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Pandemic Vaccines — The Legal Landscape

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Vaccines and vaccination law feature prominently in pandemic preparedness plans. The recent H1N1 influenza vaccine program provides an important opportunity to assess the complex and perhaps paradoxical effects of vaccine laws during a pandemic.

The vaccine market is fragile, prone to shortages of both supply and demand. These shortages have been attributed to such factors as the high costs and low profits of vaccine production, the public's failure to appreciate the importance of vaccination (due, ironically, to vaccines' success in reducing the prevalence of once-common diseases), fears about vaccine safety, and tort liability. In order to protect public health, law must address each of these concerns. Resolving one without exacerbating another is always challenging; during a pandemic, it can be especially difficult.

Ever since the 1976 National Swine Flu Vaccination Program, Congress has addressed these problems by coupling liability protection for vaccine makers with alternative compensation programs for injured patients. For example, the National Childhood Vaccine Injury Act (NCVIA, see box) provides relatively swift, but limited, compensation for persons with well-recognized listed injuries from covered vaccines. NCVIA also allows other claimants to go before a tribunal of Special Masters of the U.S. Court of Federal Claims, known as the Vaccine Court, to show that a vaccine caused their injury. This court's rulings can be reviewed by the U.S. Court of Appeals for the Federal Circuit. Parties who are dissatisfied with a Vaccine Court ruling also retain a limited right to sue in state court. Recently, the U.S. Supreme Court agreed to review a case, *Bruesewitz v. Wyeth*, in which the U.S. Court of Appeals for the Third Circuit held that NCVIA bars a state-law design-defect claim brought by a minor after the Vaccine Court found that the whole-cell diphtheria–pertussis–tetanus vaccine did not cause her neurologic injuries. The Supreme Court's decision in *Bruesewitz* should help to clarify which state-law claims survive NCVIA.

When Congress focused on pandemics in 2005, it again combined tort immunity with no-fault compensation. Under the Public Readiness and Emergency Preparedness (PREP) Act (see box), manufacturers, distributors, and health care providers administering vaccines and other pandemic countermeasures are granted total immunity (except in cases of willful misconduct) when the secretary of health and human services invokes such immunity while declaring a public health emergency. The PREP Act also au-

National Childhood Vaccine Injury Act.

- Established the National Vaccine Injury Compensation Program for adults and children who receive covered vaccines
- Finances compensation for vaccine injury by an excise tax on vaccines
- Provides administrative, no-fault compensation for claimants with any injury included in its injury table (table injury)
- Permits claimants without a table injury to go before the Vaccine Court to prove that a covered vaccine caused the injury
- Permits review by the U.S. Court of Appeals for the Federal Circuit
- Bars actions against vaccine makers for $1,000 or more in state court for covered vaccines until after the Vaccine Court has ruled or has failed to rule within a set time
- Permits claimants who receive no award or are dissatisfied with their award to file a state-law tort claim
- Bars state actions against vaccine makers for injuries that were "unavoidable" even though the vaccine was properly prepared and accompanied by proper directions and warnings
- Prohibits liability by a vaccine maker solely for failing to provide direct warnings to the injured party
- Established the Advisory Commission on Childhood Vaccines and led to the Vaccine Adverse Events Reporting System

Public Readiness and Emergency Preparedness Act.

- Provides immunity except for "willful misconduct" to the United States, manufacturers, distributors, program planners, and those who administer "covered countermeasures" when the secretary of health and human services issues an emergency declaration
- Defines "covered countermeasures" as including a qualified epidemic or pandemic product or drug, biologic products, and devices authorized for emergency use
- Creates an exclusive and limited right to sue in federal court for injuries alleged to be caused by willful misconduct
- Permits individuals who claim to be injured by a covered countermeasure to seek compensation from a fund administered by the Health Resources and Services Administration
- Bars judicial review for claims to the compensation fund

thorizes limited no-fault compensation for persons harmed by covered countermeasures, but unlike NCVIA, it does not allow for judicial review or civil litigation. In June 2009, Secretary of Health and Human Services Kathleen Sebelius issued an emergency declaration for H1N1 influenza. The declaration has since been updated and reissued several times.

Ideally, the PREP Act's immunity provisions — in conjunction with Section 564 of the Food, Drug, and Cosmetic Act, which allows the Food and Drug Administration to issue emergency-use authorizations — remove legal obstacles to the rapid production and dissemination of pandemic vaccines. The effect of these laws on the public's willingness to be vaccinated, however, is uncertain. For example, during the 2003 smallpox-vaccination program for health care providers, doubts about the availability and adequacy of compensation for vaccine-related injuries were blamed for discouraging many providers from being inoculated. NCVIA's effect on public confidence in vaccinations is also unclear. By requiring that vaccine cases first go before the Vaccine Court, NCVIA ensures that claims will be scrutinized by special masters who are well equipped to review the scientific evidence. Still, the act's relatively broad immunity provisions and the barriers it creates for patients seeking jury trials have provided rich fodder for people who distrust vaccines. After special masters recently ruled in three cases that thimerosal, a mercury-based preservative used in some vaccines, does not cause autism, Rebecca Estepp, a member of a coalition that believes that vaccines cause autism, responded by claiming that the Vaccine Court was "stacked against families."[1] Similarly, during the H1N1 influenza outbreak, critics pointed to the PREP Act's far broader immunity provisions to argue that the government had hyped the pandemic to benefit vaccine makers.[2]

Despite overwhelming scientific evidence to the contrary, many parents still believe that thimerosal causes autism. Several states therefore limit the use of mercury-containing vaccines in young children and pregnant women. For example, Washington State prohibits the use of influenza vaccines with more than 1.0 μg of mercury per 0.05-ml dose in pregnant women or children under 3 years of age. The state's secretary of health can suspend the prohibition during an outbreak of a vaccine-preventable disease or a shortage of mercury-free vaccine, but clinicians must inform pregnant patients and parents of

Cases Challenging Mandates for Health Care Workers to Receive H1N1 and Seasonal Influenza Vaccines.

Case Name	Court and Docket Number	Challenged Mandate	Outcome
Brynien v. Daines	N.Y. Sup. Ct. No. 8853–09	New York emergency regulation	Temporary restraining order issued October 16, 2009; state then withdrew regulation and case was dismissed
Patterson v. Daines	N.Y. Sup. Ct. No. 8830–09	New York emergency regulation	Temporary restraining order issued October 16, 2009; state then withdrew regulation and case was dismissed
Savoca v. New York State Dept. of Health	N.Y. Sup. Ct. No. 8855–09	New York emergency regulation	Case dismissed after state withdrew regulation
Field v. Daines	N.Y. Sup. Ct. No. 114033–09	New York emergency regulation	Case dismissed after state withdrew regulation
SEIU Local 121RN v. Healthcare Corp. of America	U.S. Dist. Ct. N.D. Cal. No. 5:09-CV-05065-JF	Hospital's order	Injunction denied on Nov. 17, 2009; parties ordered to submit to arbitration
SEIU Local 1107 v. Southern Hills Medical Center	U.S. Dist. Ct. Nev. No. 2:09-CV-02094-RCJ-PAL	Hospital's order	Temporary restraining order issued halting mandate for seasonal vaccine pending arbitration, Nov. 6, 2009
Washington State Nurses Assoc. v. Multicare Healthcare Systems	U.S. Dist. Ct. W.D. Wash. No. 3:09-CV-05614-RJB	Hospital's order	Temporary restraining order denied; parties agreed to dismiss case

children under 18 that the vaccines being used contain more mercury than is otherwise permitted. Last October, citing the shortage of mercury-free H1N1 vaccine, Washington State's health department suspended the act's prohibition, invoking the warning requirement. A local health official reported that this move may have discouraged health care providers and patients from getting vaccinated.[3]

Public wariness regarding vaccination has led some public health and elected officials to consider vaccine mandates. All states require schoolchildren to be vaccinated, but 48 states provide religious exemptions, and 21 allow philosophical exemptions.[4] Such laws regularize vaccination without penalizing families who most ardently oppose the practice.

Several states take a similar approach to promoting the vaccination of health care workers against influenza. For example, California and Massachusetts require hospital workers either to be vaccinated annually against influenza or to sign a written declination. These laws also regularize vaccination without actually compelling all hospital employees to comply.

Some officials have sought more coercive measures. In 2001, the Model State Emergency Health Powers Act proposed granting states authority to isolate people who refused vaccination during a public health emergency. Although many states have adopted this provision,[5] none implemented it during the H1N1 pandemic. Indeed, during the peak of the outbreak, vaccine was either nonexistent or in short supply, and many people who wanted to be vaccinated could not be. Under such circumstances, which are likely to exist during any pandemic, mandates are bound to be ineffective.

Nevertheless, in August 2009, New York State's health department issued an emergency regulation requiring health care workers who had contact with patients in hospitals and other specified settings to be vaccinated against H1N1 and seasonal influenza, unless they had medical contraindications. Several workers responded by filing lawsuits claiming that the department had exceeded its authority and violated their constitutional rights. On October 16, 2009, a trial court issued temporary restraining orders in two cases, blocking the implementation of the regulation (see table). The department then rescinded the regulation, citing the shortage of H1N1 vaccine.

Despite the shortage, many hospitals required workers either to be vaccinated or to wear a protective mask. Predictably, such requirements led to a spate of lawsuits charging the hospitals with violating collective bargain-

ing agreements as well as federal labor laws. Although the hospitals usually prevailed, a federal court in Nevada issued a temporary restraining order prohibiting the implementation of a mandate for vaccination against seasonal influenza, pending arbitration.

The H1N1-vaccine litigation shows that mandates not only may be ineffective when vaccine shortages exist but also may backfire. Although states can penalize people who refuse vaccination during an epidemic, the law also provides multiple ways to challenge vaccine mandates. These lawsuits can generate heated publicity that raises further doubts in people's minds about vaccine safety. Certainly, media reports about health care workers going to court to avoid vaccination are not apt to inspire the public's faith in vaccines.

As policymakers consider the role of laws in facilitating vaccination during future pandemics, such experiences warrant careful consideration. Laws can help encourage vaccine production; they can also penalize people who reject vaccines. The more difficult task is to use those laws with a light enough touch so that they do not undermine the population's willingness to bare their arms.

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

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A "Customary and Necessary" Program — Medicaid and Health Care Reform

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The recently passed U.S. health care reform law envisions a health care system that rests atop a four-legged stool consisting of employer-sponsored health plans, coverage purchased through state-based exchanges, Medicare, and Medicaid. Each leg faces important challenges, none more than Medicaid. Numerous issues confront the "new" Medicaid. Will states be able to achieve full coverage for eligible persons and align their operations smoothly with those of other coverage sources? Will coverage be adequate to the population's need? Will providers participate, and will the safety net be sustained? And perhaps above all, will states continue to operate Medicaid programs and share in their costs?

Medicaid plays a starring role in health care reform. In its final cost estimates,[1] the Congressional Budget Office (CBO) projected that 94% of the U.S. population will have health care coverage by 2019, up from 83% under current policy. Of the 32 million people gaining benefits, half — 16 million people — are expected to derive their coverage through Medicaid and the Children's Health Insurance Program (CHIP). This expansion will come at a 10-year cost of $434 billion in additional federal funding. CBO estimates also show that the Medicaid reforms will not merely boost program enrollment over 10 years but will actually stave off an increase in the number of uninsured persons resulting from, among other factors, a decline in the number of children and adults covered by Medicaid and CHIP.

To achieve these results and address other program challenges, Congress has fundamentally altered Medicaid's eligibility structure. Historically, Medicaid eligibility has been tied to both low income and demographic characteristics that are a vestige of federal cash-welfare programs designed to benefit the disabled, the aged, and extremely poor "dependent" minor children and their parents. Reforms that have