



Dissatisfaction with National and Personal Experiences with Health Care.

Data are from Gallup polls conducted in November 2006 and November 2007. For coverage and quality, the data represent the percentage of respondents who said these aspects of care were “only fair” or “poor”; for cost, the data represent the percentage who indicated they were “dissatisfied.”

cus on consumer choice may actually increase the visibility and burden of costs that fall on individuals. Democratic criticism that McCain’s proposals fail to alleviate the burden of price on Americans may well resonate with many Americans who believe that government should spend more to relieve the pressure on family budgets.

By contrast, Democrats Barack Obama and Hillary Clinton seek to mitigate anxiety about inadequate coverage and high costs by covering all or large segments of the uninsured population through mandates on individual taxpayers and businesses, expansions of government programs, and regulation of private insurers. Although both candidates plan to build on the employer-based system and are

trying to avoid the wide scope and government visibility that characterized President Bill Clinton’s 1993 plan, their plans for comprehensive change may overreach. Republican criticisms of the Democrats’ “big-government” proposals could activate Americans’ entrenched conservatism and uneasiness about government intrusion.

Health care reform efforts have been undermined not only by Americans’ ambivalence toward government but also by the split between public dissatisfaction with the overall system’s performance and patients’ satisfaction with personal health care. Whereas more than 70% of Americans are quite negative about the country’s coverage and costs, less than 40% are disappointed with their own circumstances. A mere 15% complain about the quality of care they receive.

These dueling evaluations offer ample ammunition to both reformers and their opponents. Although those supporting reform can appeal to people’s dissatisfaction with the system’s inadequate coverage and high costs, opponents can activate anxieties by warning of the personal threat reform presents, especially to the quality of care. And indeed, such tactics defined the debate over Bill Clinton’s proposal in 1993 and 1994. Clinton directed his pollsters to identify key words, symbols, and arguments to highlight the collective benefits and security that would be created by system reform, which helped to drive sup-

port for his plan to nearly 60% by the fall of 1993. Reform opponents then generated nearly equal levels of opposition by warning that new “Rube Goldberg” government rules would threaten Americans’ personal care.^{1,2}

Presidential campaigns are ill-suited to the task of designing policy reforms, but they represent critical periods for setting an incoming administration’s agenda. Without a dramatic change in public sentiment, Democrats and Republicans face daunting obstacles in rallying broad support for particular reforms.

Still, although public opinion influences legislators’ agendas and the broad contours of policy objectives, even strong public opinion cannot unify polarized decision makers. Broad agreement by those in power on an approach to reform, as well as on critical details, is necessary. It is worth remembering that Medicare was passed in 1965 despite support from only 46% of the public.³

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The FDA, Preemption, and the Supreme Court

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Everyone would like to be immune from lawsuits. Legislatures sometimes provide immunity

in order to advance important social policy goals. For example, by providing health care profession-

als with immunity under Good Samaritan statutes, legislatures hope to encourage voluntary medical as-

sistance in emergencies. Similarly, Congress provided immunity to vaccine manufacturers who claimed they could not economically manufacture vaccines with the threat of liability hanging over them.

Because providing immunity deprives injured people of their day in court, legislation that creates immunity sometimes also creates an alternative compensatory mechanism. For example, the federal law that immunized vaccine manufacturers from lawsuits created a system for the compensation of persons injured by vaccines. Nevertheless, immunity undermines the tort system's goal of deterring unreasonably dangerous actions or omissions.

When Congress creates a regulatory scheme through legislation, immunity is seldom a centerpiece. Instead, the question of immunity is usually determined by another doctrine — that of preemption. Under the U.S. Constitution's Supremacy Clause, federal laws are "supreme" over state laws: when the two conflict, the federal law rules, and the state law is unenforceable. If the two do not conflict, they can coexist — and, for example, subject those charged with drug crimes to both federal and state penalties. The Supremacy Clause also empowers the federal government to explicitly "preempt an area" over which it has authority, "completely occupying" it and depriving the states of all authority to enact and enforce laws in that area.

The theory behind preemption is that some activities, such as air-traffic control, require nationally uniform federal regulation. The doctrine of preemption itself is not controversial, but its application to lawsuits that are brought by private litigants has been contentious and is governed by a complex body of law.

In the 1992 Supreme Court case *Cipollone v. Liggett Group*, for example, the plaintiffs argued that a cigarette company failed to adequately warn consumers about the risks associated with smoking.¹ The failure to warn of risks is a well-established basis for bringing a product-liability suit, but the



manufacturer argued that the lawsuit was barred by the federal cigarette-labeling law, which included explicit preemption language: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." This language explicitly limits state legislatures' authority to "require" additional health warnings, but it was less clear that this preemption clause applied to private lawsuits by injured smokers alleging inadequate warning. The Court ruled that the preemption doctrine did apply to state courts, noting that if state juries found that additional warnings were needed to adequately protect potential cigarette purchasers, cigarette companies would be required to add more information to the federally mandated package label to avoid liability. This result would frustrate Congress's goal of protecting "the national economy from the burden imposed by diverse, nonuniform, and confusing cig-

arette labeling and advertising regulations."¹

Yet the existence of federal preemption does not always prohibit private litigants from bringing lawsuits. In 1984, the Supreme Court ruled that the estate of Karen Silkwood could sue the owner of a federally licensed nuclear facility over Silkwood's exposure to plutonium.² In a five-to-four decision, the Court ruled that the state court could award punitive damages even though the federal government has exclusive authority to "regulate the radiological safety aspects involved in the construction and operation of a nuclear plant."³ The Court noted that Congress had enacted the Price-Anderson Act to establish an indemnification scheme for personal injuries that were caused by nuclear facilities. Because the scheme anticipated state lawsuits, the Court concluded that Congress's preemption of the area of nuclear safety could not include the prohibition of private lawsuits. Even the four dissenters agreed with this general analysis; they argued only that Congress did not mean to permit the awarding of punitive damages, which are designed to change the safety-related behavior of the operators, a power the dissenters said Congress reserved for itself through the regulation of nuclear-power plants.

The differing outcomes in *Cipollone* and *Silkwood* resulted from differences in the specific preemptive language in the statutes. A recent medical-device case involving the Food and Drug Administration (FDA) also turned on specific clauses in the relevant statute.

The 2008 Supreme Court case *Riegel v. Medtronic* addressed the question of whether the Medical Device Amendments of 1976 preempted the area of device regulation — specifically, whether preemption precluded lawsuits against

Key Preemption Decisions of the Supreme Court.

Silkwood v. Kerr-McGee Corporation, 1984. State courts may award compensatory and punitive damages to a person harmed by exposure to plutonium at a federally licensed nuclear facility, even though the federal government has preempted the area of safety regulation of nuclear facilities.

Cipollone v. Liggett Group, 1992. Compliance with the federal law, which preempted the area of cigarette labeling, immunizes cigarette manufacturers from lawsuits brought on the basis of insufficient labeling.

Riegel v. Medtronic, 2008. An express preemption provision in federal law precludes lawsuits against manufacturers by persons alleging that they were injured by a defectively designed medical device that the FDA has deemed safe and effective after a full review.

Wyeth v. Levine, cert. granted, 2008. The Supreme Court will determine whether FDA approval of a drug's label preempts state-law claims of inadequate warning.

manufacturers by persons alleging that they had been injured by a defectively designed medical device that the FDA had deemed safe and effective after a full review.⁴ The fact that this question was answered in the affirmative by a vote of eight to one indicates that the issue was not a difficult one for the justices.

The Medical Device Amendments to the Food, Drug, and Cosmetics Act contain explicit preemption language that prohibits states from establishing “any requirement” that is “different from, or in addition to” requirements in the federal statute that relate “to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device” under the statute. The majority opinion concluded simply that “absent other indication [in the Medical Device Amendments], reference to a State’s ‘requirements’ includes its common-law duties” as articulated by courts or legislatures and “applied by juries under a negligence or strict-liability standard.”⁴

Justice Ruth Bader Ginsburg dissented, arguing that since the purpose of the Medical Device Amendments was to protect the public from dangerous devices, it is inconceivable that Congress would have taken away the right of injured patients to sue device manufacturers without saying this more directly. Justice Ginsburg raises an important social policy issue. Pa-

tients injured by poorly designed but FDA-approved medical devices now have no recourse. The theory behind this decision is that the FDA has such extensive expertise in safety that it can be entrusted with making decisions that are unchallengeable in court. A related argument is that there is no such thing as a “safe” device. Rather, the FDA makes value judgments that a device is “safe enough” to be marketed. Such approvals involve economic and social policy determinations that, it is argued, cannot be made on a case-by-case basis by courts and narrowly focused, nonexpert juries who see the negative effects of a device on one person but not the benefits of a device to society as a whole.

Next fall, the Court will hear a case about FDA-approved drugs (see box).⁵ Because drug approval is governed by a different law that contains no explicit preemption language, *Riegel* provides no indication of how the Court will rule. Nonetheless, the pharmaceutical industry, with the support of the Bush administration, is arguing that once the FDA approves a drug, the preemption doctrine implicitly deprives injured persons of the opportunity to prove it was inadequately labeled. As in *Riegel*, acceptance of this argument would leave the injured person with no recourse.

The support for the preemption doctrine by a starkly conser-

vative administration is probably founded in part on its outspoken disaffection for plaintiffs’ lawyers and its belief in “tort reform,” which always favors industry over injured individuals. But extensive federal preemption also runs counter to “states’ rights,” federalism, and “small government,” which are supposed to be the cornerstones of modern conservatism. In the model that the administration supports, total control is located in one federal agency.

If the Court expands the preemption doctrine and Congress does not rein it in, much closer scrutiny of the FDA’s approval process will be required. Since the processes and judgments of drug and device manufacturers and the FDA will no longer be made public through litigation, all the documentation the FDA receives from manufacturers should be made available for scrutiny by the public and Congress. Safety data for drugs and devices should not be protected as trade secrets.

The preemption doctrine plays a constructive role in the allocation of regulatory authority over national industries. But its purpose has never been to grant broad legal immunity to private industry. The solution lies not in the courts but in Congress, which is the ultimate creator of preemption.

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1. *Cipollone v. Liggett Group*, 505 U.S. 504 (1992).
2. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984).
3. *Pacific Gas and Electric Company v. State Energy Resources Conservation & Development Commission*, 461 U.S. 190 (1983).
4. *Riegel v. Medtronic*, 128 S.Ct. 999 (2008).
5. *Wyeth v. Levine, cert. granted* 128 S.Ct. 1118 (2008).

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