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Perspective

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Safety, Supply, and Suits — Litigation and the Vaccine Industry

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On February 22, 2011, the U.S. Supreme Court ruled in *Bruesewitz v. Wyeth* that vaccine makers are immune from lawsuits charging that the design of a vaccine is defective. Many physicians and public health organizations applauded this outcome, believing that it will help to ensure the availability and promote the appropriate use of childhood vaccines. Others worry about what it may mean for patients' rights.

The safety of vaccines is a thorny public health issue because vaccines occupy a unique position in the market. When other consumer goods are defective, including defects in their design, their manufacturers are generally strictly liable for resulting harms. Strict liability is strongly favorable for plaintiffs, because the manufacturer is responsible for any damages caused by its products, irrespective of the level of care it exercised. This standard is meant to provide manufacturers with an incentive to develop consumer goods that are appropriately safe. But medical products — including vaccines, drugs, and some medical devices — are unusual in that the same components that make them effective may also cause serious adverse effects. Thus, it may not be possible to design safer versions of them without losing their essential function. Influential legal experts have agreed that manufacturers of these "unavoidably unsafe products" should be exempted from strict liability for these products, as long as consumers are adequately warned about their risks.[1] This principle helps to assure that such products remain on the market, since they make a vital contribution to public health.

In the early 1980s, however, the supply of some essential childhood vaccines was threatened by manufacturers who argued that the cost of persistent lawsuits exceeded the income they could earn from these products. In particular, companies were held responsible for alleged vaccine-related injuries even when scientific evidence did not establish causation. Manufacturers claimed that the threat of such liability made it impossible to obtain liability insurance coverage and therefore to maintain operations.

In response, in 1986, Congress enacted the National Childhood Vaccine Injury Act (NCVIA), establishing a no-fault compensation system ("vaccine court") for children who were harmed by adverse events following vaccine administration, as long as there was evidence that the vaccine actually caused the problem. The system is expert-driven, and there are no jury trials. Compensation covers the costs of medical expenses, projected lost earnings,

and up to $250,000 for pain and suffering but does not include punitive damages. It is paid out of taxes levied on each dose of vaccine. Although the NCVIA permits plaintiffs to reject an outcome and file a claim in court, its key preemption provision says that "no vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."[2]

Controversy over the proper interpretation of this section of the legislation led to *Bruesewitz v. Wyeth*. In 1992, 6-month-old Hannah Bruesewitz received a third dose of her diphtheria–tetanus–pertussis (DTP) vaccine with whole-cell pertussis (Tri-Immunol) and had seizures shortly afterward, followed by a residual seizure disorder and developmental delay. In the vaccine court, the case was denied because the Department of Health and Human Services, concluding that there was no medical evidence of a connection, had recently removed residual seizure disorder from the list of adverse events eligible for administrative compensation.[3]

The Bruesewitz family rejected the judgment and sued the manufacturer for failing to develop a safer vaccine. Company documents, identified through discovery in the subsequent civil action, did refer to increased adverse reactions with Tri-Immunol — although not residual seizure disorder specifically — as compared with a vaccine with an acellular pertussis component (DTaP). In other documents, company representatives appeared to conclude that pursuing this "better pertussis component" was "not worth it for the total market."[4] The DTaP vaccine is now standard in the United States, and Wyeth removed Tri-Immunol from the market in 1998.

The case reached the Supreme Court, which held that the NCVIA preempted the Bruesewitzes' lawsuit.[5] Writing for the majority in a six-to-two decision, Justice Antonin Scalia concluded that the NCVIA provided no options for plaintiffs who set aside the vaccine court's determination, unless they could argue that the vaccine was poorly manufactured or accompanied by improper warnings. In her dissent, Justice Sonia Sotomayor rejected this view, writing that the NCVIA's preemption of further litigation was intended to apply only to cases in which the manufacturer can demonstrate that "the side effect stemming from the particular vaccine's design is 'unavoidable.'"

Their disagreement centers on the question of what Congress intended to do in the NCVIA and highlights the uneasy relationship between preemption and product safety. Federal preemption of product liability lawsuits that rely on state law is a powerful prerogative that places heavy emphasis on the quality of regulation by the Food and Drug Administration (FDA). Litigation such as the Bruesewitzes' can help the FDA in its oversight function by revealing important and previously unknown information about product-related risks, especially during the postapproval period, and by deterring manufacturers from acting irresponsibly and engaging in business tactics aimed at increasing product sales at the expense of patient safety. These considerations were prominent in *Wyeth v. Levine*, a 2009 Supreme Court decision that held that federal law did not preempt state-court lawsuits over drug safety.

However, childhood vaccines differ from drugs in many ways. They are given widely to healthy children to prevent potentially deadly infectious diseases. The childhood vaccine market is also apparently less stable than the drug market, since there are fewer vaccine suppliers and there's therefore a real risk of shortages if companies leave the field. In this environment, an administrative forum in which considerable expertise informs determinations about causation can play an essential role by resolving fairly most cases of alleged vaccine-related adverse events. For example, in the autism cases, the vaccine court rightly found no link between vaccination and that condition. But should the existence of the vaccine court necessarily preempt all lawsuits alleging that a vaccine could have been made safer? Civil litigation could be useful in the rare cases in which a plaintiff was contending that a plausible alternative vaccine design would have prevented the adverse event at issue. This argument is particularly relevant because the FDA doesn't usually consider whether a safer product design exists when deciding whether to approve a vaccine or keep a vaccine on the market.

The Court's reasoning in *Bruesewitz* was based in part on concern about the exploitation of such an exception by plaintiffs' lawyers, who could bring cases based on testimony about a "universe of alternative designs" that is "limited only by an expert's

imagination." Might opening this possibility defeat the purpose of the vaccine court and again potentially jeopardize market stability and vaccine availability? The Supreme Court noted that in place of litigation, the NCVIA "provides many means of improving vaccine design."[5] Among those listed were oversight by the FDA, voluntary reporting and monitoring of adverse events (both of which are known to be imperfect means of detecting risk and ensuring safety), and the National Vaccine Program. Amendments to the NCVIA may be required to provide additional regulatory support, because these systems are now operating without one important safety net.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

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1. Restatement (Second) of Torts § 402A cmt. k (1965).
2. 42 U.S.C. § 300aa-22(b)(1) (2010).
3. National Vaccine Injury Compensation Program revision of the vaccine injury table: final rule. Fed Regist 1995;60(26):7678-96.
4. Joint appendix, Bruesewitz v. Wyeth, No. 09-152 (May 24, 2010).
5. Bruesewitz v. Wyeth, 562 U.S. ___ (2011).

Catching a Wave — Implementing Health Care Reform in California

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The Affordable Care Act (ACA) has launched a wave of federal funding and policy changes that will extend health insurance coverage to 32 million Americans beginning in 2014. Many states have been resisting this wave by asking the federal courts to strike down the ACA on constitutional grounds. Others are preparing to catch it. Among the latter states is California, where despite a 12.3% unemployment rate and major budget problems, implementation is under way.

The stakes for Californians and their physicians are enormous. The state is expected to have more newly insured people than any other state: approximately 3.4 million.[1] Whether that expanded coverage will improve access to needed care and lead to better population health will depend in large part on how effectively physicians are engaged in implementation.

Some early signs are promising. California was one of the first states to enact enabling legislation for a new health insurance exchange from which people will be able to purchase coverage regardless of whether they have preexisting conditions. In addition, the secretary of health and human services has granted California a 5-year, $8 billion Medicaid demonstration waiver to enable it to prepare for the coverage expansion in 2014; such waivers permit states greater administrative flexibility in using the anticipated federal share of Medicaid funds to meet their program's goals. With the federal funding and this flexibility, California is pursuing three main implementation strategies.

First, the state plans to expand coverage to the uninsured before 2014 on a county-by-county basis. Several California counties, most notably San Francisco County through its Healthy San Francisco program,[2] have developed coverage initiatives that provide a defined health care benefit for low-income, childless adults — the group that's not currently eligible for the traditional Medicaid program but will be in 2014. Under the waiver, more counties will launch such initiatives, in which covered benefits will be increased to approximate those available through Medi-Cal, California's Medicaid program.

Second, California will use federal resources available under the waiver to invest in its public safety-net hospitals. Nineteen of California's acute care public hospitals (6% of all the state's acute care hospitals) currently account for approximately half of the state's hospitalizations of uninsured people each year. Most of these facilities also operate robust ambulatory care services that provide more than 10 million primary care and specialty visits for uninsured people and Medi-Cal beneficiaries annually. California aims to increase these institutions' capacity to care for their traditional patient populations, because even after health care reform is implemented, there are expected to be more than 3 million uninsured people in the state.