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Vaccines, Preemption, and Federalism Rightly Understood: Why the Supreme Court Should Find Federal Preemption in Bruesewitz v. Wyeth, Inc.

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Abstract: Despite some concerns to the contrary, federal preemption properly applied does not conflict with federalism. In fact, the two are quite compatible and can work together to ensure that regulatory decisions are not left up to state courts, which are susceptible to the machinations of America's tort bar. Presently pending before the Supreme Court, Bruesewitz v. Wyeth, Inc., addresses the question of whether federal law preempts lawsuits asserting both strict liability and negligent design defect claims related to vaccines. The Third Circuit upheld the vaccine preemption and the Supreme Court must do the same, both to preserve Congress's intent and protect the continued development and distribution of life-saving vaccines.

Should people who are injured or die as the result of a vaccination be entitled to sue the vaccine manufacturer in state court by claiming that the vaccine's defective design caused the harm? Alternatively, should such claimants go to the Vaccine Court that Congress established in 1986, where, if they prove causation, they can recover regardless of whether the vaccine manufacturer was negligent?

On October 12, 2010, the Supreme Court heard oral argument in Bruesewitz v. Wyeth, a case that raises these precise questions. Because preemption in this case is consistent with federalism and the Constitution, and because lawsuits would, once again, threaten the widespread benefits that vaccines provide—benefits that the lawsuits do not take into account—federal law should preempt those lawsuits, without regard to how they are packaged.

The National Childhood Vaccine Injury Act

In 1986, Congress enacted the National Childhood Vaccine Injury Act[1] in response to product liability litigation that exposed vaccine manufacturers to great risk and costs regardless of whether the manufacturer prevailed. As a result, vaccine manufacturers exited the market, causing shortages of crucial vaccines, including childhood vaccines that had almost completely eradicated many diseases that have crippled or killed children for centuries. Indeed, by the time that Congress acted "there [was] only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps, rubella (MMR) vaccine, and two manufacturers of the [diphtheria, pertussis, and tetanus] DPT vaccine" left in the United States.[2]

The National Childhood Vaccine Injury Act diverted claims arising from the use of vaccines from the courts to a newly established Vaccine Court. This decision was based on the fact that, no matter how safely a vaccine may be designed and manufactured, a very small percentage of the population will always have an adverse reaction, and those adverse reactions should not be treated like a product defect. In the act, Congress provided that "[n]o vaccine manufacturer shall be liable in a civil action" if

the injury "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."[3] Instead, the act set up a National Vaccine Injury Compensation Program, offering compensation to individuals who suffer injuries associated with particular childhood vaccines on a "no-fault" basis.

Bruesewitz Preempted?

In Bruesewitz v. Wyeth, Inc.,[4] the Third Circuit Court of Appeals held that the act preempts lawsuits asserting both strict liability and negligent design defect claims related to vaccines. The Bruesewitzs' daughter suffered residual seizure disorder and developmental delays, which they blamed on the DPT vaccine that she had received. The Vaccine Court denied relief, finding that Bruesewitz did not prove that the vaccine actually caused the condition. The federal district court then found that the act barred claims that the vaccine was defectively designed, and the Third Circuit affirmed that judgment.

When the Supreme Court decides whether lawsuits like the one at issue in Bruesewitz can go forward, it will have the benefit of the Solicitor General's views. In a separate, June 2009 case, the Supreme Court asked the Solicitor General's office what it thought the answer to that question should be. Nearly eight months later, at the end of January 2010, the Solicitor General correctly responded that federal law preempts such defective design lawsuits. The Solicitor General's response is not only correct, it is also particularly noteworthy: While the Obama Administration generally takes a dim view of preemption, in this case, it concluded that preemption is appropriate.

Preemption and the Obama Administration

Preemption is often misunderstood as a conflict between federal and state spheres of authority and, for that reason, an affront to federalism. But, when it functions properly, preemption is fully consistent with federalism, in that the federal and state governments have authority, including exclusive authority at times, within their respective spheres. The preemption of state court lawsuits by federal law vindicates the Supremacy Clause of the U.S. Constitution, which makes the Constitution and federal laws "the supreme Law of the Land," and helps to create national markets. While Congress has the power to regulate truly interstate commerce, the states, which have famously been characterized as laboratories for experimentation, retain the police power to regulate commerce within the state.[5] The states are, however, limited when their regulations would contradict a federal regulation.

Besides being inconsistent with federalism, an erroneous finding that a claim is not preempted frequently leaves the decision regarding whether and how to regulate to a state court jury. A state court judgment may have the effect of regulation, but it is qualitatively different in kind; a state court that applies state tort law considers only the responsibility for, and cost of, a catastrophic injury to one or more individuals. Federal regulation considers, among other things, whether the benefits to the community at large outweigh the risk that the product will harm a person or a small group of individuals.

Leaving the issue to the state courts also tends to benefit the trial lawyers, who pursue tort cases on a contingency fee basis. For their part, the trial lawyers vigorously recycle portions of their recoveries into the political election process. As the Center for Legal Policy at the Manhattan Institute notes, "In the last

decade, lawyers and law firms—excluding lobbyists—have injected $780 million into federal campaigns, on top of $725 million donated to state races. Lawyers' giving is so lavish that it exceeds all other industries', and likely would do so even if donations by defense firms were backed out of total contribution figures."[6] Their money overwhelmingly goes to Democrats.[7]

Aside from their general distaste for preemption, one of the American Association for Justice's (formerly known as The Association of Trial Lawyers of America) legislative priorities is to overturn a Supreme Court decision holding that federal law preempts state court actions alleging that certain medical devices are negligently designed, manufactured, or labeled as well as other state law claims.[8] If successful, the result would be devastating to an industry that provides benefits to millions of Americans.

In a May 20, 2009, memorandum to the heads of executive departments and agencies, President Obama declared his Administration's "general policy" to be that "preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption."[9] More specifically, agencies were instructed not to construe a federal law to preempt state law unless Congress, either expressly or otherwise clearly, shows that it intends to preempt state law or that state law directly conflicts with federal statutory law.

This memorandum places a premium on express preemption and makes it unlikely that the Administration will argue that any state law claims are impliedly preempted. A claim may be impliedly preempted where state law and federal law conflict and the conflict makes it impossible to comply with both federal and state requirements,[10] or when state law "stands as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress."[11] Because the Administration disfavors implied preemption, the Solicitor General's incentive was to find the claim expressly preempted or not preempted at all.

The Supreme Court's request for briefing from the Solicitor General came in the case of American Home Products v. Ferrari,[12] in which the Supreme Court of Georgia held that federal law does not preempt a claim that a vaccine is defectively designed. The Ferraris complained that their son suffered neurological damage because vaccines that he received contained the preservative thimerosal, which contains a small amount of mercury. They contended that the vaccines could, and should, have been manufactured without thimerosal when their son was vaccinated in 1998, even though there is no credible scientific evidence that thimerosal has any negative side effects.

The Georgia Supreme Court held that the question of whether the side effects attributed to a vaccine could have been avoided by a better design should be decided on a case-by-case basis. In reaching this decision, the Georgia Supreme Court stood alone. Its decision conflicted not only with the Third Circuit's decision in Bruesewitz, but also with decisions from federal district courts in Texas and Pennsylvania and the New York state courts.[13]

The Solicitor General's Brief and Preemption of Vaccine Claims

The Court's invitation put the Administration to the test: Did it want a viable national vaccine program or did it want to allow lawsuits to do what they did before the act in 1986: help drive vaccine manufacturers from the market to the benefit of the plaintiffs' tort bar? In response to that invitation, then Solicitor General Kagan[14] explained that, in her view, the Georgia Supreme Court was wrong, and the Third Circuit was right. More particularly, she concluded that the act preempts "all design defect claims." That conclusion flows from the words of the statute, the legislative history, and the structure and purpose of the Vaccine Act. In her brief, the Solicitor General notes that vaccines are a prime example of the kind of product that provides widespread benefits at the cost of a relatively small number of adverse reactions. Vaccines go through a rigorous approval process at the FDA, and side effects must be reported. If design defect claims can proceed in state court, promising lines of research may be shut off. In short, the Solicitor General went to bat for the program.

That was the right thing to do. Vaccines have helped to banish diseases like polio, smallpox, and rubella, and, as Solicitor General Kagan noted, litigation could derail research into promising vaccine development strategies that offer potentially significant advantages in safety and effective use. The contrary rule espoused by the Georgia Supreme Court would chase manufacturers from the field and expose children who do not receive vaccines to the risk of catastrophic illness and mass epidemics.

Construction of the Statute

As noted above, the act states that "[n]o vaccine manufacturer shall be liable in a civil action" if the injury "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."[15] The act also specifies when a vaccine "shall be presumed to be accompanied by proper directions and warnings."[16] In addition, when addressing the trial of a civil action, the act provides that a manufacturer will not be held liable for punitive damages unless it improperly withholds information from the government before or after approval or engages in other criminal or illegal activity relating to the vaccine's safety or effectiveness.[17]

The act clearly preempts some claims for money damages for any injury said to be caused by a vaccine. But which ones? The act specifically mentions defective manufacturing and defective labeling claims, so the question is what to do with defective design claims, which are not mentioned. The government and Wyeth agree that defective design claims are preempted, while defective manufacturing and defective labeling claims can proceed to the extent permitted by the act. As counsel for Wyeth put it, agreeing with Justice Ginsburg, defective manufacturing claims and defective labeling claims are "always avoidable."[18]

Defective design claims are qualitatively different. As the government noted, the vaccines on the market have been recommended for routine administration by the federal Centers for Disease Control, a recommendation that is made with advice from the Advisory Committee on Immunization Practices.[19] And, the government reads "unavoidable" to mean unavoidable with respect to the vaccine that has been approved.[20] A design defect claim necessarily involves an alternative design that is said to be

preferable to the approved design and, if that claim can go forward in state court, asks a jury to make that judgment call. In effect, the jury substitutes its judgment for that of the government's experts.

If the Court holds that defective design claims are not preempted in Bruesewitz, state court juries will be making many of those judgment calls. As the attorney for Wyeth noted, there are about 5,000 potential state court claimants who contend that the vaccine for mumps, measles, and rubella causes autism.[21] The Vaccine Court has rejected that contention, but, if the claims are not preempted, the claimants will be able to go into state court and the results of the Vaccine Court's proceedings will not be admissible.[22]

Thus, the stakes in Bruesewitz are clear.

Devastating Settlements Discourage Manufacturers

Even if design defect claims are preempted, defective manufacturing and defective labeling claims are not. A $22.5 million judgment awarded against the manufacturer of a polio vaccine by a jury in New York illustrates the potential mischief that defective manufacturing and defective labeling claims can cause. Dominick Tenuto claimed that he contracted polio while changing his infant daughter's diapers in 1979. He contended that the two doses of polio vaccine that he had received were defectively manufactured, and that the label did not sufficiently emphasize the risk that polio might be acquired through household contact. Given that he had received two injections of vaccine, though, it may have been the case that he was immune deficient. Wyeth, as the successor to Lederle, the company that made the vaccine, unsuccessfully argued that the claims were preempted in the trial court.[23]

One wonders how many $22.5 million judgments the polio vaccine could bear.[24] If the small percentage of people who suffer adverse side effects from the administration of a vaccine can file defective manufacturing and defective labeling claims, this nation may well be back where it was when Congress passed the act in 1986. Case-by-case review of claims of injury by juries in state and federal courts will discourage manufacturers from producing vaccines, and Americans will be at risk of the reappearance of preventable diseases, such as polio, diphtheria, and tetanus.

As for Bruesewitz, the Supreme Court should affirm the judgment of the Third Circuit and hold that federal law preempts state court claims that a vaccine is defectively designed. That holding would vindicate the plan of Congress and preserve a very valuable program.

—Jack Park prepared this paper while he was a Visiting Legal Fellow in the Center for Legal & Judicial Studies at The Heritage Foundation.

Show references in this report

[1]42 U.S.C. §§ 300aa-1, et seq.

[2]H.R. Rep. No. 99-908 (1986) reprinted in 1986 U.S.C.C.A.N. 6344, at 6348.

[3]42 U.S.C. § 300aa-22(b)(1). "[A] vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material effects under the Federal Food, Drug, and Cosmetic Act" and the 1986 Vaccine Act unless the manufacturer engaged in fraud or other misconduct or unless the plaintiff shows "by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance" with the approval scheme. 42 U.S.C. §§ 300aa-22(b)(2), 300aa-23.

[4]561 F. 3d 233(3d Cir. 2009).

[5] See, e.g., Abbott Laboratories v. Durrett, 746 So. 2d 316 (Ala. 1999) (Alabama antitrust statutes apply to intrastate conduct only and do not provide a cause of action for damages allegedly resulting from agreement to control the price of goods shipped in interstate commerce.).

[6]Trial Lawyers Inc.: K Street, A Report on the Litigation Lobby 2010 2–3 (Manhattan Institute 2010) (footnotes omitted.).

[7] Id., at 7–8.

[8] See, e.g., PointOfLaw.com, Trial Lawyers Association Outlines Its 2010 Legislative Agenda, www.pointoflaw.com/archives/ 2010/01/trial-lawyers-a-2.php (last visited October 13, 2010); see also Hans A. von Spakovsky, Killing Americans by Stifling Medical Innovation: The Medical Device "Safety" Act of 2009 (The Heritage Foundation, 2009).

[9]74 Fed. Reg. 24693 (2009).

[10] See, e.g., English v. General Elec. Co., 496 U.S. 72, 78–79 (1990).

[11]Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

[12]668 S.E. 2d 236 (Ga. 2008).

[13]Sykes v. GlaxoSmithKline, 484 F.S. 2d 289 (E.D. Pa. 2007); Blackmon v. American Home Products Corp., 329 F.S. 2d 659 (S.D. Tex. 2004); Militrano. v. Lederle Laboratories, 3 Misc. 3d 523, 769 N.Y.S. 2d 839(2003), aff'd, 26 A.D. 3d 475, 810 N.Y.S. 2d 506 (2006).

[14]Associate Justice Kagan has recused herself from taking part in Bruesewitz.

[15]42 U.S.C. § 300aa-22(b)(1).

[16]42 U.S.C. § 300aa-22(b)(2).

[17]42 U.S.C. § 300aa-23(d)(2).

[18]Transcipt of oral argument at 29, Bruesewitz v. Wyeth, Inc., 130 S.Ct. 1734 (2010) (No. 09-152)

[19]Transcipt of oral argument at 49. Bruesewitz, 130 S.Ct. 1734 (No. 09-152)

[20] Id., at 911.

[21] Id., at 37.

[22] See 42 U.S.C. § 300aa-23(e).

[23]This case was settled after the entry of judgment.

[24]As Chief Justice Roberts put it at oral argument, “It doesn’t take too many $60 million verdicts to make you come out on the other side of your calculus.” See Oral Argument transcript at 20. In the related field of medical devices, for example, Ernst Berndt and Mark Trusheim have concluded that the potential tort settlements are relatively large compared to the revenues and profits derived from medical devices that have undergone premarket approval review by the Food and Drug Administration. Ernst Berndt and Mark Trusheim, The Economic Impacts of Eliminating Federal Preemption for Medical Devices on Patients, Innovation and Jobs 18–19 (2009).