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“To Shield Thee From Diseases of the World”*: The Past, Present, and Possible Future of Immunization Policy

Thomas Wm. Mayo, Wendi Campbell Rogaliner, and Elicia Grilley Green

ABSTRACT: The worldwide spread of disease is a phenomenon that society has faced throughout history. Well known pathogens, such as influenza, together with new threats, such as coronavirus, work to devastate the lives of people the world over. In the past, when diseases threatened the health and survival of our population, the scientific community responded with the development of vaccines. Through vaccine technologies, professionals across a range of disciplines have virtually eradicated diseases such as smallpox and polio, which were at one time as much a health threat as influenza and coronavirus are today. However, over the past few decades, the United States has witnessed a growing trend of vaccination hesitation and refusal by parents who choose not to vaccinate their children. Thus, as the vaccination debate rages on in concert with the spread of old and new diseases alike, this article examines the history of vaccination law in the United States, parental rights to refuse vaccinations for their children, and the dire health consequences that could result from reduced vaccination rates. It analyzes the legal history and framework of vaccination laws and exemptions, as well as impediments to intervention in the form of nationally-mandated vaccinations and the invalidation of state exemptions.


*William Shakespeare, King Lear, act I, sc. 1.

1 The authors would like to thank Rachel E. Taylor and a team of talented Summer Associates working for Bradley Arant Boult Cummings in the summer of 2019 for research contributing to this article.
The Past, Present, and Possible Future of Immunization Policy

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INTRODUCTION

The World Health Organization named “vaccine hesitancy” as one of the top global health threats in 2019. In the United States, widespread utilization of non-medical exemptions to mandatory vaccination laws has led to statistically significant outbreaks of measles and other vaccine-preventable illnesses, and many headlines forecast that if vaccination exemptions continue the trajectory they are on, this country may well face a public health emergency. In early 2019, then-U.S. Food and Drug Administration Commissioner, Scott Gottlieb, made a public call for states to act to reduce vaccine exemptions, warning that if the states failed to do so, the federal government would be forced to step in. Health care practitioners are on the front lines of this potential public health crisis, regularly facing well-meaning parents who feel unfettered in their personal choice to accept or reject vaccinations for their children.

This article provides an in-depth look at the legal issues underlying the current vaccination crisis by providing background on the history and development of vaccination laws in the United States; the public health ramifications of permissive, non-medical exemptions to vaccine requirements for school children; and the legal impediments to federal intervention as urged by Gottlieb. This article is intended to provide practitioners and health care lawyers alike with background and insight into the legal issues behind this public health debate in order to support and enhance their ability to effectively interact personally and professionally with parents and other community stakeholders, and who may themselves be in a position to instruct and influence their community toward informed debate on this vital public health topic. While intended for a broader audience interested in the public health and policy debate over vaccine exemptions, practical guidance for front-line medical practitioners facing vaccine-resistant parents is also provided.

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HISTORY OF VACCINES AND VACCINATION EXEMPTIONS

Prior to the development of effective vaccinations, over twenty percent of children died from disease before reaching adolescence, and diseases that have now been made wholly preventable through vaccine technologies were a significant threat to the health, well-being, and even survival of citizens in the United States and across the world.\(^5\) Vaccination development was slow until the 20th century, when scientific understandings and advances grew dramatically and worked to profoundly impact public health through the prevention of communicable diseases. By 1999, the considerable effects of the implementation of regular and systematic vaccination on the health of the public was undeniable.\(^6\) Since their inception in the early 1900s, vaccines have led to the complete eradication of smallpox, the elimination of polio from North America, and the reduction and control of measles, rubella, tetanus, diphtheria, influenza type b, and other infectious diseases in the United States.\(^7\) This remarkable progress prompted the Centers for Disease Control and Prevention (CDC) to emphatically declare that since the start of the 20th century, the health of people living in the United States had “dramatically improved” and that the life expectancy of U.S. citizens had increased by thirty years.\(^8\) By the time the 20th century came to an end, statisticians estimated that for each year vaccines had been available to the public, approximately five million lives had been saved by the vaccination-related controls that led to the near eradication of poliomyelitis, measles, and tetanus.\(^9\)

Despite the clear scientific evidence of the efficacy of vaccination and its measurable impact on public health, the federal government has never established a compulsory vaccination program in the United States. Instead, federal power, authority, and U.S. resources have always centered on encouraging and promoting individual states to

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\(^7\) Id.

\(^8\) Id.

implement compulsory vaccination programs on their own as an exercise of each state’s police power. Thus, the first compulsory immunization law in the United States was not passed by the federal government, but by the state of Massachusetts in 1809.

PUBLIC HEALTH ENFORCEMENT POWERS

In order to efficiently and effectively oversee a large and diverse population, such as that found in the United States, divisions of power and responsibility must be made. Therefore, the federal government and each state government has its own zone of power in which it can act for the benefit of its citizens.

The U.S. Constitution

The health and safety of the communities of people that make up the United States are regulated through the powers of both federal and state governments. The Constitution grants powers and rights to the federal government, state governments, and to individual citizens. The concept of federalism—the way power is vertically divided between state and federal governments—also stems from the Constitution. The Tenth Amendment states that “[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”

Although the federal government has a “long tradition of regulating for the community’s welfare by regulating individuals, professionals, institutions, and businesses through the use of its broad powers,” the Tenth Amendment has consistently been interpreted by the courts as leaving what has been termed the “police power” to the states. This power grants to states, as sovereign governments, the right “to secure and preserve the public’s health and safety . . . [and] to secure the general welfare of the people[.]” State constitutions work in turn to further these goals by “delegate[ing] this authority to local government and local public health departments[.]”

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10 Id. (finding that national efforts to promote vaccine use among all children began with the appropriation of federal funds for polio vaccination after introduction of the vaccine in 1955. Since then, federal, state, and local governments and public and private health care providers have collaborated to develop and maintain the vaccine-delivery system in the United States. Overall, U.S. vaccination coverage was at record high levels in 1999. The U.S. Congress authorized, and James Madison signed “An Act to Encourage Vaccination,” establishing a National Vaccine Agency. James Smith, a physician from Baltimore, was appointed the National Vaccine Agent. The U.S. Post Office was required to carry mail weighing up to 0.5 oz. for free if it contained smallpox vaccine material—an effort to advance Congress’s ruling to “preserve the genuine vaccine matter, and to furnish the same to any citizen of the United States.”).

11 U.S. Const. amend. X.


13 Id.

14 Id.
Thus, when the smallpox vaccine was developed by Edward Jenner in 1796, state and local governments took note and began passing laws aimed at using this medical breakthrough to protect the health and welfare of the people who resided within their bounds. However, much like today, the compulsory vaccination laws of that time were controversial and were strongly resisted by certain members of the community. Those that disagreed with this type of government intrusion or who doubted the safety or effectiveness of being vaccinated turned to the Court to test the validity and limits of the state’s police power.

State Police Power

The Supreme Court of the United States is ultimately responsible for interpreting whether a governmental authority has overstepped the bounds placed on it by the U.S. Constitution. Therefore, the Court has often been entrusted with the difficult task of placing limits on power through balancing the jurisdiction of the state against the rights of the individual.

Jacobson v. Massachusetts

Cited by many as the most important case in the realm of public health, *Jacobson v. Commonwealth of Massachusetts* was the first case where the Supreme Court specifically recognized and sanctioned the power of state governments to enforce laws aimed at protecting the health of the public. Between 1901 and 1903, there was a major outbreak of smallpox in Boston that resulted in close to 1,600 people becoming sick and 270 dying from the illness.\(^\text{15}\) Legislation that granted broad power to cities and local governments had been put in place by the state of Massachusetts:

\[\text{[T]he board of health of a city or town, if, in its opinion, it is necessary for the public health or safety shall require and enforce the vaccination and revaccination of all the inhabitants thereof, and shall provide them with the means of free vaccination. Whoever, being over twenty-one years of age and not under guardianship, refuses or neglects to comply with such requirement shall forfeit $5.}\(^\text{16}\)


Significantly, the law also included an explicit exemption from vaccination for “children who present[ed] a certificate, signed by a registered physician” that stated they were “unfit subjects for vaccination.”

This law became an issue of contention in February 1902 when the Board of Health for the city of Cambridge, Massachusetts, in an effort to control the spread of smallpox, adopted and began enforcing the requirement that “all the inhabitants of the city who have not been successfully vaccinated since March 1st, 1897, be vaccinated or revaccinated.” Henning Jacobson alleged that he and his young son had suffered “a bad reaction” from an earlier vaccination and refused to be revaccinated in defiance of the city ordinance. Therefore, Jacobson was charged and found guilty by a jury of violating the law and was ordered to pay the $5 dollar fine. Notably, during his trial, Jacobson argued, much like those who argue against mandatory vaccination laws today, that his right to individual liberty, found in the 14th Amendment of the Constitution of the United States, was violated by the city’s mandate. In essence, his individual right to “liberty” in the sense of freedom from government intrusion and control superseded the state’s interest in protecting the health and safety of every person in the community.

In addressing Jacobson’s argument, the Court first reinforced the Constitutional right of the state to pass and enforce laws to protect the health of the public. The “police power—a power which the State did not surrender when becoming a member of the Union under the Constitution . . . must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety.” The Court then directly addressed Jacobson’s liberty-interest argument. Liberty interests, the Court wrote, are not absolute, but rather are circumscribed by the common good. Unbridled individual liberty eventually clashes with the liberty interests of others, and without some legal constraints, “[r]eal liberty for all could not exist.”

17 Id. at 11.
18 Id.
20 Jacobson, 197 U.S. at 14.
21 U.S. Const. amend. XIV.
22 Jacobson, 197 U.S. at 25.
23 Id. at 26.
In recognizing the considerable authority of the state to restrict individual rights, the Court was not suggesting that the state’s power was limitless. Instead, the Court was advancing its view that the right of the state to protect the health and safety of all people should be balanced with the rights granted to each individual. The power of the community to regulate for the common good is limited to what is reasonably necessary to protect public health, safety, and welfare. Beyond that, local governments run the risk that particular exercises of the police power will be invalidated as arbitrary and unreasonable.24

The Court then articulated situations in which it would step in and defend the Constitutional liberty interests of individual citizens. These included cases where an individual’s health would be so negatively affected by being vaccinated that it would be “cruel and inhuman” to require such a person to abide by the law.25 In Jacobson, the Massachusetts legislature carved out the exception for children who were “unfit” to be vaccinated due to health concerns. In the Court’s view, this explicit exception supported a similar, implicit exception in cases of adults that show “with reasonable certainty” that being vaccinated would “seriously impair his health or probably cause his death.”26

*Jacobson v. Massachusetts* shows that society’s views, fears, and concerns in 1905 were not so different from those being experienced by people today. When *Jacobson* was decided, the smallpox vaccine was the first and only one of its kind, and although it had not undergone the type of federally mandated FDA-imposed premarket testing and review that it would have undergone today, the Court deferred to the existing scientific and medical consensus that even though the vaccine was not perfect in terms of never causing adverse reactions or side effects, the vaccine was reasonably safe and effective.27 Some harshly criticized the Court’s wide acceptance of the views of the medical and scientific communities of that time.28 By all accounts, however, the smallpox vaccine has been a huge success; through its use, the last known “naturally occurring case” of smallpox was diagnosed in 1977, and since then, smallpox has been proclaimed as “eradicated from the world” by leading health experts.29

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24 *Id.* at 28.
25 *Id.* at 39. Thus, “‘[A]ll laws . . . should be so limited in their application as not to lead to injustice, oppression, or an absurd consequence. It will always, therefore, be presumed that the legislature intended exceptions to its language which would avoid results of this character.’” *Id.*
26 *Id.*
27 *Id.* at 34–37.
Further, just as today, the media played a large role in stoking the vaccination debate even in 1905. “Antivaccinationists” attacked compulsory vaccination as a virtual crime against humanity and as mass slaughter on a global scale.\(^{30}\) The mainstream media fired back with its own insults and rebukes, calling the debate “a conflict between intelligence and ignorance, civilization and barbarism.”\(^{31}\) In fact, when *Jacobson* was decided, the New York Times published commentary stating that the case “should end the useful life of the societies of cranks formed to resist the operation of laws relative to vaccination. Their occupation is gone.”\(^{32}\) This has clearly not proven to be the case, and the debate lives on with the media continuing to fuel its intensity. However, the case itself still stands as a lasting testament to the inherent difficulty of balancing individual interests with the interests of societies and communities of people.

**Zucht v. King**

*Zucht v. King* was the next case to test the limits of the police power in terms of restricting individual liberty and the only other Supreme Court case that specifically addresses mandatory vaccination laws.\(^{33}\) This case explicitly tested the legality of laws that require children to be vaccinated before they can be enrolled in public school. Rosalyn Zucht, a young girl from San Antonio, Texas, refused to be vaccinated against smallpox, and she was therefore excluded from attending both public and private school.

Rosalyn brought suit charging that “there was then no occasion for requiring vaccination; that the ordinances[,]” which required a record of vaccination in order for her to be enrolled, deprived her of “liberty without due process of law by, in effect, making vaccination compulsory[.]”\(^{34}\) Further, she asserted that the city’s requirements were “void” because they left “to the Board of Health discretion to determine when and under what circumstances the requirement shall be enforced, without providing any rule by which that board is to be guided in its action and without providing any safeguards against partiality and oppression.”\(^{35}\)

The Court quickly disposed of her claims in a three-paragraph opinion, stating emphatically that “it is within the police power of a State to provide for compulsory vaccination. [A] State may, consistently with the Federal Constitution, delegate to a

\(^{31}\) *Id.* at 577.
\(^{32}\) *Id.*
\(^{34}\) *Id.* at 175.
\(^{35}\) *Id.*
municipality authority to determine under what conditions health regulations shall become operative.” The Court used almost none of the necessity, reasonable means, proportionality, and harm avoidance language that it had employed in Jacobson and instead treated as settled doctrine that states may delegate broad authority to local governments to decide when to exercise their police powers through the imposition of health regulations. In turn, the Court went on to specifically reinforce the rights of municipalities to grant local officials wide latitude in enforcing laws aimed at protecting the health of the community, and recognized that under the police power, states and local authorities can impose a “reasonable classification,” even if it is not uniformly applied, without violating the equal protection clause.

Laws, such as the one being tested in Zucht, “were not widely enforced until after 1977 when a Childhood Immunization Initiative” was created with the goal of “eliminate[ing] measles from the United States.” States and municipalities soon recognized that schools that enforced mandatory vaccination policies had significantly lower rates of preventable illness, such as measles, and followed suit. Currently, children are required to be vaccinated before they can be admitted to school in all fifty states, and due in large part to mandatory vaccination laws, the United States has seen a huge decline of several diseases. “Initiatives such as mandatory school immunization laws have safeguarded nearly three generations of school-age children from diseases that once crippled and even killed thousands of Americans.”

Prince v. Massachusetts

The case of Prince v. Massachusetts affirmed the state’s police power to enforce mandatory vaccination laws that protect children over the religious objections of their parents. The statute at issue in this case was aimed at preventing child labor in the state of Massachusetts, which specifically prohibited children from selling magazines and other types of religious materials in public places. Sarah Prince, who was the legal

36 Id. at 176.
38 Zucht, 260 U.S. at 177.
40 Id. at 1051–52; see also Walter A. Orenstein et al., Immunization in the United States, VACCINES 1376 (Stanley A. Plotkin & Walter A. Orenstein eds., 4th ed. 2004).
42 Id. at 1047.
guardian of nine-year old Betty Simmons, was fined for allowing Betty to distribute religious literature on a public street corner. Both Ms. Prince and Betty were active Jehovah’s Witnesses and believed this work to be a constitutionally protected First Amendment right as well as a parental right guaranteed by the Due Process Clause.44

The Court began its analysis by balancing, yet again, the state’s role in protecting the welfare of children against the interests of individual citizens in freedom of conscience and religious practice, combined with an interest in raising children as they see fit.45 The Court recognized that in other cases, it had protected the rights of children and parents alike to exercise their religion in terms of education and practice, and prevented government intrusion into “the custody, care and nurtur[ing] of the child[,]” as this “reside[s] first in the parents.”46 However, the Court recognized that neither religious nor parental rights are absolute and that there is an appreciable boundary to the freedom a family or parent has in controlling the activities and treatment of their minor children.

The Court found an analogy in compulsory vaccination laws. The state’s authority is not curtailed when parents claim a religious basis for their opposition to vaccination: “The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death.”47 Indeed, the Court noted that the scope of the states’ police power is greater when it comes to protecting children than it is when protecting adults from themselves. As the Court famously stated, “[p]arents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children . . . .”48

In affirming the broad power of the state, the Court did not open the door to any and all state power, but simply acknowledged that laws that restrict an individual’s right to religious freedom and parental authority are constitutional, so long as they are appropriately limited in scope. In Prince, the Massachusetts law did not infringe excessively upon private religious freedom or into areas of protected parental authority, but instead sought to regulate an activity that took place in the public realm.

Similarly, mandatory vaccination laws are meant to regulate children in the public space, be it the public school setting or the myriad of other public places where children come into contact with other people. These laws are aimed at not only

44 Id. at 164.
45 Id. at 165.
46 Id. at 166.
47 Id. at 166–67.
48 Id. at 170.
protecting the child whose parents refuse to allow him or her to be vaccinated, but also protecting other children who may be too young or too sick to be vaccinated themselves. Because of the societal consequences of failing to immunize children, it has been suggested that “tort liability should be available against parents who choose not to immunize their children and who fail to use due care to prevent those children from contracting harmful diseases and infecting others.”

Many argue against laws that would punish the parents of unvaccinated children for the spread of disease and even death of children who were not given such a choice, but as the risk of disease grows with larger and larger outbreaks being seen in the U.S. and abroad, the legal latitude being given to parents may be questioned even further.

**STATE VACCINATION LAWS**

All 50 states have utilized their recognized and affirmed police power to pass laws that mandate compulsory vaccination for some component of the state’s population. Every state requires children to be vaccinated against certain communicable diseases as a condition for attendance at daycare institutions and for admission to public schools, and most such laws also apply to children entering private schools. However, the widespread availability of personal exemption options in some states has resulted in significantly decreasing vaccination rates, and arguably, a significant threat to public health and safety. All 50 states permit medical exemptions to their compulsory vaccination laws, 45 states and Washington, D.C. grant religious exemptions, and “15 states allow philosophical exemptions for those who object to immunizations because of personal moral or other beliefs.”

Obtaining exemptions typically requires different levels of paperwork and certification, with religious and personal belief exemptions being easier to secure than medical exemptions. Notably, in states that have repealed religious and/or personal belief exemptions, vaccination rates increase, but there is also a statistically significant rise in medical exemptions following such state action, as parents who are opposed to


vaccinating their children find physicians who will certify a medical exemption. California’s Senate Bill 276, which was enacted in 2019 and will become fully effective in 2021, is an attempt to address the issue of unjustified medical exemptions by, among other things, requiring a review by the Department of Public Health if a physician issues five or more medical exemptions in a calendar year.\footnote{See S.B. 276 (Cal. 2019), https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200SB276.}

It is important to note the unique nature of a medical exemption. Medical exemptions are generally only granted to individuals whose bodies simply cannot tolerate being vaccinated. Many times, this is due to these individuals being highly immunocompromised, such as children who are undergoing chemotherapy, infants who are too young to receive vaccinations, or people who are severely allergic to a component of the vaccine itself. And further, it is these children who have no real choice in the matter, who are placed at the greatest risk by those who choose not to have their children vaccinated when those children become sick and spread illness to those who are doubly vulnerable (unvaccinated and immunocompromised), through no fault of their own.

Large recent outbreaks have generated concern among citizens and politicians alike, and increasing numbers of states are reconsidering their exemption policies. “New York recently became the fifth state—after California, Maine, Mississippi and West Virginia—to enact a law requiring children in public school to be vaccinated unless they have a valid medical reason. Legislatures in several other states are considering similar legislation.”\footnote{Aleksandra Sandstrom, Amid Measles Outbreak, New York Closes Religious Exemption for Vaccinations—But Most States Retain It, Pew Research Ctr. (June 28, 2019), https://www.pewresearch.org/fact-tank/2019/06/28/nearly-all-states-allow-religious-exemptions-for-vaccinations/.} This tightening of state exemption policies came as no surprise in New York, as that state was recently the “center of a nationwide measles outbreak that has sickened more than 1,000 Americans in 28 states so far this year.”\footnote{Id.}

As the CDC reported in 1999, the scientific efficacy of vaccinations cannot be fully achieved unless parents recognize the importance of vaccines and seek them out for their children.\footnote{Ctrs. for Disease Control and Prevention, Achievements in Public Health, 1900–1999 Impact of Vaccines Universally Recommended for Children—United States, 1990–1998, 48 Morbidity & Mortality Wkly. Rep. 243, 247, Apr. 2, 1999, https://www.cdc.gov/mmwr/preview/mmwrhtml/00056803.htm (stating that “[t]o achieve the full potential of vaccines, parents must recognize vaccines as a means of mobilizing the body’s natural defenses and be better prepared to seek vaccinations for their children”).} This is due in large part to the concept of “herd immunity,” which protects even nonimmunized individuals from infection once a critical mass of
individuals are immunized.\textsuperscript{57} The threshold number of immunized individuals for herd immunity to occur varies depending on the nature of the pathogen being considered. For extremely contagious illnesses that can spread through the air, such as measles, the threshold level is as high as 95\%, meaning that measles cannot spread in a community where 95\% of people have been immunized.\textsuperscript{58} As more parents have refused to vaccinate their children, however, this threshold level of immunization has not been maintained, and many parts of the U.S. have experienced outbreaks. Interestingly, some children of parents who have refused to allow them to be vaccinated have taken note of these outbreaks and have done their own research about the science and efficacy of vaccination. Many of these children, such as Ethan Lindenberger who testified before Congress on the subject, have spoken out about their desire to choose for themselves.\textsuperscript{59} Thus, the fact that virtually every state\textsuperscript{60} requires parental consent for minors to “obtain routine childhood vaccinations” may be changing, as several states, including New York and Washington, D.C., are considering bills that would allow minors to consent to be vaccinated against their parents’ wishes.\textsuperscript{61}

New rules to allow minors to consent to immunization build upon a growing trend in the United States: the “mature minor doctrine.” At least 18 states have adopted the mature minor doctrine, which allows minors who display sufficient maturity and insight to make their own medical decisions. Although the doctrine may create a three-way conflict that can be difficult to negotiate, delegates to the 2019 Annual Meeting of the American Medical Association voted “to support ‘state policies allowing minors to override their parent’s refusal for vaccinations,’ [to] encourage ‘state legislatures to establish comprehensive vaccine and minor consent policies’ and ‘[to] direct[] the AMA to develop model legislation for mature minor consent to vaccinations.’”\textsuperscript{62}

\textsuperscript{58} Id.; H. Cody Meissner, Why is Herd Immunity So Important?, 36 AAP News (May 2015), https://www.aappublications.org/content/36/5/14.1.
\textsuperscript{60} See Ann McNary, Consent to Treatment of Minors, 11 Innovations Clinical Neuroscience 43 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4008301/pdf/icns_11_3_43.pdf (describing when, under what circumstances, and to what procedures, minors can legally give consent for without parental approval).
Opponents of compulsory vaccination laws argue that mandatory vaccination programs are totalitarian and an intrusion by government on personal autonomy.\(^63\) In other countries, compulsory vaccination programs have, at times, served to galvanize vaccination opposition and created new platforms for political candidates on each side of the philosophical debate.\(^64\) Taken to the extreme, such efforts have had a counterproductive effect on vaccination rates, and threaten the herd immunity that serves to protect those who cannot be vaccinated due to medical contraindications. Some have therefore called the effects of the anti-vaccination movement a crisis, and as noted above, then-Food and Drug Administration Commissioner Scott Gottlieb recently warned that “states are ‘going to force the hand of the federal health agencies.’”\(^65\) Moreover, many experts in the fields of public and global health and health policy agree, stating that “[i]t’s time for policymakers—especially those at the federal level—to respond decisively to this threat and protect the health of our children by eliminating broad nonmedical exemptions to vaccination mandates.”\(^66\) These calls for action raise the question of whether the federal government even has the power or authority to mandate vaccinations and/or prohibit the states from enacting personal preference objections, and further, would it be counterproductive for it to do so? If the goal is increased incidence of vaccination in the United States, persuasion and education might be more effective tools than the wholesale invalidation of personal exemptions, or development of a federally-mandated vaccination program. These questions are explored further in the next two sections.

### POTENTIAL FEDERAL INTERVENTION

An infectious disease first presents in individual patients located in individual communities. However, tracking and tracing the spread of infection by public health authorities reveals a different picture, one that often transcends state and even national

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\(^{64}\) See e.g., Daniel A. Salmon et al., Compulsory Vaccination and Conscientious or Philosophical Exemptions: Past, Present and Future, 367 LANCET 436 (Feb. 4, 2006) (describing early response to compulsory vaccination programs in the United Kingdom).


\(^{66}\) Id.
boundaries. The CDC has reported that multiple outbreaks of infectious diseases like measles have been initiated by international travelers. As a result, any state with an international airport is a potential vector for an outbreak, and any state to which an infected individual might travel before symptoms are observed is potentially the site of an outbreak. For example, current public health data paint a picture of a national measles outbreak. In the first nine months of 2019, 1,250 individual measles cases were confirmed in thirty-one states, the most vulnerable states being those with clusters of unvaccinated individuals.

It is tempting to think that a public health challenge that is national in scope would invite a national response. In fact, the federal government has relatively broad powers under section 361 of the Public Health Service Act “to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.” Read literally, the Act could authorize a federal immunization mandate “to prevent the . . . transmission[] or spread of communicable diseases,” but there is no indication in the text of the Act that Congress intended such sweeping authority. The Act identifies nine public health tools available to federal authorities, and immunization is not among them. The Act is instead focused upon identifying and responding to possible and actual cases of active infection.

In addition, section 317 of the Act provides federal funding to state and local governments “to assist them in meeting the costs of establishing and maintaining preventive health service programs,” including immunization efforts. This section specifically provides, however, that “[n]othing in this section shall be construed to require any State or any agency or political subdivision of a State to have a preventive health service program which would require any person, who objects to any treatment provided under such a program, to be treated or to have any child or ward treated under such program.”

If Congress were to consider a federal immunization mandate, it would need to pass a new statute to authorize it. As noted earlier, this could have been the message

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68 Id.
70 Id.
71 Id. § 264(a)–(b).
72 Id. § 247b(a).
73 Id. § 247b(g)(2).
from former then-FDA Commissioner Scott Gottlieb in response to an outbreak of measles around the country in 2019: “If ‘certain states continue down the path that they’re on, I think they’re going to force the hand of the federal health agencies . . . . You could mandate certain rules about what is and isn’t permissible when it comes to allowing people to have exemptions.”

**Direct Regulation**

The federal government’s ability to legislate a national immunization law is constrained by the Constitution’s enumeration of legislative powers and by the principle of “dual sovereignty,” in particular, a tradition that largely defers to the sovereignty of individual states to regulate matters of traditional state concern. These constraints leave the federal government with quite limited powers to increase immunization rates.

The United States Constitution does not contain a grant of the police power to Congress. As a result, Congress does not have broad authority to legislate to promote and protect the public health, safety, and general welfare—areas of traditional state concern and responsibility. A national law that mandated immunization except when medically contraindicated—even one that includes a religious exemption—would be as legally questionable as it is politically implausible.

As noted above, the United States Supreme Court in the *Jacobson* case recognized public health—in particular, infectious disease and immunization law—as just such an arena of traditional state authority. The Court traced state immunization laws to the “police power—a power which the State did not surrender when becoming a member of the Union under the Constitution.” In areas of traditional state regulatory authority, the Court has continued to demonstrate deference to state power and to presume (absent clear evidence of a contrary purpose) that Congress generally treads lightly, if at all, on state sovereignty, particularly with respect to “the historic police powers of the States.”

All of this makes it unlikely that Congress would even try to pass a national immunization bill. Moreover, if federal legislators were persuaded that it was desirable to wade into this arena of traditional state primacy, it would need to do so under one of Congress’s enumerated powers in the Constitution. For generations, the power repeatedly invoked by Congress to exercise broad regulatory authority was the

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The Supreme Court might even have encouraged Congress’s broad reading with its repeated observations that the power exercised by Congress under the Commerce Clause is not unlike the police power exercised by the states. By the second half of the century, however, the Court reined in Congress’s power under the Commerce Clause in an effort to draw a clearer line of demarcation between commercial and national subjects on the one hand, and local and noncommercial issues on the other.

In 1995, in *Lopez v. United States*, the Court invalidated a federal criminal statute that prohibited the possession of a handgun within 1,000 feet of a school. It concluded that the law did not fall into any of the three categories that define the outer limits of the Commerce Clause: (1) use of the channels of interstate commerce, (2) the use of instrumentalities of interstate commerce, or (3) activities that substantially affect interstate commerce. Criminal statutes with an indisputably local focus simply failed to meet the Court’s renewed interest in the “interstate” component of the Commerce Clause. In light of the similarly local nature of laws to protect public health, a federal law that established an immunization requirement can be expected to be viewed with similar hostility, and subsequent developments have confirmed this view.

For example, in 2000, the Court applied the same three-part analysis to invalidate a provision of the Violence Against Women Act. Although the Court subsequently upheld a broader view of Congress’s Commerce Clause powers, by 2012 in *National Federation of Independent Business (NFIB) v. Sebelius*, the Court returned to its narrow view of the scope of the Commerce Clause, holding that the individual mandate in the Patient Protection and Affordable Care Act (PPACA) could not be sustained under the Commerce Clause (but could be upheld as a valid exercise of Congressional power under the Taxing Clause).

In sum, in the last 25 years, the Supreme Court’s Commerce Clause doctrine has swung back from a half-century of applying a broad view of Congress’s powers to an interpretation that is considerably more constrained. There is little reason to believe that a national immunization law would be viewed any more favorably under the Commerce Clause than was PPACA’s individual mandate.

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77 U.S. Const., art. I, § 8, cl. 3.
81 See Gonzales v. Raich, 545 U.S. 1 (2005); Pierce Cty. v. Guillen, 537 U.S. 129 (2003).
Indirect Regulation

Direct regulation through a national immunization law is not the only tool available to Congress. Under the Taxing and Spending Clauses, “Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common defense and general Welfare of the United States . . . .”83 The Court’s approach to this provision has historically been permissive, including a high degree of deference to Congress’s determination that a particular legislative goal promotes the “general welfare.”84 For example, in Oklahoma v. Civil Service Commission, the Court held that “general welfare” was not limited to those subject areas that might not fall within the scope of its enumerated powers.85 As a result of the Court’s deferential stance, Congress’s legislative power under the Taxing and Spending Clauses closely resembles the police powers exercised by states.

One way Congress has exercised its Spending Power is through conditional spending measures that attach conditions on the states’ ability to receive funding through a federal program. This raises the question whether Congress could attach, as a condition to a state’s receipt of federal funds, for example, a requirement that the state have a mandatory immunization law with no exemptions other than one based on strict medical contraindication.

Traditional doctrine suggests that such a law would be upheld. As Chief Justice Burger wrote in 1980 in Fullilove v. Klutznick:

Congress has frequently employed the Spending Power to further broad policy objectives by conditioning receipt of federal moneys upon compliance by the recipient with federal statutory and administrative directives. This Court has repeatedly upheld against constitutional challenge the use of this technique to induce governments and private parties to cooperate voluntarily with federal policy.86

One year later, the Court held that if Congress wants to impose a condition on a state’s receipt of federal funds, it must do so “with a clear voice” and unambiguously.87

83 U.S. Const., art. I, § 8, cl. 1 (emphasis added).
84 See, e.g., Sabri v. United States, 541 U.S. 600 (2004) (upholding a criminal statute that prohibits the bribery of state and local officials of governments that receive at least $10,000 in federal funds); Steward Machine Co. v. Davis, 301 U.S. 548 (1937) (upholding the unemployment-compensation provision of the Social Security Act).
In 1987, the Court added more limits on Congress’s use of conditional spending laws. In *South Dakota v. Dole*, the Court considered a challenge to a law that withheld five percent of federal highway funds to any state that did not enact a drinking age of twenty-one years. The Court upheld the law but noted that two features were important to its holding: (1) that an older drinking age was directly related to increased highway safety, which was also one of the principal goals of the federal highway program, and (2) that “the financial inducement offered by Congress [was not] so coercive as to pass the point at which pressure turns into compulsion.”

Considering the size, scope, and variety of the federal government’s annual public health-related expenditures—which has leveled off in recent years to approximately $250 per capita—it should not be difficult to find programs that bear a logical relationship to immunization policy. *Dole’s* non-coercion principle, however, may prove more difficult to satisfy. Coercion and compulsion were at the heart of the Court’s most recent Spending Clause case—its 2012 review of PPACA in *National Federation of Independent Business (NFIB) v. Sebelius*. Twenty-six states had mounted a broad challenge to many features of PPACA, including a provision that tied a state’s receipt of all federal Medicaid funds to its expansion of Medicaid eligibility. As the Court noted,

On average States cover only those unemployed parents who make less than 37 percent of the federal poverty level, and only those employed parents who make less than 63 percent of the poverty line . . . . The Medicaid provisions of the Affordable Care Act, in contrast, require States to expand their Medicaid programs by 2014 to cover all individuals under the age of 65 with incomes below 133 percent of the federal poverty line.

The financial penalty for a state that did not expand Medicaid eligibility was substantial: the loss of all federal Medicaid funding. As the majority pointed out, “Medicaid spending accounts for over 20 percent of the average State’s total budget, with federal funds covering 50 to 83 percent of those costs.” The Court famously concluded that “the financial ‘inducement’ Congress has chosen is much more than ‘relatively mild encouragement’—it is a gun to the head.” Rather than declare the Medicaid-expansion provision unconstitutional, the Court interpreted it to apply only

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89 Id. at 211.
91 Id. at 575–76.
92 Id. at 581.
93 Id.
to Medicaid-expansion funds. The result was to leave existing Medicaid funds intact and to withhold only those federal funds earmarked for expanded Medicaid eligibility from states that did not expand Medicaid eligibility.94

At least one message comes through loud and clear: A conditional spending measure must respect basic principles of federalism, one of which is that sovereign states should be free to decide their own public policies. Relatively mild “inducement” to encourage a state to adopt federal policy as its own is fine, but a coercive financial penalty that compels a state to do so is not.

A second message is less clear: Tying the receipt of federal funds to a new program, rather than threatening a noncomplying state with the loss of existing federal funds for a different program, raises far less serious concerns under the Spending Clause. In the case of traditional Medicaid and the PPACA’s Medicaid expansion, there is both a tighter connection between the change in federal policy and the loss of funds as well as less draconian effect on states that decide against expanding Medicaid eligibility.

There may be a lesson here if Congress were to enact a national immunization law that encourages states to have laws that limit exemptions to medical reasons only. Tying such state laws to the receipt of existing federal funding for education or public health would invite searching scrutiny of the financial impact on states that already depend upon significant federal aid for these activities. Conditioning new federal funds specifically to promote such a policy at the state level—including financial support for public education and the increased costs of vaccinations in public programs like Medicaid and Tricare (health insurance for military dependents)—might be deemed a merely “modest inducement” for states to enact a broad immunization requirement, one akin to the inducement created by withholding expansion-related funds from states that decide not to expand Medicaid eligibility pursuant to PPACA.

Education and Persuasion

Short of direct or indirect regulation, the federal government has another tool it can deploy: the bully pulpit. In 2019, for example, the Senate passed S. Res. 165, which addressed many of the challenges that were lined up against fact-based decisions about vaccinations and concludes by “urg[ing] all people, in consultation with their health care providers, to follow the scientific evidence and consensus of medical experts in favor of timely vaccinations to protect—(A) the individual vaccinated; and (B) the

94 Id. at 585–86.
children, family, and community of the individual vaccinated. As a simple resolution, S. Res. 165 does not have the binding force of law, but it represents a step forward in educating the public about the benefits of vaccination.

Public health authorities have an array of official and social media outlets that provide opportunities for public education about the safety and efficacy of vaccines. Indeed, the United States has been down this road before (and continues to travel this road today). After the licensing of a live-virus vaccine in 1963, public health officials had great hope that measles could be eradicated. Through the Surgeon General, the CDC, and others, the Public Health Service launched an aggressive campaign to educate the public about the new vaccine and to address the widespread opinion that measles was a relatively minor childhood disease. Infection rates quickly decreased, a trend that continued through the 1980s and 1990s. By 2000, measles were no longer endemic in the United States, which meant that cases of measles were either brought into the United States from abroad or could be traced to those cases.

As the past two decades have shown, this public health victory was short-lived. Measles is most decidedly back. Professor Elena Conis has argued that progress and retrenchment are products of their times. Faith in both technology and the government as a trusted conveyor of the products of that technology has eroded since the mid-1960s. The way forward will have to contend with our own unique moment in history and against the difficulty of integrating science- and public health-based perspectives on vaccination with state vaccine laws and social values.

THE ROLE OF THE PHYSICIAN

State and federal legal developments offer the promise of a comprehensive and informed approach to vaccination policy and practices. These developments depend, however, upon political will and, ultimately, public sentiment. Meanwhile, practicing physicians (and the health lawyers who advise them) are left to deal with the issue within the limits of the law as it currently exists.

Due to the increasing number of parents who refuse to vaccinate their children, pediatricians have been placed on the frontline in terms educating families regarding

97 Id. at 120.
98 Id. at 122–23.
99 Id. at 123.
the safety and effectiveness of vaccinations. As discussed above, states that recognize a mature-minor rule may allow for consent to vaccination by some minor patients. This has the obvious potential for creating a three-way conflict that requires some delicacy in navigating.

Increasingly, however, pediatricians are responding to vaccine hesitancy by “firing” families who do not consent to vaccinating their children. In recent years, the number of physicians who have adopted such a policy has doubled to nearly one-eighth of all pediatricians. Therefore, pediatricians must also educate themselves regarding their legal right to discontinue a professional physician-family relationship with parents who refuse to immunize their children on grounds other than medical contraindication. The American Academy of Pediatrics “strongly endorses universal immunization,” encourages pediatricians who are faced with vaccination refusal by parents to “revisit the immunization discussion” over multiple appointments, and firmly asserts that pediatricians should endeavor not to “discharge patients from their practices solely because a parent refuses to immunize his or her child.” There may come a time, however, when disagreement leads to discord and to a breakdown in communications or the trust relationship. In these cases, the pediatrician may wish to terminate the physician-patient relationship.

The physician-patient relationship is contractual in nature and, as with any contract, it requires mutual consent. Once that relationship comes into existence, the physician has an ongoing duty of attention and care that must be maintained. The law varies in certain details from state to state, but the principle is well established that a physician's unilateral decision to end a physician-patient relationship must be handled carefully to avoid the tort of abandonment. At a minimum, this requires reasonable notice and opportunity to obtain another source of medical care. Therefore, if a pediatrician wishes to terminate his or her relationship with a patient due to vaccine refusal, the physician must notify the parent “long enough in advance to permit the patient to secure another physician,” and “[f]acilitate transfer of care when


102 Id.

103 Id.; see also Overstreet v. Nickelsen, 317 S.E.2d 583 (Ga. 1984); Mayer v. Baisier, 497 N.E.2d 827 (Ill. 1986); Estate of Smith v. Lerner, 387 N.W.2d 576 (Iowa 1986); Collins v. Meeker, 424 P.2d 488 (Kan. 1967); Johnson v. Vaughn, 370 S.W.2d 591 (Ky. 1963); Clark v. Wichman, 179 A.2d 38 (N.J. 1962); Lee v. DeWbre, 362 S.W.2d 900 (Tex. 1962); Ricks v. Budge, 64 P.2d 208 (Utah 1937).
appropriate." What constitutes a sufficient amount of advance notice may vary, but overall, the notice period must be reasonable when considered in light of all the facts and circumstances involved. Further, the patient should be given such notice in writing. A letter can be sent to the patient’s home address, return receipt requested, and a copy of the letter along with the return receipt should be placed in the patient’s record. Detailed instructions and sample form letters to complete this process can generally be referenced on a given state’s medical association’s website.

CONCLUSION

Autonomy is a cherished value in health care no less than it is in all aspects of American culture. Autonomy, in turn, embraces the principle of pluralism—that different individuals have their own conceptions of what makes for a happy and satisfying life, and that all such differing conceptions are entitled to respect. This type of individualism was central to Mr. Jacobson’s challenge to the City of Cambridge and the Commonwealth of Massachusetts. Indeed, the Hippocratic model of medicine, with its focus upon one physician and one patient, is also individualistic at its core.

Public health, on the other hand, is focused upon the welfare of the community and inevitably requires a weighing of individual autonomy against the greater good of the community as a whole. Although the Supreme Court recognized early in the 20th century that the police power of the states is broad enough to include reasonable measures to control the spread of infectious disease, the states themselves have in more recent times often tipped the balance in favor of autonomy, increasingly at the expense of public welfare.

The federal government has done relatively little to restore the balance toward public health for reasons that are historical and certainly political rather than scientific. Although legal constraints on federal power make the prospect of a national, uniform federal law for vaccinations unlikely, those constraints need not be fatal to federal action. In particular, greater emphasis on federal-state partnerships (along the lines of section 317 of the Public Health Service Act) and more vigorous educational efforts should encounter few, if any, legal obstacles.

Immunizations, to a greater extent than most other issues that confront medical practitioners, frame all of these competing values in stark relief. As the political and legal landscape develops, individual practitioners will be challenged to strike their own balance between respecting autonomy and protecting the public health. It’s time they received some help from their representatives.

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