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Preemption: Will Traditional State Authority Survive?

WHEN DOES STATE LAW TRIGGER PREEMPTION ISSUES?

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Executive Summary

In part I, Professor McGarity introduces his paper with an example of the human side of the preemption doctrine: the story of a cardiology patient whose medical benefit plan resisted approving the surgery deemed necessary by his heart specialist, with the result that the patient died before he could have the life-saving procedure. When the patient's family sued the benefit plan for depriving him of the chance to live, the court held that the Employee Retirement Income Security Act (ERISA) preempted their state tort cause of action, yet it provided no remedy for the patient's death.

Part II, ***"The Law of Preemption,"*** *provides a primer on the preemption doctrine—its origins in the Supremacy Clause of the U.S. Constitution, and the several forms it takes:* ***express preemption****, either through clear statements by Congress of its intent to supersede state common law or when state laws and regulations (often called "requirements" and "prohibitions") are deemed inconsistent with federal regulatory schemes; and* ***implied preemption*** *of state measures where Congress has* ***occupied a field*** *of the law, or where state measures* ***conflict*** *with federal law—either by making compliance with both federal and state law* ***impossible****, or by creating* ***an obstacle*** *to the full accomplishment of federal objectives.*

In part III, ***"Preemption as Tort Reform in the Bush Administration,"*** *Professor McGarity recounts the recent efforts of the federal government to utilize the preemption doctrine to limit or eliminate common law causes of action in two ways: by writing or rewriting Executive Branch agency regulations—or preambles to regulations—so as to create conflicts with state law; or by supporting the arguments of private litigants that certain common law causes of action are preempted. He cites several examples: drug-labeling regulations of the Food and Drug*

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Administration (FDA); mattress safety regulations of the Consumer Product Safety Commission (CPSC); motor vehicle roof crush regulations of the National Highway Traffic Safety Administration (NHTSA); and the drug products liability case Wyeth v. Levine, in which the government supported the pharmaceutical company, but the U.S. Supreme Court denied preemptive effect to the preamble to a drug labeling regulation.

Part IV, ***"Agencies, Juries, and the Decision Whether to Preempt,"*** *reviews a number of considerations that might inform decisions on what, if any, preemptive effect to grant to new enactments. Professor McGarity compares the strengths and weaknesses of the two primary institutions of consumer protection: regulatory agencies and the common law courts. He looks at their technical and policymaking expertise and their capacity to bring information to the attention of decisionmakers. He gives particular attention to the issue of regulatory failure—the extent to which regulatory agencies can be "captured" or manipulated by those they were created to regulate, are hampered by conflicts of interest, are hamstrung by limited financial resources, and tend to respond slowly to new threats to public health and safety. He also considers the power available to citizen juries to award compensation and to punish wrongdoers, the empirical evidence on the extent to which juries may misuse that power, and the role of judges in keeping jury decisionmaking within lawful bounds.*

Professor McGarity concludes that, while federal regulatory agencies have "clear institutional advantages over common law courts and juries" in some areas, legislators and courts should be cautious about assuming that the agencies can provide sufficient corrective justice for the citizens they are created to serve. Common law litigation, he writes, provides a useful "helping hand" in protecting the public, and regulators have a legal and moral duty to the beneficiaries of their programs to be sure that consumers are adequately protected.

I. INTRODUCTION

Buddy Kuhl died unnecessarily as a result of the inexcusable indifference of the administrator of his medical benefit plan. The designated primary care physician under Mr. Kuhl's employer-sponsored medical benefit plan recommended that Mr. Kuhl see a heart specialist after he suffered a serious heart attack. Because the local Kansas City hospitals lacked proper equipment for the prescribed surgery, two heart specialists recommended that Mr. Kuhl undergo surgery at a St. Louis hospital. After Mr. Kuhl and his primary care physician scheduled the necessary surgery, the medical plan's "utilization reviewer" refused to approve his pre-certification request. Because Mr. Kuhl could not afford to pay for the operation out of his own pocket, the surgery was canceled. After a third specialist agreed that surgery in St. Louis was necessary, the plan finally pre-certified the operation. But Buddy's heart had deteriorated by then to the point at which surgery was no longer a feasible option. When the St. Louis specialist recommended a heart transplant instead, the plan refused to pre-certify that surgery.

Within three months, Mr. Kuhl succumbed to his heart affliction. His family sued the medical benefit plan for malpractice, negligent infliction of emotional distress, and tortious

interference with contract. At the plan's request, the federal court dismissed the case, holding that it was preempted by the Employee Retirement Income Security Act (ERISA), and the Eighth Circuit Court of Appeals affirmed that holding.[1] The Supreme Court later reached the same result in a related case, *Aetna Health, Inc. v. Davila*.[2]

Buddy Kuhl's tragedy is just one of many cases in which defendants have successfully avoided claims by deserving plaintiffs for corrective justice by persuading courts that Congress either implicitly or explicitly preempted those claims in legislation empowering federal regulatory agencies to protect public health and safety by granting licenses to or prescribing standards for products and activities subject to their jurisdiction. In a few cases, it is clear that Congress did in fact intend to deprive alleged victims of federally regulated products and practices of their day in court. But far more frequently, it seems clear that Congress did not focus on the question of federal agency preemption of state common law claims. In these cases, the courts must divine congressional intent with very little guidance in the language of the statute or its legislative history. When the implementing agency offers a view on the preemption question, the courts must also decide the degree to which they should defer to the agency's judgment on that question. The relative competence of agencies and juries may be relevant to all of these issues.

This paper will present an overview of the law of federal preemption, focusing especially on the issue of preemption of common law claims by federal regulatory statutes. It will then describe the aggressive efforts by the George W. Bush Administration to accomplish a backdoor form of tort reform by urging courts to find that state common law claims are preempted by lax federal agency standards and approvals. Finally, it will examine the relative strengths and weaknesses of federal agencies and common law juries in deciding the kinds of questions that typically arise in these cases.

II. THE LAW OF PREEMPTION

Under the Supremacy Clause of the United States Constitution, laws duly enacted by the Congress of the United States are the "supreme Law of the Land" and therefore binding on state and federal courts, state laws "to the contrary notwithstanding."[3] Congress can therefore expressly preempt state law on questions over which Congress may constitutionally exercise its legislative power, and it has done so on hundreds of occasions.[4] According to a 2006 report issued by the National Academy of Public Administration, "[f]ederal preemption of state and local responsibilities has grown rapidly in the past 40 years and will likely continue to grow."[5]

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[1] Kuhl v. Lincoln Nat'l Health Plan of Kansas City, Inc., 999 F.2d 298 (8th Cir. 1993).

[2] Aetna Health, Inc. v. Davila, 542 U.S. 200 (2004).

[3] U.S. CONST., art. VI, para 2.

[4] Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985); JOSEPH F. ZIMMERMAN, CONGRESSIONAL PREEMPTION: REGULATORY FEDERALISM 1 (2005).

[5] NATIONAL ACADEMY OF PUBLIC ADMINISTRATION, BEYOND PREEMPTION: INTERGOVERNMENTAL PARTNERSHIPS TO ENHANCE THE ECONOMY 1 (May 2006) (quotation); *see also* ZIMMERMAN, *supra* note 4, at 7 (preemption statistics).

Although Congress can expressly delegate the power to preempt to federal agencies, it has only very rarely elected to do so.[6]

Under *Erie Railroad Co. v. Tompkins*,[7] federal courts must apply state law to state common law claims.[8] But when Congress exercises its power under the Commerce Clause to create a federal regulatory regime, it may preempt inconsistent state common law.[9] The federal law supplants the state law, and the federal courts must apply the federal law.

The Supreme Court has, however, articulated a "presumption against preemption" when Congress legislates in "a field which the States have traditionally occupied."[10] The Court has held that "[i]n areas of traditional state regulation," the courts must "assume that a federal statute has not supplanted state law unless Congress has made such intention 'clear and manifest.'"[11] The presumption is especially powerful in cases in which Congress has arguably preempted state common law remedies but failed to create a federal cause of action or some other alternate administrative compensation regime to provide corrective justice to injured plaintiffs.[12] Most students of preemption, however, agree with Professor Viet Dinh that the "actual strength" of the presumption against preemption "is a matter of considerable doubt."[13]

A. Express Preemption of State Common Law Claims

Congress only very rarely mentions state common law when it writes a provision expressly preempting state common law. When Congress has expressly preempted state common law, courts may not entertain claims based on the preempted law. Congress ordinarily expressly preempts common law claims in statutes that create alternative compensation vehicles for injured plaintiffs.[14] For example, the Federal Employers Liability Act replaces state common law with a

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[6] Richard C. Ausness, *Preemption of State Tort Law by Federal Safety Statutes: Supreme Court Preemption Jurisprudence Since* Cipollone, 62 KY. L.J. 913, 920-21 (2003); Richard J. Pierce, *Regulation, Deregulation, Federalism, and Administrative Law: Agency Power to Preempt State Regulation*, 46 U. PITT. L. REV. 607, 636-37 (1985); s*ee, e.g.*, 30 U.S.C. § 1254(g) (Surface Mine Control Act).

[7] Erie R.R. v. Tompkins, 304 U.S. 64 (1938).

[8] *Id.* at 78.

[9] Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992).

[10] Rice v. Santa Fe Elevator Corp. 331 U.S. 218, 230 (1947).

[11] Bates v. Dow Agrosciences, LLC, 544 U.S. 431, 449 (2005) (quoting N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995); Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 716 (1985)).

[12] English v. Gen. Elec. Co., 496 U.S. 72, 87-90 (1990); Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984); *see* CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993).

[13] Viet Dinh, *Reassessing the Law of Preemption*, 88 GEO. L. J. 2085, 2086 (2000) (quotation); *see also* DAVID G. OWEN, PRODUCTS LIABILITY LAW 899 (2005); Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967, 968 (2002) (arguing that there is now a de facto presumption in favor of preemption).

[14] Timothy D. Lytton, *The NRA, The Brady Campaign, & the Politics of Gun Litigation*, in TIMOTHY D. LYTTON, ED., SUING THE GUN INDUSTRY 152, 174 [hereinafter SUING THE GUN INDUSTRY] (Univ. Mich. Press 2005).

liberal federal cause of action for workers of interstate common carriers.[15] Similarly, the National Childhood Vaccine Injury Act of 1986 establishes "a remedial program designed to provide swift compensation for persons injured by vaccines, while ensuring that the nation's supply of vaccines isn't unduly threatened by the costs and risks of litigation."[16] More recently, Congress established an administrative process through which the victims of the September 11, 2001, terrorist attacks and their families could claim on a no-fault basis medical expenses, economic compensation, and limited damages for pain and suffering from a federal fund managed by a "Special Master" appointed by the Attorney General.[17] The law preempts all common law claims against defendants other than Al-Qaeda and Osama Bin Laden if a claimant accepts compensation from the fund, but potential claimants may opt out of the administrative system and pursue common law remedies subject to prescribed liability caps.[18]

B. Express Preemption of Inconsistent State "Requirements"

Congress has enacted many express preemption provisions specifically designed to substitute a federal regulatory regime for potentially inconsistent state laws and regulations.[19] These preemption clauses typically use terms like "requirements" or "prohibitions" to identify the particular state or federal actions that Congress means to preempt. In a case involving the federal labor laws, the Supreme Court in 1959 announced that state regulation "can be as effectively exerted through an award of damages as through some form of preventive relief," because "[t]he obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."[20] The Court then opened the door to expansive common law preemption arguments in *Cipollone v. Liggett Group, Inc*.[21] The plurality opinion concluded that the purpose of the 1965 Cigarette Act, which preempted any state law-imposed "statement" related to smoking and health on cigarette packages, was to prohibit "state and federal rulemaking bodies from mandating particular cautionary statements" and not to preempt "state-law damages actions." The language of the 1969 Act preempting state-imposed "requirements or prohibitions," on the other hand, "easily encompass[ed] obligations that take the form of common-law rules."[22]

Yet subsequent Supreme Court decisions make it clear that the question of congressional intent is not easily resolved by searching the language of express preemption clauses for magic words like "requirement" and "prohibition." The express preemption clause of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) allows a state to "regulate the sale or use of

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[15] 45 U.S.C. §§ 51-60; *see* DAN B. DOBBS, THE LAW OF TORTS 40, 312 (2000); Robert L. Rabin, *Federalism and the Tort System*, 50 RUTGERS L. REV. 1, 26 (1997).

[16] 42 U.S.C. § 300aa-11-15; Moss v. Merck & Co., 381 F.3d 501, 503 (5th Cir. 2004) (quotation).

[17] 49 U.S.C. § 40101.

[18] THOMAS F. BURKE, LAWYERS, LAWSUITS, AND LEGAL RIGHTS 39-40 (Berkeley, Univ. Cal. Press 2002).

[19] Rabin, *supra* note 15, at 27 (preemption of common law is rare).

[20] San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 246-47 (1959).

[21] Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992).

[22] 505 U.S. at 521 (quoting San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 247 (1959)).

any federally registered pesticide . . . , but only if and to the extent that the regulation does not permit any sale or use prohibited by" the Environmental Protection Agency (EPA).[23] In addition to this "floor preemption" provision, the clause also states that a state may "not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under" the statute.[24] Relying on *Cipollone*, defendants in pesticide litigation argued that failure to warn claims regarding federally registered pesticides were preempted.[25]

The Supreme Court, in *Bates v. Dow Agrosciences, LLC*,[26] rejected this argument. Recognizing that the term "requirements" in FIFRA's preemption provision "embrace[d] common law duties," the Count noted that it encompassed only state-imposed requirements that were "in addition to or different from" federal requirements.[27] Therefore, claims based on conduct that violated EPA-imposed requirements were likewise not preempted. The Court then found that "[a] requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement." It was not concerned that juries in 50 different states would produce "a crazy-quilt of anti-misbranding requirements different from the one defined by FIFRA itself and intended by Congress to be interpreted authoritatively by EPA."[28] The court reasoned that "FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings."[29] Indeed, "the specter of damage actions may provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement."[30]

The Court demonstrated that *Cipollone* retained considerable vitality after *Bates* in *Riegel v. Medtronic, Inc*,[31] a case that involved the Medical Device Amendments to the Food Drug and Cosmetics Act. The express preemption clause of that statute also uses the word "requirement" and does not mention state common law claims.[32] In the 1996 case of *Medtronic, Inc. v. Lohr*,[33] the Supreme Court held that that statute preempted some, but not all common law claims directed toward medical devices that had FDA had approved through a very abbreviated process for devices that are "substantially equivalent" to devices in existence in 1976. In *Riegel*, the Court held that "[a]bsent other indication, reference to a State's 'requirements' includes its

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[23] 7 U.S.C. § 136v(a).

[24] 7 U.S.C. § 136v(b).

[25] Brief for Respondents, at 27, n. 17 (Nov. 24, 2004) (collecting cases), Bates v. Dow Agrosciences, LLC, 544 U.S. 431 (2005) (collecting cases). *See also* Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. REV. 559, 588 (1997) (impact of *Cipollone* on pesticides litigation).

[26] Bates v. Dow Agrosciences, LLC, 544 U.S. 431 (2005).

[27] *Id*. at 443.

[28] *Id*. at 448.

[29] *Id*. at 451.

[30] *Id.*

[31] Riegel v. Medtronic, Inc. 128 S. Ct. 999 (2008).

[32] 21 U.S.C. § 360k(a).

[33] Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

common-law duties."[34] Noting that during the full approval process "the FDA requires a device . . . to be made with almost no deviations from the specifications in its approval application,"[35] the Court explained that "State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect."[36] To the extent that the plaintiff's claim was based on a company's violation of FDA's regulations, however, there was no variance between the duty imposed by the federal government and that imposed by the common law. Therefore, such claims were not preempted.[37]

C. Implied Preemption of State Common Law

When Congress fails to mention preemption one way or the other in the statute establishing a regulatory program, a court might be tempted to apply the presumption against preemption to conclude that Congress did not intend to preempt state common law claims because the common law is clearly "a field which the States have traditionally occupied." The Supreme Court has, however, on many occasions not yielded to that temptation, and the result has been a body of implied preemption law that is even more confusing that the Court's express preemption jurisprudence.

The conceptual framework for implied preemption is relatively straightforward.[38] If, despite its failure to address preemption directly, "Congress evidences an intent to occupy a given field, any state law falling within that field is preempted." This facet of implied preemption, called "field preemption," rarely applies to state common law claims. And, "[i]f Congress has not entirely displaced state regulation over the matter in question, state law is still preempted to the extent it actually conflicts with federal law." The Court has further subdivided "conflict preemption" into two additional subcategories. The first category, called "impossibility" preemption, encompasses situations in which compliance with both the state law and the federal law would be impossible because complying with state law would cause the actor to violate federal law and vice versa. Under the second category, called "obstacle preemption," state law is preempted to the extent that it conflicts with federal law because "the state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress."[39] The Court's most recent implied preemption holding, in *Wyeth v. Levine*,[40] discussed below, provides a good example of both doctrines: "impossibility" and "obstacle" preemption.

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[34] Riegel, 128 S. Ct. at 1008.

[35] *Id.* at 1007.

[36] *Id.* at 1008.

[37] *Id.* at 1011.

[38] The following description of the law of preemption is taken from Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 248 (1984).

[39] *Id.* at 248.

[40] Wyeth v. Levine, 129 S. Ct. 1187 (2009).

III. PREEMPTION AS TORT REFORM IN THE BUSH ADMINISTRATION

During the 2000 presidential campaign, George Bush complained that "vexatious litigation" was threatening the economic vitality of the American economy, and he promised to make "tort reform" a high priority in his presidency.[41] Once in the Oval Office, he appointed strong proponents of civil justice reform to key positions in the Justice Department and the legal offices of the relevant federal agencies. Although the Bush Administration's ambitious legislative initiatives made very little headway in Congress, its much less transparent efforts to influence the courts in preemption litigation were more successful.

A. FDA Labeling Regulations

The Administration's aggressive preemption project began at the Food and Drug Administration, where President Bush appointed Dan Troy, an attorney for the pharmaceutical industry, to be the Chief Counsel.[42] Since the Food, Drug, and Cosmetics Act did not contain an express preemption clause, Troy concluded that the agency had discretion to interpret the statute to hold that common law failure to warn claims were preempted.[43] His theory, and that of the drug industry, was that it would be impossible for a drug manufacturer to comply with the statutory duty to use only the FDA-approved label and with any common law duty that prescribed a particular warning that differed from the language on that label. At the very least, the common law claim would be an obstacle to the agency's policy of maintaining uniformity in drug labels throughout the country. In this regard, however, Troy faced an uphill battle, because the agency's position had traditionally been exactly the opposite. His predecessor had written "that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."[44]

Troy's initial strategy was to file *amicus curiae* briefs in courts that were entertaining motions to dismiss cases based on federal preemption, and he invited defense counsel to request such briefs from the agency in pending cases.[45] The first opportunity presented itself in a California case involving the SSRI (selective serotonin reuptake inhibitor) antidepressants when the manufacturer's attorneys decided to raise the preemption defense in an appeal to the Ninth Circuit. One of the company's outside lawyers asked Dan Troy to file an *amicus curiae* brief supporting Pfizer's position. Troy had a slight problem with the request, because he had represented the defendant at his old law firm just months before joining the Bush

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[41] BURKE, *supra* note 18, at 6, 25.

[42] Michael Kranish, *FDA Counsel's Rise Embodies U.S. Shift*, BOSTON GLOBE, Dec. 22, 2002, at A1.

[43] Daniel E. Troy, *FDA Involvement in Product Liability Lawsuits*, UPDATE, Jan.-Feb. 2003, at 4, 7-8 (article based on speech "originally delivered at [the Food and Drug Law Institute's] annual Advertising and Promotion Conference, Sept. 11-12, 2002"); *see also* Margaret H. Clune, *Stealth Tort Reform: How the Bush Administration's Aggressive Use of the Preemption Doctrine Hurts Consumers* 2-3 (Center for Progressive Regulation White Paper No. 403, Oct. 2004); Robert Pear, *In a Shift, Bush Moves to Block Medical Suits*, N.Y. TIMES, July 25, 2004, at A1.

[44] Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7 (1997)

[45] Troy, *supra* note 43; Aff. of Jessica R. Dart, Mar. 1, 2004, at 2, Dusek v. Pfizer, Inc., 2004 WL 2191804 (S.D. Tex. 2004); s*ee also* Clune, *supra* note 43; Pear, *supra* note 43.

Administration.[46] However, persuaded that his was "a classic case in which the government's interests ought to be the same" as those of the regulated companies, Troy agreed to write the brief.[47] Mr. Troy was also convinced that FDA had "absolute control over the label,"[48] despite FDA regulations allowing manufacturers to change labels without FDA approval, and despite the legal reality that courts make the final determination whether a drug is misbranded when FDA brings an enforcement action. The amicus brief argued that if the manufacturer had amended its label to provide the warning suggested by the plaintiff, the drug would have been "misbranded" and subject to seizure.[49] The court of appeals upheld the district court's dismissal on causation grounds without reaching the preemption issue.[50]

After the California litigation, other defense counsel did not have to persuade Troy to file *amicus curiae* briefs in their cases. They simply cited the government's brief to courts throughout the country in support of motions to dismiss pending cases. Their efforts, however, achieved mixed results: some courts accepted the preemption argument while others rejected it on the ground that it represented a radical departure from the agency's former position.[51]

Sensing that the amicus briefs were not sufficiently persuasive, agency lawyers decided to write the agency's new position on preemption into law. In early 2006, the agency revived a Clinton Administration "midnight regulation," a proposed labeling rule that had remained dormant since late 2000 as a vehicle for writing. The proposed regulations established requirements for the "content and format" of labels for human prescription drugs and biological products.[52] Although the Clinton Administration's notice of proposed rulemaking had stated that the regulations did "not preempt state law,"[53] the preamble to the Bush Administration's final regulation took the opposite position.

Responding to industry concerns that the new regulations might make them more vulnerable to product liability claims, the preamble stated that "under existing preemption principles such product liability claims would be preempted," because "FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary state law."[54] The preamble stressed that the FDA was the "expert Federal public health agency charged by

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[46] 5 C.F.R. § 2635.502; Kranish, *supra* note 42.

[47] Amicus Brief for the United States (Sept. 3, 2002), Motus v. Pfizer, Inc., 358 F.3d 659 (9th Cir. 2004); Kranish, *supra* note 42.

[48] Kranish, *supra* note 42.

[49] Amicus Brief for the United States at 21 (Sept. 3, 2002), Motus v. Pfizer, Inc., 358 F.3d 659 (9th Cir. 2004).

[50] Motus v. Pfizer, Inc., 358 F.3d 659 (9th Cir. 2004).

[51] *Compare* Dusek v. Pfizer, Inc., 2004 WL 2191804 (S.D. Tex. 2004) *and* Needleman v. Pfizer, Inc., 2004 WL 1773697 (N.D. Tex. 2004) *with* Witczak v. Pfizer, Inc., 377 F. Supp. 2d 726 (D. Minn. 2005) *and* Cartwright v. Pfizer, Inc., 369 F. Supp. 2d 876 (E.D. Tex. 2005).

[52] Food and Drug Administration, Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products, 71 Fed. Reg. 3922 (2006).

[53] Food and Drug Administration, Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products, 65 Fed. Reg. 81082, 81103 (2000).

[54] Food and Drug Administration, *supra* note 52, at 3934.

Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading."[55] State common law actions, by contrast, "encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public . . . sometimes on behalf of a single individual or group of individuals."[56] The agency now read the statute "to establish both a 'floor' and a 'ceiling,' such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading."[57] It stated that judicial opinions that had relied on FDA regulations allowing a manufacturer "latitude" to "revise labeling by adding or strengthening warning statements without first obtaining permission from FDA"[58] misconstrued the regulations because "in practice manufacturers typically consult with FDA before [strengthening labels] to avoid implementing labeling changes with which the agency ultimately might disagree."[59]

B. CPSC Mattress Regulations

The Flammable Fabrics Act,[60] which authorizes the Consumer Product Safety Commission (CPSC) to promulgate "flammability standards" protecting consumers and homeowners against the risk of fires, contains an express preemption section providing that no state may establish or continue in effect a "flammability standard or other regulation" addressing the same fire risk unless it is identical to the federal standard.[61] On March 15, 2006, CPSC promulgated the first flammable fabric regulation in more than 25 years when it issued a new flammability standard for mattresses.[62] The preamble to this final rule stated that it would "preempt inconsistent state standards and requirements, whether in the form of positive enactments or court created requirements." The Commission's legal analysis cited no judicial precedent for the agency's new position, because none existed. It did, however, find the word "requirement" in the legislative history, and relied on past judicial interpretations of that word to find that the regulation would preempt future common law claims.[63]

C. NHTSA Roof Crush Regulations

In response to press reports of litigation involving Ford Explorer SUVs outfitted with Bridgestone/Firestone tires in the early 2000s, highlighting the auto industry's failure to equip

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[55] *Id.*

[56] *Id.*

[57] *Id.*

[58] *Id.*

[59] *Id.*

[60] Pub. L. 83-88, 67 Stat. 111 (1953).

[61] 15 U.S.C. § 1203.

[62] Consumer Product Safety Commission, Standard for the Flammabilty (Open Flame) of Mattresss Sets; Final Rule, 71 Fed. Reg. 13472, 13472, 13476, 13496-97 (2006).

[63] 71 Fed. Reg. at 13496-97.

passenger vehicles with easily available technologies for increasing roof strength,[64] the National Highway Traffic Safety Administration (NHTSA) published a proposed rule in 2005 upgrading its aging roof strength regulations.[65] Consumer groups urged NHTSA to adopt one of the two available "dynamic" tests for roof strength that the industry had developed and was using to improve some high-end vehicles,[66] but the auto industry persuaded NHTSA to stick with a slightly modified version of its largely discredited "static" test. Since almost 70 percent of current models already complied with the proposed rules, the change would have cost less than $11 per vehicle.[67] The proposal also announced the agency's conclusion that the final regulations would preempt all future common law roof strength claims.[68] Thus, the agency proposed to give the industry a liability shield worth billions of dollars at a bargain basement cost of $11 per vehicle.

The rules were not finalized during the Bush Administration. The Obama Administration promulgated a final rule on May 12, 2009 that was considerably more stringent. More importantly for present purposes, the final regulation disavowed the proposal's position on preemption, stating simply that the agency did not "foresee any potential State tort requirements that might conflict with" the rule.[69] President Obama subsequently wrote a memorandum to all federal agency heads telling them that they should not include preemption statements in regulations unless such provisions are "justified" under relevant legal principles.[70]

D. *Wyeth v. Levine*

The Supreme Court rejected the Bush Administration's position in the context of drug regulation in Wyeth v. Levine.[71] That case involved a Vermont musician, Diana Levine, who lost the lower half of her right arm after a nurse injected the anti-nausea drug Phenergan directly into an artery using the "IV-push," rather than the "IV-drip," technique. The label on the drug cautioned that the IV-push technique was risky because it might be injected into an artery instead of a vein, but it did not instruct doctors not to use the direct injection technique. Ms. Levine's lawyers argued that the label should have either "contraindicated" the technique or included a stronger warning. Wyeth's lawyers argued that the Food and Drug Administration's approved of the Phenergan label demonstrated that it was not defective. The jury agreed with Ms. Levine's

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[64] *See* Jeff Plungis & Bill Vlasic, *European Vehicles Exceed Standard for U.S. Car Roofs*, DETROIT NEWS, Apr. 12, 2004, at A9; Christopher Jensen, *Regulators Considering Making Car Roofs Safer*, CLEVELAND PLAIN DEALER, Nov. 8, 2001, at F1.

[65] National Highway Traffic Safety Administration (NHTSA), Federal Motor Vehicle Safety Standards; Roof Crush Resistance, Notice of Proposed Rulemaking, 70 Fed. Reg. 49223 (August 23, 2005).

[66] Jeff Plungis & Bill Vlasic, *Safety Test Ignores Real-Life Conditions*, DETROIT NEWS, April 11, 2004, at A9.

[67] NHTSA, *supra* note 65.

[68] *Id.* at 49245.

[69] National Highway Traffic Safety Administration, Federal Motor Vehicle Safety Standards; Roof Crush Resistance, Phase-In Reporting Requirements, 74 Fed. Reg. 22348 (May 12, 2009), at 22349.

[70] Memorandum for the Heads of Executive Departments and Agencies re: Preemption, May 20, 2009, available at www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption/.

[71] Wyeth v. Levine, 129 S. Ct. 1187 (2009).

lawyers and awarded $7.4 million in damages. The Vermont Supreme Court upheld the jury verdict.[72]

The Supreme Court, in a 6-3 opinion, affirmed the Vermont Supreme Court's determination that Ms. Levine's claim was not impliedly preempted under either the impossibility or the obstacle branches of implied preemption. Stressing that the key to preemption was congressional intent, the Court explicitly invoked the presumption against preemption. The Court first held that the impossibility branch of conflict preemption was inapplicable because the drug manufacturer could change its label at any time to make the warning more stringent or to add a contraindicated use, subject only to FDA's never-exercised right to disapprove. Wyeth therefore could have complied with both its common law duty and the FDA regulations by merely submitting a more stringent warning or contraindicating the IV-push technique. The Court stressed that "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times."[73]

The Supreme Court held that Ms. Levine's claim was not impliedly preempted because the purpose of the statute was to protect patients, and the FDA had far too few resources to do an adequate job of that all by itself. Furthermore, Congress had in fact amended the statute on several occasions in full knowledge that failure to warn suits were being decided by state courts and had not added an express preemption provision. Finally, the Court was unwilling to defer to the agency's interpretation of the statute as expressed in the preamble to the final labeling regulation. Instead of deferring to the agency's new position under *Chevron*,[74] the Court applied the *Skidmore/Mead* test for deference in which the agency's interpretation is entitled to some deference, but the weight that it receives depends on its "thoroughness, consistency, and persuasiveness."[75]

Under the *Skidmore/Mead* test, FDA's interpretation did not warrant deference. Among other things, the preamble was added at the last minute and did not go through the normal notice-and-comment of a regulation, a fact that Justice Stephen Breyer stressed in his concurring opinion.[76]

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[72] Levine v. Wyeth, 944 A.2d 179 (Vt. 2006).

[73] 129 S. Ct. at 1197-98.

[74] Chevron, U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837 (1984). The Court in *Chevron* explained the judicial review of agency statutory interpretation as follows:

> When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

Id. at 842.

[75] 129 S. Ct. at 1201 (citing United States v. Mead Corp. 533 U.S. 218 (2001); Skidmore v. Swift & Co., 323 U.S. 134 (1944)).

[76] 129 S. Ct. at 1204 (Breyer, J. concurring).

Furthermore, the preamble was at odds with the available evidence on congressional intent. The Court stressed that "state tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly."[77] Importantly, the Court noted that the common law provides a compensatory function that the regulatory regime lacked.[78]

IV. AGENCIES, JURIES, AND THE DECISION WHETHER TO PREEMPT

The decision to preempt requires Congress to balance a number of important considerations, not the least of which is the comparative institutional competence of federal regulatory agencies and state common law courts in advancing the goals of federal statutes, providing corrective justice to injured victims of defective products and irresponsible activities, and fostering an efficient national economy. The following discussion will focus on the comparative strengths and weaknesses of common law courts and federal regulatory agencies in providing technical expertise, policymaking expertise, relevant information, common sense judgment, and responsiveness to important policy issues as they arise.

A. Technical Expertise

Federal agencies have an "enormous comparative advantage" over judges and juries when it comes to the expertise required to resolve the technical questions of science, engineering, and economics that typically arise when federal regulatory requirements come into conflict with common law duties.[79] Agencies can call on expert resources and information-gathering abilities "that dwarf those of any trial jury." Preemption proponents worry that "unsophisticated jurors" with "20-20 hindsight" may attempt to second-guess the considered judgment of technically sophisticated agencies.[80]

Although regulatory agencies can ordinarily draw on more technical resources than juries, their ability to resolve complex technical issues is often quite limited.[81] At the same time, trial lawyers and defense counsel in major cases can devote considerable resources to hiring expert

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[77] *Id*. at 1202.

[78] *Id*. at 1199.

[79] Richard J. Pierce, *supra* note 6, at 654-55 (quotation); W. Kip Viscusi, *Overview*, in W. KIP VISCUSI, ED., REGULATION THROUGH LITIGATION 2 (Washington, D.C., AEI-Brookings 2002).

[80] Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2150-51 (2000) (unsophisticated jurors); W. Kip Viscusi, Steven R. Rowland, Howard L. Dorfman & Charles J. Walsh, *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1467-68 (1994) ("20-20 hindsight"); Brief of Washington Legal Foundation as Amicus Curiae, Nov. 19, 1999, at 17, Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000) ("dwarf" quotation). *See generally* W. Kip Viscusi, *Jurors, Judges, and the Mistreatment of Risk by the Courts*, 30 J. LEGAL STUDIES 107 (2001).

[81] Thomas O. McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729-810 (1979); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995).

consultants.[82] Moreover, many of the issues that both regulatory agencies and common law courts frequently address do not directly implicate expertise. For example, experts may be no more competent than jurors when it comes to evaluating the adequacy of a warning in communicating the nature and magnitude of risks to ordinary consumers.[83] Critics of preemption argue that what juries lack in scientific and technical expertise, they more than make up for in good sense and sound moral judgment, two qualities that are often sorely lacking in bureaucracies.[84]

B. Policymaking Expertise

Agencies can develop a "policymaking" expertise that in many ways transcends technical expertise. Policymaking expertise stems from the experience that agency staffs gain by dealing with the nitty gritty of policymaking on a day-to-day basis through procedures that are designed to maximize the number of interests and the range of information that the agency considers.[85] Most serious public policy disputes are "polycentric" in nature, in that their legitimate resolution requires the decisionmaker to weigh a number of different perspectives no one of which necessarily aligns with any of the others.[86] Soliciting input from the full range of affected interests will ordinarily make more useful information available to the decisionmaker.[87] In contrast (the tort "reformers" argue), courts "only receive the information that the litigants choose, for their own self-interested reasons, to provide," and the adjudicatory model that they employ becomes rather unwieldy when the number of perspectives exceeds two.[88] Attempts by plaintiffs to accomplish "regulation through litigation" in the courtroom are wholly lacking in this highly relevant policymaking expertise.[89]

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[82] Timothy D. Lytton, *Tort Claims Against Gun Manufacturers for Crime-Related Injuries: Defining a Suitable Role for the Tort System in Regulating the Firearms Industry*, 65 MO. L. REV. 1, 53 (2000) (agency resources questioned).

[83] *See* General Motors Corp. v. Farnsworth, 965 P.2d 1209, 1220 (Alaska 1998) (allowing claim based on defective seatbelt design based on consumer expectation test).

[84] David C. Vladeck, *Defending Courts: A Brief Rejoinder to Professors Fried and Rosenberg*, 31 SETON HALL L. REV. 631, 641 (2001) (good sense of jurors); Clayton P. Gillette & James E. Krier, *Risk, Courts, and Agencies*, 138 U. Pa. L. Rev. 1027, 1064 (1990) (comprehensive rationality quote); Mary L. Lyndon, *Tort Law and Technology*, 12 YALE J. ON REG. 137, 153-54, 157-58 (1995) (making both points).

[85] Viscusi, *supra* note 79, at 1; Lars Noah, *supra* note 80, at 2149-50; Edward T. Schroeder, *A Tort by Any Other Name? In Search of the Distinction Between Regulation Through Litigation and Conventional Tort Law*, 83 TEX. L. REV. 897, 922-23 (2005); Peter H. Schuck, *Why Regulating Guns Through Litigation Won't Work*, in SUING THE GUN INDUSTRY, *supra* note 14, at 225, 234.

[86] James A. Henderson & Aaron D. Twerski, *Achieving Consensus on Defective Product Design*, 83 CORNELL L. REV. 867, 884-85 (1998); Richard B. Stewart, *The Reformation of American Administrative Law,* 88 HARV. L. REV. 1667, 1693-97 (1975).

[87] Victor Schwartz & Leah Lorber, *State Farm v. Avery: State Court Regulation Through Litigation Has Gone Too Far*, 33 CONN. L. Rev. 1215, 1220 (2001).

[88] Schuck, *supra* note 85, at 234 (quotation); Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L. J. 2167, 2174 (2000).

[89] Viscusi, *supra* note 79, at 1; *see also* Peter W. Huber, LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES 83 (1988).

C. Regulatory Failure

Since federal agency preemption completely divests the courts of their corrective justice function, the assumption underlying preemption must be that agencies will do their job so well there will be no need for corrective justice, because no one is likely to be wrongfully damaged by the regulated products or activities. This is, of course, a preposterous assumption. The literature on federal regulation is filled with instances of regulatory failure, and scholars have identified several systemic causes of this failure. Although this is not the place to examine each of these failings in detail, the following brief summary should give some sense of the magnitude of the problem.

1. Agency Capture

Agencies over time can become "captured" by the industries they are supposed to be regulating and become much less aggressive in implementing their statutory responsibilities.[90] Capture theory posits that profit-seeking companies support the reelection of key legislators in return for sympathetic legislation and legislative oversight. The bureaucrats charged with implementing the legislation, who look to Congress for their rewards and punishment, then run the regulatory programs in a way that benefits the regulatees. In this way, agencies trade regulatory leniency for reduced congressional oversight purchased with generous campaign contributions. The process becomes a vicious circle that benefits regulatees at the expense of the intended public beneficiaries of the regulatory programs.

Less conspiratorial versions of the capture theory posit that agencies succumb to the sustained influence of one-sided information and blandishments and threats from the ever-present regulated entities. The simple rule of bureaucratic life that "you can't go to the mat every time" limits the extent to which an agency can force a recalcitrant industry to conform to the statute's conception of the public interest. Even when individual beneficiaries are sufficiently affected by a regulatory decision to take notice, they generally lack sufficient resources to make their preferences felt on a day-to-day basis.[91] Single industry regulatory agencies are especially susceptible to capture, because they depend so heavily upon the industry they regulate for the information they need and for political support in the appropriations process.[92]

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[90] CHARLES MCCARRY, CITIZEN NADER 217 (1972); George Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 335 (1971); *see also* PAUL J. QUIRK, INDUSTRY INFLUENCE IN FEDERAL REGULATORY AGENCIES 4-21 (1981); Jerry L. Mashaw & David L. Harfst, *Regulation and Legal Culture: The Case of Motor Vehicle Safety*, 4 YALE J. REG. 257, 270 (1987) (permanent campaigns); Cass R. Sunstein, *Constitutionalism After the New Deal*, 101 HARV. L. REV. 421, 448-49 (1987). *But see* David B. Spence, *The Shadow of the Rational Polluter: Rethinking the Role of Rational Actor Models in Environmental Law*, 89 CAL. L. REV. 917 (2001) (criticizing the capture theory as outdated and unsupported by the evidence).

[91] QUIRK, *supra* note 90, at 13 (quotations); Gillette et al., *supra* note 84, at 1067-69.

[92] QUIRK, *supra* note 90, at 5, 12 (single industry agencies susceptible); MICHAEL D. GREEN, BENDECTIN AND BIRTH DEFECTS 49 (1996) (FDA drug approval); Thomas O. McGarity, *Politics by Other Means: Law, Science, and Policy in EPA's Implementation of the Food Quality Protection Act*, 53 ADMIN. L. REV. 103, 203 (2001) (process for approving and amending regulations establishing pesticide tolerances); Lars Noah & Richard Merrill, *Starting from Scratch? Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 364 (1998) (process for affirming that food additives are "generally recognized as safe" at FDA); Teresa M. Schwartz, *Regulatory Standards and*

Proponents of preemption respond that the capture thesis is not well supported as an empirical matter.[93] Others maintain that a close relationship between agencies and regulatees is an entirely appropriate vehicle for ensuring that politically unaccountable agency officials weigh the interests of the regulated community in the course of determining the public interest. While this is undoubtedly true, it is still troubling that the beneficiaries of the regulatory programs, who also have a strong interest in keeping the agencies accountable, generally lack the same access to agency decisionmakers.

Because courts are not supposed to be politically accountable, judicial common law trials are generally insulated from the outside political pressures that can give rise to agency capture. Unlike single-industry agencies, common law courts entertain claims from hundreds of plaintiffs against hundreds of different defendants every year. Although some perennial defendants may press for tort reform in state legislatures and Congress, they do not attempt to influence judges in the same direct way that they importune agency officials.[94]

2. Conflict-of-Interest

According to the "revolving door" theory of government service, conflict-of-interest pervades the decisionmaking process as high-level agency officials rotate in and out of the government from the corporate offices or law firms of the regulated entities. Public officials may attempt to build "a store of goodwill with industry" if they know that a job awaits them at the end of their stints in the agencies.[95] While it is virtually impossible to prove that this has happened after-the-fact, cases raising serious suspicions of undue influence are not uncommon. Although most judges were employed by law firms prior to assuming their positions, and an occasional judge leaves the bench to practice with a law firm, strict rules that are policed by attorneys for the parties ensure that judges do not hear cases involving their former colleagues. The juries that decide the facts and apply the relevant standard of care to those facts are carefully screened by lawyers for both sides to ensure that they do not have an economic stake in the outcome. Indeed, any offer of a future job to a juror while serving on the jury would be prosecuted as a serious crime.

3. Agency Manipulation

Those agencies that avoid capture can be manipulated by regulatees who exploit informational advantages and known agency weaknesses to their economic advantage. Because federal agencies typically rely heavily upon regulated entities for the scientific, economic and statistical information that they need to support effective regulation, regulatees can manipulate agency assessments of their products and activities in at least three broad ways. They can

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Products Liability: Striking the Right Balance Between the Two, 30 MICH. J.L. REFORM 431, 445 (1997) (CPSC product regulation).

[93] Noah, *supra* note 80, at 2154.

[94] Anita Bernstein, *Products Liability in the United States Supreme Court: A Venture in Memory of Gary Schwartz*, 53 S.C. L. REV. 1193, 1219 (2002).

[95] QUIRK, *supra* note 90, at 19.

withhold relevant information. They can misreport, mischaracterize or otherwise present in a misleading way the information that they do provide to the agency. And they can attempt to "manufacture uncertainty" about the risks posed by their products and activities by "deconstructing" information that operates to their detriment.[96] Although regulatory agencies do not realize that they are being manipulated at the time it happens and rarely detect manipulation even after the fact, lawyers for injured plaintiffs have every incentive to uncover evidence of agency manipulation.

4. Limited Resources

Agencies are perennially lacking sufficient resources to do their jobs in an age of "hollow government." When federal agencies lack sufficient resources to implement their preemptive decisions by monitoring regulatee compliance and punishing noncompliance, then the implicit promise that their regulatory requirements will eliminate the need for corrective justice is only a mirage. Sadly, this appears to be the case for most, if not all, of the agencies that have been active in preempting common law claims.[97] Even if we are entering a period of more activist government, it is highly unlikely that regulatory agencies will see major increases in their enforcement budgets, because the enormous federal deficit that will plague the country in the wake of the financial institution bailouts will force Congress to remain parsimonious. Lawyers for the victims of accidents resulting from violations of agency regulations or fraudulent manipulation of federal regulatory processes can supplement scarce agency enforcement resources both by uncovering fraud and violations and by providing a strong additional incentive to comply with regulatory requirements.[98]

5. Limited Responsiveness

Resource shortages and a general "ossification" of the regulatory process prevent agencies from keeping up with evolving industry practices and improving safety technologies.[99] For many reasons, regulatory agencies are generally cautious about launching new regulatory initiatives. Rulemaking at the federal level has become so burdened by extraneous procedures, analytical requirements, and the necessities of compiling an adequate rulemaking record for judicial review, that agencies are reluctant to take on controversial issues unless forced to do so by political pressure or lawsuits. Once an agency has completed the effort, it is understandably reluctant to revisit the regulation in response to new information or technological improvements.

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[96] THOMAS O. MCGARITY AND WENDY E. WAGNER, BENDING SCIENCE (2007); Michael D. Green, *Safety as an Element of Pharmaceutical Quality: The Respective Roles of Regulation and Tort Law*, 42 ST. LOUIS L. J. 163, 182 (1998); Sheldon Krimsky, *Publication Bias, Data Ownership and the Funding Effect in Science: Threats to the Integrity of Biomedical Research*, in RESCUING SCIENCE FROM POLITICS: REGULATION AND THE DISTORTION OF SCIENTIFIC RESEARCH (WENDY WAGNER & RENA STEINZOR, EDS. 2005); Carl T. Bogus, *War on the Common Law: The Struggle at the Center of Products Liability*, 60 MO. L. REV. 1, 74 (1995).

[97] *See* THOMAS O. MCGARITY, THE PREEMPTION WAR 195-99 (Yale Univ. Press 2008).

[98] Timothy D. Lytton, *Introduction*, in SUING THE GUN INDUSTRY, *supra* note 14, at 1, 29; Teresa M. Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357, 1405 (1994); Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. POLICY & LEGAL ETHICS, 587, 591 (2005).

[99] OWEN, *supra* note 13, at 887; Lyndon, *supra* note 84, at 174; Schwartz, *supra* note 92, at 444-45.

Thus, the federal regulatory requirements that defendants invoke to preempt state common law claims usually reflect not current information and technologies, but the information and technologies that were available at time the agency completed the rulemaking exercise.[100] Common law litigants, by contrast, can assemble one team of experts who are familiar with the latest scientific studies and safety technologies for one case and assemble a different team for the next one.[101]

6. Consequences

In a perfect world, federal agencies would ensure that regulatees do not expose the beneficiaries of regulatory programs to undue risks to their health and economic well-being, and there would be no need for common law litigation to redress harms due to past wrongdoing. But, as Professor Vladeck observes,

> that would be a world where the [relevant agency] never lacks the information, personnel, technical data and other resources needed to deal immediately with emerging . . . hazards; where the agency acts as soon as it identifies a problem requiring a regulatory solution; where rules are updated swiftly to reflect needed design changes, technological advances or scientific knowledge; where companies quickly and candidly inform the [agency] about the problems they identify; and where regulatory decisions are made free from political considerations -- without pressure from regulated industry, congressional committees and the White House and the Office of Management and Budget.[102]

When an agency fails to deliver on its promise to protect, preemption deprives the beneficiaries of both the incentives that the common law courts can provide and the corrective justice to which deserving plaintiffs are entitled.

D. Information

One important measure of the institutional capacity of agencies and courts is the extent to which each provides incentives to bring relevant information to the attention of the decisionmaker.[103] When the decisionmaker needs the kind of information that is typically generated by the social sciences about the impact of policies on affected communities, constituencies, and economies, the information-gathering capacity of agencies generally exceeds that of courts.[104] Agencies may also have greater access to scientific and technical information, although that information is typically available to litigation experts as well. Agencies tend to take

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[100] Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims after Medtronic*, 64 TENN. L. REV. 691, 712 (1997); Schwartz, *supra* note 92, at 445.

[101] Leflar et al., *supra* note 100, at 712; Lyndon, *supra* note 84, at 163-64.

[102] David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 132 (2005).

[103] Wendy Wagner, *Stubborn Information Problems & the Regulatory Benefits of Gun Litigation*, in SUING THE GUN INDUSTRY, *supra* note 14, at 271, 273-74; *see also* Richard Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L. 1, 17 (2006) (referring to the ability of the common law to provide "information updating").

[104] Noah, *supra* note 80, at 2161.

both kinds of information at face value in the decisionmaking process.[105] Even if they were inclined to probe, agencies often lack the necessary investigational tools, like the power to demand underlying data or compel testimony.[106]

State common law litigation provides strong incentives to lawyers for private litigants to uncover information relevant to the hazards of the products and activities at issue. Common law litigants also have the wherewithal to obtain underlying data and get to the bottom of possible fraud and deception.[107] Indeed, the information that agencies obtain on underlying malfeasance by regulatees often comes to them indirectly through tort litigation.[108] The informational advantages of litigation must, however, be discounted to the extent that information obtained in litigation never sees the light of day. Corporate defendants routinely stamp damning documents produced in litigation "Confidential" and insist that they be protected by judicial protective orders subjecting anyone who discloses that information to steep civil and even criminal penalties. The companies then demand that all of those documents be returned or destroyed as a precondition to settling the cases. Unless a case actually goes to trial and the documents are introduced as evidence, the public and the relevant federal agencies may never learn of their existence.[109]

Despite the prevalence of secrecy agreements, common law litigation generally yields a great deal of information about the risks of regulated products and activities that would otherwise not come to the attention of federal regulatory agencies. Federal preemption of common law claims deprives agencies and the public of this valuable source of risk information.

E. Jury Nullification and Bias

Many proponents of preemption believe that juries are usually biased in favor of plaintiffs and that juries therefore are inclined to disregard the judge's instructions and render favorable verdicts without regard to the legal principles that should be governing their decisions. Worse, they are inclined to award excessive damages for "pain and suffering" and to impose "blockbuster" punitive damages awards on corporate defendants in the absence of strong evidence of culpability. At the same time, it is argued, juries are insufficiently attuned to the benefits that the products and activities at issue provide to consumers and society as a whole.[110]

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[105] Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L. J. 2049, 2069 (2000).

[106] Vladeck, *supra* note 84, at 633-34.

[107] Wagner, *supra* note 103 at 271, 274; *see also* Lytton, *supra* note 82, at 81; Vladeck, *supra* note 84, at 632.

[108] Bogus, *supra* note 96, at 4; Schwartz, *supra* note 98, at 1386; Vladeck, *supra* note 84, at 633-34.

[109] Laurie Kratky Doré, *Public Courts Versus Private Justice: It's Time to Let Some Sun Shine in on Alternative Dispute Resolution*, 81 CHI.-KENT L. REV. 463 (2006); Andrew D. Goldstein, *Sealing and Revealing: Rethinking the Rules Governing Public Access to Information Generated Through Litigation*, 81 CHI.-KENT L. REV. 375, 378 (2006) (arguing that current judicial nondisclosure rules "give too much weight to the interests of privacy and expediency at the expense of promoting judicial accountability, democratic engagement, and public confidence in the judicial system").

[110] RICHARD A. EPSTEIN, OVERDOSE 201 (2006); HUBER, *supra* note 89, at 186-87; Viscusi, *supra* note 79, at 2; Charles Fried & David Rosenberg, *Redressing Harm: Who Decides?,* 31 SETON HALL L. REV. 625, 627 (2001); Noah, *supra* note 80, at 2163.

Politically accountable federal agencies, by contrast, take a broader view of cumulative, systemic effects of government intervention and of the "inevitable tradeoffs" involved in designing products and disclosing "risk information."[111]

These empirical claims, however, remain largely unproven. What empirical evidence does exist seems to tell a different story.[112] According to careful statistical analyses prepared by Professor Theodore Eisenberg of 30 years' worth of data from federal cases compiled by the Administrative Office of the United States Courts, juries are much less inclined to find for the plaintiff in products liability cases than judges are, and they are inclined to award lower damages when they do.[113] A major study funded by the National Science Foundation found that jurors are not biased against corporations and are not swayed by the financial resources available to corporate defendants.[114] In any event, a jury does not get to decide a case until the judge first concludes that the plaintiff has offered sufficient evidence to support a claim under an accepted legal theory.[115] Judges retain the power to overturn "outlier" jury verdicts, and the available empirical evidence suggests that judges and the lawyers themselves, in post-trial settlement negotiations, tend to adjust large awards downward.[116]

V. CONCLUSION

Federal agencies have clear institutional advantages over common law courts and juries when it comes to some kinds of technical and policymaking expertise, but those advantages are not overwhelming, and they are irrelevant to many of the issues that arise in both regulation and litigation. The suggestion that federal agencies so thoroughly consider the potential beneficial and adverse consequences of regulated products or activities that after-the-fact liability is unnecessary seems tenuous at best. The very real possibility of regulatory failure suggests, at the very least, that Congress and the courts should be very cautious about presuming that agencies can adequately fill the corrective justice void that remains when a federal action preempts state common law clams.

Because the promise of protection that federal agencies offer is frequently a hollow one, policymakers and courts should not dismiss out of hand the helping hand offered by common law litigation. Concerns about irrational jury verdicts and "blockbuster" verdicts have a very poor empirical foundation and therefore should be heavily discounted in preemption debates. At the end of the day, the agencies have a legal and moral duty to the beneficiaries of their regulatory programs to ensure that their preemptive reach does not exceed their regulatory grasp.

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[111] Noah, *supra* note 80, at 2163 (quotation); Stewart, *supra* note 88, at 2175.

[112] Marc Galanter, *Real World Torts: An Antidote to Anecdote*, 55 MD. L. REV. 1093, 1110-11 (1996); Neil Vidmar, *The Performance of the American Civil Jury: An Empirical Perspective*, 40 ARIZ. L. REV. 849, 868-71 (1998).

[113] Theodore Eisenberg, *Judicial Decisionmaking in Federal Products Liability Cases, 1978-1997*, 49 DEPAUL L. REV. 323, 323 (1999); *see also* Theodore Eisenberg, et al., *Juries, Judges, and Punitive Damages: An Empirical Study*, 87 CORNELL L. REV. 743, 779 (2002) (similar results for punitive damages awards).

[114] Valerie P. Hans, *The Contested Role of the Civil Jury in Business Litigation*, 79 JUDICATURE 242 (1996).

[115] Vladeck, *supra* note 84, at 641.

[116] Vidmar, *supra* note 112, at 898.