
TOWARD A TWENTY-FIRST-CENTURY
JACOBSON V. MASSACHUSETTS

Biomedical advances are pushing the foundational public health law case *Jacobson v. Massachusetts*¹ towards obsolescence. The 1905 Supreme Court decision established the constitutionality of state compulsory vaccination laws when they are “necessary for the public health or the public safety.”² But the case addressed issues of medicine, disease, and society that are increasingly irrelevant. *Jacobson*’s rationale has little to say about two recently developed controversial vaccines — the hepatitis B vaccine and the human papillomavirus (HPV) vaccine — and it will likely have even less to say about vaccines that are still in the pipeline. These vaccines are qualitatively different from their predecessors in that they are not medically essential to preventing the spread of disease. Vaccine law and policy — whether through common law, statutes, or agency directives — must develop clear ways to recognize these distinctions.

This Note suggests that vaccine law distinguish between two kinds of necessity — what this Note calls “medical necessity” and “practical necessity.” Those vaccines classified as “medically necessary” would be those that are the only known viable defenses against diseases taking hold in a community. “Practically necessary” vaccines are those to which there are alternatives, but which alternatives are, in practice, not used by a significant number of people.

For example, *Jacobson* involved compulsory vaccination in the midst of a smallpox epidemic when there was no other less coercive means available to staunch the outbreak. In this situation, vaccination was a medical necessity to combat the disease. On the other hand, for sexually transmitted diseases (STDs) like HPV, compulsory vaccination is not a medical necessity because individuals can protect themselves through some combination of sexual knowledge, disease screening, safe sex, and abstinence. But vaccination may still be necessary in practice if people do not take adequate precautions, and legally compelled immunization is the only practical way to combat the disease effectively. Of course, the line between medical and practical necessity will not always be clear. Nonetheless, creating such a classification can still prove a useful device for sorting among vaccines that combat diseases that are different in the ways that they are spread.

This Note does not argue that courts should find compulsory vaccination against STDs or similar diseases unconstitutional. Indeed, as discussed below, there are strong arguments that compulsory vaccina-

¹ 197 U.S. 11 (1905).

² *Id.* at 27.

tion against HPV may be justified. Rather, this Note's primary claim is that vaccine law must be updated — whether by courts, legislators, or expert bureaucrats — to respond better to future biomedical advances. Amazingly powerful medicines and vaccines are in the pipeline, and these new drugs will not fit into the old paradigm of responding only to airborne infectious diseases such as smallpox, polio, and measles. New legal understandings must keep pace with these breakthroughs. Updating vaccine law to distinguish between two degrees of necessity, and thus better accounting for vaccines like those against HPV and hepatitis B, is an important early step in that process.

This Note proceeds as follows. Part I presents the *Jacobson* decision, emphasizing the social and medical context in which it was decided. Part II examines recent developments in vaccine law and policy, focusing on the introduction of the hepatitis B and HPV vaccines. Part III evaluates two competing views of *Jacobson's* legacy by public health law Professors Lawrence Gostin and George Annas. It then presents the novel argument that modern vaccine law should recognize a distinction between medically necessary vaccines and practically necessary vaccines. Presently, new vaccine mandates are presumed constitutionally valid under *Jacobson*, even when the vaccines combat diseases that are not airborne and from which individuals have some other recourse to protect themselves. Recognizing the proposed distinction would allow state and federal policymakers and courts to balance more precisely civil liberty and public health needs. Part IV concludes.

I. JACOBSON V. MASSACHUSETTS

Jacobson is a foundational public health law case. Its reasoning and logic pervade vaccine law decisions to this day. But as this Part shows, *Jacobson* was decided in a different time. It addressed issues about medicine, disease, and society that are no longer relevant today.

A. The Case

Vaccine efficacy against infectious diseases rests on the concept of herd immunity.³ Vaccines are never one hundred percent effective for everybody, so even vaccinated people can become infected with diseases against which they were immunized. But if enough people in a population are effectively immunized against a disease, the population can achieve a herd immunity that protects everybody. The idea is that the disease will not break out in the population because too few people are capable of carrying it and passing it on to others. The vaccination

³ See Paul E. M. Fine, *Herd Immunity: History, Theory, Practice*, 15 EPIDEMIOLOGIC REVS. 265, 267 (1993).

rate needed for herd immunity in a population varies by vaccine, but such immunity typically requires vaccination rates of eighty to ninety-five percent.⁴ The upshot of herd immunity is that, to protect everybody in a community, a significant percentage of the population — but not everybody — must be vaccinated. That is why, to ward off infectious diseases, it is sensible for public health officials to strive for vaccination rates as close to one hundred percent of the population as is practicable.

In 1901, a smallpox epidemic swept through the Northeast. In Cambridge, Massachusetts, the city government sought to subdue the epidemic by requiring all adults to receive smallpox inoculations. Failure to do so would result in a five-dollar fine.⁵ In 1902, Henning Jacobson refused to be vaccinated and to pay the fine.⁶ In state court, Jacobson argued that the vaccine law violated both the Massachusetts and U.S. constitutions.⁷ The state courts, including the Massachusetts Supreme Judicial Court, rejected his claims.⁸ Jacobson appealed to the U.S. Supreme Court. He soon found himself before the Justices in a room packed with officers from the Massachusetts Anti-Compulsory Vaccination Association.⁹ The stakes were high for the anti-vaccine movement. At the time, only eleven states had compulsory vaccine laws.¹⁰ The decision could shoot those laws down or, conversely, clear the way for dozens of other states to adopt similar laws.

Jacobson's argument boiled down to the claim that the treatment could not be imposed upon healthy citizens simply because they have the potential to contract the disease.¹¹ "Compulsion to introduce disease into a healthy system is a violation of liberty," he argued.¹² Although it was not his focus, Jacobson argued that vaccination might be unnecessary to prevent the spread of smallpox,¹³ but this argument was implausible because in the midst of an outbreak sanitation and isolation were paltry defenses compared to vaccination.

Writing for the 7–2 majority, Justice Harlan rejected Jacobson's arguments. He grounded the opinion in social compact theory and state police power — that is, the power of the states to protect public health and safety. Constitutional liberties, he wrote, are limited by a funda-

⁴ See *id.* at 268 tbl.1.

⁵ See *Jacobson*, 197 U.S. at 12–13 (Statement of the Case).

⁶ *Id.* at 13–14.

⁷ *Commonwealth v. Pear*, 66 N.E. 719, 720 (Mass. 1903).

⁸ *Id.* at 722.

⁹ See JAMES KEITH COLGROVE, *VACCINATION POLICY, POLITICS AND LAW IN THE TWENTIETH CENTURY* 65 (2004).

¹⁰ *Jacobson*, 197 U.S. at 15 (Argument for Plaintiff in Error).

¹¹ *Pear*, 66 N.E. at 721.

¹² *Jacobson*, 197 U.S. at 17 (Argument for Plaintiff in Error).

¹³ See *id.* at 15.

mental “social compact”¹⁴ and the “government is instituted ‘for the common good, for the protection, safety, prosperity and happiness of the people, and not for the profit, honor or private interests of any one man.’”¹⁵ The Court recognized a sphere of protected individual liberties, but insisted that the state had broad powers to encroach on that sphere when “the safety of the general public may demand.”¹⁶

B. *The Aftermath*

Soon after *Jacobson*’s holding came down, the inchoate anti-vaccine movement exploded. As Professor James Keith Colgrove notes, “a diverse assortment of activists would, over the next quarter-century, redouble their efforts at combating attempts to force vaccination upon the people.”¹⁷

Most prominently, three years after *Jacobson*, the Anti-Vaccination League of America was founded in Philadelphia. At its founding conference it announced its main objective — “to promote universal acceptance of the principle that health is nature’s greatest safeguard against disease and that therefore no State has the right to demand of anyone the impairment of his or her health”¹⁸ — as well as its political aims — “to abolish oppressive medical laws and counteract the growing tendency to enlarge the scope of state medicine at the expense of the freedom of the individual.”¹⁹ Hoping to rally widespread public support, the group’s cofounder invoked shared constitutional principles, asking, “We have repudiated *religious* tyranny; we have rejected *political* tyranny; shall we now submit to *medical* tyranny?”²⁰ Pamphlets became the medium of choice for the group. It published titles such as *The Crime Against the School Child* and *Horrors of Vaccination Exposed and Illustrated*, both of which depicted victims disfigured by unsafe vaccines.²¹

The Anti-Vaccination League, along with similar anti-vaccine groups,²² was driven by two distinct anxieties. First, anti-vaccinationists were concerned about the health and safety risks that vaccines posed. Vaccine injuries and deformities certainly occurred.

¹⁴ *Id.* at 27 (majority opinion).

¹⁵ *Id.* (quoting MASS. CONST. pt. I, art. VII).

¹⁶ *Id.* at 29.

¹⁷ COLGROVE, *supra* note 9, at 72.

¹⁸ ARTHUR ALLEN, *VACCINE: THE CONTROVERSIAL STORY OF MEDICINE’S GREATEST LIFESAVER* 103 (2007) (internal quotation marks omitted).

¹⁹ *Id.* at 104 (internal quotation mark omitted).

²⁰ COLGROVE, *supra* note 9, at 84.

²¹ *Id.*

²² *See id.* at 86–87, 88–89. Other groups opposed compulsory vaccination on religious, professional, and moral grounds. *See id.* at 87–88, 89–91 (describing anti-vaccination efforts of Christian Scientists, chiropractors, and anti-vivisectionists).

But, notably, the anti-vaccinationists were generally not arguing that the smallpox vaccine was not medically necessary to stop the disease. It was clear that the vaccine was the most effective means of attacking smallpox. Second, the anti-vaccine groups were tapping into larger public anxieties. Professor Colgrove convincingly argues that anti-vaccinationism should be seen in part “as an expression of anxiety about the expansion of government and the penetration of medical science into previously private spheres, issues which held special resonance during the Progressive Era.”²³ Historically, massive industrial growth and immigration led to greater need for a strong central government in this era. But, as historian John Whiteclay Chambers II observes, the nineteenth-century ideals of a limited role for the state and a suspicion of concentrated power were not easily altered.²⁴ The anti-vaccinationists appealed to those who wanted to hold on to these beliefs in turbulent social and political times.

C. Jacobson *Reaffirmed*: *Zucht v. King*

In 1922, the anti-vaccine movement had its day in court again. The question before the Court in *Zucht v. King*²⁵ was whether states may bar school enrollment for children who have not offered proof of immunization.²⁶ Like many cities, San Antonio, Texas, had an ordinance requiring all students to present a certificate of vaccination before they could enroll in school.²⁷ Texas student Rosalyn Zucht refused to be vaccinated; the city thus barred her from attending school, and she sued.²⁸

The Supreme Court unanimously rejected Zucht’s claims. “Long before this suit was instituted,” Justice Brandeis declared, “*Jacobson v. Massachusetts* had settled that it is within the police power of a state to provide for compulsory vaccination.”²⁹ He continued: “[t]hese ordinances confer not arbitrary power, but only that broad discretion required for the protection of the public health.”³⁰

Zucht marked the beginning of the end for the anti-vaccine movement of the day. The decision shut the door on any hope of the court system’s embrace of its constitutional claims. In the 1920s and 1930s, the anti-vaccine groups that held sway through their publications and

²³ *Id.* at 93.

²⁴ See JOHN WHITECLAY CHAMBERS II, *THE TYRANNY OF CHANGE: AMERICA IN THE PROGRESSIVE ERA, 1890–1920*, at 4 (2d ed. 2000).

²⁵ 260 U.S. 174 (1922).

²⁶ *Id.* at 175.

²⁷ See *id.*

²⁸ *Id.*

²⁹ *Id.* at 176 (citation omitted).

³⁰ *Id.* at 177.

in newspapers folded one by one.³¹ Meanwhile, by the early 1930s, concerns over the safety of vaccines had waned, as the public widely accepted physicians' recommendations about the efficacy of vaccines.³²

II. RECENT DEVELOPMENTS IN VACCINE LAW AND POLICY

Jacobson's reasoning and discussion of "necessity" became cemented in modern vaccine law. Broad challenges to compulsory vaccine laws ceased; challenges were instead limited to piecemeal applications for individual exemptions to vaccination laws. The anti-vaccine groups were quieted. But the introduction in recent years of two controversial vaccines — the hepatitis B and HPV vaccines — dramatically changed this trend toward general acceptance of compulsory regimes. These vaccines combatted diseases that were different from those targeted by most vaccines that had come before, and many families felt that the vaccines should not be lumped together with older ones for airborne diseases like smallpox. Families that were opposed not to all vaccination but just to hepatitis B vaccination went to court to seek exemptions for their children. Later, anti-vaccine groups publicly railed against attempts to make HPV vaccination compulsory. Courts and policymakers were largely caught flatfooted because vaccine law lacked the means to consider and classify hepatitis B and HPV vaccines as qualitatively different from the smallpox vaccine. This Part provides background on modern vaccine law and then discusses the hepatitis B and HPV vaccines.

A. Vaccine Exemptions

Since the early 1980s, all fifty states have had compulsory vaccination laws for schoolchildren on the books, most of them written years earlier.³³ Although only a few states offer philosophical exemptions to their compulsory vaccine laws, almost all have exemptions for those who hold religious beliefs that supposedly conflict with receiving vaccinations.³⁴ Anti-vaccine plaintiffs have challenged some exemption provisions on First Amendment grounds, arguing that a religious exemption only for members of established churches violates either the Free Exercise or Establishment Clauses; various courts have struck

³¹ See COLGROVE, *supra* note 9, at 120.

³² As journalist Arthur Allen notes in his comprehensive book on vaccines and vaccine history, "[i]n the 1930s, successful [vaccination] campaigns against diseases like diabetes, tetanus, diphtheria, and tuberculosis gave scientific medicine a legitimacy it had never previously enjoyed." ALLEN, *supra* note 18, at 111.

³³ See COLGROVE, *supra* note 9, at 299–300.

³⁴ See Ross D. Silverman, *No More Kidding Around: Restructuring Non-Medical Childhood Immunization Exemptions To Ensure Public Health Protection*, 12 ANNALS HEALTH L. 277, 282 (2003).

different balances between the public health and First Amendment issues at stake.³⁵ But, so long as herd immunity is preserved, the imprecise nature of these exemptions does not really threaten public health. Of course, if the number of parents truly opposed to vaccination rose too high, or if those parents clustered in one community, then herd immunity would be at risk.

In the 1980s and early 1990s, with the anti-vaccine movement nearly invisible for decades, almost all people chose to receive their vaccinations with no questions asked, and herd immunity was not threatened. Anti-vaccinationists were in such dire straits that the National Vaccine Information Center (NVIC), the leading anti-vaccine group, was on the verge of financial collapse.³⁶ Meanwhile, many states were tightening their vaccine laws to make religious or philosophical exemptions narrower.³⁷

But strikingly, by the end of the 1990s, this trend had reversed. State legislatures began to consider less restrictive exemption clauses.³⁸ Moreover, as the number of anti-vaccinationists has grown in recent years, some towns have developed especially large proportions of parents opposed to vaccination. For example, although nationwide fewer than two percent of parents opted not to vaccinate their children in the early 2000s, a group of anti-vaccinationists chose to congregate in the town of Ashland, Oregon, pushing the town's population up to 20,000 and giving it a vaccine exemption rate of one-third.³⁹ Towns like Ashland face greater health risks due to their higher exemption rates.⁴⁰

There are two convincing explanations for the resurgence of anti-vaccine groups. First, vaccines have become a victim of their own success. Vaccination has substantially obliterated many diseases in

³⁵ For example, in 1971, the Massachusetts Supreme Judicial Court struck down the religious exemption because it was impermissibly limited to established religions. *See Dalli v. Bd. of Educ.*, 267 N.E.2d 219, 223 (Mass. 1971). A federal court in New York echoed the Massachusetts court more than a decade later. *See Sherr v. Northport-E. Northport Union Free Sch. Dist.*, 672 F. Supp. 81 (E.D.N.Y. 1987). However, a federal court in Kentucky reached the opposite result, finding that the state could limit its exemption to members of nationally established churches without violating the Establishment Clause. *See Kleid v. Bd. of Educ.*, 406 F. Supp. 902 (W.D. Ky. 1976).

³⁶ *See COLGROVE*, *supra* note 9, at 390.

³⁷ *See id.* at 391.

³⁸ *See id.*

³⁹ *See ALLEN*, *supra* note 18, at 331.

⁴⁰ *See, e.g.*, JACKSON COUNTY, OR., DEP'T OF PUB. HEALTH, ASHLAND COMMUNITY VACCINATION SURVEY, EXECUTIVE SUMMARY (2003), available at <http://www.co.jackson.or.us/files/ashland1.pdf> (noting lower level of protection from disease due to high rate of exemption); *see also* JACKSON COUNTY, OR., DEP'T OF PUB. HEALTH, SCHOOL EXEMPTIONS AND DISEASE RISK IN ASHLAND, OREGON 10 (2002), available at <http://www.co.jackson.or.us/files/school%20exemptions%20and%20disease%20risk%20-%20final.pdf> (noting an increased risk of measles outbreaks in Ashland due to high numbers of international visitors and students).

this country to the point where new generations of Americans are totally unaware of them, unlike earlier Americans who lived through the epidemics. Second, parents are eager to find a culprit for the spate of idiopathic illnesses such as autism that are cropping up in their children. An examination of a recent study of the twenty-two leading anti-vaccine websites is revealing.⁴¹ All of the sites asserted the scientifically dubious claim that vaccines cause idiopathic illnesses such as autism, diabetes, brain damage, and asthma.⁴²

Most relevant for this Note, however, is that most anti-vaccine sites alleged that vaccines were not medically necessary. In fact, many sites went further and argued that vaccination actually eroded immunity and health by suppressing the natural immune system, in part explaining why more children are developing asthma and allergies.⁴³ Similarly, about seventy percent of the sites also alleged that more natural, holistic medicine like homeopathy is an effective alternative to vaccination.⁴⁴ According to ninety-one percent of the sites, the influence of the drug manufacturers' lobby is a prime reason why states continue with vaccine mandates despite the lack of medical necessity.⁴⁵ Some of the more conspiratorial sites claimed that the government covered up and purposely underreported vaccine injuries.⁴⁶

How do these anxieties and claims differ from those voiced by the anti-vaccine movement nearly one hundred years ago? The concern in the early twentieth century was government power in and of itself. The claim now is not that the government lacks the power to compel vaccination but that it is medically unnecessary for the government to exercise that power because vaccines are not needed to protect the public health. While the study of anti-vaccination group websites reveals that some anti-government fears still motivate anti-vaccinationists, the emphasis today is very much on the efficacy of natural immunity and natural medicine.

The claims about the lack of medical necessity are troubling in some ways. The modern anti-vaccinationists are overlooking that vaccines have been one of the most effective developments in suppressing diseases and prolonging life. More troubling is that when these anti-vaccinationists move into town, they threaten herd immunity and endanger all their neighbors. But the anti-vaccinationist claims are not

⁴¹ Robert M. Wolfe et al., *Content and Design Attributes of Antivaccination Web Sites*, 287 JAMA 3245 (2002).

⁴² See *id.* at 3246.

⁴³ See *id.* at 3247.

⁴⁴ See *id.* at 3246 fig.1.

⁴⁵ See *id.* at 3247.

⁴⁶ See *id.* (“[T]here is a pervasive sense of distrust, expressed in beliefs that governmental oversight bodies suppress reports of adverse vaccine reactions and collude with pharmaceutical industries to profit from vaccine sales.”).

entirely baseless either. Many diseases for which vaccines are being developed do not require widespread immunization to establish herd immunity and prevent outbreaks — that is, the vaccines are not medically necessary to prevent the disease from spreading. It is in opposition to these kinds of vaccines that the anti-vaccine movement has been the most effective and found the most widespread public support. It is also with regard to these vaccines that *Jacobson* offers little guidance.

B. *The Hepatitis B Vaccine*

The hepatitis B vaccine is the paradigmatic example of the distinction between medical necessity and practical necessity. In the 1980s, there were about 200,000 to 300,000 new cases of hepatitis B in the United States each year.⁴⁷ Most infections spread through unprotected sex or intravenous drug use.⁴⁸ The most troubling aspect of the virus is that it can later cause liver cancer.⁴⁹ So, when it was developed, the hepatitis B vaccine was hailed as the “first effective anti-cancer vaccine ever developed.”⁵⁰ As a sexually transmitted disease, hepatitis B is qualitatively different from the archetypal disease for which vaccination is required. It is highly contagious but it is not airborne. Hepatitis B epidemics can and do occur because many carriers are unaware they have the disease and do not take proper precautions. But if people are informed, they can protect themselves by not sharing needles or avoiding unprotected sex with someone who is a carrier or has not been tested. This might not always be easy, but it is less onerous than avoiding smallpox by sealing oneself away in a room. Thus, having a large group of unvaccinated people does not destroy herd immunity and put the general public more at risk of contracting hepatitis B in the way it does for airborne diseases. In short, the vaccine is not *medically* necessary to protect people from the disease.

Accordingly, despite the potential to prevent thousands of cancer cases, states did not rush to mandate the hepatitis B vaccine. When it comes to vaccine policy, the Advisory Committee on Immunization Practices (ACIP) sets the agenda.⁵¹ Congress established the group to advise the Centers for Disease Control and Prevention (CDC). Based on the ACIP’s advice, the CDC recommends vaccine policy to the

⁴⁷ WILLIAM MURASKIN, *THE WAR AGAINST HEPATITIS B*, at 4 (1995).

⁴⁸ *Id.*

⁴⁹ *See id.* at 1.

⁵⁰ *Id.* at 5 (emphasis omitted).

⁵¹ *See* Advisory Committee on Immunization Practices, <http://www.cdc.gov/vaccines/recs/ACIP/default.htm> (last visited Apr. 5, 2008).

states.⁵² Although the CDC's recommendations are not binding, nearly all states choose to follow them.⁵³ A cynical take on the CDC-state relationship is noted by one commentator, who writes: "The power and prestige of the CDC and other administrative heavy artillery easily intimidates state legislators and even health care professionals who might otherwise deviate from the official path."⁵⁴

At first, the ACIP did not recommend universal or compulsory hepatitis B vaccination for students. Instead, it recommended vaccination only for high-risk individuals — "drug users or [those who] have multiple sex partners (more than one partner/6 months)."⁵⁵ The goal, of course, was to achieve the public health benefits without ruffling the broader public unnecessarily.⁵⁶ However, members of high-risk groups are often notoriously hard to reach through non-compulsory means. First, it is not always possible for public health officials to identify and thereby target those who are high risk. Second, because there is a stigma attached to the behavior associated with the disease, members of these groups are often reluctant to identify themselves.⁵⁷ Unsurprisingly then, the approach of targeting high-risk individuals did not yield satisfactory results, leaving a powerful anti-cancer prophylactic sitting on the shelves while thousands of Americans continued to become infected.⁵⁸ In short, it appeared that mandatory general use of the hepatitis B vaccine was necessary in practice if public health officials wanted to eradicate the disease in this country.

The CDC subsequently changed its methods and, in 1991, recommended mandatory hepatitis B vaccination for school children.⁵⁹ As usual, most states followed suit and mandated hepatitis B vaccinations. With rapid approval of the vaccine in the state legislatures, anti-vaccinationists missed the chance to launch a sustained lobbying effort against the mandates. Thus, they had to resort to ex post court challenges for individual exemptions, a second-best strategy because it was slow-going and unlikely to generate much media coverage. Moreover, it would take a judge disrespectful of precedent to void the hepa-

⁵² KURT LINK, THE VACCINE CONTROVERSY: THE HISTORY, USE, AND SAFETY OF VACCINATIONS 171 (2005).

⁵³ See *id.* at 170-71.

⁵⁴ *Id.* at 171.

⁵⁵ Ctrs. for Disease Control & Prevention, *Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP)*, MORBIDITY & MORTALITY WKLY. REP.: RECOMMENDATIONS & REPS., Nov. 22, 1991, at 1, 13, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm>.

⁵⁶ See ALLEN, *supra* note 18, at 310-11.

⁵⁷ See Scott Burris, *Disease Stigma in U.S. Public Health Law*, 30 J.L. MED. & ETHICS 179, 182 (2002).

⁵⁸ ALLEN, *supra* note 18, at 311.

⁵⁹ See Ctrs. for Disease Control & Prevention, *supra* note 55.

titis B mandates as unconstitutional, given that courts had upheld every vaccine mandate for school children since *Jacobson*.⁶⁰ Realistically, the best the movement could hope for was to secure broad individual exemptions.

The hepatitis B issue was placed front and center in the Wyoming case *In re LePage*.⁶¹ The Wyoming state health department had received an exemption petition from the LePage family stating that due to their strong religious beliefs, “[their] daughter [would not] engage in behavior that involve[d] exposure to blood or body fluids” and alleging that the state’s mandating “[h]epatitis B vaccines [was] the direct result of our children growing up in a declining moral culture.”⁶² After requesting additional material to gauge the sincerity of the religious belief, the state health officer denied the LePages’ exemption request.⁶³ The family sought review of the decision in state court. The conflict ended with the Wyoming Supreme Court drastically cutting back the discretion of the state’s department of health. The court broadly construed the state statute on vaccine exemptions. The health department, the court found, had to grant exemptions for any request it received; it had no ability to consider the sincerity or credibility of those requesting exemptions.⁶⁴ In effect, the court’s decision expanded the exemption provision to a no-questions-asked opt-out.

Faced with a similar issue, Arkansas courts took an opposing though even more dramatic tack; they threw out the exemption clause entirely. In the summer of 2002, two complaints in Arkansas federal courts — one in the Eastern District of Arkansas, the other in the Western District — challenged the constitutionality of the state’s compulsory vaccine law generally and the exemption clause particularly. In *McCarthy v. Boozman*,⁶⁵ the plaintiff sought to qualify for an exemption as stipulated by the state’s compulsory vaccine law because he felt people have God-given immune systems that should not be altered.⁶⁶ Additionally, in *Boone v. Boozman*,⁶⁷ the plaintiff sought to qualify for a religious exemption after she refused to have her daughter receive the hepatitis B vaccine. Both plaintiffs’ applications were denied.

⁶⁰ See, e.g., *Hanzel v. Arter*, 625 F. Supp. 1259 (S.D. Ohio 1985) (upholding Ohio’s compulsory vaccination requirement for schoolchildren); *Syska v. Montgomery County Bd. of Educ.*, 415 A.2d 301 (Md. Ct. Spec. App. 1980) (upholding Maryland’s requirement).

⁶¹ 18 P.3d 1177 (Wyo. 2001).

⁶² *Id.* at 1178 n.1.

⁶³ *Id.* at 1178–79.

⁶⁴ *Id.* at 1180–81.

⁶⁵ 212 F. Supp. 2d 945 (W.D. Ark. 2002).

⁶⁶ See *id.* at 947.

⁶⁷ 217 F. Supp. 2d 938 (E.D. Ark. 2002).

The *McCarthy* court severed the religious exemption clause from the compulsory vaccination statute, holding that the exemption provision was unconstitutional under the test the Supreme Court articulated in *Lemon v. Kurtzman*⁶⁸ for finding violations of the Establishment Clause. The court, however, upheld the mandatory requirements of the vaccination law.⁶⁹ The *Boone* court subsequently reached the same results, relying in part on the *McCarthy* holdings and rationale.⁷⁰ Interestingly, in *Boone*, the plaintiff had argued that “*Jacobson* and *Zucht* are utterly archaic in 14th Amendment substantive due process terms, and worthless as precedent in light of the extensive jurisprudence of the 20th Century.”⁷¹ If the plaintiffs thought *Jacobson* was inapplicable because the disease at issue was avoidable without vaccination, they had a point.⁷² Nonetheless, the court rejected this argument only because “[i]t is the responsibility of this Court, however, until the Supreme Court says otherwise, to give effect to immunization cases like *Jacobson* and *Zucht*.”⁷³ The effect of the two decisions was that Arkansas had compulsory vaccination with no exemptions for religious or philosophical reasons.

The lack of exemptions, however, was politically untenable in Arkansas. In 2003, the Arkansas General Assembly rewrote the exemption provision, making it both constitutional and remarkably broad. Today, all parents in Arkansas can exempt their child simply by objecting that the immunization conflicts with the parents’ religious or philosophical beliefs.⁷⁴ By tossing the exemption decision to the political process, the courts effectively awarded a victory to anti-vaccine parents in Arkansas.

The application of state police power to non-airborne diseases, like hepatitis B, appears to have troubled judges. But importantly, courts have not been prepared to reexamine *Jacobson* and ask whether the century-old precedent applies in full to hepatitis B vaccine laws. Legislators and other policymakers may be the ones best positioned to recognize a distinction between older vaccines and more modern vaccines

⁶⁸ 403 U.S. 602 (1971).

⁶⁹ See *McCarthy*, 212 F. Supp. 2d at 948–50.

⁷⁰ See *Boone*, 217 F. Supp. 2d at 941 n.1.

⁷¹ *Id.* at 956 (internal quotation marks omitted).

⁷² The plaintiffs challenging mandatory vaccination against hepatitis B and HPV may also be opposed to vaccination on the ground that these diseases are STDs, and thus vaccination in some way encourages premature sexual behavior. However, it is difficult to separate this claim from the medical necessity claim, given that the opposition to vaccination for STDs may be linked with the belief that families rather than government should control information about abstinence and premarital sex.

⁷³ *Boone*, 217 F. Supp. 2d at 956.

⁷⁴ See ARK. CODE. ANN. § 6-18-702(d)(4)(A) (2007); see also M. Craig Smith, Note, *A Bad Reaction: A Look at the Arkansas General Assembly’s Response to McCarthy v. Boozman and Boone v. Boozman*, 58 ARK. L. REV. 251, 258 (2005).

for non-airborne diseases against which individuals are better situated to protect themselves. Therefore, with courts adhering unquestioningly to the conception of *Jacobson* as applicable to all modern vaccines, the anti-vaccine movement would have to take its fight to the legislatures — which is exactly what it did when the HPV vaccine became available.

C. *The HPV Vaccine*

Like the hepatitis B vaccine, the HPV vaccine is an anti-cancer vaccine and an example of a vaccine that may be practically necessary but not medically necessary. HPV is the most common sexually transmitted disease, with 6.2 million newly diagnosed individuals in the United States each year.⁷⁵ It is also a primary cause of cervical cancer — responsible for 3700 deaths a year.⁷⁶ While the vast majority of women fight off the virus on their own within two years, those who do not are at risk of later developing cervical cancer.⁷⁷ Accordingly, after the HPV vaccine was introduced, an editorial in the *New England Journal of Medicine* proclaimed that the vaccine offered “enormous potential for medical progress.”⁷⁸

The FDA approved the HPV vaccine in June 2006.⁷⁹ This let drug manufacturing giant Merck sell the vaccines on the market. But the real money for the drug makers would come if states mandated that school children receive the shots. Shortly after the FDA’s decision, the ACIP recommended universal vaccination for girls aged eleven to twelve.⁸⁰ However, the vaccine did not fit “the paradigm for the exercise of compulsory vaccination.”⁸¹ Put another way, the vaccine is not medically necessary because HPV is not spread by an airborne virus, and thus infection can be prevented by means other than vaccination. But unlike the hepatitis B vaccine debate, this time the anti-vaccine movement mobilized early — a year before the vaccine even came

⁷⁵ Lawrence O. Gostin & Catherine D. DeAngelis, Editorial, *Mandatory HPV Vaccination: Public Health vs Private Wealth*, 297 JAMA 1921, 1921 (2007).

⁷⁶ *Id.*

⁷⁷ Ctrs. for Disease Control & Prevention, Genital HPV Infection — CDC Fact Sheet, <http://www.cdc.gov/std/HPV/STDFact-HPV.htm> (last visited Apr. 5, 2008).

⁷⁸ Lindsay R. Baden et al., Editorial, *Human Papillomavirus Vaccine: Opportunity and Challenge*, 356 NEW ENG. J. MED. 1990, 1990 (2007).

⁷⁹ See Press Release, Food & Drug Admin., FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus (June 8, 2006), <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html>.

⁸⁰ See Press Release, Ctrs. for Disease Control & Prevention, CDC’s Advisory Committee Recommends Human Papillomavirus Vaccination (June 29, 2006), <http://www.cdc.gov/od/oc/media/pressrel/r060629.htm>. The recommendation was limited to girls, as boys cannot develop cervical cancer. However, some have suggested that boys should be vaccinated because they can be carriers who pass the disease to others. See Gostin & DeAngelis, *supra* note 75, at 1922.

⁸¹ Gostin & DeAngelis, *supra* note 75, at 1922.

onto the market.⁸² It was not forced to play catch up in the courts and could instead raise public awareness and pressure elected officials.

The first state to act on the recommendation to mandate HPV vaccination was Texas. In February 2007, Governor Rick Perry, by executive order, made the HPV vaccine mandatory for girls entering sixth grade.⁸³ But the mandate included a broad, yet vague, opt-out provision.⁸⁴ It also made the opt-out process quite easy, allowing parents to opt out online.

Despite such allowances, the anti-vaccine movement attacked Governor Perry and similarly minded politicians across the country. The NVIC stressed that the vaccine was unnecessary to protect women's health. Not only would abstinence and safe sex protect women, but, as the NVIC president declared at a rally in Washington, D.C., "more than 90 percent of all girls and boys, who become infected with HPV, asymptotically clear the infection from the body."⁸⁵ She concluded that the HPV vaccine is "unnecessary, expensive and potentially dangerous."⁸⁶

So why then would states want to mandate a medically unnecessary vaccine? The NVIC protested that the mandate was the result of aggressive lobbying by Merck, the vaccine's manufacturer. A political cartoon depicted Governor Perry accepting money from a Merck lobbyist and declaring "We finally found a *legal* way to exploit the bodies of teenage girls!" while a line of young girls marches into a building called "The Best Little Vaccine House in Texas."⁸⁷ Similarly, after several other states began considering mandating the HPV vaccine, the NVIC called for increased anti-vaccinationism "in every state where HPV vaccine mandates are being aggressively pursued by drug company lobbyists and legislators trying to force young girls to use HPV vaccine without the voluntary, informed consent of parents."⁸⁸

By 2007, the NVIC's arguments had convinced the public and physicians. Polls showed that fifty-seven percent of physicians did not support mandating the HPV vaccine, while only forty-four percent of

⁸² See ALLEN, *supra* note 18, at 431.

⁸³ Tex. Exec. Order No. RP65 (Feb. 2, 2007), available at <http://www.governor.state.tx.us/divisions/press/exorders/rp65>.

⁸⁴ See *id.*; see also Press Release, Statement of Gov. Rick Perry on HPV Vaccine Executive Order (Feb. 5, 2007), <http://www.governor.state.tx.us/divisions/press/pressreleases/PressRelease.2007-02-05.4721> ("I am a strong believer in protecting parental rights, which is why this executive order allows them to opt out.")

⁸⁵ Barbara Loe Fisher, Co-Founder and President, NVIC, Statement at Washington, D.C., Rally (March 8, 2007) (transcript available at http://www.nvic.org/Loe_Fisher/HPVDC.htm).

⁸⁶ *Id.*

⁸⁷ Mike Adams & Dan Berger, Counterthink, Feb. 7, 2007, <http://www.naturalnews.com/021571.html>.

⁸⁸ Fisher, *supra* note 85.

parents favored the mandate.⁸⁹ Accordingly, the anti-vaccine movement gained enough public support to stall the HPV mandates working through state governments across the country. Most notably, in Texas, the state legislature voted to overturn the executive order mandating the HPV vaccine.⁹⁰

The Texas experience had a chilling effect across the country. In early 2007, HPV vaccine mandates were pending in most state assemblies in the country. To date, no state has passed an HPV mandate.⁹¹ But such a sweeping victory against the HPV mandate for the anti-vaccinationists is unlikely to persist. More studies will likely come out documenting the long-term effectiveness of the HPV vaccine.⁹² When those results are known, and if they are coupled with continuing evidence of the vaccine's safety, states may feel emboldened to try the mandates again — particularly given that many public health researchers continue to tout the vaccine's amazing powers. However, even if states eventually pass HPV mandates, that may not be a complete defeat for the anti-vaccinationists. The partial victory would come from the fact that states may feel that they must include explicit no-questions-asked, conscientious opt-outs for HPV vaccines.

III. UPDATING VACCINE LAW

This Part considers the two predominant, conflicting views about the legacy of *Jacobson's* framework: that it endures as a useful guideline for public health law, and that it is a relic. This Part shows that, although these two views may shed light on *Jacobson's* relevance to state police power and public health law more broadly, they are inapplicable when it comes to vaccine law. This Part then presents the novel argument that, to update vaccine law, it is preferable to split the necessity standard from *Jacobson* into two parts: “medical necessity” and “practical necessity.” The vaccine experts who sit on the ACIP may be in the best position to change vaccine law, given that most

⁸⁹ *Mandate for Sex? Doctors in the US Speak Out About Mandating the HPV Vaccine*, VACCINE WKLY., Apr. 11, 2007, at 12; *Majority of U.S. Parents Not in Favor of HPV Vaccine Mandates*, VACCINE WKLY., June 6, 2007, at 8.

⁹⁰ See Act effective May 8, 2007, ch. 43 § 1, 2007 Tex. Gen. Laws 41, 42 (amending TEX. EDUC. CODE ANN. § 38.001 (Supp. 2007)); see also Dan Frosch, *Texas House Rejects Order by Governor on Vaccines*, N.Y. TIMES, Mar. 14, 2007, at A14.

⁹¹ This success of the anti-vaccination movement should not be entirely surprising. As Professors Jack Balkin and Reva Siegel show, social movements often can tap into anxieties about new technologies — in this case a cutting-edge biologic — to “try to push the law in their favored direction.” Jack M. Balkin & Reva B. Siegel, Essay, *Principles, Practices, and Social Movements*, 154 U. PA. L. REV. 927, 929 (2006).

⁹² See J.L. Schwartz et al., *Lessons from the Failure of Human Papillomavirus Vaccine State Requirements*, 82 CLINICAL PHARMACOLOGY & THERAPEUTICS 760, 762 (2007).

state legislatures follow its recommendations and that the ACIP has the expertise to classify new vaccines thoughtfully.

A. Jacobson: *Enduring Landmark or Relic?*

Professor George Annas is the strongest proponent of the view that *Jacobson* has become a relic of a bygone era when civil liberties were less valued. The most controversial tenet of Professor Annas's view is that public health and civil liberties are rarely in tension because "constitutional rights need not be compromised for effective public health intervention."⁹³ When civil liberties are compromised, Professor Annas posits, public health measures often backfire because they undermine the public's trust, an essential ingredient in any well-operating public health endeavor.⁹⁴

In defending this view of *Jacobson* as a relic, Professor Annas and others emphasize the vast changes in both medicine and constitutional law since 1905. In the words of Professor Annas and co-authors Professors Wendy Mariner and Leonard Glantz:

Public health programs that are based on force are a relic of the 19th century; 21st-century public health depends on good science, good communication, and trust in public health officials to tell the truth. In each of these spheres, constitutional rights are the ally rather than the enemy of public health. Preserving the public's health in the 21st century requires preserving respect for personal liberty.⁹⁵

AIDS is used as the primary example of this credo. "Public health officials recognized early that draconian mandatory HIV screening measures, for example, would simply help drive the epidemic underground where it would spread faster and wider."⁹⁶ Professor Annas extrapolates from these arguments about AIDS that compulsory health measures are "much more likely to cost lives than to save them."⁹⁷

Professor Lawrence Gostin and others vehemently counter Professor Annas's view. Public health often involves difficult trade-offs — for example, whether to adopt a coercive measure against a disease-carrying individual to lower the risk that the individual will spread the

⁹³ George J. Annas, *Blinded by Bioterrorism: Public Health and Liberty in the 21st Century*, 13 HEALTH MATRIX 33, 56 (2003).

⁹⁴ *Id.*

⁹⁵ Wendy K. Mariner et al., *Jacobson v. Massachusetts: It's Not Your Great-Great-Grandfather's Public Health Law*, 95 AM. J. PUB. HEALTH 581, 588 (2005).

⁹⁶ Annas, *supra* note 93, at 56. Writing a decade after the disease emerged in the United States, Professor Martha Field made a similar point: "In most contexts, mandatory testing not only promises to waste vast resources that can be spent in more constructive ways, but it can be actually destructive by driving people underground and by suggesting that people with HIV are readily identifiable when this simply is not true." Martha A. Field, *Testing for AIDS: Uses and Abuses*, 16 AM. J.L. & MED. 33, 105 (1990).

⁹⁷ Annas, *supra* note 93, at 57.

disease and cause great aggregate harm.⁹⁸ This trade-off suggests there are times when the government must act quickly and infringe on liberties to save lives. The 1918 influenza epidemic — the worst in this nation's history — is an example. Recent studies have shown that the cities and towns that most quickly enacted quarantines and medical isolations had lower death rates than those that were slow to act.⁹⁹

Consider also the hepatitis B vaccine. In the United States, states and municipalities first attempted voluntary vaccination targeting high risk groups.¹⁰⁰ These efforts failed, as did similar ones for HIV screening, because high-risk groups were hard to reach. Thousands of Americans continued to contract hepatitis B. But compulsory vaccination for school children has succeeded in dramatically decreasing hepatitis B in the United States.¹⁰¹ The high vaccination rate for the disease now means fewer cancers and more saved lives — yet it also means using coercive measures. This calculus contradicts the strong claim that compulsory vaccination measures will not save lives.

It is true that a more narrow version of Professor Annas's claim may withstand such critiques. The argument could simply be that avoiding coercive health measures encourages social solidarity, which fosters greater trust toward public health officials and is a public good in itself. But it is not clear in what direction social solidarity cuts when applied to vaccine policy. In fact, the increased deaths from lower vaccination rates might damage social solidarity even more than would mandated vaccination. Take two examples from the vaccine debate. Mandating the HPV vaccine may be said to foster mistrust of public health authorities because it involves coercion that some may view as unnecessary. But does this mistrust hurt social solidarity more than would having hundreds of women die each year from cervical cancer that could have been prevented? Similarly, consider the clusters of anti-vaccinationists who live around Ashland, Oregon, or Boulder, Colorado.¹⁰² A parent will likely feel little social solidarity with parents who do not vaccinate their children if her own vaccinated child nevertheless contracts whooping cough because low vaccination rates prevent herd immunity.

⁹⁸ LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 21 (2000).

⁹⁹ See, e.g., Robert J. Hatchett et al., *Public Health Interventions and Epidemic Intensity During the 1918 Influenza Pandemic*, 104 *PROC. NAT'L ACAD. SCI.* 7582 (2007); see also Nicholas Bakalar, *How (and How Not) To Battle Flu: A Tale of 23 Cities*, *N.Y. TIMES*, Apr. 17, 2007, at F5 (reporting on studies).

¹⁰⁰ See *supra* section II.B, p. 1829.

¹⁰¹ See Ctrs. For Disease Control & Prevention, *Viral Hepatitis B — Fact Sheet*, <http://www.cdc.gov/ncidod/diseases/hepatitis/b/fact.htm> (last visited Apr. 5, 2008) (noting that the number of "new infections per year has declined from an average of 260,000 in the 1980s to about 60,000 in 2004").

¹⁰² See ALLEN, *supra* note 18, at 331–32.

Professor Lawrence Gostin is the most vocal advocate of the position that “*Jacobson* endures as a reasoned formulation of the boundaries between individual and collective interests in public health.”¹⁰³ He has cogently laid out the argument that *Jacobson* “established a floor of constitutional protection that consists of 4 overlapping standards: necessity, reasonable means, proportionality, and harm avoidance.”¹⁰⁴ “These standards,” Professor Gostin continues, “while permissive of public health intervention, nevertheless required a deliberative governmental process to safeguard liberty.”¹⁰⁵

Professor Gostin embraced much of the rigor of *Jacobson*’s four standards when he led the effort to craft the Model State Emergency Health Powers Act.¹⁰⁶ The model law was designed to provide “responsible state actors with the powers they need to detect and contain a potentially catastrophic disease outbreak and, at the same time, protect individual rights and freedoms.”¹⁰⁷ The fact that many states have passed some version of the Model Act¹⁰⁸ shows that, indeed, *Jacobson*’s framework endures.

But the Model Act is aimed at public health emergencies like bioterrorist attacks and natural disasters — instances in which government reaction is clearly necessary to maintain order and secure the public health. It is not clear that *Jacobson*’s framework is relevant for modern vaccine law, particularly for diseases for which the need for government action is not as clear. Tellingly, when Professor Gostin argues that states should not mandate the HPV vaccine, he does so on policy rather than legal grounds. He argues that it is too early to tell the long-term effects of the HPV vaccine and thus making it mandatory could undermine public health by “heightening parental and public apprehensions about childhood vaccinations.”¹⁰⁹ But he dodges the question of whether *Jacobson*’s logic compels the result that HPV mandates are unconstitutional:

¹⁰³ Lawrence O. Gostin, *Jacobson v. Massachusetts at 100 Years: Police Power and Civil Liberties in Tension*, 95 AM. J. PUB. HEALTH 576, 580 (2005).

¹⁰⁴ *Id.* at 579.

¹⁰⁵ *Id.*

¹⁰⁶ See MODEL STATE EMERGENCY HEALTH POWERS ACT (Ctr. for Law & the Public’s Health, Georgetown Univ. & Johns Hopkins Univ., Discussion Draft 2001), available at <http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf>.

¹⁰⁷ Lawrence O. Gostin et al., *The Model State Emergency Health Powers Act: Planning For and Response to Bioterrorism and Naturally Occurring Infectious Diseases*, 288 JAMA 622, 622 (2002).

¹⁰⁸ See *id.*

¹⁰⁹ Gostin & DeAngelis, *supra* note 75, at 1922. The authors also question the influence of the drug manufacturing lobby and suggest that politically insulated experts like “[p]ublic health authorities, pediatricians, and infectious disease specialists” and not state legislatures are in the best positions to craft vaccine policies. *Id.*

Human papillomavirus is not a highly infectious airborne disease, which is the paradigm for the exercise of compulsory vaccination. There is no immediate risk of rapid transmission of HPV in schools, as is the case, for example, with measles. The HPV vaccine does not create herd immunity, although it would probably reduce the prevalence of HPV infections. . . . But because the HPV vaccine is not immediately necessary to prevent harm to others, it does suggest that compulsory measures need to be more carefully thought through.¹¹⁰

Professor Gostin seems concerned that treating the HPV vaccine differently may set a precedent that could ultimately undermine state public health powers and the public's health generally. For example, other infectious diseases preventable by vaccines — like tetanus — do not fit the “paradigm” for compulsory vaccination either; yet declaring the tetanus mandate laws unconstitutional under *Jacobson* could lead to needless cases of the gruesome lockjaw caused by the disease. Scrutinizing vaccine mandates disease by disease could unravel the greatest public health successes of the past century. But, had Professor Gostin gone further and recognized that the HPV vaccine is not medically necessary, as opposed to many vaccines that came before it, his concerns might have been allayed.

*B. Updating Jacobson: “Medical Necessity”
and “Practical Necessity”*

Jacobson held that compulsory vaccination was constitutional when “necessary for the public health or the public safety.”¹¹¹ The decision did not, and had no need to, press too far on what exactly necessity entailed. In 1905, when a smallpox outbreak emerged, the only effective way to mitigate its effects was through widespread vaccination. If one person refused vaccination, he risked the health of the entire town by giving the incredibly infectious disease a point from which to leap from person to person and stay alive as long as possible. Vaccination was necessary because there were no other reliable options to preserve the public health.¹¹²

Now consider HPV. Vaccination is not medically necessary to protect the public health in the same way that it was medically necessary to attack smallpox. People can protect themselves through sexual health knowledge, disease screening, safe sex, or abstinence. These steps may not always be easy to follow, but one can perform them and still function in society; it is of course impossible to avoid smallpox by

¹¹⁰ *Id.*

¹¹¹ *Jacobson v. Massachusetts*, 197 U.S. 11, 27 (1905).

¹¹² Of course, necessity is not an absolute concept. People perhaps could protect themselves by hermetically sealing themselves off from the outside world for months. Given that this response is impractical and would shut down society, it is not an option the law favors.

not breathing or through total isolation. It is this qualitative difference between the HPV vaccine and more traditional vaccines that resonated with the public and with state lawmakers in seeking broad exemptions to mandatory HPV vaccination.

The reality is, however, that few Americans lead such constrained sex lives. This means that, according to the CDC, at least fifty percent of sexually active people will become infected with HPV at some point in their lives.¹¹³ The natural immune system beats back most of these 6.2 million new infections every year in the United States, but HPV persists in enough people that about 11,000 women are expected to be diagnosed with cervical cancer each year.¹¹⁴ Thus, if society's public health goal is to move that 11,000 number closer to zero, then vaccination is a practical necessity, even if it may not be a medical necessity. To properly analyze the validity of mandates for the HPV vaccine and similar drugs, society should recognize this distinction. Such a distinction would give policymakers and perhaps courts a more precise way to balance civil liberties and public health. If a vaccine is a practical necessity but not a medical necessity, then the public may not accept a full mandate for that vaccine. Accordingly, lawmakers may instead wish to avoid a mandate for that vaccine or provide a no-questions-asked opt-out for that vaccine.

Hepatitis B also illustrates the distinction between medical necessity and practical necessity. Recall that when the hepatitis B vaccine became available, U.S. public health officials first sought to curb the virus by targeting high risk individuals. But this approach failed. Ultimately, although people could in fact protect themselves by practicing safe sex and not sharing drug needles, the public health officials found it a practical necessity to mandate hepatitis B vaccination.

The line between medical necessity and practical necessity is not always clear and bright. Nonetheless, as a first step, determining whether a vaccine or drug can be categorized as a "medical necessity" or a "practical necessity" should help inform our legal and policy analysis. Such a distinction could take place in our courts. Consider the case discussed earlier, *Boone v. Boozman*, in which an Arkansas family argued that *Jacobson* was "archaic" and should not apply to their attempts to exempt their daughter from receiving the hepatitis B vaccine.¹¹⁵ The *Boone* court was wrong to cite *Jacobson* so readily as definitive in the case. The court should have upheld the validity of compulsory laws in general under *Jacobson*, while also recognizing that the hepatitis B vaccine did not fit neatly into *Jacobson's* holding

¹¹³ Ctrs. for Disease Control & Prevention, *supra* note 77.

¹¹⁴ *See id.*

¹¹⁵ *Boone v. Boozman*, 217 F. Supp. 2d 938, 956 (E.D. Ark. 2002).

because the vaccine is only necessary in practice. However, it does not follow that the court should have found the hepatitis B vaccine mandate unconstitutional. We may recognize the distinction between medical necessity and practical necessity but still decide that compulsory hepatitis B and HPV vaccine laws are constitutionally permissible, given the likelihood that significant numbers of people will not or cannot reasonably protect themselves from the diseases and that thousands of deaths will result if the mandate were not in place. But this may not always be the case for future vaccines and drugs that fall into the “practical necessity” category. The payoff from some vaccines and drugs may not be great enough to warrant the liberty infringement. For example, vaccines for diseases that are far from deadly or infect only a small portion of the population may not warrant state mandates. The primary point is that, to determine properly when compelled use of new treatments is valid, it is important to recognize qualitative differences embedded in the necessity standard.

Courts, however, may lack the technical and medical expertise to best flesh out the distinction between medical necessity and practical necessity. It may be best for the vaccine experts on the ACIP to build this distinction into their policy recommendations. As these policy-makers update vaccine law recommendations, they could draw lessons from the HPV vaccine debate presented here. Though the public may not countenance a traditional compulsory vaccine law for drugs that fall on the practical necessity side of the line, as indicated by the public’s reaction to proposed HPV mandates, many state legislators seem to believe that mandates coupled with easy, no-questions-asked opt-outs may be more palatable. In some ways, it makes sense to create this two-tiered system in which medically necessary vaccines are linked with narrower exemptions and practically necessary vaccines are instead linked with generous exemptions. So, vaccine laws could explicitly state that parents can exempt their children from hepatitis B and HPV vaccines with no questions asked, unlike vaccines for diseases listed elsewhere in the statute.

This two-tiered system strikes a reasonable balance between liberty and the public health. It is less of a liberty infringement when the state eschews broad compulsory orders and instead crafts a default rule that applies to all individuals unless they actively opt out. When states set such default rules, they are still paternalistically pushing people toward what government believes promotes the public welfare. But, as Professors Cass Sunstein and Richard Thaler write, it is a “libertarian paternalism”: “a relatively weak and nonintrusive type of pa-

ternalism, because choices are not blocked or fenced off.”¹¹⁶ Indeed, Professors Sunstein and Thaler even suggest that a true libertarian paternalist might select an approach that allows individual choice but “*minimizes the number of opt-outs*”¹¹⁷ — which is precisely what coupling proposed compulsory HPV vaccine laws with opt-outs aims to do by starting from the baseline assumption that everyone will receive a vaccination.

Notably, if the distinction between medical necessity and practical necessity were combined with a two-tiered system of exemption clauses or opt-outs, it should assuage Professor Gostin’s concern that a broad exemption for HPV vaccination will create a precedent that unravels compulsory vaccination for other drugs. That is because the two tiers would provide a standard to apply to cut off any slippery slope problem. Vaccines that fell into the practical necessity tier would get the broader exemptions. No erosion of long-held state police powers need occur to compel vaccination when it is medically necessary, as in public health emergencies.

IV. CONCLUSION

A recent *New York Times* headline proclaimed: “Vaccines and Their Promise Are Roaring Back.”¹¹⁸ The article described how, after several decades of little innovation in the field, “the research pipeline is bulging” with future vaccines.¹¹⁹ It is important that when these new vaccines arrive — whether they protect against AIDS or some obscure and as-yet-unknown virus — we have updated vaccines laws and policies that properly apply to them. In assessing whether government action is necessary to protect the public health, recognizing a qualitative distinction between vaccines that are medically necessary and practically necessary is an important step in the direction of a more nuanced evaluation. Vaccine policymakers, state legislators, and courts should cooperate in finding a way to recognize this distinction.

¹¹⁶ Cass R. Sunstein & Richard H. Thaler, *Libertarian Paternalism Is Not an Oxymoron*, 70 U. CHI. L. REV. 1159, 1162 (2003).

¹¹⁷ *Id.* at 1195.

¹¹⁸ G. Pascal Zachary, *Vaccines and Their Promise Are Roaring Back*, N.Y. TIMES, Aug. 26, 2007, § 3, at 3.

¹¹⁹ *Id.*