



# AAI Position Statement

## Vaccine Policy

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### Introduction

Vaccination is one of the greatest public health achievements in history. While practices to prevent smallpox existed centuries before Edward Jenner, his innovative development of a smallpox vaccine in the late 1700s laid the foundation for modern vaccination. Prior to widespread immunization, 300 million people died of smallpox in the 20<sup>th</sup> century alone. Global immunization efforts ultimately led to complete eradication of the disease in 1980, demonstrating the extraordinary power of vaccines to prevent suffering and save lives.<sup>1</sup>

Centuries of scientific advances have enabled the development of dozens more vaccines that have prevented hundreds of millions of deaths, averted trillions of dollars in healthcare costs, transformed global health, and drastically increased life expectancy.<sup>2</sup> Moreover, the power of vaccines extends far beyond the prevention of infectious diseases. Vaccines prevent some forms of cancer and show promise in the treatment of many others. Emerging evidence suggests potential additional benefits of vaccines in reducing the risk of dementia and in treating and/or preventing a wide range of conditions, including autoimmune diseases, cardiovascular disease, allergies, and even addiction.<sup>3,4,5</sup>

Despite this remarkable progress and promise, the United States faces growing challenges to maximizing the potential of vaccination, including declining vaccine coverage and eroding public trust in vaccine science – trends exacerbated by the COVID-19 pandemic.<sup>6</sup> Recent federal actions, while increasing attention to vaccine safety, have upended robust, trusted, and evidence-based vaccine policies and practices. This has caused significant uncertainty and confusion and undermined public confidence in vaccines, which will lead to worse health outcomes for the nation. Understanding and addressing these challenges – while preserving life-saving vaccine access, uptake, and funding - is critical.

The next era for vaccines holds tremendous potential. Strong, consistent investment in rigorous and transparent vaccine research is essential to accelerate progress, address knowledge gaps, and enhance understanding of safety concerns. These efforts can inform the development of evidence-based policy and bolster public confidence in immunization as a cornerstone of modern medicine.

### Background

#### *Health and economic impacts of vaccines*

Over the last five decades, global immunization efforts have saved more than 150 million lives and account for 40% of the observed decline in infant mortality.<sup>7</sup> In the U.S. 1994-2023 birth cohort, routine childhood vaccination prevented 508 million illnesses, 32 million hospitalizations, more than 1.1 million deaths, and will result in a net savings of \$540 billion in direct medical costs and \$2.7 trillion in broader societal costs.<sup>8</sup> In addition to preventing disease, vaccines have eliminated or significantly reduced many devastating disease-related conditions that were once common, including paralysis from polio, deafness in people born to mothers with rubella, and liver cancer from hepatitis B infection. The vaccine against human papillomavirus (HPV) is a

striking example of the impact vaccination can have on public health. In the U.S., cervical precancer rates and higher-grade cancer among women aged 20-24 decreased by 79% and 80%, respectively, from 2008 to 2022, following FDA approval of the first HPV vaccine in 2006.<sup>9</sup>

### *Success of Operation Warp Speed and the promise of mRNA vaccines*

The first Trump Administration's Operation Warp Speed (OWS),<sup>10</sup> launched early in the COVID-19 pandemic, successfully accelerated the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. This profound initiative, built upon decades of research on messenger RNA (mRNA), directly supported the development of COVID-19 mRNA vaccines which have saved millions of lives, significantly reduced COVID-19 related hospitalizations and deaths, averted trillions of dollars in healthcare costs, and positively contributed to the nation's economic recovery.<sup>11,12,13</sup> A recent cohort study of 22.7 million individuals vaccinated with COVID-19 mRNA vaccines and 5.9 million unvaccinated individuals found a 74% lower risk of death from severe COVID-19 among vaccinated individuals, with no increase in overall deaths from any cause over four years.<sup>14</sup>

The mRNA vaccine platform is now driving significant innovation in cancer and in many other chronic and infectious diseases, offering new therapeutic and preventative possibilities for previously hard-to-treat cancers like pancreatic and other solid tumors.<sup>15,16,17</sup> However, the future success of mRNA and other future platforms will depend on strengthening public acceptance. The unprecedented speed of COVID-19 mRNA vaccine development fueled perceptions of inadequate validation, largely due to a lack of public understanding that massive, targeted investment and large-scale clinical trials accelerated research and development without compromising safety. Federal funding for mRNA research is critical to harness the immense promise of this technology, to more fully understand rare risks, and to dispel misconceptions through clear communication to the public.

### *Recent changes of concern in federal vaccine policy*

Recent actions by the Department of Health and Human Services related to vaccine policy have caused significant confusion among the public and concern from the medical and scientific communities. These include drastic changes to the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) membership and procedures,<sup>18</sup> revisions to federal COVID-19 vaccine recommendations without robust evidence to support the changes,<sup>19</sup> the cancellation of some mRNA vaccine related contracts,<sup>20</sup> the recommendation to end hepatitis B vaccination for all infants at birth,<sup>21</sup> and the recent unprecedented overhaul of the CDC childhood immunization schedule, which significantly reduced the number of vaccines recommended for all children, making the US an outlier among the vast majority of peer nations.<sup>22,23,24</sup> Additional concern stems from baseless calls to separate the measles, mumps, and rubella (MMR) vaccine into three individual shots and to remove the very small amounts of aluminum (used as an adjuvant to boost the immune response) found in many childhood vaccines, contrary to robust evidence of safety and effectiveness.<sup>25,26</sup> While the reported intent of these actions may be to strengthen oversight and enhance public trust, the rapid pace, limited consultation with independent stakeholders, and dearth of evidence and rationale accompanying many of these changes have generated great concern about vaccine acceptance and uptake among clinicians, scientists, and the public.<sup>27,28,29,30</sup>

## **Considerations**

### *Declining trends in vaccine coverage risk public health*

While overall routine childhood vaccination rates remain high, they have been declining each year since 2019.<sup>31</sup> For example, coverage of children in kindergarten for the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine dropped from 94.9% to 92.1%, and MMR coverage has fallen from 95.2% to 92.5%. At the same time, exemptions from one or more vaccines are increasing each year. Importantly, these trends threaten not only individuals, but herd immunity, a threshold of collective immunity required to prevent

transmission of a disease that is achieved through vaccination or prior infection. For example, measles is so contagious that it requires 92-94% of people to be immune to prevent outbreaks.<sup>32</sup> When MMR coverage drops below that level, infections can spread quickly. One unvaccinated individual who becomes infected can put an entire group at risk, endangering vulnerable community members. The consequences of low coverage are already being seen. In 2025, the U.S. experienced the largest number of confirmed measles cases since the disease was declared eliminated in 2000.<sup>33</sup> Three people, including two unvaccinated children, died. The 2024-2025 flu season was exceptionally severe with the highest number of cases since tracking began in 2004 and a record number of pediatric deaths, 90% of whom were unvaccinated.<sup>34</sup> As vaccination rates decline, outbreaks of preventable diseases will lead to increased illness, long-term complications, and death in children.

### *Increasing hesitancy and public distrust of vaccination*

While vaccine hesitancy can be traced back to the origins of immunization, events during the COVID-19 pandemic exacerbated the increasing trend of U.S. public distrust in vaccines.<sup>35</sup> The false perception of compromised development of the COVID-19 vaccines, vaccine mandates, and challenges with public health messaging during the evolving pandemic resulted in significant confusion and backlash, contributing to decreased trust in science and U.S. federal public health agencies. Pervasive vaccine misinformation and disinformation, including about vaccine safety, have also added substantially to increasing hesitancy and public distrust. For example, claims that babies and young children are being harmed by receiving “too many vaccines at once” are not supported by scientific evidence yet have caused considerable confusion for parents and caretakers. Early-life immunization is critical for protecting infants and children from dangerous diseases during a highly vulnerable period, and the childhood immunization schedule is carefully designed so that multiple vaccines can be safely given together.<sup>36</sup> In addition, side effects of vaccination, even mild, may induce enough discomfort to make people decline future vaccines (e.g., influenza vaccines inducing “flu-like” symptoms). Strengthening vaccine acceptance and public trust requires a better understanding of public attitudes towards vaccines, sources the public uses to access information about vaccines, and identities of individuals trusted to provide information about vaccines. Public concerns can then be addressed by coupling high-quality science with evidence-based, effective communication.

### *Addressing knowledge gaps and public concern*

Concerns regarding vaccine safety have been used to justify many recent changes to federal vaccine policy. However, decades of rigorous evidence demonstrate that for the vast majority of people, the immense benefits of vaccines far outweigh the risks. Though serious adverse effects and vaccine injuries do occur, they are exceedingly rare. Of course, understanding the risk factors and mechanisms associated with these events is essential and should continue to be investigated.<sup>37</sup> Sustained research is also needed to enhance understanding of the mechanisms that dictate how immune responses to vaccines differ based on characteristics like age, sex, and immune status; what mechanisms govern the durability and magnitude of protection; and which biological pathways lead to off-target effects, some of which may be beneficial.<sup>38</sup> Addressing these and other knowledge gaps, and transparently communicating established evidence and remaining uncertainties, will help to strengthen trust and public support of vaccines, the scientific process, and federal public health institutions. It is critical, however, that life-saving and protective vaccines remain accessible while research advances, and that vaccine policy decisions are guided by transparent, evidence-based processes free from political influence.

## **Recommendations**

AAI is committed to ensuring continued and robust federal support for vaccine research and evidence-based vaccine policy. AAI will continue to work with policymakers, public health agencies, advisory panels, and the broader scientific community to help ensure that U.S. vaccine policy remains transparent, evidence-based, and centered on protecting public health. AAI recommends that Congress and federal agencies, including the

National Institutes of Health and CDC, in close coordination with the scientific community, take the following actions to accomplish these important goals:

### **Ensure evidence-based vaccine policy and strengthen public trust in vaccines**

- 1. Fortify the independence and transparency of federal vaccine advisory committees.**  
*Ensure thorough vetting of candidates and a transparent appointment process for membership on federal vaccine advisory committees, including public disclosure of all conflicts of interest. Committees should comprise individuals with demonstrated professional training and expertise in vaccinology, immunology, infectious disease, public health, and/or other highly relevant fields, and should be insulated from ideology and partisan interests.*
- 2. Ensure vaccine policy is rooted in evidence-based science.**  
*Ensure that modifications to the CDC immunization schedules, and other changes to vaccine policy, are firmly grounded in robust, evidence-based science and conducted through rigorous, expert-driven review processes with input from stakeholders outside the federal government. Maintain full transparency in vaccine policy decision making, including public disclosure of the scientifically justified rationale for the re-evaluation of existing recommendations.*
- 3. Invest in strengthening vaccine information and confidence.**  
*Targeted, transparent, evidence-based communication and community engagement, from federal and non-federal public health entities, that also address public questions and concerns, are essential to reestablish and strengthen confidence in vaccine effectiveness and safety.*

### **Address gaps in vaccine science knowledge**

- 1. Ensure robust and sustained federal support for foundational immunology, vaccinology, and infectious disease research.**  
*Basic research underpins vaccine innovation. Continued federal investment is essential to discovery, optimization of current vaccines, and preparedness for future pandemics.*
- 2. Advance mechanistic understanding of human immune responses to vaccination.**  
*Increase research and ensure dedicated funding to identify the molecular and cellular mechanisms underlying vaccine induced immunity. Leverage comprehensive technological advances, new approach methodologies, and systems vaccinology (integration of large-scale, multi-omic, computational, and single cell analyses) to provide comprehensive insights into vaccine efficacy, safety, durability, and variability across individuals, populations, and stages of life, including predictors of protective and adverse responses.*
- 3. Invest in next-generation vaccine development.**  
*Increase investment in the innovation and optimization of vaccine platforms (e.g., mRNA, viral-vectored, and protein subunit), adjuvants, and vaccine delivery systems that enhance the magnitude, safety, and durability of protection. Development should be guided by mechanistic insights into immune activation, memory formation, and safety considerations.*

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