v. Tracy*, 2006 WL 1314261, at \*4 (R.I. Super. May 11, 2006) (citations omitted).

<sup>104</sup> Letter of the United States to Judge Dalzell, *Perry v. Novartis Pharma. Corp.*, 456 F. Supp. 2d 678 (E.D. Pa. 2006) (filed Oct. 12, 2006).

<sup>105</sup> See, e.g., *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 730 (D. Minn. 2005) (refusing to defer to the FDA’s position on the ground that “[t]he Court . . . declines to treat statements from a single FDA legal brief as declarations afforded the preemptive force of law.”); *McNellis v. Pfizer, Inc.*, 2005 WL 3752269 (D. N.J. Dec. 29, 2005) (“This Court, however, declines to treat statements from the *amicus* legal briefs as declarations to be afforded the preemptive force of law.”), *motion to vacate denied, interlocutory appeal granted*, 2006 WL 2819046 (D.N.J. Sept. 29, 2006) (“[T]his Court, as it did in its December 29 Opinion with respect to legal positions taken by the FDA in *amicus* briefs, declines to give the Preamble preemptive force of law”); *appeal docketed*, No. 06-5148 (3d Cir. 2006).

<sup>106</sup> See, e.g., *Weiss v. Fujisawa Pharm. Co.*, 464 F. Supp. 2d 666, 674 (E.D. Ky. 2006) (“[T]he Supreme Court has also held that ‘the consistency of an agency’s position is a factor in assessing the weight that position is due.’ FDA’s position has not been consistent and is therefore entitled only to [weaker “power to persuade” *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)] deference.”) (internal citations omitted).

<sup>107</sup> 432 F. Supp. 2d 964 (D. Neb. 2006).

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communicate with the states and to allow the states an opportunity to participate in the proceedings prior to a preemption decision.”<sup>108</sup> The court likewise declined to give either the amicus briefs filed by the FDA in prior Zolof cases or the amicus brief in *Colacicco* “force of law.”<sup>109</sup>

While, as of yet, no stark outcome-based distinction between state and federal courts has emerged,<sup>110</sup> there is, nonetheless, a discernible difference in flavor in the character of the opinions, which relates to the priority accorded to the FDA’s views. State

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<sup>108</sup> *Id.* at 968 n.3 (citing Executive Order 13132). Other federal district courts have followed suit, with little in the way of additional analysis. *See* *Reeves v. Wyeth*, No. 05-163, at 1 (E.D. Ark. June 15, 2006) (“I have reviewed Judge Bataillon’s erudite order in *Jackson v. Pfizer, Inc., et al.*, and adopt his reasoning in its entirety—it is a mule-and-bicycle case.”). Three additional “anti-preemption” federal district courts contain nary a mention of deference to the FDA’s position (as embodied in amicus briefs or the preamble). *See* *Laisure-Radke v. Par Pharm., Inc.*, 426 F. Supp. 2d 1163 (W.D. Wash. 2006); *Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051 (W.D. Wis. 2006); *Baumgardner v. Wyeth Pharms.*, No. 05-05720, 2006 WL 1308232 (E.D. Pa. Aug. 23, 2006).

<sup>109</sup> *Jackson*, 432 F. Supp. 2d at 969 n.4. Wyeth and Pfizer filed motions for certification of interlocutory appeal. Memorandum in Support of Wyeth Defendants’ Motion for Certification for Interlocutory Appeal, 2006 WL 1887007 (D. Neb. June 9, 2006); Defendant Pfizer, Inc.’s Brief in Support of Motion for Certification for Interlocutory Appeal, 2006 WL 1887002 (D. Neb. June 13, 2006). The case settled in August 2006. *See* Notice of Settlement, No. 8:05CV18-88 (filed Aug. 7, 2006).

<sup>110</sup> In the sample of cases listed in the Appendix (setting to one side the five cases that either settled or were withdrawn or decided on other grounds), federal courts have deferred to the agency’s position in seven out of seventeen drug labeling claims since 2000, while state courts have preempted claims in three out of seven cases. Federal courts have thus been 2 percent less likely to defer to the agency’s position—a statistically insignificant difference that affirms a finding of parity. The result does not change if only those cases that follow the announcement of the preamble are used in the analysis. Among post-preamble cases, federal courts have deferred to the agency’s position in four out of ten decisions, whereas state courts have preempted two out of four cases—a result likewise of near parity, with federal and state courts deferring to the agency’s position at rates of 40 percent and 50 percent, respectively. More than the usual cautionary caveat applies here, however, where the post-preamble sample size is so small.

courts are far less likely than federal courts to wrestle in any serious way with the rich case law that has emerged surrounding the FDA's position on preemption, including the complicated administrative law underpinnings.<sup>111</sup>

#### CONCLUSION: FEDERALISM IMPLICATIONS

The ambitions of this Essay necessarily exceed its scope. Having scratched the surface of what promises to be a fruitful area of further study—state versus federal court differences in realms of statutory interpretation—and having posited some potential explanatory variables to explore, I close with a few thoughts on the wide-ranging federalism implications of such an inquiry.

Forum allocation decisions clearly implicate federalism concerns. First, should federal forums prove more sympathetic than their state counterparts to preemption arguments—particularly those premised upon the stated preemption positions of federal agencies—and should outcome-determinative distinctions emerge over time, plaintiffs will have an added incentive to bring cases in state court and forcefully to resist removal to federal court.<sup>112</sup>

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<sup>111</sup> It is striking, for example, that *Levine v. Wyeth*, \_\_ A.2d \_\_, 2006 WL 3041078 (Vt. Oct. 27, 2006), is the only state court case in the sample surveyed that even cites *Chevron* or *Mead*, whereas it is the rare federal court case that neglects their mention. Cf. Anderson, *supra* note 76, at 1020 (“The *United States v. Mead Corp.*, *Barnhart v. Walton*, and *Christensen v. Harris County* refinements are known by some state courts, but do not seem to play a serious role in outcomes.”).

<sup>112</sup> In the sample surveyed here, four of the cases were successfully removed from state to federal court. *Weiss v. Fujisawa Pharm. Co.*, 464 F. Supp. 2d 666 (E.D. Ky. 2006); *McNellis v. Pfizer Inc.*, 2005 WL 3752269, at \*1 (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. 06-8056 (3d Cir. 2006); *Needleman v. Pfizer Inc.*, 2004 WL 1773697 (N.D. Tex. Aug. 6, 2004); *Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085, 1086 (C.D. Cal. 2000).

While it is way too soon to tell, post-FDA preamble, we may be witnessing an increase in state pharmaceutical cases. In the year since the

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Second, and perhaps less readily apparent, the subject of this Essay has implications for the debate over whether courts should accord *Chevron* deference to federal agencies' preemption positions, as enshrined in amicus briefs, preambles, or formal rules and regulations. In addition to the reluctance (explored above) of state courts to seek out, and accord respect to, the views of the relevant federal agency, the Supreme Court would undoubtedly face a tall task in terms of enforcing a *Chevron* regime in products cases, given the sheer number of cases that come up through the diverse state jurisdictions.

This leads to a final parting thought relating to federal jurisdiction. To the extent that *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*<sup>113</sup> opened the door to federal question "arising under" jurisdiction (28 U.S.C. § 1331) over federal issues embedded in state-law claims between nondiverse parties,<sup>114</sup> a reluctance on the part of state courts to consider, yet alone defer to, the views of the relevant federal agencies when interpreting federal statutes might strengthen the claim that these preemption determinations implicate "a serious federal interest in claiming the advantages thought to be inherent in a federal forum."<sup>115</sup>

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publication of the preamble, there have been four state cases decided, as compared to three state cases decided in the six years prior to the preamble.

<sup>113</sup> 545 U.S. 308 (2005).

<sup>114</sup> This was a door presumed closed by courts and commentators who read *Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804 (1986), as effectively limiting federal jurisdiction to express and implied federal causes of action. *Id.* (holding that a state-law negligence per se claim, based upon a violation of the FDCA, did not present a sufficient federal ingredient to justify federal question jurisdiction). See Issacharoff & Sharkey, *supra* note 2, at 1413-14, 1428-31 (arguing that "*Grable* has reinvigorated federal question jurisdiction" and proposing an extension of "arising under" jurisdiction for cases "when both the underlying standard of tort liability is predicated on federal law and the potential for punitive damages threatens to spill across a state's borders" as "consistent with the flexible standard employed by the Court in 'exploring the outer reaches of § 1331.'").

<sup>115</sup> *Grable*, 545 U.S. at 313. On the other hand, the countervailing concern with respect to the "potentially enormous shift of traditionally state cases into federal courts" would persist. *Id.* at 319. See also *Empire HealthChoice Assurance, Inc. v. McVeigh*, 126 S. Ct. 2121, 2137 (2006)

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Much more than first meets the eye may be involved in whether pharmaceutical products cases are tried in state versus federal court.

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(“*Grable* emphasized that it takes more than a federal element ‘to open the “arising under” door.’”).

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*Appendix***Federal Cases**

1. Ackermann v. Wyeth Pharms., 2006 WL 2591078 (E.D. Tex. Sept. 8, 2006) (magistrate report and recommendation), *withdrawn*, 2006 WL 3780913 (E.D. Tex. Dec. 20, 2006)\*
2. Baumgardner v. Wyeth Pharms., No. 05-05720 (E.D. Pa. Aug. 23, 2006)\*
3. Bernhardt v. Pfizer, Inc., 2000 WL 1738645 (S.D.N.Y. Nov. 22, 2000) (*decided on other grounds*)
4. In re: Bextra and Celebrex Marketing Sales Practices and Prod. Liab. Litig., 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006)\*
5. Caraker v. Sandoz Pharms. Corp., 172 F.Supp. 2d 1018 (S.D. Ill. 2001)
6. Cartwright v. Pfizer, Inc., 369 F.Supp. 2d 876 (E.D. Tex. 2005)
7. Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514 (E.D. Pa. 2006), *appeal docketed*, No. 06-3107 (3d Cir. 2006)\*
8. Dusek v. Pfizer Inc., 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004)
9. Ehliis v. Shire Richwood, Inc., 233 F.Supp. 2d 1189 (D. N.D. 2002)
10. Jackson v. Pfizer, Inc., 432 F.Supp. 2d 964 (D. Neb. 2006)\*
11. Kallas v. Pfizer Inc., No. 2:04CV0998 (D. Utah Sept. 29, 2005) (*settled*)
12. Laisure-Radke v. Par Pharm., Inc., 426 F.Supp. 2d 1163 (W.D. Wash. 2006)\*
13. McNellis v. Pfizer Inc., No. 05-1286, 2006 WL 2819046 (D. N.J. Sept. 29, 2006), *appeal docketed*, No. 06-8056 (3d Cir. 2006)\*
14. Motus v. Pfizer, Inc., 358 F.3d 659 (9th Cir. 2004) (*decided on other grounds*)
15. Needleman v. Pfizer Inc., 2004 WL 1773697 (N.D. Tex. Aug. 6, 2004)

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16. In re Paxil Litig., 218 F.R.D. 242 (C.D. Cal. 2003) (*settled*)
17. Perry v. Novartis Pharma. Corp., 456 F.Supp. 2d 678 (E.D. Pa. 2006)\*
18. Peters v. Astrazeneca, LP., 417 F.Supp. 2d 1051 (W.D. Wis. 2006)\*
19. Reeves v. Wyeth, No. 05-163 (E.D. Ark. June 15, 2006)\*
20. Witczak v. Pfizer, Inc., 377 F.Supp. 2d 726 (D. Minn. 2005)
21. Weiss v. Fujisawa Pharm. Co., 464 F. Supp. 2d 666 (E.D. Ky. 2006)\*
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7. Kurer v. Parke, Davis & Co., 679 N.W.2d 867 (Wis. App. 2004)

\* Post-preamble