TESTIMONY OF

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on

Short-change for Consumers and Short-shrift for Congress? The Supreme Court's Treatment of Laws that Protect Americans' Health, Safety, Jobs and Retirement

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My name is Tom McGarity. I hold the Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law at the University of Texas School of Law, where I teach courses in Torts and Environmental Law. I am also a member of the Board and immediate past president of the Center for Progressive Reform. With my colleague Wendy Wagner, I have recently published a book entitled *Bending Science: How Special Interests Corrupt Public Health Research* (Harvard Univ. Press 2008). My forthcoming book, entitled *The Preemption War: When Federal Bureaucracies Trump Local Juries*, will be published by Yale University Press in October of this year. I am very pleased to be here to testify on the importance of the Supreme Court as the ultimate interpreter of the statutes that Congress enacts to address serious social problems and the serious injustices that can result when the Court exercises its power to interpret federal statutes to reach a result that Congress arguably never intended and then employs the doctrine of federal preemption to impose its questionable interpretation on state common law courts.

Although the Supreme Court is quite correctly insulated from the pull and tug of electoral politics, its decisions can have a powerful impact on the lives of ordinary citizens. Most citizens are well aware of the Court's controversial decisions interpreting the United States Constitution in the areas of abortion, equal protection, freedom of speech and religion, and the death penalty. But we hear much less of the Court's power to shape our lives in its role as the interpreter of last resort of the laws that Congress enacts to protect citizens from the risks to health, safety and well-being posed by dangerous products, fraud in the marketplace, and environmental pollution.

In recent years, the Supreme Court has been far less vigilant than in the past in ascertaining the purpose underlying federal statutes when it exercises its power to interpret those statutes. An increasing number of the sitting justices appear to limit their inquiry to the words of the statute and the dictionary. At the same time, they seem more willing to interpret laws that Congress enacted to implement humanitarian and protective social goals in accordance with their views of sound public policy to reach results that are at odds with those goals. Long-standing judicial doctrines, like the "presumption against federal preemption" of state statutes and common law are either tacitly ignored or artfully avoided by some justices in their willingness to accommodate the interest of the business community in nationally uniform implementation of weak federal regulations.

Yet when the Supreme Court narrowly interprets the substantive protections provided by federal statutes to limit their range or when the Court broadly interprets preemption clauses in those statutes to restrict the ability of state court juries to award damages to innocent victims of negligence and fraud, the suffering and pain that results is no less real because it is hidden from public view.

To illustrate this point, I will focus my attention primarily on the injustice that has resulted from the Court's narrow interpretation in several cases of the remedial provisions of the Employee Retirement Income Security Act of 1974 (ERISA) and its broad interpretation of the statute's express preemption clause to preempt long-standing

common law remedies that would otherwise be available to victims of negligence (often bordering on medical malpractice) on the part of insurance companies and health maintenance organizations when they arbitrarily deny coverage to beneficiaries of employer-sponsored employee benefit plans. Ms. Kurtek's experience is, sadly, but one of hundreds of similar instances of medical benefit plans errors that have resulted in uncompensated physical and mental damage to the erstwhile beneficiaries of such plans.

I will also briefly discuss how recent Supreme Court holdings that federal regulatory agency action preempts state common law claims deprive innocent plaintiffs of corrective justice and undercut the "backstop" role that the common law courts play in encouraging companies to behave responsibly. In this connection, I will focus particularly on recent Supreme Court holdings in cases involving medical devices, such as the defibrillator that malfunctioned in Ms. Robb, and cases involving regulated companies that have defrauded federal agencies as they attempt to implement their regulatory responsibilities.

The Supreme Court's ERISA Muddle.

The committee has just heard about the injustice suffered by Ms. Maureen Kertek. In my forthcoming book, *The Preemption War*, I relate the story of Buddy Kuhl, a Kansas City resident who 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 he see a heart specialist after he suffered a serious heart attack. Two different specialists in turn recommended that Mr. Kuhl undergo heart surgery at a St. Louis hospital, because the local Kansas City hospitals lacked the proper equipment for the prescribed surgery. After Mr. Kuhl and his primary care physician scheduled the necessary surgery, his 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 therefore canceled. After a third specialist agreed that surgery in St. Louis was necessary, the plan did pre-certify 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 as well. Within three months, Mr. Kuhl succumbed to the heart affliction. Buddy's 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 ERISA.[1]

The Statutory Language.

Congress enacted the ERISA in 1974 to address mounting public concerns stemming from numerous reports of abuse of employee pension funds by employers, unions and

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

other entities with fiduciary responsibilities for administering those funds.[2] In that statute, Congress delegated to the Department of Labor (DoL) broad authority to promulgate regulations defining relevant terms and establishing standards for administering pensions and other employee benefit plans, including those that, "through the purchase of insurance or otherwise," provide for medical care for covered employees through insurance companies and Health Maintenance Organizations (HMOs).[3] The statute also establishes a fairly elaborate civil enforcement regime that empowers the federal government, employer participants and beneficiaries to obtain relief when fiduciaries violate such plans or otherwise mishandle their fiduciary responsibilities. In particular, a participant or beneficiary may bring a civil action in federal court "to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan" and "for appropriate relief under" the section establishing the fiduciary duties of plan administrators.[4]

Unlike many federal laws, the ERISA contains an express preemption clause stating that the Act's provisions "shall supercede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." A savings clause provides that nothing in the Act "shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities." Neither clause explicitly mentions state common law claims of the sort that Ms. Kurtek and Mr. Kuhl brought against their medical benefit plans.[5] The courts were therefore left to determine both the scope of the express preemption clause and the reach of the savings clause.

The Supreme Court Interprets ERISA.

The injustice that Ms. Kurtek and Mr. Kuhl suffered at the hands of medical benefit plans resulted from two lines of Supreme Court precedent and the Department of Labor's failure to exercise its rulemaking power effectively to address the problem of medical benefit plans.

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[2] 29 U.S.C. § 1001(b). Aetna Health, Inc. v. Davila, Brief of United Policyholders as Amicus Curiae, January 22, 2004, at , at *24-*29; Donald T. Bogan, Protecting Patient Rights Despite ERISA: Will the Supreme Court Allow States to Regulate Managed Care? 74 Tulane L. Rev. 951 (2000), at 996; Stacy Roberts Sharp, Note, ERISA Preemption and MCO Liability: The Court's Search in Aetna Health, Inc. v. Davilla for Congress's Elusive Intent, 84 Tex. L. Rev. 1347, 1351 (2006).

[3] 29 U.S.C. § 1002(1). See Pilot Life Insurance Co. v. Dedeaux, 481 U.S. 41, 44 (1987); John H. Langbein, What ERISA Means by "Equitable": The Supreme Court's Trail of Error in Russell, Mertens, and Great-West, 103 Colum. L. Rev. 1317 (2003), at 1325 n. 52.

[4] 29 U.S.C. § 1132(a)(1)-(3).

[5] 29 U.S.C. § 1144(a) (preemption clause); 29 U.S.C. § 1144(b)(2)(A) (savings clause); 29 U.S.C. § 1144(b)(2)(B) (deemer clause).

In the first line of cases, the Supreme Court interpreted the language in the statute providing a private remedy for violations of ERISA and its implementing regulations. In several cases, the Court drastically limited the relief available under the statute.[6] In particular, the Supreme Court held that the "equitable relief" available to a plaintiff did not include money damages. The Court majority based this strained interpretation on the hypertechnical ground that nineteenth century equity courts did not entertain claims for consequential damages attributable to violations of fiduciary obligations.[7] Yale Law School Professor John Langbein, a prominent legal historian, has concluded that this holding was probably wrong as a historical matter. The Court, in his opinion, "rendered the protections of ERISA illusory in any case in which the victim of ERISA-proscribed wrongdoing needs damages for consequential injury in order to be made whole."[8]

The second line of precedent stemmed from the Supreme Court's interpretation of the ERISA's preemption clause. In *Pilot Life Insurance Co. v. Dedeaux*, the Court held that ERISA's broad preemption clause applied to state common law claims, as well as state statutes and regulations. In particular, Congress meant for "all suits brought by beneficiaries or participants asserting improper processing of claims under ERISA-regulated plans [to] be treated as federal questions governed by" the ERISA's civil action provision.[9] In the Court's view, the ERISA established "a federal common law of rights and obligations under ERISA-regulated plans" that displaced state common law on any issue "related to" such plans.[10] The Court later held in *Metropolitan Life Insurance Co., v. Massachusetts* that Congress intended the ERISA and its implementing regulations "to displace all state laws that fall within its sphere, even including state laws that are consistent with ERISA's substantive requirements."[11] This had the effect of displacing not only state common law claims based on conduct that complied with ERISA, but also conduct that amounted to gross violations of ERISA's requirements. The Court greatly expanded the ERISA's preemptive "sphere" when it broadly construed the words "related

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[6] Great-West Life and Annuity Insurance Co. v. Knudson, 534 U.S. 204 (2002); Mertens v. Hewitt Associates, 508 U.S. 248 (1993); Massachusetts Mutual Life Insurance Co. v. Russell, 473 U.S. 134 (1985).

[7] Great-West Life and Annuity Insurance Co. v. Knudson, 534 U.S. 204 (2002); Mertens v. Hewitt Associates, 508 U.S. 248, 255 (1993).

[8] John H. Langbein, What ERISA Means by "Equitable": The Supreme Court's Trail of Error in Russell, Mertens, and Great-West, 103 Colum. L. Rev. 1317, 1362 (2003).

[9] Pilot Life Insurance Co. v. Dedeaux, 481 U.S. 41 (1987). See also Donald T. Bogan, Protecting Patient Rights Despite ERISA: Will the Supreme Court Allow States to Regulate Managed Care? 74 Tulane L. Rev. 951, 956 (2000).

[10] Pilot Life Insurance Co. v. Dedeaux, 481 U.S. 41 56, 58 (1987).

[11] Metropolitan Life Insurance Co., v. Massachusetts, 471 U.S. 741, 749 (1985). See also Ingersoll-Rand Corp. v. McClendon, 498 U.S. 133 (1990) (holding that ERISA preempted state common law claims); Catherine L. Fisk, The Last Article About the Language of ERISA Preemption? A Case Study of the Failure of Textualism, 33 Harv. J. Legis. 35, 60-66 (1996).

to" quite literally to reach any common law claim that "has a connection with or reference to such a plan."[12]

The reach of the ERISA's preemption provision soon exceeded the statute's substantive grasp. Congress drafted the statute with *pensions* in mind, and it addressed "employee welfare benefit plans" providing medical and disability coverage only as an afterthought.[13] The Department of Labor could fill this gap by promulgating substantive regulations for welfare benefit plans restricting the power of unqualified HMO and insurance company "reviewers" to deny pre-certification of coverage for medical procedures recommended by qualified doctors. Fearing that such restrictions would discourage employers from adopting medical benefit plans in the first place, however, the Department has consistently failed to promulgate regulations safeguarding the rights of medical benefit plan beneficiaries.[14] Since welfare benefit plans clearly "relate to" employee benefit plans, there is a disconnect between the limited scope of the substantive requirements relating to medical coverage in welfare benefit plans and the much broader scope of the statute's express preemption provision, as interpreted by the Supreme Court.

The net effect of the combination of Supreme Court holdings and DoL inaction has been to substitute a virtually content-free regulatory regime for a rich body of common law in which fiduciaries who negligently fail to perform their fiduciary obligations are subject to injunctive relief and liability for damages caused by such failures.[15]

The ERISA Train Wreck.

These judicial trends converged with disastrous consequences for some beneficiaries in the 1990s when employers began to replace traditional insurance policies providing "fee-for-service retrospective pay" with Health Maintenance Organizations (HMOs), Preferred

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[12] Shaw v. Delta Airlines, Inc., 463 U.S. 85, 97 (1983); District of Columbia v. Greater Washington Board of Trade, 506 U.S. 125, 129 (1992) (quoting Black's Law Dictionary 1288 (6th ed. 1990)). See Donald T. Bogan, Protecting Patient Rights Despite ERISA: Will the Supreme Court Allow States to Regulate Managed Care? 74 Tulane L. Rev. 951, 986 (2000), at; Catherine L. Fisk, The Last Article About the Language of ERISA Preemption? A Case Study of the Failure of Textualism, 33 Harv. J. Legis. 35, 64 (1996).

[13] Aetna Health, Inc. v. Davila, Brief of United Policyholders as Amicus Curiae, January 22, 2004, at *14; Donald T. Bogan, Protecting Patient Rights Despite ERISA: Will the Supreme Court Allow States to Regulate Managed Care? 74 Tulane L. Rev. 951 (2000), at 964-72, 974, 976-77.

[14] Aetna Health, Inc. v. Davila, Brief for the United States as Amicus Curiae, December 18, 2003, at *25-*26; Aetna Health, Inc. v. Davila, Brief for the Chamber of Commerce of the United States as Amicus Curiae, December 18, 2003, at *13, *25-*26.

[15] See Donald T. Bogan, Protecting Patient Rights Despite ERISA: Will the Supreme Court Allow States to Regulate Managed Care? 74 Tulane L. Rev. 951, 958 (2000); Catherine L. Fisk, The Last Article About the Language of ERISA Preemption? A Case Study of the Failure of Textualism, 33 Harv. J. Legis. 35, 39 (1996).

Provider Plans (PPOs), and other types of "prospective pay" managed care plans."[16] The latter plans were popular with employers because they were supposed to reduce the costs of unnecessary treatment. However, they "often ignore[d] the individual needs of a patient in order to improve the HMOs' bottom lines."[17] Most important for present purposes, these new cost-containment devices permitted the fiduciary to determine whether or not to pay for the prescribed health care in advance of treatment.[18] As one court noted, "a system of prospective decisionmaking influences the beneficiary's choice among treatment options to a far greater degree than does the theoretical risk of disallowance of a claim facing a beneficiary in a retrospective system."[19]

When plaintiffs like Ms. Kurtek and Mr. Kuhl who are damaged by gross mismanagement of employee medical benefit plans sue under the exclusive "federal common law" created by the ERISA and its implementing regulations, they first encounter an empty body of substantive law, because the statute and implementing regulations by-and-large ignore such plans. The rare plaintiffs who can prove violations of the regulations cannot recover compensatory damages for bodily injury or emotional distress or punitive damages.[20] Beneficiaries who attempt to opt out of a system that is clearly rigged against them quickly discover that the statute's preemption provisions deprive them of any state common law remedies as well. The result is that health care for thousands of Maureen Kurteks and Buddy Kuhls throughout the country is determined not by their doctors, but by anonymous nurses working phone banks for an HMO or insurance company who have every incentive to deny expensive medical procedures and no incentive to allow them.

The message to HMOs and insurance companies is to ignore their fiduciary obligations and deny legitimate requests for coverage from patients who are, in the words of one court, "often in the throes of medical crises and entirely unable to assert what meager rights they possess."[21] HMOs and insurance companies receive a fixed income stream that they may invest as it comes in from employers, but their payouts depend on the number of claims they honor and the amounts that they allocate to those claims. Since

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[16] Donald T. Bogan, Protecting Patient Rights Despite ERISA: Will the Supreme Court Allow States to Regulate Managed Care? 74 Tulane L. Rev. 951, 998 (2000).

[17] Pegram v. Herdrich, 530 U.S. 211, 220 (2000).

[18] Jonathan J. Frankel, Note, Medical Malpractice Law and Health Care Cost Containment: Lessons for Reformers from the Clash of Cultures, 103 Yale L. J. 1297 (1994), at 1303.

[19] Corcoran v. United Healthcare, 965 F.2d 1321 (5th Cir. 1992), at 1332. (quote). See Stacy Roberts Sharp, Note, ERISA Preemption and MCO Liability: The Court's Search in Aetna Health, Inc. v. Davilla for Congress's Elusive Intent, 84 Tex. L. Rev. 1347 (2006), at 1354-56.

[20] Nancy Mansfield, Joan T.A. Gabel, & Laurie B. Jablow, Evolving Tension Between HMO Liability Precedent and Legislation, 36 Tort & Ins. L. J. 949 (2001), at 951.

[21] DiFelice v. Aetna U.S. Healthcare, 346 F.3d 442 (3d Cir. 2003) (Becker, J. concurring).

the money otherwise paid to satisfy claims remains in the HMO's account to be invested by the HMO, the company can make money by denying or delaying claims. The only serious consequence of even gross breaches of fiduciary obligations is the highly unlikely prospect of injunctive relief or the contingent prospect of a court order to reimburse the rare beneficiary who elects to undergo treatment at his own expense. While the matter is being litigated, the employer's premiums are still piling up interest in the HMO's account.[22]

The HMOs and insurance companies that administer employee benefit plans are, of course, well aware of the positive effects of denying claims on the bottom line. A 1990s-vintage training video for claims handlers for one provider instructed them on the critical difference between ERISA-covered claims and non-ERISA claims. The lawyers stressed that claims in the latter category required a "reasonable investigation" and review by a "Specialty Review Team" before being denied because wrongful denials could result in state common law "bad faith failure to settle" claims with possible punitive damages. Handlers of ERISA-covered claims, on the other hand, should make the claimants undertake the investigation, and if they did not present precisely the right proof or filed the claim late, the handlers were to deny the claim. Since ERISA beneficiaries cannot sue at common law and cannot receive compensatory damages under federal law, "[a]fter we send the final letter, it doesn't matter what they send us any more."[23]

The American Medical Association and numerous state medical examination boards have concluded that when claims handlers render prospective judgments about whether or not the treatment recommended by a beneficiary's doctor is "medically necessary," they are engaged in medical decisionmaking that should be subject to the same ethical and common law principles that constrain the prescribing physician's judgment.[24] Yet, absent the threat of common law liability, a claims handler with little or no relevant expertise is free to second-guess highly credentialed medical experts. By the late 1990s, the ERISA juggernaut had yielded hundreds of horror stories, several of which I relate in *The Preemption War*.

The Court's Missed Opportunity to Fix the Problem.

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[22] DiFelice v. Aetna U.S. Healthcare, 346 F.3d 442 (3d Cir. 2003) (Becker, J. concurring), at 454; Aetna Health, Inc. v. Davila, Brief Amicus Curiae of California Consumer Health Care Council, Congress of California Seniors and California Coalition for Ethical Mental Health Care, January 22, 2004, at *29.

[23] Jane Bryant Quinn, Health Insurance Firms Shielded Against Most Suits, Florida Sun-Sentinal, November 24. 1998, at D3; Patients' Right to Sue Needed Check on Health Care Industry, USA Today, October 19, 1998, at A26.

[24] Aetna Health, Inc. v. Davila, Brief Amicus Curiae of the American College of Legal Medicine, January 20, 2004, at *9-*11; Aetna Health, Inc. v. Davila, Brief of the Council of State Governments, National Conference of State Legislatures, National Association of Counties, and International City/County Management Association as Amicus Curiae, January 22, 2004, at *11.

The Supreme Court had an opportunity to adjust the ERISA's misguided course when it agreed in 2004 to hear two consolidated appeals in *Aetna Health, Inc. v. Davila*.[25] In one of the cases, Juan Davila's treating physician prescribed the painkiller Vioxx for his arthritis pain, but his employer-provided HMO refused to pay for that drug because it was deemed to be too expensive. When Mr. Davila took the generic drug Naproxen that the HMO was willing to pay for as a suitable alternative, he suffered a severe reaction that required extensive hospitalization and left him unable to take any orally administered painkillers at all.[26] Davila sued the HMO under a Texas statute, signed by then-Governor George W. Bush, that authorized a common law claim for tort damages against HMOs for failure to use ordinary care in making coverage determinations. Twenty states, the National Council of State Legislatures, and a number of consumer groups filed amicus curiae briefs urging the Court to correct its past mistakes and allow the lawsuits to proceed.[27]

The Court held that the ERISA preempted all of Mr. Davila's claims. The majority opinion reasoned that the "limited remedies available" under the ERISA "are an inherent part of the 'careful balancing' between ensuring fair and prompt enforcement of rights under a plan and the encouragement of the creation of such plans."[28] State common law tort claims against HMOs, even for violations of the statute's substantive requirements, could undermine that "careful balance" by recognizing rights or providing remedies that might discourage employers from creating such plans in the first place. The Court believed that the ERISA's enforcement tools could adequately protect the legitimate

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

[26] Aetna Health, Inc. v. Davila, Brief Amicus Curiae of California Consumer Health Care Council, Congress of California Seniors and California Coalition for Ethical Mental Health Care, January 22, 2004, at *6-*7.

[27] Aetna Health, Inc. v. Davila, Brief of United Policyholders as Amicus Curiae, January 22, 2004; Aetna Health, Inc. v. Davila, Brief for Amicus Curiae Senators Edward M. Kennedy, John McCain, Bob Graham and Representatives John D. Dingell, Charlie Norwood, George Miller and Charles B. Rangel, January 22, 2004; Aetna Health, Inc. v. Davila, Brief of Amicus Curiae Health Administration Responsibility Project, January 22, 2004; Aetna Health, Inc. v. Davila, Brief Amicus Curiae of the American College of Legal Medicine, January 20, 2004; Aetna Health, Inc. v. Davila, Brief Amicus Curiae of California Consumer Health Care Council, Congress of California Seniors and California Coalition for Ethical Mental Health Care, January 22, 2004; Aetna Health, Inc. v. Davila, Brief of the Council of State Governments, National Conference of State Legislatures, National Association of Counties, and International City/County Management Association as Amicus Curiae, January 22, 2004; Aetna Health, Inc. v. Davila, Brief of Texas, California, Connecticut, Delaware, Illinois, Kansas, Louisiana, Maryland, Minnesota, Missouri, Montana, Nevada, New Mexico, New York, Ohio, Oklahoma, Oregon, Puerto Rico, Utah, Vermont, Washington as Amicus Curiae, January 22, 2004.

[28] Aetna Health, Inc. v. Davila, 542 U.S. 200 (2004), at 215; Aetna Health, Inc. v. Davila, Brief for the United States as Amicus Curiae, December 18, 2003, at *9, *25-*26.

rights of plan beneficiaries.[29] For example, Mr. Davila could have sued the HMO for an injunction requiring it to provide those benefits in advance of treatment, or he could have "paid for the treatment [himself] and then sought reimbursement" in an action under ERISA's claims procedures.[30]

In my view, the Court's analysis is wildly unrealistic. Mr. Davila was in no position to forego the generic drug proffered by his HMO, hire a lawyer at his own expense, and endure his arthritis pain while the lawyer sought injunctive relief.[31] Maybe it would not have been too burdensome to expect him to dip into savings and purchase his own Vioxx until he could sue for reimbursement after the fact, assuming that he could persuade a lawyer to take the case for what would have been a very small contingency fee. But the reason that most employees join their employers' health benefit plans is that they cannot afford to pay for medical treatment in advance.[32] As one doctor noted, "[t]he economic reality is that, if these insurance companies are not going to pay for something, it won't get done."[33] Taking the time to write a special concurring opinion, a frustrated Justice Ginsburg "join[ed] 'the rising judicial chorus urging that Congress . . . revisit what is an unjust and increasingly tangled ERISA regime.'"[34]

The "rising judicial chorus" alluded to in Justice Ginsburg's outraged concurring opinion includes some very prominent occupants of the federal courts of appeals. For example, Judge Edward R. Becker, who until his death last year was the Chief Judge of the United States Court of Appeals for the Third Circuit, wrote that "ERISA, generally, and § 514(a) particularly, have become virtually impenetrable shields that insulate plan sponsors from any meaningful liability for negligent or malfeasant acts committed against plan beneficiaries in all too many cases." He noted that "ERISA's remedial scheme gives HMOs every incentive to act in their own and not in their beneficiaries best interest while simultaneously making it incredibly difficult for plan participants to pursue what meager remedies they possess, a confounding result for a statute whose original purpose was to protect employees."[35] Similarly, Second Circuit Judge Guido Calabresi, a former dean

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[29] Aetna Health, Inc. v. Davila, Brief for the United States as Amicus Curiae, December 18, 2003, at *16-17.

[30] Aetna Health, Inc. v. Davila, 542 U.S. 200, 211-12 (2004).

[31] See Andrews-Clarke v. Travelers Ins. Co., 984 F. Supp. 49, 59 (D. Mass. 1997).

[32] Stacy Roberts Sharp, Note, ERISA Preemption and MCO Liability: The Court's Search in Aetna Health, Inc. v. Davilla for Congress's Elusive Intent, 84 Tex. L. Rev. 1347 (2006), at 1376; Aetna Health, Inc. v. Davila, Brief of the Council of State Governments, National Conference of State Legislatures, National Association of Counties, and International City/County Management Association as Amicus Curiae, January 22, 2004, at 3.

[33] Under Fire, St. Louis Post-Dispatch, August 30, 1998, at A1.

[34] Aetna Health, Inc. v. Davila, 542 U.S. 200, 222 (2004) (Ginsburg, J., concurring) (quoting DiFelice v. Aetna U.S. Healthcare, 346 F.3d 442, 453 (3d Cir. 2003)).

[35] DeFelice v. U.S. Healthcare, 346 F.3d 442, 456, 459 (3d Cir. 2003) (Becker, J., concurring).

of the Yale Law School, has observed that "the injury that the courts have done to ERISA will not be healed until the Supreme Court reconsiders the existence of consequential damages under the statute, or Congress revisits the law to the same end."[36] More recently, Judge Michael McConnell has quoted Justice Ginsburg's opinion at length in holding that an insurance company's determination that the appropriate drug for the plaintiff's condition was Ritalin, rather than the less risky drug Provigil fell within the scope of ERISA's express preemption clause.[37]

Justice Ginsburg's plea was, however, somewhat unrealistic. Congress undoubtedly has the power to fix the problem with appropriate amendments to the ERISA. However, when the demand for reform comes from a diffuse or economically disadvantaged segment of society and status quo arrangements are congenial to a concentrated and economically powerful segment, the prospects for reform are best in periods of social ferment following a long history of past injustice and abuse. Proponents for the victims of managed care abuse thought the late 1990s and early 2000s was a propitious time to address the injustices brought on by the Supreme Court's strained interpretations of the ERISA. But their efforts to enact a "Patient's Bill of Rights" that would have, among other things, amended the ERISA's express preemption provision to allow state common law claims against managed care providers for unreasonable denial of coverage were unsuccessful.

Other Preemption Hurdles.

The ERISA experience is an especially disturbing example of the power of the Supreme Court to undermine the protective policies underlying federal remedial legislation through aggressive federal preemption of state common law. But it is by no means the only such example. I discuss may more areas in which the Court has interpreted express preemption clauses in federal regulatory statutes to hold that state common law is preempted. Another area that has received a great deal of recent attention is the preemptive effect of the Medical Device Amendments to the Food, Drug and Cosmetics Act.

Express Preemption of Claims Addressed to Medical Devices.

Although the Supreme Court has frequently invoked a "presumption against preemption" in "areas of traditional state regulation,"[38] it has nevertheless expanded the range of federal programs that preempt state common law during the past 20 years.[39] Its 1992

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[36] Cicio v. Does, 321 F.3d 83, 106 (Calabresi, J., dissenting in part).

[37] Lind v. Aetna Health, Inc., 466 F.3d 1195 (10th Cir. 2006).

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

[39] McGarity, Preemption War, ch. 4; Robert L. Rabin, Federalism and the Tort System, 50 Rutgers L. Rev. 1, 27 (1997).

holding, in *Cipollone v. Liggett Group, Inc*., that the word "requirement" in an express preemption clause included state common law claims[40]invited defendants to raise a federal preemption defense in every case in which the relevant statute used the word "requirement" or a closely related word.

The Medical Device Amendments to the Food, Drug and Cosmetics Act contain an express preemption clause that uses the magic word "requirement" and does not have a savings clause.[41] In the 1996 case of *Medtronic, Inc. v. Lohr*,[42] the Court held that that the Medical Device Amendments preempted some, but not all common law claims directed toward medical devices that FDA had approved using a very abbreviated process for devices that are "substantially equivalent" to devices in existence in 1976. The Court took up the harder issue of devices that had undergone the full FDA approval process earlier this year in *Riegel v. Medtronics, Inc*.[43]

The Court held that Riegel's common law claims came within the meaning of the word "requirement" in the statute's express preemption clause. In broad dicta that defendants will no doubt rely on in future cases, the Court added that "[a]bsent other indication, reference to a State's 'requirements' includes its common-law duties."[44] 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,"[45] 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."[46]

Implied Preemption of Claims Based on Fraud on Federal Agencies.

The Court has not limited its propensity to preempt to statutes containing express preemption clauses. In several other areas, the Court has found state common law claims to be "impliedly" preempted by a federal statute that does not explicitly address preemption one way or the other.

First, "[i]f Congress evidences an intent to occupy a given field, any state law falling within that field is pre-empted." This form of implied preemption, referred to as "field preemption," is rarely applicable to state common law claims. Second, "[i]f Congress has

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[40] Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992).
[41] 21 U.S.C. § 360k(a).
[42] Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).
[43] Riegel v. Medtronics, Inc. 128 S.Ct. 999 (2008).
[44] 128 S.Ct., at 1008.
[45] 128 S.Ct., at 1007.
[46] 128 S.Ct., at 1008. 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.

not entirely displaced state regulation over the matter in question, state law is still pre-empted to the extent it actually conflicts with federal law."[47]

The second category of "conflict preemption" is further subdivided into two subcategories. The first, called "impossibility" preemption, exists when compliance with both the state law and the federal law is impossible because complying with state law will cause the actor to violate federal law and visa versa. The second, called "obstacle preemption," preempts state law 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."[48]

A good example of implied obstacle preemption is *Buckman v. Plaintiffs' Legal Committee*, a case involving a common law claim based upon a medical device company's alleged fraud in obtaining FDA approval of its spinal screws.[49]

An entity subject to a federal licensing requirement, like the FDA drug and device approval process, can affect the outcome of the regulatory process by manipulating the information available to the agency and managing public perceptions about the implications of the relevant information. Professor Wagner and I discuss this ability of regulatees to "bend" science to their economic and ideological ends in our recently published book *Bending Science*.

First, a regulated entity may engage in overt fraud by submitting fraudulently conducted studies to the agency or by withholding relevant information. Second, it can covertly "massage" or otherwise manipulate the scientific, economic and statistical information in misleading ways to fit the company's view of the scientific facts. Third, it can affect agency decision-making by finding flaws with or otherwise attempting to undermine scientific, economic and statistical studies from sources over which the company has no control. Finally, it can attempt to bring pressure to bear on an agency to take lenient regulatory action through public relations exercises aimed at manipulating public perceptions of publicly available scientific information. Some of these techniques are clearly unlawful under federal law; others are clearly lawful; and still others fall into grey areas that require further analysis and investigation.[50]

It is, of course, very difficult for the relevant federal agency to know at the time that it is being misled or defrauded, and it may never uncover the deception. After-the-fact prosecution of fraud can protect the government's interest in the integrity of the regulatory process and provide incentives to regulatees not to dissemble with federal agencies in the future. But that happens only very rarely.

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[47] Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 248 (1984).
[48] Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 248 (1984).
[49] Buckman Co. v. Plaintiffs' Legal Committee 531 U.S. 341 (2001). Except where otherwise noted, the facts and the Court's analysis are drawn from Id., at 341, 346-51.
[50] Thomas O. McGarity & Wendy E. Wagner, Bending Science (2008).

The Supreme Court resolved the question in the context of FDA device regulation in a fairly unique factual setting in *Buckman Co. v. Plaintiffs' Legal Committee*.[51] In that case, a class consisting of more than 2300 plaintiffs claimed that its members had been damaged by defective orthopedic bone screws that doctors had installed in the pedicles of their spines. Like the pacemaker in *Lohr*, the bone screws went through the "expedited" FDA approval process that is available for devices that are "substantially equivalent" to "predicate" devices that were on the market prior to 1976.[52] During the approval process, the submitter had to certify that "all data and information submitted" during the expedited process were "truthful and accurate" and that "no material fact" had been omitted.[53]

After FDA twice found that the screws were riskier than pre-1976 spinal-fixation devices and therefore not substantially equivalent, the manufacturer hired the Buckman company, a consultant with experience in the expedited approval process, to assist in a third try. On Buckman's advice the manufacturer split the device into its component parts, renamed them, and filed separate applications for approval for use in the long bones of the arms and legs instead of in the spine. Both Buckman and the manufacturer fully expected that doctors would prescribe the screws for "off-label" use in spinal-fixation systems.[54] This time the FDA approved the devices as substantially equivalent to predicate devices used in long bone surgery.[55]

The plaintiffs settled their claims against the manufacturer,[56] but they litigated their claim that Buckman's misleading manipulation of the regulatory process violated its common law duty to the plaintiffs as foreseeable victims of the alleged fraud.

The Supreme Court held that the Medical Device Amendments impliedly preempted the plaintiffs' claims. The Court reasoned that although the plaintiffs' common law claims were not clearly inconsistent with FDA's authority to regulate medical devices, they presented a subtler conflict with the "delicate balance of statutory objectives" that the agency had to strike in deciding whether or not to investigate and punish fraud. Since doctors could lawfully prescribe approved medical devices for unapproved uses, FDA faced an especially difficult balancing job in "regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals." The Court

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[51] Buckman Co. v. Plaintiffs' Legal Committee 531 U.S. 341 (2001). Except where otherwise noted, the facts and the Court's analysis are drawn from Id., at 341, 346-51.
[52] 21 U.S.C. § 360e(b)(1)(A), (B).
[53] 21 C.F.R. § 807.87(k).
[54] 21 U.S.C. § 360aaa (prohibition on marketing drugs for off-label uses).
[55] The agency much later approved the bone screws for use in spinal-fixation systems. Orthopedic Devises: Classification and Reclassification of Pedicle Screw Spinal Systems, 63 Fed. Reg. 40025, 40032 (July 27, 1998).
[56] Buckman Co. v. Plaintiffs' Legal Committee, Brief of Amicus Curiae of Public Citizen, October 23, 2000, at 2.

concluded that Congress did not intend to allow common law juries to second-guess the agency's discretion in striking this balance.

The Court also found that state common law claims based upon alleged fraud on the FDA could increase the regulatory burdens on potential applicants who might "be discouraged from seeking expedited approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates (such as petitioner) to unpredictable civil liability." In addition, they could "deter off-label use despite the fact that the [statute] expressly disclaims any intent to directly regulate the practice of medicine . . . and even though off-label use is generally accepted." Finally, a common law claim based on fraud on the FDA would "cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the [agency], will later be judged insufficient in state court." Alternatively, massive prophylactic submissions by applicants concerned about state tort liability could tie up the agency and slow down the flow of approved predicate devices, thus impeding competition and delaying health care professionals' ability to prescribe appropriate off-label uses. Since all of these possibilities had the potential to erect serious obstacles to the agency's efforts to implement the statutory goals, the Medical Device Amendments impliedly preempted the plaintiffs' claims.

Apart from its rather speculative "deluge of information" concern, the Court did not cite any evidence suggesting that the plaintiffs' claims would interfere with the agency's regulatory efforts. Significantly, the Court's opinion did not pay even passing deference to the statute's *primary* purpose, which is "to provide for the safety and effectiveness of medical devices intended for human use."[57] Rather than reflecting the statutory policy of protecting consumers, the Court implemented a policy of protecting the ability of doctors to prescribe drugs for unapproved uses and an even more dubious policy of protecting drug companies from burdensome investigations into the bona fides of their FDA filings.

From the perspective of consumers, who have a strong interest in both corrective justice and ensuring corporate accountability for misleading agencies into approving dangerously defective products, *Buckman* moves the law in exactly the wrong direction.

Conclusion.

Although the arcane law governing federal preemption of state common law claims is rarely featured in daily news reports, it has a profound effect on the rights of ordinary citizens to seek justice at the hands of a jury of their peers. The common law jury is a profoundly democratic institution that has been a part of the American civil justice system from the first and remains one of the American institutions best able to protect individuals against the tyranny of government and the marketplace. When the Supreme Court concludes that Congress meant for the questionable judgment of a federal bureaucracy to supercede the common sense wisdom of the common law jury, it leaves

[57] Pub.L. No. 94-295, 90 Stat. 539, 539 (1976) (preamble).

behind a hole in the law has an enormous potential for injustice. It is imperative that the public become aware of this potential and for this Committee to perform its critical confirmation role conscientiously.