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Vaccination Mandates: The Public Health Imperative and Individual Rights

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In 1796, Edward Jenner demonstrated that inoculation with material from a cowpox (vaccinia) lesion would protect against subsequent exposure to smallpox. This began the vaccine era, although it was nearly 100 years until the next vaccine (against rabies) was introduced. In the twentieth century, many new vaccines were developed and used, with spectacular impact on the occurrence of disease. The Centers for Disease Control and Prevention (CDC) declared vaccinations to be one of the 10 great public health achievements of the twentieth century.[1,2]

This chapter describes the impact of vaccines in dramatically reducing infectious diseases in the United States, the role of mandatory vaccination in achieving that impact, and the constitutional basis for these mandates. The chapter also briefly reviews the federal government's role in immunization practices.

BACKGROUND

Concept for Community Disease Prevention

Garrett Hardin's classic essay *The Tragedy of the Commons*[3] describes the challenges presented when societal interest conflicts with the individual's interest. Hardin notes the incentives present when the cattle of a community are com-

mingled in a common pasture. At capacity, each owner still has an incentive to add additional cattle to the common because even though the yield from each animal decreases with the addition of more cattle, this decrease is offset for the individual owner by the additional animal. With this incentive, individual owners continue to add cattle to the commons to reap their individual benefit, leading to the inevitable failure of the common from overgrazing. The community interest in maximizing food production, therefore, can be achieved only by placing controls on the interests of the individual owners in favor of those of the community.

Analogously, a community free of an infectious disease because of a high vaccination rate can be viewed as a common. As in Hardin's common, the very existence of this common leads to tension between the best interests of the individual and those of the community. Increased immunization rates result in significantly decreased risk for disease. Although no remaining unimmunized individual can be said to be free of risk from the infectious disease, the herd effect generated from high immunization rates significantly reduces the risk for disease for those individuals. Additional benefit is conferred on the unimmunized person because avoidance of the vaccine avoids the risk for any adverse reactions associated with the vaccine. As disease rates drop, the risks associated with the vaccine come even more to the fore, providing further incentive to avoid immunization. Thus, when an individual in this common chooses to go unimmunized, it only minimally increases the risk of illness for that individual, while conferring on that person the benefit of avoiding the risk of vaccine-induced side effects. At the same time, however, this action weakens the herd effect protection for the entire community. As more and more individuals choose to do what is in their "best" individual interest, the common eventually fails as herd immunity disappears and disease outbreaks occur. To avoid this "tragedy of the commons," legal requirements have been imposed by communities (in recent times, by states) to mandate particular vaccinations.

Vaccine Safety and Effectiveness

Vaccines are safe and effective. However, they are neither perfectly safe nor perfectly effective. Consequently, some persons who receive vaccines will be injured as a result, and some persons who receive vaccines will not be protected. Most adverse events associated with vaccines are minor and involve local soreness or redness at the injection site or perhaps fever for a day or so. Rarely, however, vaccine can cause more serious adverse events. Whether an adverse event that occurs after vaccination was caused by the vaccine or was merely temporally related and caused by some totally independent (and often unknown or unidentified) factor is often difficult to ascertain. This is particularly problematic during infancy, when a number of conditions may occur spontaneously. In

a given instance, determining whether vaccine was responsible may be impossible.[4] Particularly when dealing with rare events, large-scale case–control studies or reviews of comprehensive records of large numbers of infants may be necessary to ascertain whether those who received a vaccine had a higher incidence of the event than those who did not. The CDC operates an extensive linked database involving several large health-maintenance organizations. This Vaccine Safety Datalink project includes more than 6 million persons (approximately 2% of the U.S. population) and has proved invaluable for attempting to determine causality.[5]

Decisions about use of vaccines are based on the relative balance of risks and benefits. This balance may change over time. For example, recipients of oral polio vaccine (OPV) and their close contacts have a risk of developing paralysis associated with the vaccine of 1 in approximately every 2.4 million doses of vaccine distributed. This risk is small and was certainly outweighed by the much larger risk for paralysis from wild polioviruses at the time they were circulating in the United States. However, because wild polioviruses no longer circulate in the United States and the risk of importation of wild viruses has been greatly reduced by the global effort to eradicate polio, the balance has shifted. There has not been a case of paralysis in the United States from indigenously acquired wild poliovirus since 1979, and the entire Western Hemisphere has been free from wild poliovirus circulation since 1991.[6] The Advisory Committee on Immunization Practices (ACIP), an advisory group to the CDC, recommended, in 1997, that children should receive a sequential schedule with two doses of inactivated polio vaccine (IPV) (which carries no risk for paralysis but has slightly less effect in preventing community spread of wild poliovirus), followed by two doses of OPV. In 2000, the recommendation was made to switch to an all-IPV regimen.[7]

An important characteristic of most vaccines is that they provide both individual and community protection. Most of the diseases against which we vaccinate are transmitted from person to person. When a sufficiently large proportion of individuals in a community is immunized, those persons serve as a protective barrier against the likelihood of transmission of the disease in the community, thus indirectly protecting those who are not immunized and those who received vaccine but are not protected (vaccine failures). One commentator has suggested that a social contract exists among parents to immunize their children not only to provide them individual protection, but also to contribute to the protection of other children who cannot be immunized or for whom the vaccine is not effective.[8] The proportion of the population that has to be immune to provide this "herd immunity" varies according to the infectiousness of the agent. For poliomyelitis, that proportion is considered to be on the order of 80%, whereas for measles it exceeds 90%.

When a community has a high level of vaccination, an individual might decide

to not be vaccinated to avoid the small risk for adverse events while benefitting from the vaccination of others. Of course, if a sufficient number of individuals make this decision, the protection levels in the community decline, the herd immunity effect is lost, and the risk of transmission rises.

Impact of Vaccines

The introduction and widespread use of vaccines have profoundly affected the occurrence of several infectious diseases. Smallpox was eradicated from the world—onset of the last naturally occurring case was in 1977—and vaccination against smallpox stopped. Poliomyelitis is on the verge of eradication (the last indigenous case in the United States associated with wild virus occurred in 1979, and only 20 to 30 countries were still reporting transmission as of mid-2001).

Because approximately 11,000 infants are born every day in the United States, the need to ensure that children continue to be protected is ongoing. In addition, a continuing threat exists of importation of disease from other countries. In the United States, infants and young children are currently vaccinated against 11 diseases: diphtheria, *Haemophilus influenzae* type b, hepatitis B, measles, mumps, pertussis, poliomyelitis, rubella, *Streptococcus pneumoniae*, tetanus, and varicella.[9] In states with high risk for hepatitis A, children are also vaccinated against this disease. With the exception of tetanus, each of these diseases is spread from person to person by direct contact or by aerosol droplet transmission. Most of the diseases historically have had very high incidence in school-aged children because of the high potential for transmission in the congregate setting. With more children in preschool programs, outbreaks have occurred at earlier ages. In contrast, hepatitis B has its highest incidence in young adulthood as a result of transmission through sexual contact or needle sharing. Tetanus is acquired by contamination of wounds and is not transmitted from person to person. Table 13–1 shows the representative annual morbidity (typically, average morbidity reported in the 3 years before introduction of the vaccine) in the twentieth century and the number of cases reported in 2000 for diseases against which children have been routinely vaccinated.[10] Most diseases have declined by 99% or more (pneumococcal disease and varicella are not reportable conditions) and are at all-time lows. Vaccination coverage in 19–35-month-old children is at an all-time high (Table 13–2).[11]

Modern Government Role in Immunization

Vaccines are subject to licensure in the United States by the Food and Drug Administration (FDA) following studies that address safety and efficacy.[12,13] With declining vaccine production capacity in the United States, in 1986 Congress approved the National Childhood Vaccine Injury Act (NCVIA).[14] This comprehensive law established the National Vaccine Program within the U.S.

TABLE 13–1. Comparison of Twentieth Century Annual Morbidity* and Current Morbidity of Vaccine-Preventable Diseases of Children in the United States

DISEASE	TWENTIETH CENTURY ANNUAL MORBIDITY	2000†	PERCENTAGE DECREASE
Smallpox	48,164	0	100
Diphtheria	175,885	4	99.99
Measles	503,282	81	99.98
Mumps	152,209	323	99.80
Pertussis	147,271	6755	95.40
Polio (paralytic)	16,316	0	100
Rubella	47,745	152	99.70
Congenital rubella syndrome	823	7	99.10
Tetanus	1314	26	98.00
Haemophilus influenzae type b and unknown (<5 years)	20,000	167	99.10

*Typical average during the 3 years before vaccine licensure.

†Provisional data.

TABLE 13–2. Vaccination Coverage Levels Among Children Aged 19–35 Months in the United States, 2000

VACCINE, DOSES	COVERAGE (%)
DTP, 3	94.1
DTP, 4	81.7
Polio, 3	89.5
Hib, 3	93.4
MMR, 1,	90.5
Hepatitis B, 3	90.3
Varicella	67.8
Combined series	
4 DTP/3 polio/1 MMR	77.6
4 DTP/3 polio/1 MMR/3 Hib	76.2
4 DTP/3 polio/1 MMR/3 Hib/3 Hep B	72.8

DTP, diphtheria and tetanus toxoids and pertussis vaccine; Hib, *Haemophilus influenzae* type b vaccine; MMR, measles-mumps-rubella vaccine; Hep B, hepatitis B vaccine.

Department of Health and Human Services to coordinate and oversee all activities within the U.S. government related to vaccine research and development, vaccine-safety monitoring, and vaccination activities. In addition, the Act established the National Vaccine Injury Compensation Program (VICP) to compensate for injuries associated with routinely administered childhood vaccines (42 U.S.C. §§ 300aa-10–300aa-23). At least some of the decline in the number of vaccine producers in the United States had been attributed to liability costs. The VICP effectively removes this as a significant consideration.

Acknowledging that vaccines, as with any medication, are not without risk to the patient, that vaccines, unlike other medications, are a medical intervention generally given to healthy individuals, and that vaccination has benefits beyond the individual by significantly benefitting the public health through creation of herd immunity, the VICP was established to shift the monetary costs of vaccine injuries away from vaccine recipients and manufacturers. Using a vaccine injury table and a simplified administrative process through the U.S. Court of Federal Claims, this no-fault system is designed to fairly compensate children and their families (along with adult recipients of these vaccines) for the costs associated with the rare injuries related to vaccination. An excise tax on each dose of covered vaccine funds the compensation program.

Individuals alleging vaccine injury must go through the VICP before filing any tort actions against the administering health-care provider or the vaccine manufacturer. If the judgment of the court is accepted, further actions against the provider and manufacturer are barred. Even if the judgment is declined, the NCVIA significantly narrows the scope of any tort action against the manufacturer. Since the inception of the VICP, few individuals have chosen to reject the judgment of the court and file suit against the provider or manufacturer. Thus, liability costs of the vaccine manufacturers have dropped dramatically since the establishment of the VICP.

With the product liability incentive for vaccine improvement substantially reduced by the existence of the VICP, the role of the government in monitoring vaccine safety becomes more prominent. Beyond post-licensure surveillance requirements of the FDA, the NCVIA also established the Vaccine Adverse Event Reporting System (VAERS), which requires reporting of adverse events by vaccination providers (42 U.S.C. § 300aa-25). Providers must also record lot numbers of vaccines administered. Furthermore, various federal agencies, including the CDC's National Immunization Program, have expanded vaccine-safety activities. In addition, with diminished liability costs, more pharmaceuticals have entered the vaccine production arena with the resultant competition leading to further vaccine improvements and development of new vaccines against other diseases.

The NCVIA also seeks to improve the knowledge level of parents through

its requirement that the CDC produce vaccine information materials for mandatory distribution by providers to patients or parents before administration of VICP-covered vaccines (42 U.S.C. § 300aa-26). Through these materials, called Vaccine Information Statements, parents are informed about the schedules for administration of the vaccines, are alerted to contraindications that dictate against administration to particular individuals, and are informed about potential adverse reactions to look for to encourage timely medical intervention, as needed.

Most children in the United States receive their vaccinations in the private sector, from pediatricians or family physicians. A significant minority receive vaccinations in the public sector, typically from local health departments. There is considerable variation around the country.[15] At current prices, the cost for vaccines alone (irrespective of physician fees) is approximately $600 in the private sector (CDC, unpublished data). Most employer-based insurance plans now cover childhood vaccinations.

Since 1962, the federal government has supported childhood vaccination programs through a grant program administered by the CDC.[16] These "317" grants, named for the authorizing statute, support purchase of vaccine for free administration at local health departments and support immunization delivery, surveillance, and communication and education. As of 2000, the CDC purchased over half the childhood vaccine administered in the United States through two federally overseen, state-administered programs. In addition to the 317 program, in 1994 the Vaccines for Children (VFC) [17] program began, under which all Medicaid-eligible children, all children who are uninsured, all American Indian and Alaska Native children, and insured children whose coverage does not include vaccinations (with limitations on the locations where this last group can receive VFC vaccine) qualify to receive routine childhood vaccines at no cost for the vaccine. The VFC program operates in both public health clinics and private provider offices. The 317 grant program provides additional vaccines to the states for administration to adults and to children who do not qualify for VFC vaccine. Additional federal assistance for vaccination is provided by the Children's Health Insurance Program through expanded Medicaid eligibility for low-income children.[18] Many states use state funds to purchase additional quantities of vaccine.

The ACIP determines the vaccines to be administered in the VFC program and the schedules for their use. In addition, the ACIP issues recommendations for use of adult and pediatric vaccines in the United States and, generally in coordination with the American Academy of Pediatrics and the American Academy of Family Physicians, establishes a recommended schedule for administration of routine childhood vaccines. The ACIP recommendations are often considered by states as they determine which vaccinations to mandate for school attendance.

To assist parents in complying with the often complex vaccine schedules, many states and localities, with the assistance of the CDC and professional organizations, have established vaccination registries to send parents reminders when vaccines are due. In a mobile era when families move often and frequently change health-care providers, these registries also help avoid over-vaccination and ensure catch-up vaccination when needed.[19]

School and Daycare Vaccination Laws

School vaccination laws have played a key role in the control of vaccine-preventable diseases in the United States. The first school vaccination requirement was enacted in the 1850s in Massachusetts to prevent smallpox transmission in schools.[20] By the beginning of the twentieth century, nearly half of the states had requirements for children to be vaccinated before they entered school. By 1963, 20 states, the District of Columbia, and Puerto Rico had such laws, with a variety of vaccines being mandated.[21] However, enforcement was uneven.

In the late 1960s, efforts were undertaken to eradicate measles from the United States. Transmission in schools was recognized as a significant problem.[22] In the early 1970s, states that had school vaccination laws for measles vaccine had measles incidence rates 40% to 51% lower than states without such laws.[23] In 1976 and 1977, measles outbreaks in Alaska and Los Angeles, respectively, led health officials to strictly enforce the existing requirements.[24] Advance notice was given that the laws were to be enforced, and major efforts were undertaken to ensure that vaccination could be easily obtained. In Alaska, on the announced day of enforcement, 7418 of 89,109 students (8.3%) failed to provide proof of vaccination and were excluded from school. One month later, fewer than 51 students were still excluded. No further cases of measles occurred.[25] In Los Angeles, approximately 50,000 of 1,400,000 students (<4%) were excluded; most were back in school within a few days, and the number of measles cases dropped precipitously. These experiences demonstrated that mandatory vaccination could be enforced and was effective.

Because of declining vaccination levels in children, a nationwide Childhood Immunization Initiative was undertaken in 1977 to raise vaccination levels in children to 90% by 1979. An important component of this initiative was to support enactment and enforcement of school vaccination requirements. During a 2 year period, more than 28 million records were reviewed, and children in need were vaccinated.[26]

An analysis of six states that strictly enforced comprehensive laws (affecting all grades) beginning with the 1977–1978 school year compared with the rest of the country showed that in the 1975–1976 school year, they had comparable incidence rates of measles. However, in the 1977–1978 school year, the six

states that strictly enforced the laws had incidence rates less than half those of the rest of the country; and in the 1978–1979 school year, the incidence rates were less than one tenth those of the rest of the country.[27] An analysis of states with the highest and lowest incidences of measles in 1979–1980 found that states with the lowest incidence rates were significantly more likely to have laws covering the entire school population (rather than just first entrants) and more likely to be strictly enforcing the laws.[28]

By the 1980–1981 school year, all 50 states had laws covering students first entering school. In most states, these laws affected children at all grade levels, as well as those involved in licensed preschool settings. Some of the laws specified the particular vaccines required (and the numbers of doses of each); others authorized the State Health Officer (or public health board) to designate which vaccines (and doses) were required, often after a public rule-making process.

As of the 1998–1999 school year, all states but four (Louisiana, Michigan, South Carolina, and West Virginia) had requirements covering all grades from kindergarten through 12th grade. In all states, the District of Columbia, and Puerto Rico, the requirements covered daycare centers; in 48 states (all but Iowa and West Virginia), the requirements covered Head Start programs. Thirty states, the District of Columbia, and Puerto Rico had some requirements for college entrance. The requirements covered diphtheria toxoid and polio, measles, and rubella vaccines in all 50 states; 49 states required tetanus toxoid, 46 required mumps vaccine, 44 required pertussis vaccine, and 28 required hepatitis B vaccine.[29]

Since 1981, vaccination levels in school entrants have been 95% or higher for diphtheria and tetanus toxoids and pertussis vaccine (DTP), polio vaccine, and measles vaccine. All states require vaccination for children attending licensed daycare centers and as a result such children have vaccination levels 90% or higher. Nonetheless, overall levels in preschool children have not been as high, as manifested by the resurgence of measles that occurred during 1989–1991, primarily affecting unvaccinated preschool-aged children.[30] Levels in preschool-aged children have recently been raised to their currently high levels as a result of major efforts (and major infusions of resources) directed at this population.[15]

The Task Force on Community Preventive Services is an independent body carrying out evidence-based reviews of the literature to assess the claims that preventive interventions directed to populations are effective. One of the 17 interventions reviewed for vaccine-preventable diseases was mandatory vaccination requirements. The Task Force found that sufficient evidence existed to demonstrate the effectiveness of these requirements in increasing vaccine coverage, thereby reducing disease incidence, and so recommended their use.[31]

Historical Context

Duffy's description of smallpox vaccination in early American history highlights both the significant positive public health impact of vaccines and the ongoing challenges that this success presents[20]:

> Smallpox . . . was the great scourge of the American colonies until the introduction of inoculation or variolation, and the subsequent discovery of vaccination in 1796 relegated it to minor importance among the great epidemic diseases. As memories of the horrifying outbreaks of smallpox gradually faded, and a generation appeared which had had little contact with its victims, vaccination was neglected, and the incidence of smallpox began to rise. Beginning in the 1830s its attacks gradually intensified, and by the time of the Civil War the disorder was once again a serious problem.
>
> By chance, the rise of smallpox coincided with the enactment of compulsory school attendance laws and the subsequent rapid growth in the number of public schools. Since the bringing together of large numbers of children clearly facilitated the spread of smallpox, and since vaccination provided a relatively safe preventive, it was natural that compulsory school attendance laws should lead to a movement for compulsory vaccination. . . ."

Many other childhood diseases for which vaccines were developed also frequently occurred in school-based outbreaks; consequently, when polio and measles vaccines were introduced in 1955 and 1963, respectively, adding them to the list of requirements for school entry was a logical consideration. The 1963 survey of state laws found that, of 20 states with requirements, 18 included smallpox, 11 included diphtheria, 10 included polio, 7 included tetanus, and 5 included pertussis. Measles requirements were soon added. By 1970, 20 states required measles vaccination, and by 1983 all 50 states did.[32]

LEGAL AUTHORITIES—CONSTITUTIONAL BASIS OF MANDATORY VACCINATION

Police Power

The first state law mandating vaccination was enacted in Massachusetts in 1809; in 1855, Massachusetts became the first state to enact a school vaccination requirement. The constitutional basis of vaccination requirements rests in the police power of the state. Nearly 100 years ago, the U.S. Supreme Court issued its landmark ruling in *Jacobson v. Massachusetts,*[33] upholding the right of states to compel vaccination. The Court held that a health regulation requiring smallpox vaccination was a reasonable exercise of the state's police power that did not violate the liberty rights of individuals under the Fourteenth Amendment to the U.S. Constitution. The police power is the authority reserved to the states by the Constitution and embraces "such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety"[a] (197 U.S. at 25, 25 S.Ct. at 361).

In *Jacobson*, the Commonwealth of Massachusetts had enacted a statute that authorized local boards of health to require vaccination. Jacobson challenged his conviction for refusal to be vaccinated against smallpox as required by regulations of the Cambridge Board of Health. While acknowledging the potential for vaccines to cause adverse events and the inability to determine with absolute certainty whether a particular person can be safely vaccinated, the Court specifically rejected the idea of an exemption based on personal choice.[b] To do otherwise "would practically strip the legislative department of its function to [in its considered judgment] care for the public health and the public safety when endangered by epidemics of disease" (197 U.S. at 37, 25 S.Ct. at 366). The Court elaborated on the tension between personal freedom and public health inherent in liberty: "The liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good. On any other basis organized society could not exist with safety to its members" (197 U.S. at 26, 25 S.Ct. at 361).

School Vaccination Laws

The Supreme Court in 1922 addressed the constitutionality of childhood vaccination requirements in *Zucht v. King*.[34] The Court denied a due process Fourteenth Amendment challenge to the constitutionality of city ordinances that excluded children from school attendance for failure to present a certificate of vaccination holding that "these ordinances confer not arbitrary power, but only that broad discretion required for the protection of the public health"[c] (260 U.S. at 177, 43 S.Ct. at 25).

More recently, in the face of a measles epidemic in Maricopa County, Arizona, the Arizona Court of Appeals rejected the argument that an individual's right to education would trump the state's need to protect against the spread of infectious diseases short of confirmed cases of measles in the particular school. Given the nature of the spread of measles and the lag time in getting laboratory confirmation of cases, the court in *Maricopa County Health Department v. Harmon*[35] was satisfied that it is prudent to take action to combat disease by excluding unvaccinated children from school when there is a reasonably perceived, but unconfirmed, risk for the spread of measles (156 Ariz. at 166, 750 P.2d at 1369). Although the court considered the right to education under Arizona's constitution, the decision is instructive in showing the reach of the police power to ensure the public health. The court in *Maricopa* specifically noted that *Jacobson* did not require that epidemic conditions exist to compel vaccination (156 Ariz. at 166, 750 P.2d at 1369).

Parens Patriae

Further authority to compel vaccination of children comes under the doctrine of *parens patriae* in which the state asserts authority over child welfare. In the 1944 case of *Prince v. Massachusetts,*[36] which involved child labor under an asserted right of religious freedom, the U.S. Supreme Court summarized the doctrine, noting that

> Neither rights of religion nor rights of parenthood are beyond limitation. Acting to guard the general interest in youth's well being, the state as *parens patriae* may restrict the parent's control by requiring school attendance, regulating or prohibiting the child's labor, and in many other ways. Its authority is not nullified merely because the parent grounds his claim to control the child's course of conduct on religion or conscience. Thus, he cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds. 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.[d] (321 U.S. at 166–7, 64 S.Ct. at 442)

LEGAL ISSUES AND CONTROVERSIES—EXEMPTIONS TO MANDATORY VACCINATION

Although vaccines are safe and effective, they are neither perfectly safe nor perfectly effective. Some persons who receive vaccines will have an adverse reaction, and some will not be protected. In developing vaccines, the challenge is to minimize the likelihood of adverse effect while maximizing effectiveness. Some people have medical conditions that increase the risk for adverse effect, and therefore they should not receive vaccines. Recognizing this fact, all state vaccination laws provide for exemptions for persons with contraindicating conditions.

The religious beliefs of some people are in opposition to vaccination, and other people oppose vaccination on other grounds, including philosophic. In addition, some persons are not opposed to all vaccines but oppose the concept of mandatory vaccination or mandates for specific vaccines. In the latter case, they may believe they (or their children) are not at risk for a particular disease or that, if contracted, the disease is not severe. If the disease in question is uncommon (as is the case in the United States today for most vaccine-preventable diseases), they might not be willing to undertake any level of risk of adverse effect.

Forty-eight states allow religious exemptions (all but Mississippi and West Virginia), and 15 (California, Colorado, Idaho, Louisiana, Maine, Michigan, Minnesota, New Mexico, North Dakota, Ohio, Oklahoma, Utah, Vermont, Washington, and Wisconsin) permit philosophic exemptions[29] (RH Snyder, National Immunization Program [NIP], CDC, personal communication). The criteria for allowing these exemptions vary greatly. Some states require member-

ship in a recognized religion,[e] whereas others merely require an affirmation of religious (or philosophic) opposition. Nationwide, fewer than 1% of school entrants have medical, religious, or philosophic exemptions to mandatory vaccination. Seven states had more than 1% with exemptions in the 1997–1998 school year (*Colorado, Michigan*, Oregon, South Dakota, *Utah, Washington*, and West Virginia [those with philosophic exemptions are italicized]). Michigan had the highest level of exemption at 2.3% (RH Snyder, NIP, CDC, personal communication.). However, in some communities, the levels of exemptors may be as high as 5%. In 1995, 84% of California schools had fewer than 1% of students with exemptions, but 4% of schools had 5% or more with exemptions (NA Smith, Immunization Program, California Department of Public Health, personal communication).

Thirteen outbreaks of measles were identified during 1985–1994 in religious groups opposing vaccination. These outbreaks resulted in more than 1200 cases and 9 deaths. Outbreaks of polio (in the 1970s), pertussis, and rubella have been documented among Amish groups.[37] Salmon et al.[38] found that persons with religious or philosophic exemptions were 35 times more likely to contract measles than were vaccinated persons during 1985–1992. They also found that persons living in communities with high concentrations of exemptors were themselves at increased risk for measles because of increased risk for exposure.

Rota et al.[39] studied the processes required to obtain religious and philosophic exemptions to school vaccination laws and found an inverse correlation between the complexity of the exemption process and the proportion of exemptions filed. None of 19 states with the highest level of complexity in gaining exemptions had more than 1% of students exempted compared with 5 of 15 states with the simplest procedure. In these latter states, less effort was required to claim a nonmedical exemption than to fulfill the vaccination requirement.

Is There a Constitutional Right to a Religious Exemption from Mandatory Vaccination?

Challenges to mandatory vaccination laws based on religion or philosophic belief have led various courts to hold that no constitutional right exists to either religious or philosophic exemptions.

First Amendment[f] *free exercise clause*

Freedom to believe in a religion is absolute under the First Amendment. However, freedom to act in accordance with one's religious beliefs "remains subject to regulation for the protection of society."[40] The U.S. Supreme Court in the 1963 case of *Sherbert v. Verner*[41] established a balancing test for determining whether a regulation violated a person's First Amendment right to free exercise of religion. The test, which prevailed until 1990, required the government to justify any substantial burden on religiously motivated conduct by a compelling

government interest and by means narrowly tailored to achieve that interest (374 U.S. at 406–8, 83 S.Ct. at 1795–6).

Notwithstanding the state's power as *parens patriae*, instances occur in which a parent's claim of religious freedom under the Free Exercise Clause will prevail, as in *Wisconsin v. Yoder.*[42] *Yoder* involved a challenge by Amish parents of a Wisconsin law that required formal education of children to age 16 years. The parents asserted that formal schooling beyond the eighth grade would gravely endanger the free exercise of their religion because of their belief that the values taught in higher education, including the exposure to worldly influences, are in marked variance with Amish values and the Amish way of life. While acknowledging the state's interest in universal education, the U.S. Supreme Court, in applying the *Sherbert* compelling interest test, rejected Wisconsin's argument of a compelling state interest in requiring formal education of the Amish beyond eighth grade given the strong religious interference of such a requirement and the fact that the Amish provided adequate alternative informal vocational education. The Court in *Yoder* articulated its application of the compelling interest test as follows. "[W]here fundamental claims of religious freedom are at stake," the Court will not accept a state's "sweeping claim" that its interest in compulsory education is compelling; "despite its admitted validity in the generality of cases, we must searchingly examine the interests that the State seeks to promote . . . and the impediment to those objectives that would flow from recognizing the claimed Amish exemption" (406 U.S. at 221, 92 S.Ct. at 1536).

Little recent case law directly addresses the existence of a First Amendment free exercise right to a religious exemption from mandatory vaccination because 48 states have provided by statute for religious exemptions to school vaccination laws.[29] However, dicta in both *Sherbert*[43] and *Yoder*[44] referring to the *Jacobson* and *Prince* decisions clearly indicate that on both *parens patriae* and police power grounds the U.S. Supreme Court sees a compelling state interest in mandating vaccination of children because of the health threat to the community and to the children themselves. With little practical alternative to vaccination to avoid or be a disease risk (e.g., inability to avoid contact with other persons, except for those totally isolated from society), mandatory vaccination of all school children should also meet the "narrowly tailored" criterion of *Sherbert*.

In addition, in a case that predates the *Yoder* decision and enactment of a statutory religious exemption by Arkansas, the Arkansas Supreme Court in *Wright v. DeWitt School District*[45] held that no First Amendment right existed to a religious exemption given the state's compelling interest in mandating vaccination under its police power to protect the public health.[g] (238 Ark. at 913, 385 S.W.2d at 648). Significantly, the U.S. Supreme Court in *Yoder* referenced the *Wright* decision in dicta regarding cases in which the health of the child or public health are at issue, with the implication that a vaccination mandate providing no religious exemption would meet the compelling state interest test (406 U.S. at 230, 92 S.Ct. at 1540–1).

Whether a vaccination law that does not provide for religious exemptions would meet the compelling state interest test is essentially moot now because of a U.S. Supreme Court ruling that significantly lowers the bar for states to prevail. In its 1990 decision in *Employment Div., Dept. of Human Resources of Oregon v. Smith,*[46] the Supreme Court rejected the compelling interest test and established a new standard that holds that "the right of free exercise does not relieve an individual of the obligation to comply with a 'valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes)' " (494 U.S. at 879, 110 S.Ct. at 1600 [quoting *United States v. Lee*, 455 U.S. 252, 263, n. 3, 102 S.Ct. 1051, 1058, n. 3 (1982)]).

Congress attempted to legislatively override the ruling in *Smith* by enacting the Religious Freedom Restoration Act of 1993 (RFRA), which reestablished the compelling interest test as the standard for considering the constitutionality of free exercise claims.[47] However, the U.S. Supreme Court in *City of Boerne v. Flores*[48] struck down RFRA, holding that Congress had exceeded its constitutional authority in implementing the statute (521 U.S. at 510–37, 117 S.Ct. at 2160–72). Thus, the *Smith* standard is the current law. Whether judged under the neutral law of general applicability test of *Smith* or the compelling interest test of *Sherbert*, it is reasonable to conclude that there is no First Amendment free exercise right to an exemption from mandatory vaccination requirements.

Is a Statutory Religious Exemption Constitutional?

With no First Amendment free exercise right to a religious exemption, the next question is whether the states have the discretion to allow such exemptions by statute. The court decisions are mixed. The Establishment Clause[h] of the First Amendment establishes the constitutional limits within which a state may accommodate a religious exemption to a law of general application, including whether such an exemption is allowed and how inclusively the exemption must be defined. As noted above, 48 states have provided by statute for religious exemptions to school vaccination laws.[29]

In *Brown v. Stone,*[49] the Mississippi Supreme Court struck down the religious exemption that appeared in the Mississippi school vaccination statute, holding that the statutory religious exemption violated the Equal Protection Clause of the Fourteenth Amendment because it would "require the great body of school children to be vaccinated and at the same time expose them to the hazard of associating in school with children exempted under the religious exemption who had not been immunized" (378 So.2d at 223). Thus, the *Jacobson* argument comes full circle. The fact that no vaccine confers immunity on all vaccinees illustrates the point that even persons who comply with vaccination statutes can be placed at increased risk by exposure to individuals never vaccinated because of exemptions.

First amendment—establishment clause

Most challenges to religious-based vaccination exemptions have been decided by the courts on establishment grounds and concern the inclusiveness of such exemptions rather than their existence. The U.S. Supreme Court in *Lemon v. Kurtzman,*[50] a case involving state supplementation of parochial school salaries, defined a three-pronged test for determining whether a state religious accommodation complies with the Establishment Clause: "First, the statute must have a secular legislative purpose; second, its principal or primary effect must be one that neither advances nor inhibits religion; finally, the statute must not foster 'an excessive government entanglement with religion' " (403 U.S. at 612–3, 91 S.Ct. at 2111 [citation omitted] [quoting *Walz v. Tax Commission*, 397 U.S. 664, 674, 90 S.Ct. 1409, 1414 (1970)]).

Scope of statutory exemptions—sincerely held religious belief

In *Sherr v. Northport-East Northport Union Free School District,*[51] the plaintiffs had been denied an exemption under the state's religious exemption statute by the school district because, although they claimed religious opposition to vaccination, they were not "bona fide members of a recognized religious organization" whose teachings oppose vaccination, as required by New York law (672 F.Supp. at 84 [quoting subsection 9 of N.Y. Pub. Health L. § 2164]). The U.S. District Court for the Eastern District of New York found that New York's limitation of the religious exemption violated both the Establishment and Free Exercise clauses of the First Amendment.[i]

The court found that this limitation violated the Establishment Clause by running afoul of at least the last two prongs of the *Lemon* test[j]: (*1*) by inhibiting the religious practices of individuals who oppose vaccination of their children on religious grounds but are not members of a religious organization recognized by the state and (*2*) by restricting the exemption to "recognized religious organizations" requires that the government involve itself in religious matters to an inordinate degree through such government approval (672 F.Supp. at 89–90). In addition, the court held that the limiting language violated the Free Exercise Clause because no compelling societal interest existed to justify the burden placed on the free religious exercise of "certain individuals while other persons remain free to avoid subjecting their children to a religiously objectionable medical technique because they may belong to a particular religious organization to which the state has given a stamp of approval" (672 F.Supp. at 90–1). There "surely exist less restrictive alternative means of achieving the state's aims than the blatantly discriminatory restriction . . . the state has devised" (672 F.Supp. at 91). Striking down New York's limitation, the court found that "sincerely held religious beliefs" in opposition to vaccination, whether or not as part of a recognized religion, should suffice (672 F.Supp. at 98).

Do Statutory Religious Exemptions Encompass Philosophic Opposition?

Strength of convictions aside, defining "religious" belief can be difficult, and understanding its implications for philosophic exemptions that a state may or may not wish to voluntarily confer is a challenge. As the Supreme Court noted in *Yoder*: "to have the protection of the Religion Clauses, the claims must be rooted in religious belief" (406 U.S. at 215, 92 S.Ct. at 1533). Decisions by the U.S. Supreme Court in two conscientious objector cases indicate that a bright line may not always exist between the religious and the philosophic and that at least some amount of philosophic opposition to vaccination may rise to the level of being religious and therefore incorporated into a voluntarily conferred religious exemption, regardless of whether the state explicitly provides for a philosophic exemption.[k] In *United States v. Seeger*[52] and *Welsh v. United States,*[53] the Court interpreted "religious," as it appeared in a federal statutory religious-based conscientious objector exemption from military conscription, very expansively to extend beyond traditional religious beliefs. *Seeger* defined the test as "[a] sincere and meaningful belief which occupies in the life of its possessor a place parallel to that filled by the God of those admittedly qualifying for the exemption" (380 U.S. at 176, 85 S.Ct. at 859). The Court elaborated in *Welsh*: "to be 'religious' . . . this opposition . . . [must] stem from . . . moral, ethical, or religious beliefs about what is right and wrong and that these beliefs be held with the strength of traditional religious convictions" (398 U.S. at 340, 90 S.Ct. at 1796).

However, the *Welsh Court* clarified that "moral, ethical, or religious principles" do not incorporate "considerations of policy, pragmatism, or expediency" (398 U.S. at 342–3, 90 S.Ct. at 1798). *Yoder* provides further illumination: "A way of life, however virtuous and admirable, may not be interposed as a barrier to reasonable state regulation of education if it is based on purely secular considerations. . . . [T]he very concept of ordered liberty precludes allowing every person to make his own standards on matters of conduct in which the society as a whole has important interests. Thus, if the Amish asserted their claims because of their subjective evaluation and rejection of the contemporary secular values accepted by the majority, much as Thoreau rejected the social values of his time and isolated himself at Walden Pond, their claims would not rest on a religious basis. Thoreau's choice was philosophical and personal rather than religious, and such belief does not rise to the demands of the Religion Clauses" (406 U.S. at 215–6, 92 S.Ct. at 1533). Thus, the court in *Mason v. General Brown Central School District*[54] rejected fear of the possible side effects from vaccination, although based on strong convictions, as rising to the level of religious beliefs because of evidence that the plaintiff's beliefs were "simply an embodiment of secular chiropractic ethics" (851 F.2d at 51–2). *Mason*, and similar decisions, indicate that the expansive religious interpretation of *Seeger* and *Welsh* should not be read too broadly.

Impact of Evolving Privacy Rights

Finally, the general concept of a liberty interest in bodily integrity was first articulated by then-Judge, later Justice, Cardozo in *Schloendorff v. Society of New York Hospital*: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body" regarding medical needs.[55] Recognition by the courts in recent years of a liberty right, or right to privacy, in medical decision making emanating from the due process clause of the Fourteenth Amendment and noted most prominently by the U.S. Supreme Court in its 1973 decision *Roe v. Wade*[56] might be used as the basis of a claimed privacy right by a college student subject to mandatory vaccination. However, the Court in *Roe,* referencing *Jacobson,* noted that the medical privacy right is not unlimited and must be balanced against important state interests in regulation (410 U.S. at 154, 193 S.Ct. at 727). More recently, in dicta in the 1990 "right to die" case of *Cruzan v. Director, Missouri Dept. of Health,*[57] the U.S. Supreme Court again acknowledged the viability of the *Jacobson* holding, leading to the conclusion that, as long as the public health need for widespread vaccination exists, the courts will not recognize a privacy right to refuse state-mandated vaccination and will uphold the police power of states to mandate vaccination.

PRACTICE CONSIDERATIONS AND EMERGING ISSUES

As new vaccines have been introduced and recommended for universal use in infants and children, states have responded by expanding the scope of their vaccination laws. Vaccination laws were first enacted to control epidemic diseases. Now they are also used to increase coverage with vaccines that are deemed important to protect the public's health even in the absence of epidemics. This practice is increasingly becoming subject to challenge, particularly with vaccines such as the varicella vaccine. Varicella is typically a mild disease in children, although nationwide it accounts for more than 50 deaths each year. Some parents have argued that no compelling state interest exists in preventing this disease. With hepatitis B vaccine, the argument has been that most hepatitis B occurs in adults whose sexual or drug-using behavior puts them at risk and that school children should not be forced to be vaccinated against a disease that often results from voluntary behavior of adults.

Publicity about adverse events alleged to be caused by vaccine fuels controversy about the wisdom or necessity of requiring vaccination, particularly in the absence of visible threat from disease. In the 1970s, concern about the possibility of pertussis vaccine causing sudden infant death syndrome or infantile spasms led to debate about pertussis vaccination requirements, even though studies showed that the vaccine caused neither event.[58] More recently, concern about the possibility that measles-mumps-rubella vaccine (MMR) might cause autism

has led to congressional hearings and challenges to requirements for this vaccine.[59] Persons opposed to vaccination have extensively used the Internet to communicate their beliefs.

Of course, the appearance of new adverse events caused by vaccines further feeds the controversy. The occurrence of intestinal intussusception after administration of the recently licensed rotavirus vaccine led to withdrawal of the vaccine and lent some support to the arguments of those opposed to vaccination.[60]

CONCLUSION

School vaccination requirements have been a key factor in the prevention and control of vaccine-preventable diseases in the United States. Their constitutional basis rests in the police power of the state as well as in the *parens patriae* doctrine. No constitutional right exists to either a religious or philosophic exemption to these requirements, although most states allow religious exemptions and several allow philosophic exemptions. The courts have generally upheld these exemptions. Most litigation regarding exemptions has focused on the scope of the exemption, with courts holding that religious exemptions may not be limited to members of organized religions but rather must allow all who have sincerely held religious beliefs in opposition to vaccination to qualify. "Religious" may be defined broadly enough to incorporate some amount of philosophic opposition but should not be interpreted to bring purely secular-based "philosophic" opposition to vaccination within the meaning of religion.

With the increasing numbers of vaccines being introduced and the generally low level of visible threat from disease, continued challenges to school vaccination requirements are expected. School vaccination laws continue to play a central role in avoiding "the tragedy of the commons" by preventing disease through high vaccination coverage. These laws can be expected to be upheld by the courts as long as the balance of protecting the public health is achieved by mandating such requirements.

Notes

[a] Compulsory vaccination is not beyond the police power without arbitrariness or extreme injustice under particular facts. (See note b regarding medical-based exemption). In *Jacobson*, the Court—in addition to holding that providing for compulsory vaccination is within the police power of a state—also held that such authority may be delegated to a local body (197 U.S. at 25, 25 S.Ct. at 361).

[b] In dicta, the Court in *Jacobson* indicated, however, that there would be a liberty right to an exemption based on known medical contraindication "to protect the health and life of the individual concerned" (197 U.S. at 39, 25 S.Ct. at 366). (Dicta is discussion in a court decision that addresses an issue outside the direct facts presented by the case and therefore outside the court's holding and thus is of no precedential value in directing future court decisions.)

[c] See also *Brown v. Stone* (378 So. 2d 218, 222–3) (Miss. 1979), *cert. denied* 449 U.S. 887 (1980) for discussion regarding the logical nexus between mandatory vaccination and school attendance: "overriding and compelling public interest . . . [in] exclusion of a child until such immunization has been effected, not only as a protection of that child but as a protection of the large number of other children comprising the school community and with whom he will be daily in close contact in the school room."

[d] See also *In re: Christine M.*, 157 Misc.2d 4, 595 N.Y.S.2d 606 (N.Y. Fam. Ct. 1992) in which the court, citing *Prince*, held that a father's knowing failure to have his child vaccinated against measles in the midst of a measles outbreak, and not qualifying for a statutory religious exemption, caused the child to be a "neglected child" under state law. However, the court declined to order vaccination because the measles outbreak had ended by then and the child was not yet old enough to be subject to the school attendance law.

[e] But see discussion regarding holding in *Sherr* striking down state religious exemption requirement that an individual be a "bona fide member of a recognized religious organization."

[f] The First Amendment to the U.S. Constitution states in pertinent part, "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof. . . ." The Free Exercise and Establishment Clauses have been held applicable to the States through the Due Process Clause of the Fourteenth Amendment.[40]

[g] See also *Cude v. State*, 237 Ark. 927, 377 S.W.2d 816 (Ark. 1964) (upholding ruling of neglect and appointment of temporary guardian to consent to vaccination of children despite parents' good faith religious beliefs in opposition).

[h] See note f, above.

[i] See also *Davis v. State*, 294 Md. 379, 451 A.2d 107 (Md. 1982), which held that limiting religious exemption to children whose parents were "members" (as statute provided) or "adherents" (as health department regulation further attempted to narrow the qualification) of a "recognized church or religious denomination" opposing vaccination violated the Establishment Clause. On the basis of rules of statutory construction in Maryland, the court severed the offending religious exemption from the statute and upheld the conviction of Davis under the remaining statute that compelled vaccination (294 Md. at 382–5, 451 A.2d at 114–5). Rules of statutory construction vary so that in the *Sherr* case the court struck down the limiting "bona fide members of a recognized religious organization" language but otherwise upheld the religious exemption. In addition, the court enjoined enforcement of the "bona fide" language as to one of the two sets of plaintiffs, who otherwise qualified, and further enjoined the state from enforcing the offending language in the future (672 F.Supp. at 97–9).

[j] The court in *Sherr*, having noted the constitutional infirmity of the "bona fide" limitation under the other two prongs of *Lemon*, did not resolve whether the "bona fide" portion of the religious exemption possessed a secular purpose as required under the first prong. However, in dicta, the court noted that the legislature may have had a number of secular purposes for adopting such language, including "as a guard against claims of exemption on the basis of personal moral scruples or unsupported fear of vaccinations, as a means of allowing certain exemptions without risking lessened effectiveness of the state's inoculation program due to the granting of a large number of exemptions, or perhaps because of the difficulties inherent in devising a legally workable definition of religion" (672 F.Supp. at 89).

[k] Fifteen states provide a separate philosophic exemption to school attendance vacci-

nation laws, in addition to religious exemptions[29] (RH Snyder, NIP, CDC, personal communication).

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