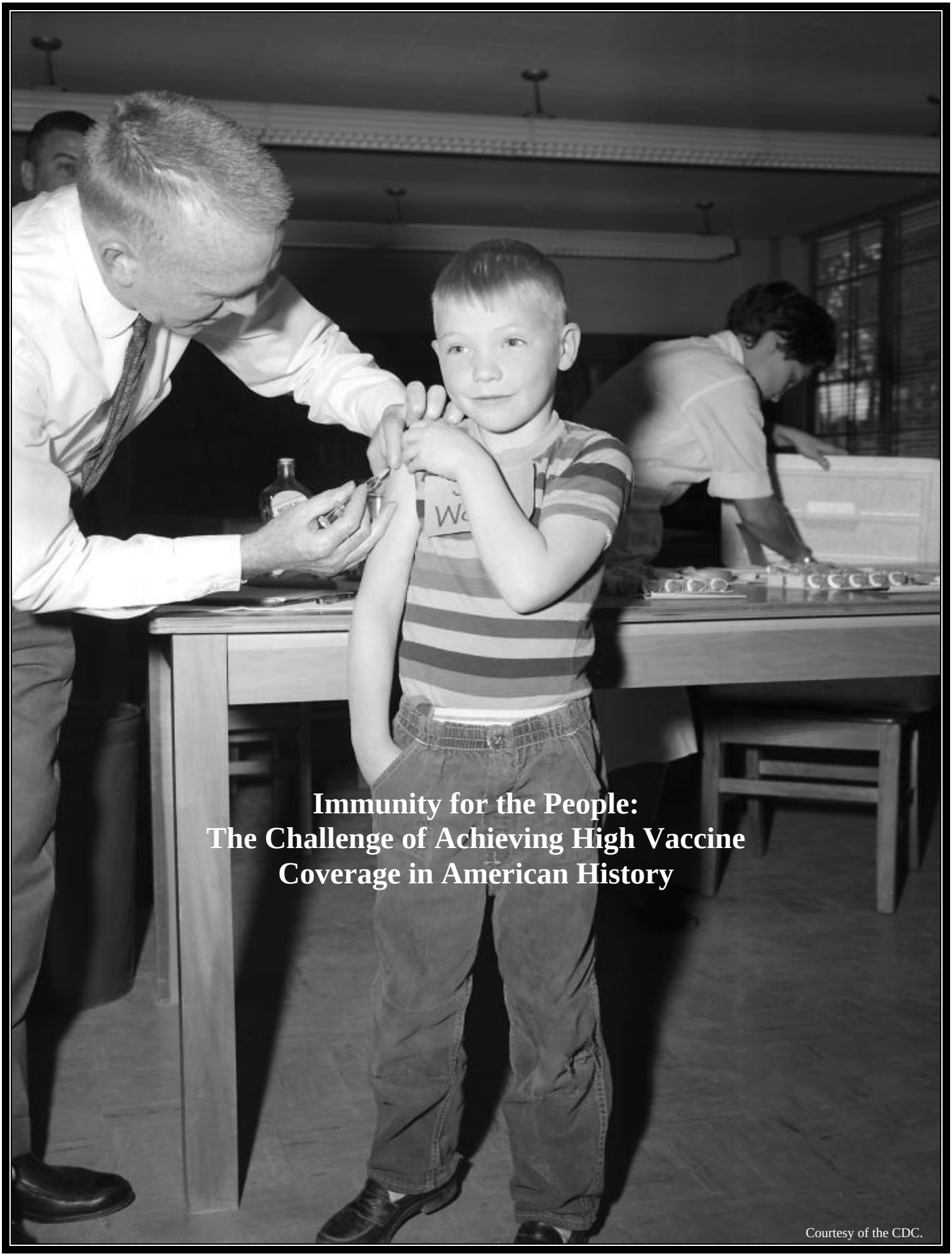
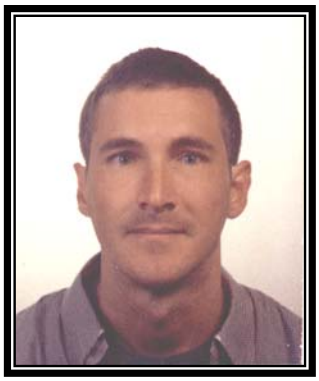


Immunity for the People: The Challenge of Achieving High Vaccine Coverage in American History

Courtesy of the CDC.



Dr. James Colgrove

Hello. On behalf of *Public Health Reports* and the Association of Schools of Public Health, I'd like to welcome you to *Vaccination.* The following narrative, *Immunity for the People: The Challenge of Achieving High Vaccine Coverage in American History,* was written by Dr. James Colgrove, a historian of public health and medicine. Dr. Colgrove received his BA from the University of California, Davis, his MA from San Francisco State University, his MPH from Columbia University, and his PhD in sociomedical sciences from Columbia University. Currently, he is an Associate Research Scientist in the Center for the History and Ethics of Public Health and the Department of Sociomedical Sciences at the Mailman School of Public Health at Columbia University. His research focuses on the historical evolution of the relationship between the individual and the community; the ways that both law and popular culture have framed notions of rights, responsibilities, and citizenship; and the mechanisms through which the state and the institutions of civil society have shaped the choices and actions of individuals.

Dr. Colgrove is the author of *State of Immunity: The Politics of Vaccination in Twentieth-Century America*, published by the University of California Press. This book analyzes the ethical, political and legal questions that have accompanied the use of vaccines over the past century. We thank Dr. Colgrove for donating his time and expertise in order to contribute the script for *Vaccination*, as well as all of those involved with the production of the CD. Thank you.

For the next hour, you will hear a narration of *Vaccination*, which will be divided into four segments discussing vaccines from their first use in the United States through their proliferation and widespread public acceptance, concluding with reflections on their current status and future direction. We begin with Dr. Colgrove's introduction and first segment, *Vaccination in the Nineteenth Century: Keeping the Pox at Bay*:

Introduction

On June 8th, 2006 the Food and Drug Administration licensed Merck's vaccine Gardasil, a product shown in trials to prevent infection with human papillomavirus known as HPV. HPV is the most common sexually transmitted disease and a leading cause of cervical cancer.[1] Although the vaccine was heralded as a major breakthrough with the potential for significant public health

benefits, it also raised difficult policy issues. Its expected price of approximately $360 for a full course of three injections called into question whether it would be accessible to the uninsured. It was recommended to be given to girls at eleven to twelve years of age, a time when many youth have no regular contact with a primary care provider. Some religious conservatives voiced opposition to the vaccine, arguing that offering protection against a sexually transmitted disease would undermine prevention messages that stress abstinence.[2]

The licensing of the HPV vaccine highlights both the successes and the challenges of the United States immunization system. This system is widely regarded as one of the most important public health achievements of the past one hundred years. At the same time, however, critical questions have surrounded vaccination use. How can the benefits of immunity be distributed equitably to everyone, especially people of low socioeconomic status who experience disparities in medical care access and outcomes? Who should bear the costs of vaccination? How should responsibility for promotion and delivery be divided among federal, state, and local health agencies, medical professionals, charitable organizations, and insurers? How should resistance or opposition to vaccines be dealt with?

The urgency of these questions has heightened over the past two decades as a consequence of the success of vaccine research and development. For instance, the number of recommended pediatric vaccines doubled, from seven to fourteen, between 1990 and 2006. Although coverage rates for most recommended vaccines are high, there is wide agreement that the system remains vulnerable. An analysis by three staff members of the Institute of Medicine, a nonprofit research organization that advises the government on health issues, observed: "The United States lacks a comprehensive scientific and policy approach to explore fully the ramifications of the increasing number of vaccines that will soon be available."[3]

At this critical juncture, with increasingly expensive new vaccines either licensed or set to join an already crowded schedule, it is valuable to understand the historic evolution of immunization in the United States. This chronicle describes the successive introduction of new vaccines from the late eighteenth century to the present. It also addresses the efforts of key stakeholders to achieve high levels of use, with a particular focus on two broad policy areas that have been central to vaccination programs and have also been repeated flashpoints for controversy.

First, what are the most effective and ethical ways of achieving high levels of acceptance among people who are indifferent, wary, or antagonistic toward vaccination? It is a widely accepted tenet of public health practice that persuasive approaches are preferable to coercive ones whenever possible. But because the failure to immunize oneself or one's children can contribute to the spread of infectious diseases, the United States has invoked compulsory measures, primarily laws requiring immunization before children may enter school. Whether such laws are appropriate and under what circumstances exemptions should be allowed from them has been the subject of extensive debate and litigation.

Second, what is the proper scope of government activity in paying for and delivering vaccines? The United States has traditionally relied on market mechanisms rather than public sector support for health care, with limited categorical programs providing some services for the poor. Yet vaccination has always fit awkwardly within this perspective because, unlike other health interventions that benefit the individual, it also carries a societal benefit through the herd immunity it creates. As a result, some observers have compared immunization to public health responsibilities like providing clean water or sewage disposal. These are public services that are not left to the free market.[4]

This review will show that the current challenges facing the country's immunization system have deep roots within American politics and society. Further, this history will allow us to make more informed decisions about how to achieve immunity for the people through an increasingly sophisticated and extensive vaccine regimen.

Vaccination in the Nineteenth Century: Keeping the Pox at Bay

Smallpox was one of history's most highly feared diseases because of its gruesome symptoms, high fatality rate, and rapid spread. Its symptoms began with chills, ache and fever, then progressed ominously to nausea, vomiting and difficulty breathing. About a week after infection, bright red pustules developed on the victim's face and hands, eventually spreading to cover the entire body. The pustules would dry, become intensely itchy, scab over, and fall off. About one out of four victims died; those who survived were usually scarred for life and often blinded. Children, who were generally more vulnerable to infectious disease, died from the condition more often than did adults, but it struck young and old alike and without regard to social class.

The British physician, Edward Jenner, observed that milkmaids infected with the cattle disease cowpox rarely contracted smallpox. This discovery introduced vaccination to the western world. Infecting humans with cowpox, which produced only mild symptoms, provided protection against smallpox. In 1798, Jenner published his findings in a famous treatise. Within a few years, vaccination was introduced in America. Its success at protecting communities from a feared killer led to its widespread adoption.

Vaccination was an improvement over inoculation. Inoculation was an older method of inducing immunity in which a small amount of smallpox pustular material was introduced into the bloodstream. This technique could accidentally bring on a full-blown case of the disease, and even trigger an epidemic. The new technique joined other long-standing control measures such as quarantine, removal of sick persons to a local "pest house," or infectious disease hospital, and disinfection of living quarters with sulphur and steam.

An outbreak of smallpox in a town provoked a severe crisis, disrupting virtually all civic and commercial activity. As a result, many localities not only provided vaccination to all residents, but compelled it by law in order to assure the common welfare. Massachusetts, an early leader in the development of public health activities, enacted the country's first mandatory vaccination law in 1809. In subsequent decades, many other cities and states followed suit. Most of these laws required vaccination for people of all ages. Some were only in effect when an outbreak of the disease occurred nearby. As public education became common around the middle of the century, laws specifically aimed at children attending school became widespread.[5]

The severity of the threat of smallpox led to one of the few instances where federal involvement in health occurred in the early republic. In 1813, the U.S. Congress passed "An Act to Encourage Vaccination," which, among other provisions, appointed an agent to furnish certified vaccine matter to anyone who requested it. The act also required the postal service to ship the vaccine free of charge. Nine years later, however, it was repealed after an incident in which smallpox rather than cowpox was mistakenly shipped, resulting in several deaths.[6]

Although securing the vaccination of all citizens was clearly recognized as a public duty, it did become a focal point for debates about the authority of local governments to levy taxes. In 1820, the residents of North Hero, Vermont, voted to institute a tax to pay for vaccination of all the town's residents after cases of smallpox were diagnosed in the area. Dan Hazen was present at the town meeting where the tax was approved but did not vote for it and refused to pay it. In

response, the town constable seized Hazen's cow and sold it to raise the payment. Hazen sued, leading to a ten-year legal battle that ended when the state Supreme Court upheld the confiscation.[7]

By far the most controversial aspect of vaccination programs in the nineteenth century was not how they should be paid for—Dan Hazen's challenge notwithstanding, there was general agreement that providing it free with public funds was appropriate. But whether it should be forced upon those who were reluctant to undergo it was another matter. As vaccination led to the decline of smallpox over the course of the century, success bred complacency. Many people who had never experienced an epidemic became reluctant to undergo a procedure they viewed as unpleasant and of questionable necessity. And, the procedure was not without its own risks. The arm was scraped multiple times with a lancet, usually made of ivory, until the skin was broken. The vaccine matter—lymph drawn from a cow infected with cowpox, mixed with glycerin—was then applied to the wound. The procedure was uncomfortable and caused the arm to remain sore for several days, often preventing people from working. It left a small scar. And, with little oversight of medical practice, many physicians failed to exercise proper care in performing vaccination; antiseptic procedures did not become the norm until late in the century. Instances of vaccination sores becoming contaminated, leading to serious illness and even death, were not uncommon. So, reluctance to undergo vaccination was not entirely unreasonable.

Furthermore, many people believed that smallpox was not a contagion but was actually caused by miasmas or filth. They felt that clean living rather than vaccination was the best preventive. Others simply gambled that they would escape harm when an epidemic struck. In the 1880s, New York City health commissioner, Cyrus Edson, viewed with dismay his fellow citizens' reluctance to be vaccinated. He declared, "It is easy to be bold against an absent danger, to despise the antidote when one has no experience with the bane!"[8]

Numerous anti-vaccination societies were established in the second half of the century. Members distributed pamphlets and broadsides, lobbied legislatures for the repeal of compulsory laws, filed lawsuits, and sought to discourage the use of vaccination. Their rhetoric rested on two linked claims: that vaccination was a dangerous, unnecessary procedure and that to compel it through law was a violation of the country's foundational belief in individual liberty.[9]

Opinions on whether compulsory vaccination was effective or ethical varied widely among public health officials and doctors. The secretary to the state board of health of

Connecticut declined to make vaccination mandatory. He explained the decision this way: "The people of this country are too thoroughly imbued with a sense of personal independence to submit patiently to personal compulsion. The attempt would excite hostility to vaccination that does not exist at present, and would hinder rather than promote the cause of vaccination."[10] In Louisiana, which also abstained from compulsion, a health official said that such a law "would probably meet the passive resistance of one-third of our people, the violent opposition of another third, the unwilling compliance of most of the remaining third, and cheerful compliance by the small fraction comprising the intelligent and law-abiding class."[11] Very different, however, was the view of Kentucky's health commissioner, who declared that compulsory vaccination "has never yet failed to bring an outbreak under quick control."[12]

Such conflicting views about compulsion among medical professionals, lawmakers, and the public resulted in dozens of challenges to vaccination laws in state courts around the country. Results varied. Most rulings upheld the laws, especially those requiring the procedure as a condition of school entry, but others limited the scope of compulsion. An Illinois court, for example, held that vaccination for the general population could be mandated only after an outbreak of smallpox had occurred. The question of whether compulsory vaccination contravened the U.S. Constitution finally reached the Supreme Court in 1905. In the case of Jacobson v. Massachusetts, a Lutheran minister from Cambridge challenged that state's law. In a seven-two ruling, the justices declared that compulsory vaccination was a legitimate exercise of state governments' police powers to guard the health, welfare, safety, and morals of its citizens. If duly elected legislatures had determined that smallpox was a threat and that vaccination was an effective way to prevent it, then laws requiring all citizens to comply were not unreasonable. The decision stated, "Society based on the rule that each one is a law unto himself would soon be confronted with disorder and anarchy."[13]

During the nineteenth century, the contours of vaccination policy became clear, as medical professionals, lawmakers, and the public all sought to define the rights and responsibilities of government in guarding the communal well-being and the scope of individual autonomy.

That concludes our first segment. Now we will continue with *Immunization in the Early Twentieth Century: "Selling" Good Health*, which discusses vaccination in the wake of the Bacteriological Revolution.

Immunization in the Early Twentieth Century: "Selling" Good Health

A 1914 New York Times headline asked "Will Vaccine Be the Greatest Cure in Medical Science?"[14] The article reflected the excitement and uncertainty in the wake of the Bacteriological Revolution of the late nineteenth century. It also mirrored the expansion of the pharmaceutical industry in the early twentieth century, when many new products were developed and the modern vaccine era began.

The identification of many disease-causing microbes sparked attempts to create vaccines against various contagions, including tuberculosis, cholera, plague, and typhoid. Most of these vaccines remained experimental and were never widely deployed; their efficacy remained a matter of dispute, and most of the diseases they protected against were no longer significant threats in this country. Plague, for example, was a rare occurrence, but when it struck San Francisco and Honolulu at the turn of the century, vaccine was rushed to the scene.[15,16] The typhoid vaccine proved valuable in the military, where it reduced troop mortality. Among civilians however, advances in sanitation made its use unnecessary except in rural areas with poor sewage disposal. Nevertheless, the idea that it was possible to stimulate artificial immunity to many diseases, not just smallpox, gained currency.

The most successful of the new products was a preparation against diphtheria, called toxin-antitoxin, which became the second immunizing procedure to become commonplace. The vaccine was developed in the Bureau of Laboratories of the New York City Department of Health. The Bureau's director, William Hallock Park, conducted a pioneering series of trials beginning in 1913, first on children in the city's orphanages and institutions, and then in the public school system. Park and his colleagues published favorable results in a series of important medical journal articles in the early 1920s. The increasing awareness among physicians set the stage for broad campaigns to bring this breakthrough to children across the country.[17]

The first challenge was convincing the public that diphtheria immunization was safe, effective, and worth the time and effort it took to bring children in for a series of three shots two

weeks apart. Efforts to stimulate interest in the new procedure were needed, in part, because the incidence of diphtheria had dwindled considerably – as had most of the other contagions that had been feared killers in the nineteenth century. By the 1920s, heart disease and cancer had already surpassed infectious diseases as the country's leading causes of death. Immunization was no longer a crisis-control measure designed to forestall an imminent threat to the common welfare. Not only was there less urgency that might spur the public to action; there was a less compelling argument that the government was responsible for providing immunization as a public safety function. One policy aimed at achieving high levels of vaccine coverage was to require immunization by law. As early as 1921, some public health and medical experts suggested that immunization against diphtheria be made compulsory for school entry.[18] Such proposals continued to be advanced over the following two decades as use of toxin-antitoxin gained popularity.[19] But only a few states took such a step. Most public health officials were wary of triggering a political and legal backlash against the new vaccine similar to that which had developed against the smallpox vaccine. In addition, diphtheria immunization was recommended for the first years of life, and many doctors feared that a requirement tied to school entry would lead parents to postpone the procedure until it was too late.

To sell the importance of immunizing children against diphtheria, public health officials turned instead to the new techniques of marketing and persuasion that were becoming widespread around that time to sell consumer goods such as cars, appliances, and cigarettes. They used advertisements in newspapers and mass-circulation magazines, billboards, posters, publicity stunts, and short films.[20] Businesses and charitable organizations also played key roles in popularizing diphtheria immunization and making it available to the public. The Metropolitan Life Insurance Company, for example, placed full-page ads in popular magazines such as the *Saturday Evening Post* heralding the new preventive. (See http://www.adclassix.com/a3/29metlifeinsurance.htm.) Its staff of visiting nurses advised policy-holders to take advantage of this new development in health.[21] Charities like the Milbank Memorial Fund and the American Child Health Association provided funding to set up health clinics and pay the salaries for nurses and doctors.[22]

Yet it was clear that advertising, by itself, was insufficient to move parents to action. High coverage was generally achieved only when parents had in-person contact with a physician or nurse and when the product was made available in a free clinic.[23] Although the price of each

shot varied according to region and individual practitioner, it could cost as much as $5, which would be about $50 in 2006.

Public health activities, like general government functions, were carried out almost exclusively at the local level. To a lesser extent, state health authorities also participated. While some agencies, notably in northeastern cities such as Boston, New York, and Providence, had active public health programs, funding in most localities was paltry. Even basic functions such as the registration of births and death remained spotty in many parts of the U.S. There was no federal department of health, and the U.S. Public Health Service had evolved little from its origins in port control and quarantine enforcement.

City health departments that did have sufficient resources adopted contrasting strategies for making the new preventive available. Some set up free clinics for all children regardless of the financial circumstances of the parents. Others set strict limits on access by anyone who was able to afford the services of a private physician. Some cities, including Chicago, provided free toxin-antitoxin to physicians on the agreement that they would charge only for their labor in administering it. Others sought to negotiate with their local medical practitioners to offer the shots at a discounted rate. In New York City, the health commissioner worked out a voluntary agreement with medical societies through which members would offer the full series of three shots for $6.[24]

The political climate during the 1920s was not conducive to public provision of immunization. In the aftermath of the "Red Scare" of 1919, potential incursions of communism into American society were a source of great anxiety. Libertarian and anti-government civic organizations lobbied against a range of developments they viewed as socialistic. This included bills to ban child labor and to create a federal department of education.[25] In this environment, public health professionals in local and state health departments found that efforts to provide diphtheria immunization for free were a hard sell to the tax-paying public. Efforts at public provision of immunization provoked especially sharp criticism from physicians in private practice. They accused health departments of trying to steal their patients and encroach on their professional turf.

At the same time, however, the inability of many citizens to pay for medical services emerged as a prominent political issue.[26] In 1926, the Committee on the Costs of Medical Care was formed. This committee consisted of physicians, economists and public health experts.

They studied how advances in medicine might be made accessible to all Americans. Underlying their mission was the question of whether the provision of medical services should remain subject to the rules of the marketplace or whether medical care was an entitlement. The Committee's final report, issued in 1932, called for the promotion of group practice and group payment systems, recommendations that were profoundly threatening too many physicians who saw them as socialistic schemes. In fact, the American Medical Association denounced the recommendations in an editorial in its journal.[27]

During the Depression, Franklin Roosevelt's New Deal rolled out a set of federal programs to alleviate the nation's economic distress. The notion that it was the appropriate role of the government to intervene in urgent matters of domestic policy became more accepted. The Social Security Act of 1935 included matching grants to states to support public health activities and maternal and child health programs. But, the provision of immunization remained firmly within the fee-for-service model that dominated medical care. Some forms of relief during the Depression aided immunization efforts. One example is the Works Progress Administration, which sent workers to assist with outreach efforts such as visiting the homes of poor families to urge them to seek immunization.[28] Such programs were curtailed, however when funds were cut in the early 1940s.

In spite of the financial barriers, public acceptance of diphtheria immunization grew steadily, as did vaccination against pertussis (also known as whooping cough), which became available in the 1930s. Since there was no systematic surveillance of immunization coverage levels, it is impossible to determine vaccination rates with any certainty, but special surveys provide some indications of moderate to high acceptance. In the late 1930s, for example, a survey in New York City found that about two-thirds of parents did have their children immunized against diphtheria. Parents increasingly followed the advice of pediatricians and other child-rearing experts on how best to care for children. The American Academy of Pediatrics, founded in 1930, published its first recommendations for the routine immunization of children in 1934. This guide, nicknamed the "Red Book," was subsequently updated every two years.[29] Articles by medical journalists in *Good Housekeeping* and *Reader's Digest* stimulated public demand for experimental pertussis vaccines in the 1930s and '40s. This was occurring even when scientific evidence for the vaccine was inconclusive and medical professionals were divided over its efficacy.[30]

In the first half of the twentieth century, vaccines against diphtheria and pertussis joined smallpox vaccination as commonplace and widely used preventive measures. This era may be characterized as one of limited government involvement in immunization and having partnerships between the public and private sector. There was a slow but steady increase in acceptance, accomplished through the increasingly influential mass media and the advice of medical and public health experts.

That concludes our second segment. Now we will continue with *Immunization at Mid-Century: The Ascendance of Science, the Fight Against Poverty:*

Immunization at Mid-Century:
The Ascendance of Science, the Fight Against Poverty

An opinion pollster wrote in 1959, "For the public the caduceus of medicine sits proudly at the top of the totem pole of science."[31] The unprecedented level of support and respect for the nation's scientific experts, and above all for its physicians, provides the backdrop for vaccination policy in the middle decades of the century. Medical breakthroughs elevated researchers and practitioners to the status of cultural heroes. Such breakthroughs included: the antibiotic penicillin, the anti-tuberculosis drugs streptomycin and isoniazid, and the blood product gamma globulin. The nationwide trials of Jonas Salk's polio vaccine in 1954 and 1955 both contributed to and drew upon the sense that scientific medicine was destined to banish infectious disease.

Although polio imposed a relatively small burden of morbidity and mortality, it was the subject of extraordinary public fear. Its image as a crippler of children, along with the excitement surrounding the trials, shaped events when the vaccine was licensed in April of 1955. The demand for the Salk vaccine was instantaneous and overwhelming, in contrast to the introduction of diphtheria and pertussis immunization, when interest had to be stimulated among an often wary and uncertain public. The most urgent practical choices were related to getting the most vaccine into the most arms as quickly as possible.

But confusion reigned over how this was to be accomplished. It would be impossible for the pharmaceutical companies making the vaccine to produce enough doses in time for the summer polio season. Some kind of rationing would be necessary, although how this would be carried out fairly or consistently was unclear. The Department of Health, Education and

Welfare, which had been created in 1953, became the subject of harsh public criticism for its failure to anticipate the demand for the vaccine and for its hands-off response to its distribution once it did become available. Reflecting the country's tradition of private sector initiatives, it was not the government but a charitable organization—the National Foundation for Infantile Paralysis, later known as the March of Dimes—that funded and coordinated the Salk trials. The Foundation played a leading role in distribution, having arranged bulk purchase of vaccine from the manufacturers to distribute free to states once it was licensed.

Rationing was carried out through voluntary agreements in each state among public health entities and medical associations. In New York State, for example, 80% of the vaccine was reserved for official health agencies, while 20% was made available through commercial distribution channels. The state and local medical societies pledged that private physicians would give the vaccine only to children in the priority age groups.[32] During the early period of temporary shortage, children aged five through nine were given first priority. Any additional vaccine left over went to children between the ages of one and nineteen. Priorities within this group were determined locally.

Members of the U.S. Congress went to great pains to declare that public health decision-making transcended politics. Hearings on proposed legislation to provide financial assistance to states, however, made it clear that programs for polio vaccination reflected an ideology about the proper role of government in caring for the health of its citizens.[33] As had been the case in the 1920s, opposition toward "socialized medicine" loomed large over discussions of government responsibility for providing the polio vaccine. Fear of communism, which was at a high-water mark during the Cold War, had been a key factor in the defeat of Harry Truman's plan for universal medical care in 1949. Similarly, President Dwight Eisenhower's Secretary of Health, Education and Welfare adamantly opposed suggestions to bring distribution of the vaccine under federal control.

Nevertheless, Congress did pass a bill with bipartisan support that allocated federal funds to states to provide for free immunization of people less than twenty years of age and pregnant women of all ages. Grants were awarded based on the number of children in the state and its per capita income. The act explicitly forbade use of means testing to limit eligibility of those receiving the vaccine.[34] Over the next two years Congress appropriated almost $54 million through the act.[35]

In spite of this assistance, surveys showed that rates of vaccination among the poor lagged far behind those of the middle and upper socioeconomic classes. Polio outbreaks in the late 1950s struck urban ghettoes in Chicago, Newark, Baltimore, and Providence, and rural poverty areas in Appalachia. This trend prompted heightened efforts to reach out to the poor. Doctors typically paid about $2 for a dose of the Salk vaccine and in turn offered it to their patients for about $3 to $5 per shot. Many doctors were charging more, however. In 1958, the March of Dimes and the American Medical Association worked out a plan through which doctors' organizations would sponsor "dollar clinics" where people could receive their shots for $1 each, which would be about $7 in 2006.[36]

A second polio vaccine was licensed in 1961, a live attenuated vaccine developed by Albert Sabin. This raised the visibility of vaccination further and opened a window of opportunity through which immunization proponents could argue that the federal government should play an increased role. The new presidential administration of John Kennedy was more receptive to the idea of federal involvement in health than Eisenhower had been. In 1962, Congress passed the Vaccination Assistance Act, which created a permanent home for immunization programs within the U.S. Public Health Service. The Act provided grants-in-aid for states to support delivery of the diphtheria, pertussis, tetanus, and polio vaccines. Smallpox was not included in this act because it had been virtually eliminated from the U.S.

The passage of the Vaccination Assistance Act exposed long-standing fissures between public health entities and private practitioners over whether it was appropriate for the government to intervene in the "marketplace" of medical care. Although doctors' groups, such as the American Academy of Pediatrics, provided the authoritative voice that the public trusted, their vision for how vaccines should be administered was often in conflict with that of their counterparts in public health. As an example of the ways that the issue of medical care for the poor could provoke controversy, a letter from a private pediatrician to the editor of the *American Journal of Diseases of Children* called the Vaccination Assistance Act "a waste of money" that might, "in any state with a politically inclined director of health, be the beginning of removing all immunizations from the physicians' offices, into the public health clinics and health departments of that state."[37]

In quick succession, the licensing of vaccines against measles in 1963, mumps in 1967, and rubella in 1969, further reinforced the belief that immunization was a cornerstone of medical

science's triumph over disease. At the same time, these developments stimulated political debate about the costs of medical care and concern about how the benefits of immunization would be available to all members of society. A dose of one of the two measles vaccines licensed in 1963 cost about $3; the cost to parents to have one child immunized against measles, including the doctor's fee, a possible shot of gamma globulin that was given with the live vaccine, or three doses of the killed vaccine, averaged around $10, or $60 in 2006.[38] As a result, few public clinics for the poor made the new vaccines available. Middle- and upper-class families who could afford the services of a private pediatrician were the main beneficiaries of the new products. Only after federal funding to states became available through the Vaccination Assistance Act in 1965 did use of the measles vaccine become more routine and coverage rates increase.

Against the backdrop of the activist social programs of Lyndon Johnson's War on Poverty, immunization activities became more explicitly focused on efforts to bring vaccination to the poor. The federal government was seen as having a key role to play in financing medical care for those who could not afford it. Medicaid was enacted in 1965 and two years later the Early and Periodic Screening, Diagnosis and Treatment program – or EPSDT – was created. The EPSDT program was a Medicaid benefit intended to ensure that poor children would receive preventive care. With this political momentum, an ambitious campaign to eradicate measles (though ultimately unsuccessful) was launched in 1966.

The belief that government intervention was needed to achieve high vaccination coverage lay behind the other major policy initiative of the 1960s: the enactment of laws requiring immunization for school attendance. A hodgepodge of state and local laws, many dating from the era of smallpox in the nineteenth century, existed in about half the states. In 1967, in concert with its national eradication campaign, the CDC launched a push to make the laws more extensive and uniform. Between 1968 and 1974, the number of states with laws requiring all or most recommended vaccinations prior to school entry increased from twenty-five to forty.[39] States without laws gradually fell in line with the national trend, and by 1981, Idaho, Iowa and Wyoming had become the last states to enact such laws.

Charitable organizations continued to play a role in vaccine promotion. The Joseph P. Kennedy Foundation, which was concerned with mental retardation, sought to promote use of the measles vaccine, since complications of measles were a leading cause of retardation. The

Foundation had joined the CDC in urging lawmakers around the country to enact laws requiring children to be vaccinated before they could enter school.[40] In 1971, the Foundation sent a letter to the wives of governors and congressional representatives around the country urging them to coordinate efforts by "women's groups" in the state, such as the PTA or the Junior League.[41] The Foundation's proposed programs emphasized education aimed at mothers since "many mothers simply have not been educated about the benefits of and need for immunization. If they knew, they would make sure their children were protected."[42] In addition to a strong gender bias, the wording of the Foundation's letter gave voice to the view that, no matter how expansive the governmental role in providing vaccines grew, getting children immunized ultimately depended upon parental action.

As school laws were enacted, immunization levels among school-age children climbed, but the laws did little to improve coverage among infants and pre-schoolers. In the early 1970s, the nation saw repeated outbreaks of vaccine-preventable diseases. And, the Vaccination Assistance Act had expired in 1968. In response, the U.S. Congress created a new program that authorized the Public Health Service to provide grants-in-aid to help states and localities deliver vaccines. These so-called "317" grants would provide an important source of funds in subsequent years. Nevertheless, support for vaccines remained highly variable and, according to most experts, inadequate to the need. Immunization programs lacked a natural constituency of political support that might have lobbied for expanded funding. Samuel Katz, chair of the American Association of Pediatrics' Committee on Infectious Diseases, chided his colleagues for "their exquisite attention to detail but detachment from concern with some basics such as immunization status."[43]

Vaccination policy during the middle of the twentieth century was characterized by dramatic strides in vaccine development that brought new acclaim for the power of scientific medicine to banish disease. Ironically, however, this recognition did not translate into a steady and reliable source of financial support – support necessary to assure that these vaccines would get into the bodies of the vulnerable children who needed them most.

That concludes our third segment. Now we will continue with *Immunization in the Contemporary Era: New Products, Old Challenges:*

Immunization in the Contemporary Era: New Products, Old Challenges

A *USA Today* headline in 1991 declared, "Public health needs a shot in the arm." This comment came in the wake of a measles epidemic that had spread across the country.[44] In spite of the enactment of laws, many years of education and promotion, and a patchwork of public sector programs for free or low-cost immunization, the promise of vaccines remained partially unfulfilled. This point was driven home by an outbreak of measles beginning in 1989. It struck primarily poor African American and Latino pre-school children in large cities including Los Angeles, Chicago, Houston, Milwaukee, and Washington, D.C. The epidemic threw into stark relief the disparities in health coverage for poor children.

Everyone agreed that immunization rates lagged far below what they should be and that more efforts were needed to boost coverage rates. But as a subsequent analysis in the *American Journal of Preventive Medicine* noted, there was no consensus on what exactly was the source of the problem. According to some observers, parental apathy or ignorance was to blame, and intensified education programs were needed. According to others, the high cost of vaccines was the problem. Many private insurers did not cover routine immunization. Even children with health insurance sometimes had to be taken to a public clinic when it was time for shots. Still other accounts attacked the fragmented nature of the U.S. health care system. Having children's records scattered among many providers led to missed opportunities to vaccinate.

Dissatisfaction with vaccine costs and the system through which children received their shots was part of a larger debate. Should the United States join the world's other industrialized democracies in establishing national health care for its citizens? A window of political opportunity for proponents of universal insurance opened with the election of Bill Clinton to the presidency in 1992.[45] One of the administration's first legislative priorities was the Children's Immunization Initiative. Although the proposal was originally intended to provide free vaccines for all children regardless of family income level, it was eventually scaled back and passed as an entitlement program called "Vaccines for Children." This final version was designed to reach youth who were eligible for Medicaid, those who lacked insurance, and Native American children. Created as an amendment to Title XIX of the Social Security Act (Medicaid), the program provided federal dollars to states to purchase vaccines from manufacturers and distribute them free to health care providers in the public and private sectors who served poor

children.[46] For the first time, federal funds could also be used to support costs directly related to administering vaccines, such as the salaries of doctors and nurses.

The new funding stream coincided with a dramatic growth in the schedule of recommended vaccinates. During the 1990s, vaccines against *haemophilus influenza* type B, hepatitis B, chickenpox, and invasive pneumococcal disease joined the CDC's schedule of recommended pediatric vaccines. The number of injections climbed steeply. This made it even more difficult to assure that children would get all recommended vaccines in a timely manner and at an affordable cost.

Another consequence of the rising number of shots that children received was increasing anxiety about the safety of vaccines. Attention to the potential for adverse effects had achieved high visibility during the 1980s. It was alleged that the whole-cell pertussis vaccine, typically given as one component of the trivalent diphtheria-pertussis-tetanus shot (DPT), might in rare instances cause brain damage. This controversy led to the passage in 1986 of the National Childhood Vaccine Injury Act. This act created a system of compensation for those harmed by vaccine-related adverse events. During the 1990s, these concerns increased and there emerged the most vocal and politically active anti-vaccination movement since the nineteenth century.

This development grew in part out of broad social trends. The general decline in trust and respect for institutions and authority that had occurred in the 1970s afflicted doctors. Widely publicized scandals, such as the U.S. Public Health Service's Tuskegee syphilis study, had also damaged other health professionals' credibility. This transformation set the stage for open challenges to the expert judgment of immunization proponents. The growth of the internet facilitated the spread of rumors and unproven hypotheses. Connections were alleged between vaccination and conditions as diverse as sudden infant death syndrome, multiple sclerosis, attention-deficit-hyperactivity disorder, and diabetes. Most inflammatory of all were charges of a connection between vaccines and an apparent rise in rates of autism in children. A 1998 paper in the *Lancet* alleged that the measles component of the measles-mumps-rubella vaccine might be causally linked to autism. This conclusion was subsequently disavowed by a majority of the paper's authors after charges of conflict of interest were brought against the lead researcher. A connection was also alleged between autism and thimerosal, a mercury-based preservative used in some multi-dose vaccine vials to prevent contamination after the vial was opened.

One consequence of the growing sense of public unease about vaccine safety was effort on the part of vaccine skeptics to liberalize exemptions to school entry requirements. Most public health experts agreed that exemptions served as a "safety valve" that prevented backlash against the use of law to achieve compliance with vaccine recommendations. But many expressed concern that overly liberal exemption policies might lead more parents to opt out. This would put communities at a heightened risk for outbreaks of vaccine-preventable illnesses. Empirical research had demonstrated that unvaccinated clusters of children could pose serious risks to the health of the community.[47,48]

The roots of exemptions lay in religious objections to vaccination. When school entry laws were enacted during the late 1960s, members of the Christian Science Church successfully lobbied legislatures in many states to include exemptions for individuals whose religious tenets specifically proscribed vaccination. During the 1990s, many states expanded their exemptions to include people with secular philosophical objections as well. As of 2005, eighteen states had exemptions for religious and philosophical beliefs, while in thirty states parents could opt out only for religious beliefs, and in two states exemptions only for medical contraindications were allowed.

What is perhaps most remarkable is that, given many obstacles, the United States has achieved levels of vaccine coverage equal to or greater than most other industrialized democracies. Coverage rates for recommended childhood vaccines reached record high levels in 2004. But there are several caveats to this success. Reflecting the country's highly decentralized public health system, rates varied substantially among states.[49] Vaccine production remains concentrated in just a handful of pharmaceutical companies, a situation that led to repeated shortages of pediatric vaccines from 2000-2002 and rationing of the flu vaccine in 2004. A report of the Institute of Medicine in 2000 on vaccine financing noted that the country's system was "fragile and unstable" and called for a major federal commitment to ensure that the achievement was sustained.[50]

It is also clear that a substrate of anxiety remains among the public about the alleged harmful effects of vaccines. These fears continue to find voice in articles in the popular media charging that public health officials at the Centers for Disease Control and the Food and Drug Administration have engaged in a conspiracy to conceal the evidence of a causal connection between thimerosal and autism.[51] At least seven states have passed legislation barring mercury

in childhood vaccines, and another twenty are considering such bills. These are moves that critics claim would increase the cost of vaccines without a clear public health benefit.[52]

As immunization pioneer Samuel Katz argued in the early 1970s, "There are many complex, interacting reasons for the persistent failure to achieve optimal immunization of all children. Sociologic, economic, educational, political, and logistical factors are all involved. They do not permit any simple, immediate solutions." Katz's observation remains true today. Fundamental characteristics of American political and civic culture continue to shape and often constrain efforts to achieve immunity for the people. These characteristics include:

- the absence of a universal medical care system;
- a more general preference for addressing social problems through voluntary, private sector solutions;
- devolution of responsibility for public health activities to state and local units rather than federally coordinated efforts, resulting in great regional and local variation in health outcomes;
- and, a strongly libertarian orientation, especially toward matters of healing and bodily integrity.

The central issues that have dominated vaccination policy for the past two centuries are: how to convince the unwilling or uncertain and how to meet the demand among the ready and enthusiastic. These issues will take on new salience in the coming years as vaccines increase in price and target diseases that afflict fewer people. Among health interventions, vaccines have always had one of the most favorable cost-benefit ratios. For a relatively low price they have not just prevented huge expenditures in medical care but have also reduced burdens of human suffering. While such calculations were straightforward in the past, they are becoming more complex in proportion to the growth of the schedule of recommended vaccines. Each newly licensed product will have to be carefully weighed not only in terms of its financial costs but also in terms of the number of additional shots it will require children to undergo and the severity and prevalence of the disease that it is preventing.[53] These calculations will also need to take into account less readily quantifiable but equally critical considerations of the social and political climate in which efforts to create population-level immunity will be implemented.

That concludes our presentation of *Immunity for the People: The Challenge of Achieving High Vaccine Coverage in American History*. We hope you enjoyed it. Please remember to view the visual supplements available on this CD using your computer. In addition to a written version of

the script, you will have access to several of *Public Health Report's* past articles on vaccination, as well as a timeline of public health achievements and other publications selected for the CD.

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You might also want to test your knowledge of the material presented in the script by visiting our website. Or, you might simply want to sign up for a chance to win an iPod or one of fifty one-year subscriptions to *PHR*. If you like what you see, please also consider a subscription to the Journal. It's a bargain.

To learn more about what vaccinations you or someone you know should consider getting, explore the wealth of material available to you via the Centers for Disease Control and Prevention at www.cdc.gov, the Immunization Action Coalition at www.immunize.org, or the National Academies Press at www.nap.edu. These sources give you access to information regarding the benefits and risks of vaccination, history and current news on immunization, personal testimonies on vaccination, and several other topics and resources for health care professionals and the general public.

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