



HISTORY OF MEDICINE

## A Half-Century of Prevention — The Advisory Committee on Immunization Practices

Jason L. Schwartz, Ph.D., M.B.E., and Adel Mahmoud, M.D., Ph.D.

Shortly after the Salk and Sabin polio vaccines had demonstrated the transformative benefits of childhood vaccination but long before the ill-informed controversy over the measles–mumps–rubella vaccine

became fodder for refusal movements and television talk shows, the Vaccination Assistance Act of 1962 established a U.S. vaccination program against polio, diphtheria, tetanus, and pertussis. With that effort launched and growing attention directed to imminent vaccination campaigns against influenza, measles, and rubella, Secretary of Health, Education, and Welfare Anthony Celebrezze approved the establishment of a committee of outside experts to advise the federal government on vaccination activities. That group, the Advisory Committee on Immunization Practices

(ACIP), marks its 50th anniversary this year.

A panel providing guidance to the Centers for Disease Control and Prevention (CDC), the ACIP is a globally respected voice in vaccination policy and profoundly influences the design, scope, and funding of U.S. vaccination efforts. Its recommendations inform the use of vaccines in every U.S. child, adolescent, and adult. The committee has been an arbiter of controversies in vaccine science and policy, a model for similar advisory bodies around the world, and ahead of its time in demonstrating how U.S. health

agencies can promote the use of medical interventions beyond matters related to licensure and regulatory oversight.

The first ACIP meeting in May 1964 was chaired by CDC Director James Goddard; he and his agency successors would hold this position for the ACIP's first 15 years. Its nine other founding members included D.A. Henderson, a CDC physician who also served as secretary to the committee, along with state health officials, academic physicians, and representatives of other Public Health Service divisions. At the committee's first few meetings, members considered how ACIP recommendations could complement, rather than duplicate, those of other existing vaccine advisory bodies, such as those at the American Academy of Pediatrics

and the Department of Defense. Members agreed to focus on public health practice, to make state health departments — which bore primary responsibility for vaccination efforts — their primary audience, and to rapidly update guidance as new evidence emerged.<sup>1</sup> Possessing no legal or regulatory authority, the committee could rely only on the strength of its evidence and analysis to influence public health practice.

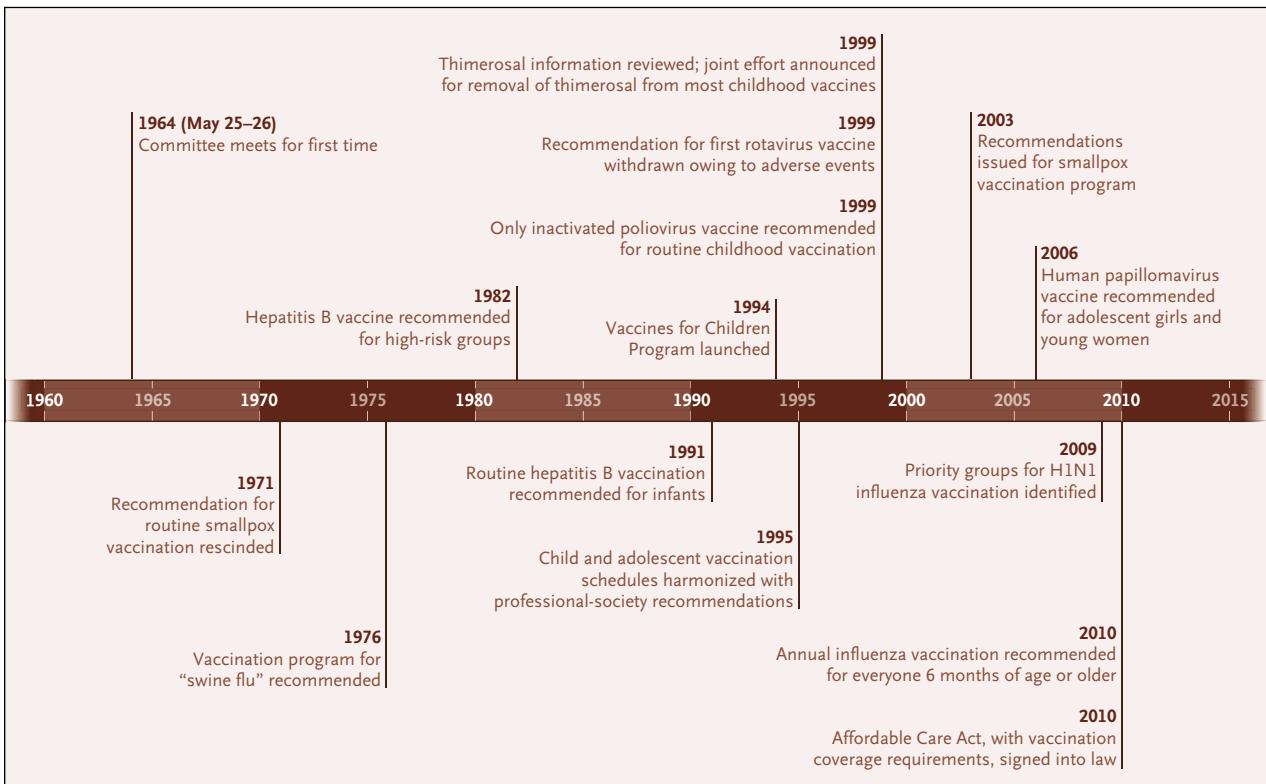
In the late 1960s, when President Richard Nixon’s administration called for a government-wide moratorium on appointing new members to outside advisory committees, the CDC sought an exemption for the ACIP, arguing that it filled “a vitally important role for the United States in regularly evaluating the full range of vaccines and other immunizing agents available for prevention and control of important diseases

in this country and elsewhere.” The committee’s judgments, the CDC authors wrote, “are based on an intensive evaluation of the risks and benefits of available vaccines, of their applicability in contemporary health practice, and of the relationships which must exist in promoting uniform immunization activities supported by various medical, public health, and voluntary health groups.”<sup>2</sup>

This description remains apt today. The ACIP has been actively involved in essentially every significant development in U.S. vaccination policy since its creation (see timeline). The committee has substantially shaped the addition of many new vaccines (such as hepatitis B, varicella, and meningococcus) to the recommended schedules; the vaccination programs against swine influenza in 1976 and H1N1 influenza in 2009; the removal of thimerosal from

most vaccines beginning in 1999; and the evaluation of innumerable other alleged and confirmed vaccine-safety concerns (such as those involving whole-cell pertussis vaccines and the timing of the childhood vaccination schedule). Its adoption of the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach in 2010 systematized its methods for evaluating evidence, an activity central to its development of recommendations.

Since the ACIP advises the CDC, its assessments and recommendations formally apply only to the U.S. population, but they have been closely watched by international public health authorities, even as other countries have developed their own immunization advisory groups.<sup>3</sup> At times, ACIP evaluations of the risks and benefits of specific vaccines in the U.S. context have served as de



facto global judgments, as was the case with the first rotavirus vaccine in 1999.<sup>4</sup>

Yet the ACIP faces multiple challenges moving forward, the most important of which relate to the policymaking responsibilities it holds along with its scientific advisory role. The committee has had this dual identity since the 1994 establishment of the Vaccines for Children Program, which provides ACIP-recommended vaccines free to uninsured and underinsured children. Vaccines newly recommended by the ACIP are added to this entitlement program, whose annual budget now exceeds \$4 billion. The Affordable Care Act (ACA) has expanded the ACIP's policymaking role, since the vaccinations it recom-

 An audio interview with Dr. Schwartz is available at [NEJM.org](http://NEJM.org)

mends are automatically included among the preventive services that new insurance policies are required to cover. A strong ACIP recommendation has long been viewed as an essential determinant of the success or failure of a U.S. vaccination program, and these delegated policy-setting responsibilities add to the committee's importance in this regard.

In developing its recommendations, the ACIP routinely considers cost-effectiveness.<sup>5</sup> Unfavorable results of economic modeling are a common justification for narrow recommendations that ultimately limit access to and affordability of the vaccines in question. Cost issues have influenced ACIP recommendations on vaccines against human papillomavirus, varicella, pneumococcus, and Lyme disease, for example. This aspect of the ACIP's work long predates the ACA, which largely prohibits using cost-effectiveness analyses in government

evaluations of medical interventions. Economic costs are not considered by the U.S. Preventive Services Task Force (USPSTF), which evaluates evidence regarding nonvaccine-based preventive care strategies. Favorable USPSTF assessments also result in coverage requirements under the ACA.

Although it's increasingly essential to spend limited health care resources wisely, it is less clear that vaccination programs should be held to a higher standard in this regard than other preventive or therapeutic interventions, as is currently the case in the United States. Even if evaluating economic analyses is viewed as an appropriate and desirable activity for the federal government, a public health advisory body largely composed of state and local health officials, infectious-disease specialists, and pediatric and family medicine clinicians may not be the best group to undertake such work. We believe that the formation of a separate group for examination of economic issues could have significant value.

A more general challenge for the ACIP has been defending the independence of its findings and recommendations. In its early years, independence from its CDC sponsors was a principal concern of critics, who questioned whether the committee's structure allowed for truly independent advice. The Federal Advisory Committee Act of 1972 led to significant reforms of the ACIP's membership and operations: voting members were no longer permitted to be government employees, the CDC director stopped chairing the committee, and the public was given far greater access to committee meetings and materials.

Recently, more attention has

been paid to financial relationships between committee members and vaccine manufacturers. The adequacy of the procedures for monitoring and addressing conflicts of interest for federal advisory groups has been questioned frequently by Congress, consumer groups, and even the Office of Inspector General of the Department of Health and Human Services, and the ACIP has been a specific focus of several inquiries. Ongoing efforts to identify and eliminate meaningful threats to the committee's independence, whatever their source, remain essential to preserving the value of the ACIP's recommendations and public confidence in government vaccination activities.

For a half-century, U.S. vaccination efforts have benefited greatly from the ACIP's expertise. Outside advisors frequently contribute to the government's regulatory work in health and medicine — for example, by evaluating products' safety and efficacy for the Food and Drug Administration. Groups providing evidence-based guidance on using such products are far less common. As the ACIP continues to play its influential role, its foremost challenge will be preserving its reputation as an inclusive and credible voice on vaccination. Success requires not simply continued attention to rigorous analyses and high-quality recommendations, but also a similar focus on dissemination of its guidance and its reception by clinicians, parents, and patients. With hesitancy regarding vaccines posing a growing threat to vaccination efforts, insights from the fields of health communication, decision making, and related social and behavioral sciences will be increasingly important to the ACIP's work and

the continued success of U.S. vaccination activities.

Disclosure forms provided by the authors are available with the full text of this article at [NEJM.org](http://NEJM.org).

From the University Center for Human Values (J.L.S.), the Woodrow Wilson School of Public and International Affairs (A.M.), and the Department of Molecular Biology (A.M.), Princeton University, Princeton, NJ.

1. Minutes — meeting of Surgeon General's Advisory Committee on Immunization Practice — May 25–26, 1964, June 8, 1964. CDC Papers RG 442, 75A69. Morrow, GA: National Archives and Records Administration, 1964.
2. Policy guidelines and procedures for public advisory committees. May 7, 1969. CDC Papers RG 442, 10-003. Morrow, GA: National Archives and Records Administration, 1969.
3. Duclos P, Dumolard L, Abeysinghe N, et al. Progress in the establishment and strengthening of national immunization technical

advisory groups: analysis from the 2013 WHO/UNICEF joint reporting form, data for 2012. *Vaccine* 2013;31:5314-20.

4. Schwartz JL. The first rotavirus vaccine and the politics of acceptable risk. *Milbank Q* 2012;90:278-310.

5. Smith JC. The structure, role, and procedures of the U.S. Advisory Committee on Immunization Practices (ACIP). *Vaccine* 2010;28:Suppl 1:A68-A75.

DOI: 10.1056/NEJMp1410049

Copyright © 2014 Massachusetts Medical Society.

## Can Government Regulate Portion Sizes?

Jennifer L. Pomeranz, J.D., M.P.H., and Kelly D. Brownell, Ph.D.

External cues can have powerful effects on people's eating habits. One thoroughly studied environmental trigger is portion size: studies show that larger portions encourage greater consumption of a range of foods and beverages.<sup>1</sup> This effect is especially problematic when it comes to sugar-sweetened beverages, which are associated with obesity and diabetes and are being sold in ever-increasing portion sizes. The original Coca-Cola bottle was 6.5 oz (190 ml); many bottles intended for individual consumption are now triple that size.

There are no government restrictions on portion sizes for food prepared and consumed outside the home, which accounts for more than 43% of Americans' food expenditures.<sup>2</sup> A regulation enacted by the New York City Board of Health that limited portion sizes of sugar-sweetened beverages was struck down in 2014.<sup>3</sup> Although this case applies only in New York State, the precedent it set may help address fundamental questions about whether restricting food and beverage portion sizes is defensible on public health and legal grounds in other U.S. jurisdictions.

The New York City Board of Health adopted the portion-cap rule in 2012, limiting the size of sugar-sweetened beverages sold in food-service establishments — which are licensed by the city — to 16 oz (470 ml).<sup>4</sup> Grocers and convenience stores are regulated by New York State and hence were not subject to the rule. The ordinance applied to calorically sweetened beverages with more than 25 calories per 8 oz (235 ml) and excluded drinks containing more than 50% milk or milk substitute.<sup>4</sup> Consumers were free to purchase multiple drinks, and sellers could offer free refills. State and national nonprofit and labor organizations representing food-service establishments and the beverage industry sued the city to prevent enforcement of the law. The state's highest court, the New York Court of Appeals, ultimately struck down the ordinance.<sup>3</sup>

The first industry complaint in the litigation was that the Board of Health exceeded the authority granted to it by the City Charter and thus improperly acted in a legislative capacity — an argument based on the separation of powers. The Board of

Health is part of an administrative agency in the executive branch of the government, and therefore it can act only within the parameters set forth by the legislative body. According to the court's majority opinion, the Board exceeded this authority because the regulation interfered with activities preferred by large numbers of people and required “complex value judgments” concerning public health, personal autonomy, and economics.<sup>3</sup> The court found that the Board of Health made difficult choices among “broad policy goals” and engaged in a form of “policy-making,” an activity reserved for legislatures, rather than standard agency “rule-making,” which consists of “subsidiary policy choices” based on an enabling legislation's requirements.<sup>3</sup>

The second industry argument was that the ordinance was “arbitrary and capricious” and hence not rational. States — and to the extent permitted, local governments — possess the authority to enact laws to protect, preserve, and promote the health, safety, and welfare of their citizens (known as the “police power”), as long as such regulation has a rational basis. The Court of Ap-