

## The New Federalization Movement and the Roberts Court

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### I. THEME<sup>1</sup>

When I was working as a lawyer in the Clinton administration, first in the Department of Justice (DOJ), and then as Deputy General Counsel in the Department of Health and Human Services (HHS), I was involved in the debate about the merits of what I call the federalization movement of the 1990s.<sup>2</sup> I arrived to work in the administration just before the passage of the Violent Crime Control and Enforcement Act of 1994, which included a plethora of new federal crimes and enhanced penalties for existing crimes.<sup>3</sup> Among the additions were the Violence Against Women Act (VAWA)<sup>4</sup> and the Freedom of Access to Clinic Entrances Act.<sup>5</sup> Earlier the Congress had enacted the Child

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1. In music, "theme" signifies "a musical idea . . . that forms the basis or starting point for a composition or a major section of one." DON M. RANDEL, *THE HARVARD CONCISE DICTIONARY OF MUSIC AND MUSICIANS* 666 (1999).

2. See, e.g., Renée M. Landers, *Federalization of State Law: Enhancing Opportunities for Three-Branch and Federal-State Cooperation*, 44 *DEPAUL L. REV.* 811, 811 (1995) [hereinafter Landers, *Federalization of State Law*] (presenting theory and practice of DOJ's approach to expanded federal jurisdiction); Renée M. Landers, *Prosecutorial Limits on Overlapping Federal and State Jurisdiction*, 543 *ANNALS AM. ACAD. POL. & SOC. SCI.* 64, 66 (1996) (arguing federal expansion of criminal jurisdiction into traditionally state-dominated areas supplements state authority); Renée M. Landers, *Reporter's Draft for the Working Group on the Mission of the Federal Courts, Roundtable on State and Federal Jurisdiction*, 46 *HASTINGS L.J.* 1255 (1995) [hereinafter Landers, *Reporter's Draft*]. Professor Kathleen Sullivan has identified three great federalization events in United States history: the adoption and ratification of the Constitution, Reconstruction, and the expansion of federal power during the New Deal made possible by the Supreme Court's acquiescence to broad interpretations of the commerce power. Landers, *Reporter's Draft*, at 1257-58.

3. See Pub. L. No. 103-322, 108 Stat. 1796 (1994) (codified at 42 U.S.C. §§ 13701-14223 (1996)) (creating new federal crimes and enhancing existing penalties).

4. Title IV of the Violent Crime Control and Law Enforcement Act of 1994, Pub. L. No. 103-322, 108 Stat. 1796 (codified as amended at 18 U.S.C. § 2247 (Supp. V 2005)) (expanding federal jurisdiction to encompass violent crimes against women). The Violence Against Women Act also created a civil remedy for victims of gender-motivated violence. 42 U.S.C. § 13981 (Supp. V 2005). In *United States v. Morrison*, the Supreme Court invalidated this civil remedy provision, holding that Congress may not "regulate noneconomic, violent criminal conduct based solely on that conduct's aggregate effect on interstate commerce." 529 U.S. 598, 617 (2000).

5. Pub. L. No. 103-259, 108 Stat. 694 (1994) (current version at 18 U.S.C. § 248 (Supp. V 2005))

Support Recovery Act of 1992<sup>6</sup> and the Gun-Free School Zones Act of 1990.<sup>7</sup>

These expansions of federal jurisdiction into areas of criminal-law enforcement traditionally within the purview of the states spawned energetic criticism. Federal judges expressed concern that these legislative enactments expanded the reach of federal jurisdiction and that the resulting effects on federal court dockets would cause an erosion of the traditional mission of the federal courts.<sup>8</sup> In their view, constitutional and policy considerations indicated the wisdom of a limited role for the federal courts in these areas, and continued expansion of the role of federal courts would threaten quality and competence.<sup>9</sup>

In some of these statutory initiatives, congressional conservatives and liberals were united in the view that federal judicial power should be invoked to address criminal activity that crossed state boundaries.<sup>10</sup> In the case of the Freedom of Access to Clinic Entrances Act (FACE), Congress sought to address activity that interfered with the exercise of a federal constitutional right.<sup>11</sup> Like earlier actions by Congress that gave federal courts jurisdiction to deal with civil-rights crimes of violence,<sup>12</sup> these enactments introduced federal

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(prohibiting destructive conduct intended to injure, intimidate, or interfere with persons seeking to obtain or provide reproductive health-care services).

6. Pub. L. No. 102-521, 106 Stat. 3403 (1992) (codified at 18 U.S.C. §§ 228, 3563(b)(20) (2006)) (establishing criminal penalty for willful failure of noncustodial parent to pay child support obligations). Penalties attach when the noncustodial parent resides in a different state and the support remains unpaid for one year or longer or exceeds \$5,000. *Id.* § 228(a)-(c). The statute also created a grant program to help the states improve enforcement of criminal interstate child support. 42 U.S.C. §§ 3796cc to 3796cc-6 (2006).

7. 18 U.S.C. §§ 921-922, 924 (2006) (creating federal offense for knowing possession of firearm in school zone).

8. *See, e.g.,* Landers, *Federalization of State Law*, *supra* note 2, at 811 (citing Letter from J. Clifford Wallace, Chief Judge, U.S. Court of Appeals for the Ninth Circuit, to William H. Rehnquist, Chief Justice, U.S. Supreme Court; Janet Reno, Attorney Gen., Dep't of Justice; Joseph R. Biden, Chair, Senate Judiciary Comm.; and Jack Brooks, Chair, House Judiciary Comm. (Mar. 29, 1993)); Chief Justice William H. Rehnquist, *1994 Year-End Report on the Federal Judiciary*, 18 AM. J. TRIAL ADVOC. 499, 502-03 (1995) (stating "[t]here is considerable sentiment in the federal judiciary at the present time against further expansion of federal jurisdiction into areas which have been previously the province of state courts enforcing state laws").

9. WILLIAM H. SCHWARZER & RUSSELL R. WHEELER, ON THE FEDERALIZATION OF THE ADMINISTRATION OF CIVIL AND CRIMINAL JUSTICE, 9-38 (Fed. Jud. Ctr. 1994). Schwarzer and Wheeler advanced the following critiques of expansive federal jurisdiction: 1) "The Constitution dictates a limited role for the federal courts"; 2) "Sound public policy mandates a limited role for the federal courts"; 3) "The continued expansion of the role of the federal courts subverts their traditional role and purpose"; and 4) "The continued expansion of the role of the federal courts threatens their quality and competence." *Id.* at 9.

10. *See* Freedom of Access to Clinic Entrances Act § 248. The Freedom of Access to Clinic Entrances Act is an exception to the liberal/conservative unity on expansions of federal jurisdiction. In this instance, opponents of abortion were not supportive of expansions of federal jurisdiction to protect a constitutional right with which they disagreed.

11. Two constitutional rights are implicated by the FACE. The statute seeks to balance the First Amendment interests of people who wish to show their opposition to abortion and contraception by demonstrating at health-care facilities, with the interests of women seeking to exercise their right to access reproductive health care without interference.

12. *See* 18 U.S.C. § 241 (2006) (specifying punishment for conspiracy to interfere with rights or privileges from Constitution or federal law). A violation of this statute carries a maximum sentence of ten years in prison and fines. *Id.* If death results from the violation, or if the violation includes kidnapping,

enforcement as an additional tool designed to protect the public, but did not preempt state law-enforcement activities. The states, however, were concerned that overlapping jurisdiction would result in duplicative and competitive law enforcement activities.<sup>13</sup>

Congress relied on its authority to regulate commerce in enacting many of these statutes.<sup>14</sup> Two Supreme Court decisions demonstrate the Court's displeasure at Congress's attempt to use its commerce power to regulate noneconomic activity. In *United States v. Lopez*,<sup>15</sup> the Court invalidated the Gun Free School Zones Act as an impermissible infringement on state police power, and in *United States v. Morrison*,<sup>16</sup> the Court overturned a federal VAWA civil damages remedy on similar grounds. Until *Lopez*, the Court had not invalidated a federal statute as exceeding Congress's commerce power for nearly sixty years.<sup>17</sup>

## II. VARIATIONS<sup>18</sup>

When I made the move from DOJ to HHS in 1996, my first task was to work with lawyers in both agencies on the government's amicus brief in a case called *Medtronic v. Lohr*.<sup>19</sup> The case raised the issue of whether the declaration of the Food and Drug Administration (FDA) that a device is "substantially equivalent" to devices already on the market under the premarket notification provisions of the Medical Devices Amendments (MDA) preempted state tort claims.<sup>20</sup> Lora Lohr had received an implanted Medtronic pacemaker equipped

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aggravated sexual abuse, or an attempt to kill, the sentence can be increased to life in prison or a death sentence. *Id.*; see also *id.* § 242 (criminalizing willful deprivation of Constitutional right or privilege while acting under color of law).

13. See Landers, *Reporter's Draft*, *supra* note 2, at 1267-70 (addressing relative competencies of federal and state judicial and prosecutorial systems and problems with federalizing crimes).

14. *Id.* at 1258-59 (suggesting Supreme Court's restrictive interpretation of nineteenth-century amendments spawned civil-rights legislation based on Commerce Clause); see also *Slaughter-House Cases*, 83 U.S. 36, 71, 77-78 (1873) (holding Fourteenth and Fifteenth Amendments did not prevent restrictive exercise of state police power).

15. 514 U.S. 549, 567 (1995) (declaring link between gun possession in schools and interstate commerce too attenuated to support legislation).

16. 529 U.S. 598, 617 (2000) (holding aggregate effect on interstate commerce improper basis for regulating noneconomic violent conduct).

17. KATHLEEN M. SULLIVAN & GERALD GUNTHER, *CONSTITUTIONAL LAW* 106 (16th ed. 2007).

18. See RANDEL, *supra* note 1, at 701. In music, "variation" is a "technique of modifying a given musical idea, usually after its first appearance; a form based on a series of such modifications." *Id.*

19. 518 U.S. 470 (1996).

20. *Id.* at 477-81 (describing premarket notification process allowing device manufacturers to avoid full premarket approval). Under the premarket approval (PMA) process, the FDA establishes with "a reasonable assurance" that a device is both safe and effective after a rigorous review. See 21 U.S.C. § 360e (2006) (prescribing rigorous review process for Class III medical devices). Such devices "presen[t] a potential unreasonable risk of illness or injury," or are "purported or represented to be for a use in supporting or sustaining human life or for use which is of substantial importance in preventing impairment of human health." *Id.* § 360c(a)(1)(C). The PMA process requires a substantial investment of time and resources by the FDA. The agency was not able to keep up with the PMA process after the MDA to the Food Drug and Cosmetic Act

with a lead, the part of the pacemaker that transmits the electrical signal from the “pulse generator” to the heart, which the FDA had found to be “substantially equivalent” to devices already on the market.<sup>21</sup> When the pacemaker failed, Lohr and her husband sued Medtronic in state court on negligence and strict-liability claims.<sup>22</sup>

The Supreme Court considered whether the claims against Medtronic were preempted by a provision of the MDA which provides that no state may establish or continue in effect any requirement “which is different from, or in addition to, any requirement” applicable to the device under the MDA.<sup>23</sup> The government’s amicus position was that the statute created only a very limited range of preemption, mostly of states’ positive regulation.<sup>24</sup> Medtronic essentially argued that FDA’s authorization for the device to be marketed—even though the device had not been approved under the rigorous premarket approval process—should insulate manufacturers from state tort claims.<sup>25</sup>

A fractured Court, in a plurality opinion written by Justice Stevens, held that the Lohrs’ defective design, defective manufacture, and failure-to-warn claims were not preempted.<sup>26</sup> The plurality concluded that the statute had a limited preemptive effect because its legislative history indicated that “§ 360(k) simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions.”<sup>27</sup>

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were adopted in 1976. *See Lohr*, 518 U.S. at 476, 477-79. The MDA allows devices on the market before 1976 to remain on the market until the FDA completes the requisite PMA process. 21 U.S.C. § 360e(b)(1)(A). To avoid the manufacturers of devices relieved of PMA requirements from gaining monopolies, the MDA permits manufacturers of devices that are “substantially equivalent” to existing devices to avoid the PMA process by using the more limited and less rigorous premarket notification process. *Id.* § 360(k); *id.* § 360e(b)(1)(B) (creating exemption from PMA process for “substantially equivalent” devices).

21. *Lohr*, 518 U.S. at 480-81 (noting Medtronic device similar to existing approved pacemakers).

22. *See id.* (discussing factual background). The failed pacemaker led to heart blockage that required Ms. Lohr’s doctor to perform emergency surgery. *Id.* Although the action originated in state court, Medtronic removed the case to federal district court. *Id.*

23. *See* 21 U.S.C. § 360(k) (outlining state preemption requirements).

24. *See* Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 7, 10 (1997) (noting state tort claims generally not preempted under premarket notification provisions). The author notes that the Court’s decision in *Lohr* is the “logical extension[] of the [FDA’s] long-standing presumption against preemption.” *See generally* Brief for the United States as Amicus Curiae Supporting Respondents/Cross-Petitioners, *Lohr*, 518 U.S. 470 (Nos. 95-754, 95-886), 1996 WL 118035 (arguing section 360k of the MDA does not categorically preempt state tort remedies). The United States also argued that the MDA did not preempt the Lohrs’ defective-design claims, that the existence of good manufacturing practices promulgated by the FDA did not require summary judgment for Medtronic on the defective manufacture claims, and that the labeling provisions of the MDA did not require summary judgment for Medtronic on the Lohrs’ failure-to-warn claims. *Id.*

25. *See* *Medtronic v. Lohr*, 518 U.S. 470, 481 (1996).

26. *Id.* at 494, 497, 502 (considering as not preempted negligent-design claims, state requirements identical to FDA requirements, and defective manufacturing and labeling claims).

27. *Id.* at 491. Justice Breyer concurred in the judgment and wrote separately to emphasize his view that

insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action. It is possible that the plurality also

Under the administration of President George W. Bush, however, the FDA has changed its position on whether the MDA preempts state regulation, including state common-law tort claims. It has filed briefs in several cases siding with manufacturers to argue for preemption.<sup>28</sup> In addition, in issuing new drug labeling regulations in 2006, the FDA stated in a preamble to the regulations that it viewed the drug labeling act as preempting state law, including state tort claims.<sup>29</sup> Similar changes in position on regulatory preemption have been advanced by the Consumer Product Safety Commission

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agrees on this point, although it does not say so explicitly.

*Id.* at 504-05 (Breyer, J., concurring). In the interests of time, this discussion oversimplifies a complicated statutory analysis, but others have carefully explored this ground. *See, e.g.,* ERWIN CHERMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES 401 (3d ed. 2006); Porter, *supra* note 24; Catherine M. Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 J.L. & POL'Y 1013, 1040-41 (2007) [hereinafter Sharkey, *Federalism in Action*]; Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 238-39 (2007) [hereinafter Sharkey, *Preemption by Preamble*]; David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 102-13 (2005).

28. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) (noting Department of Justice "had filed a number of amicus briefs" on FDA's behalf). These briefs suggested that FDA approval of labeling preempts conflicting or contrary state law. *Id.*; Jeffrey Rosen, *Supreme Court Inc.*, N.Y. TIMES MAG., Mar. 16, 2008, at 38, 66-68 (describing FDA's change of position held for twenty-five years). The FDA now argues that its "premarket approval of medical devices should prevent injured consumers from bringing product-liability suits in state court." Rosen, *supra*, at 38, 66-68; *see also* Linda Greenhouse, *Justices to Hear Cases on Product Liability*, N.Y. TIMES, Jan. 19, 2008, at A1 (describing Bush administration's support of pharmaceutical manufacturer's Supreme Court appeal in six-million-dollar product-liability suit). The state courts of Vermont allowed the plaintiff to sue for damages under state law and upheld the large jury verdict. Greenhouse, *supra*. The manufacturer's appeal argued that the suit was preempted by the FDA's approval of the label. *Id.*; Gardner Harris & Alex Berenson, *Drug Makers Near Old Goal: A Legal Shield*, N.Y. TIMES, Apr. 6, 2008, at A1 (describing how Bush administration "has argued strongly in favor of the [preemption] doctrine" in product liability cases); Jeanne Lenzer, *FDA's Counsel Accused of Being Too Close to Drug Industry*, 329 BMJ 189, 189 (2004), available at <http://bmj.com/cgi/content/full/329/7459/189> (detailing FDA chief counsel's filing of briefs in defense of four companies sued in product-liability cases). "Since coming to the FDA, [Chief Counsel Daniel] Troy has filed briefs defending four companies, including Pfizer, SmithKline Beecham Consumer Products, and GlaxoSmithKline, arguing the side of the defendant corporation against people who were suing for damages after using that corporation's product." Lenzer, *supra*.

29. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934. In part VI, section D of the preamble to the labeling regulations dealing with federalism, the FDA announced its belief "that under existing preemption principles, FDA approval of labeling . . . preempts conflicting or contrary State law." *Id.*; *see also id.* at 3967 (reiterating preemption of state law). The preamble went on to state as follows:

If State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness information disseminated with respect to drugs for which FDA has already made a series of regulatory determinations based on its considerable institutional expertise and comprehensive statutory authority, the federal system for regulation of drugs would be disrupted. Where a drug has not been reviewed by FDA and decisions with respect to safety, effectiveness, and labeling have not been made by the agency, expert determinations would not yet have been made by FDA, and such disruption would not occur.

*Id.* at 3969.

and the National Highway Traffic Safety Administration (NHTSA).<sup>30</sup> These positions threaten to eviscerate any ability for individuals injured by defective products to receive compensation for their injuries under state law. At the same time, preemption would remove the additional incentive that the potential for tort claims provides to encourage manufacturers to err on the side of safety in the design, manufacture, and marketing of products.

These movements toward preemption also are taking place against a background of what Georgetown Law Professor David Vladeck calls “regulatory failure.”<sup>31</sup> While the agencies mentioned and others are arguing that state tort claims would interfere with federal safety regulation, many of their regulatory programs are in crisis. The air-traffic gridlock experienced in March and April of 2008 by much of the country was caused by FAA efforts to return once again to vigorously enforcing safety regulations.<sup>32</sup> Meanwhile, despite this recent history of weak enforcement, the United States Court of Appeals for the Second Circuit recently agreed with the *Air Transport Association of America*, an airline industry group, that the Airline Deregulation Act of 1978 preempts New York’s Airline Passenger Bill of Rights, on the grounds that the New York statute hinders the Federal Aviation Administration’s ability to maintain uniform standards for air travel.<sup>33</sup>

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30. See Sharkey, *Preemption by Preamble*, *supra* note 27, at 230-33 (discussing CPSC mattress-flammability regulation with preamble purporting to preempt state positive and judicial law); *id.* at 232-37 (discussing NHTSA proposed standard for vehicle roof safety that would preempt state tort law requirements); see also *id.* at 237-42 (discussing preemption language in FDA prescription drug labeling regulation); *supra* note 29 and accompanying text.

31. Vladeck, *supra* note 27, at 126-30 (observing inability of optimally functioning FDA to prevent harm to consumers from defective medical devices). Professor Vladeck further observes that regulation does not operate in an ideal world where the FDA always has perfect information, personnel, and other resources to react to safety hazards; where rules are updated swiftly to reflect needed changes; where firms promptly and candidly inform the FDA about problems with devices and drugs; and “where regulatory decisions are made free from political considerations.” *Id.* at 132.

32. See Nicole C. Wong, *Plane Groundings Create Snags for Logan Travelers*, BOSTON GLOBE, Mar. 28, 2008, at C1 (reporting grounding of planes to conduct delayed safety inspections). The grounding caused cancellations of 734 flights over two days and left passengers stranded. *Id.*; see also Matthew L. Wald, *Long List of To-Do’s at F.A.A.*, N.Y. TIMES, May 8, 2008, at C1 (addressing FAA’s regulatory dilemma). The grounding caused the FAA to “confront[] long-term questions about whether it should act more like a tough regulator, rather than a partner, of the airlines.” Wald, *supra*.

33. See *Air Transp. Ass’n of America, Inc. v. Cuomo*, 520 F.3d 218, 219 (2d Cir. 2008); see also Ken Belson, *Court Strikes Down State Law Protecting Stranded Fliers*, N.Y. TIMES, Mar. 26, 2008, at B2. Regulation of airlines is not the only area of the economy where preemption impedes an effective role for the states. In a 2007 decision, the Supreme Court upheld a regulation exempting state-chartered subsidiaries of national banks from regulation by state banking authorities. *Watters v. Wachovia Bank*, 550 U.S. 1, 9-12 (2007). Rejecting the arguments of fifty state attorneys general and bank regulators, the Court concluded in *Watters* that the federal statute barred Michigan banking officials from regulating the mortgage-lending affiliate of Wachovia. *Id.* at 33-35. The case involved a rule of the Office of the Comptroller of the Currency, which can hardly be said to have been an effective advocate for the consumer in the sub-prime mortgage crisis. See Robert M. Morgenthau, *Who’s Watching Your Money?*, N.Y. TIMES, Apr. 30, 2007, at A21. The five-three decision presented an unusual line-up of Justices with Justice Ginsburg writing an opinion for herself and Justices Breyer, Alito, Kennedy, and Souter, and with Justices Stevens, Roberts, and Scalia dissenting. Justice

News reports of regulatory failures of the FDA, which is responsible for regulating nearly 25 percent of the GDP, are frequent.<sup>34</sup> A recent television exposé about diseased cattle being kicked, prodded, and otherwise forced to slaughter presented graphic evidence of diseased meat entering the food supply.<sup>35</sup> In April 2008, the *New York Times* reported that contaminated heparin imported from China was implicated in more than sixty deaths in this country.<sup>36</sup> A 2007 Institute of Medicine (IOM) study pointed out numerous inadequacies in the process for initial approval and ongoing monitoring of the safety of drugs during their entire lifespan on the market.<sup>37</sup> Critics question whether the FDA has sufficient resources to regulate effectively in all the areas over which it has jurisdiction, including the safety and efficacy of drugs and medical devices and protecting the public from contaminated food.<sup>38</sup> Indeed, FDA Commissioner Andrew C. von Eschenbach recently wrote Congress to request an immediate infusion of \$275 million to upgrade oversight of foods,

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Thomas did not participate in the decision. *Watters*, 550 U.S. at 36. The unfathomable decisions interpreting the preemption provisions of the Employee Retirement Income Security Act (ERISA) also indicate that Congress hardly writes clear statements on preemption in statutes. The Court has a difficult time reconciling seemingly broad preemption provisions with equally global savings clauses in the same statutes. See *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 364-65 (2002). Justice Souter writes,

The “unhelpful” drafting of these antiphonal clauses occupies a substantial share of the Court’s time. In trying to extrapolate congressional intent in a case like this, when congressional language seems simultaneously to preempt everything and hardly anything, we “have no choice” but to temper the assumption that “the ordinary meaning . . . accurately expresses legislative purpose,” with the qualification “that the historic police powers of the States were not [meant] to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”

*Id.* (citations omitted); see also CHEMERINSKY, *supra* note 27, at 400; Sara Rosenbaum & Joel Teitelbaum, *Aetna Health, Inc. v. Davila: Implications for Public Health Policy*, 119 PUB. HEALTH REP., Sept.-Oct. 2004, at 510, 512 (noting Court’s ERISA jurisprudence shields health plans “from any serious financial consequences” of coverage decisions). The current environment offers “virtually no oversight by the U.S. Department of Labor of the quality of health plan coverage decision-making.” Rosenbaum & Teitelbaum, *supra*.

34. PETER BARTON HUTT, RICHARD A. MERRILL, & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW CASES AND MATERIALS* 20 (3d ed. 2007) (estimating twenty- to twenty-five cents of every consumer dollar is spent on products regulated by FDA).

35. Andrew Martin, *Largest Recall of Ground Beef Is Ordered*, N.Y. TIMES, Feb. 18, 2008, at A10 (explaining slaughterhouse recall resulting from distribution of undercover video showing workers abuse sick cows at meat-processing facilities).

36. See Walt Bogdanich, *Heparin Is Now Suspected in 62 Fatalities Across U.S.*, N.Y. TIMES, Apr. 10, 2008, at A17 (describing sophisticated analyses by FDA that identified cause of contamination in heparin ingredients imported from China). Kaiser Family Found., *Capitol Hill Watch: FDA Cannot Properly Inspect Foreign Companies that Manufacture Medications, Medication Ingredients, Report Finds*, KAISER DAILY HEALTH POL’Y REP., Apr. 23, 2008, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=3&DR\\_ID=51707](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=51707) (last visited Sept. 15, 2008) (reporting on findings in study conducted by Government Accountability Office).

37. INST. OF MED., *THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC* (2006), available at <http://www.iom.edu/CMS/3793/26341/37329.aspx>.

38. Mark B. McClellan, *Give FDA the Resources to Do Its Job*, THE HILL, Mar. 30, 2008, available at <http://thehill.com/op-eds/give-fda-the-resources-to-do-its-job-2007-03-05.html> (highlighting implications of underfunded FDA).

drugs, and devices produced abroad.<sup>39</sup> Legislation is pending in Congress to authorize the FDA to regulate tobacco products—overruling the Court’s decision in *FDA v. Brown & Williamson*.<sup>40</sup> The tobacco industry is arguing that the FDA is too overwhelmed by its current responsibilities to have tobacco added to its jurisdiction.<sup>41</sup> This position seems inconsistent with the arguments by the pharmaceutical device and drug manufacturers that FDA regulation provides adequate protection for consumers.

What has the Supreme Court’s response been to these developments? In February 2008, the Court decided in *Riegel v. Medtronic, Inc.* that state common-law tort claims were preempted by the premarket approval provisions of the MDA.<sup>42</sup> Unlike the closely divided Court in the *Lohr* case, Justice Ginsburg was the lone dissenter in *Riegel*, reasoning that because Congress failed to create any compensatory remedy for consumers injured by products approved through the premarket approval process, it did not intend a broad preemption of state common-law suits.<sup>43</sup> In November 2008, the Court will review a case, *Wyeth v. Levine*, that may involve the new FDA preamble on preemption, although the cause of action arose before the preamble was issued.<sup>44</sup> The case causes the Court to review a decision of the Vermont Supreme Court that FDA approval of the drug in question did not preempt a state law failure-to-warn claim.<sup>45</sup>

The issues decided in *Riegel* and presented in *Levine* share at least one feature with the Court’s decision of last term in *Massachusetts v. EPA*.<sup>46</sup> In that case, the Court held that the EPA has the authority to regulate greenhouse-gas emissions from new motor vehicles despite the EPA’s contrary

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39. Gardiner Harris, *F.D.A. Chief Writes Congress for Money*, N.Y. TIMES, May 14, 2008, at A15.

40. Stephanie Saul, *Reynolds Ads Say Tobacco Oversight Is Burden F.D.A. Doesn't Need*, N.Y. TIMES, Apr. 2, 2008, at C1 (reporting legislation would create a new center for tobacco regulation within FDA). The center is to be financed by tobacco industry fees, would ban candy-flavored cigarettes, and give the agency the authority to regulate the content of tobacco products. *Id.* This legislation would overrule the Supreme Court’s decision in *FDA v. Brown & Williamson Tobacco Corp.*, which held that Congress had precluded the FDA’s jurisdiction to regulate tobacco products. *See* 529 U.S. 120 (2000).

41. Saul, *supra* note 40.

42. 128 S. Ct. 999 (2008). Note that *Riegel* involved the FDA’s more rigorous premarket approval process, not the premarket notification process involved in the *Lohr* case. Apparently, it is no accident that Medtronic was a party in both the *Lohr* and *Riegel* cases. According to Rosen, “The company is colloquially referred to in the business community as ‘the preemption company’ because of its practice of arguing that the Food and Drug Administration’s ‘premarket approval’ of its products preempts product-liability suits in state courts.” Rosen, *supra* note 28, at 66.

43. *Riegel*, 128 S. Ct. at 1015, 1018-19 (Ginsburg, J., dissenting) (stating regulatory history and legislative history of statute indicate “Congress did not regard FDA regulation and state tort claims as mutually exclusive”). Justice Ginsburg noted that while the defendant could assert compliance with FDA regulations as an affirmative defense in the tort action, the Riegels’ claims were not automatically preempted. *Id.* at 1019-20.

44. *See* No. 06-1249, available at <http://www.supremecourtus.gov/docket/06-1249.htm>. The decision below is *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006) (affirming jury verdict of over six-million dollars for plaintiff).

45. *Levine*, 944 A.2d at 182.

46. 127 S. Ct. 1438 (2007).

interpretation of the statute. Similarly, *Riegel* required, and *Levine* will require, the Court to evaluate the extent of the relevant agency's substantive authority to regulate. In addition, *Levine* will require the Court to examine the extent to which an agency is authorized to interpret the reach of federal preemption and the extent to which this interpretation is entitled to deference.<sup>47</sup> Considering the issue of when agency interpretations of statutory authority are entitled to deference has been nearly a full-time occupation for administrative law scholars over the last twenty-five years.<sup>48</sup>

These legal issues exist in parallel to the significant policy arguments about whether overlapping federal and state regulation in these regulatory arenas is possible or desirable. In this regard, the twenty-first century federalization movement presents several features that distinguish it from the late twentieth-century effort to add federal enforcement power and programmatic resources to augment state efforts to address serious crime.<sup>49</sup> In the current movement, federal agencies, not the Congress, are taking the lead in promoting federalization. Decisions by the elected branch to strike a balance in favor of an enhanced federal role or preemption inherently have more legitimacy than the regulatory actions of the federal agencies. Second, the form of federalization these agencies are promoting—preemption—does not

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47. See *Levine*, 944 A.2d at 193 (concluding FDA's interpretation of federal preemption deserves no deference); see also *Gonzales v. Oregon*, 546 U.S. 243, 255-58 (2006) (holding agency's interpretation of preemptive effect of regulation on state law not entitled to deference under *Chevron*); *United States v. Mead*, 533 U.S. 218, 226-27 (2001) (reasoning less deference due when agency adopts interpretive position without notice and comment rulemaking or formal adjudication); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208-09 (1988) (deciding agency interpretation cannot have retroactive application without express statutory approval); *Chevron v. Natural Res. Def. Council*, 467 U.S. 837, 842-43 (1984) (creating two-step process for court review of agency interpretation of statutes). If a statute is unambiguous, the reviewing court and agency must follow the clear intent of Congress, but if a statute is ambiguous, the court must give deference to an agency's "permissible" construction of the statute. *Chevron*, 467 U.S. at 842-43. See generally David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461 (2008) (arguing against FDA's preemption determination).

48. See, e.g., Richard A. Nagareda, *Administrating Adequacy in Class Representation*, 82 TEX. L. REV. 287, 352 (2003) (labeling *Chevron* "perhaps the most discussed administrative law case of all time"). *Chevron* "frames the judicial inquiry into the existence of legal authority on the part of an agency to fill gaps and resolve ambiguities in the statutes it administers." Linda Jellum, *Chevron's Demise: A Survey of Chevron From Infancy to Senescence*, 59 ADMIN. L. REV. 725, 727 (2007) (questioning whether "there is anything new to say about *Chevron* given the vast commentary it has generated"); Nagareda, *supra*. *Chevron* is also cited extensively by courts. Donald S. Dobkin, *The Rise of the Administrative State: A Prescription for Lawlessness*, 17 KAN. J.L. & PUB. POL'Y 362, 373 (2008) (noting, "In a remarkably short period, *Chevron* has become one of the most cited cases in all of American law"). By December 2001, *Chevron* had "been cited in federal courts over 7000 times—far more than *Brown v. Board of Education*, *Roe v. Wade*, and *Marbury v. Madison*. In terms of sheer citations, *Chevron* may well qualify as the most influential case in the history of American public law." Torrey A. Cope, *Judicial Deference to Agency Interpretations of Jurisdiction After Mead*, 78 S. CAL. L. REV. 1327, 1328 (2005) (observing, "Courts have cited *Chevron* nearly 8000 times, a testament to both the ubiquity of administrative government and the extensive scope of *Chevron's* reach"); Dobkin, *supra*.

49. See *supra* text accompanying notes 1-17 (detailing increased use of federal power to combat crime in late twentieth century).

contemplate overlapping and parallel state and federal jurisdiction.<sup>50</sup> Unlike the Clinton era federalization efforts, which augmented state remedies with overlapping and expanded federal remedies, the preemption movement will eliminate state-law remedies.<sup>51</sup> These efforts will diminish the traditional and historic role of the states in the areas preempted.<sup>52</sup>

Third, the federal courts should not be complicit in the process of altering the balance of federal and state power and responsibility<sup>53</sup> or the balance between private and public enforcement of standards.<sup>54</sup> Fourth, Congress could take a role in clarifying for the courts and the agencies the preemptive effect of statutes. Indeed, after the Court's recent decision in the *Riegel* case, Congressman Henry Waxman and Senator Edward Kennedy, leaders on committees with jurisdiction over the FDA, stated that the Court's interpretation in *Riegel* is not what Congress intended and expressed their intention to introduce legislation to overturn the decision.<sup>55</sup>

### III. COUNTERPOINT<sup>56</sup>

What will the Roberts Court do? As noted at the outset, this area pits two core conservative values against each other: preserving a powerful role for the states in the federal system—valuing federalism, and minimizing regulation and letting markets determine appropriate levels of product safety. Jeffrey Rosen predicted in a recent article in the *New York Times Magazine* that

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50. See Landers, *Federalization of State Law*, *supra* note 2, at 819-22 (discussing potential for federal-state cooperative enforcement and programmatic efforts through enhanced federal role in spheres previously sole province of state law).

51. See Adam Cohen, *What Ever Happened to (the Good Kind of) States' Rights?*, N.Y. TIMES, May 23, 2008, at A24 (arguing federal regulation should set minimum level of rights, not prevent states from doing more to protect their citizens).

52. See Stephen Labaton, 'Silent Tort Reform' is Overriding States' Powers, N.Y. TIMES, Mar. 10, 2006, at C5 (explaining opinions of sixteen state attorneys general that state courts serve important check on government safety standards); National Conference of State Legislatures, *FDA Final Rule on Prescription Drug Labeling*, Jan. 19, 2006, <http://www.ncsl.org/statefed/health/FDArule.htm> (last visited Sept. 15, 2008) (stating opposition to preemption provision on several grounds, including policy against preempting state authority). The preemption provision usurps the authority of Congress, state legislatures, and state courts; violates the Federalism Executive Order that requires federal agencies to consult with states; is contrary to the consumer-protection goals of the rest of the rule; and is contrary to the NCSL's long-standing and unwavering official-policy position against preemption of state authority. *Id.*

53. See Sharkey, *Preemption by Preamble*, *supra* note 27, at 258 (arguing elected body should take lead in areas implicating balance of federal-state relations).

54. See *id.* at 248-50 (noting "troubling asymmetry: agencies are given significant discretion to interpret or declare the preemptive scope of the regulations they promulgate, but when it comes to conferring private rights of action under those same regulations, court tied their hands").

55. Linda Greenhouse, *Justices Shield Medical Devices from Lawsuits*, N.Y. TIMES, Feb. 21, 2008, at A1 (reporting "[c]rucial Democratic lawmakers" stated intention to seek legislation to correct Court's decision in *Riegel*).

56. In music, "counterpoint" describes "the combination of two or more melodic lines," and "is a feature of all music in which combinations of two or more simultaneously sounding pitches are regularly employed." RANDEL, *supra* note 1, at 162.

protecting corporate interests from regulation will prevail in the end because of allies like Justices Stevens and Breyer, both of whom voted with the majority in *Riegel*.<sup>57</sup> Rosen also identified Justice Ginsburg as an adherent to this view, but her dissent in *Riegel* suggests otherwise.<sup>58</sup> Appointments to the Court by the next President will be crucial to defining the direction the law will take in these preemption cases.

#### IV. CODA<sup>59</sup>

Another aspect of these cases involving the interpretation of federal statutes illustrates a potentially new role for Justice Stevens. He was the author of the Court's earlier decision involving FDA preemption of state tort law in *Medtronic v. Lohr*.<sup>60</sup> In *Lohr*, the Court ruled that certain state tort claims are not preempted for a product approved for market under a process much less rigorous than the full premarket approval process involved in *Riegel*.<sup>61</sup> In *Riegel*, Justice Stevens concurred in the judgment, but wrote separately to voice his agreement with Justice Ginsburg's analysis of the history and principal purpose of the preemption provision at issue, while siding with the majority in its conclusion that Congress enacted a statute that covered more territory than envisioned by its authors.<sup>62</sup> Justice Stevens may be playing a mediating role by trying to build bridges to span the ideological and philosophical distance separating the majority and dissenting justices in these cases.

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57. Rosen, *supra* note 28, at 40-41, 43.

58. See *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1013 (2008) (Ginsburg, J., dissenting) (asserting Congress did not intend curtailment of lawsuits against medical-device manufacturers).

59. See RANDEL, *supra* note 1, at 146. "In instrumental music following regular musical forms," a "coda" is "a concluding section extraneous to the form as usually defined; any concluding passage that can be understood as occurring after the structural conclusion of a work and that serves as a formal closing gesture." *Id.*

60. 518 U.S. 470.

61. See *supra* text accompanying notes 19-27.

62. *Riegel*, 128 S. Ct. at 1011-13 (Stevens, J., concurring in part and concurring in the judgment) (conceding that "[a]s Justice Ginsburg persuasively explains, the overriding purpose of the legislation was to provide additional protection to consumers, not to withdraw existing protections," but nevertheless concluding that "its text does preempt state law requirements that differ"). In another recent case, involving the effect of certain treaty obligations on state courts, Justice Stevens wrote a concurrence voicing his agreement with certain aspects of the dissenting opinion. *Medellin v. Texas*, 128 S. Ct. 1346, 1372 (2008) (Stevens, J., concurring) (acknowledging "great deal of wisdom" in Justice Breyer's dissent). Justice Stevens noted that "this case presents a closer question than the Court's opinion allows." *Id.*