U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

Decision Memo

DATE: January 5, 2026

TO: Jim O'Neill, Acting Director, Centers for Disease Control and Prevention (CDC)

FROM: Jay Bhattacharya, MD, PhD, Director, National Institutes of Health
Mehmet Oz, MD, MBA, Administrator, Centers for Medicare and Medicaid Services
Marty Makary, MD, MPH, Commissioner of Food and Drugs

SUBJECT: DECISION REQUESTED – Adopting Revised Childhood and Adolescent Immunization Schedule

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PURPOSE

This memorandum proposes a revised childhood and adolescent immunization schedule for your review and approval.

RECOMMENDATION AND ACTION REQUESTED

After considering the data and recommendations contained in TAB 1, "Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries," and your discussions with relevant health officials, you should approve the revised immunization schedule.

BACKGROUND AND SUMMARY OF RECOMMENDED ACTION

On December 5, 2025, the President directed the Department of Health and Human Services (HHS) and the Centers for Disease Prevention and Control (CDC) to review best practices from peer, developed nations regarding core childhood vaccination recommendations and the scientific evidence underlying those practices. The President further instructed that, "if [HHS and CDC] determine that those best practices are superior to current domestic recommendations, update the United States core childhood vaccine schedule to align with such scientific evidence and best practices from peer, developed countries while preserving access to vaccines currently available to Americans."

As part of this review, you discussed childhood immunization recommendations and policy with health officials from Japan, Germany, and Denmark. You also discussed immunizations with CDC and Food and Drug Administration (FDA) officials with duties and responsibilities related to vaccine safety and efficacy, respectively.

TAB 1 is the review of peer nations' best practices and the scientific evidence underlying those practices. Dr. Tracy Beth Høeg, Acting Director of the FDA Center for Drug Evaluation and Research (CDER), and Dr. Martin Kulldorff, Chief Science and Data Officer, HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), authored TAB 1 in consultation with subject matter

officials at CDC, FDA, the National Institutes of Health (NIH), and the Centers for Medicare and Medicaid Services (CMS). After a careful review of the current U.S. childhood and adolescent immunization schedule, peer nations' schedules and best practices, and the underlying evidence and data, TAB 1 recommends adopting a revised childhood and adolescent immunization schedule that is based on those vaccines for which there is broad-based international consensus. The consensus vaccines are recommended for all children.

The recommended schedule includes consensus vaccines for measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Haemophilus influenzae type B (Hib), pneumococcal disease, human papillomavirus (HPV), and varicella. This vaccine schedule reflects the Danish schedule except that this revised schedule adds the varicella vaccine, which is not currently on the Danish schedule. TAB 1 proposes that the CDC recommend these vaccines for all children.

In addition to the consensus vaccines, the schedule recommended in TAB 1 includes immunizations for high-risk groups and immunizations based on shared clinical decision making. Unlike the consensus vaccines, these are immunizations for which there is not broad-based consensus and TAB 1 discusses the scientific evidence regarding why they should not be recommended for all children.

TAB 1 does not assess and propose any changes to recommendations for high-risk populations. Those immunizations include: Respiratory syncytial virus (RSV) monoclonal antibodies, and hepatitis A, hepatitis B, meningococcal B, meningococcal ACWY, and dengue.

TAB 1 also proposes that CDC's recommended childhood and adolescent immunization schedule list vaccines for hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and COVID-19 be based on shared clinical decision making. The CDC applies shared clinical decision-making recommendations when evidence indicates that individuals may benefit from vaccination based on an analysis of the individual's characteristics, values, and preferences, the provider's medical judgment, and the characteristics of the vaccine being considered.

The recommendation to realign the CDC's immunization schedule under a framework built on 11 consensus vaccines is not a significant departure from the current recommended immunization construct. The current CDC schedule (TAB 2) categorizes routine immunization recommendations into three general categories: (1) population-based (i.e., age-based, including catch-up), (2) risk-based (i.e., immunosuppression, other underlying medical conditions, work-related, or other special circumstances that increase risk of illness), and (3) shared clinical decision-making-based.

Under the new framework, measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib, pneumococcal disease, HPV, and varicella constitute category 1, the population-based category of routine immunizations, and are recommended for all children. Immunizations currently recommended for high-risk groups continue to be recommended for high-risk groups under category 2 in the preceding paragraph. Hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and COVID-19 remain on the schedule based on shared clinical decision-making, category 3 above.

Finally, consistent with the President's direction to "preserv[e] access to vaccines currently available to Americans," all the immunizations listed in the preceding paragraphs are (i) on the current schedule, (ii) will remain on the revised schedule, and, therefore, (iii) continue to be covered without cost sharing by

private insurance and covered by Medicaid, Children's Health Insurance Program (CHIP), and the Vaccines for Children Program.

*** Figure 1 on pages 2-3 of TAB 1 illustrates the proposed schedule with recommended doses and ages.**

DISCUSSION

Before reviewing and assessing the current childhood and adolescent immunization schedule relative to those of peer nations, it is important to first understand what, if any, problems currently exist with childhood immunization in the United States.

Current Problem: Decreased Vaccine Uptake and Trust

Childhood vaccination rates in America have fallen over the past five years. From the 2019/20 to 2023/24 school year, there was a decline in childhood measles, mumps, and rubella (MMR) vaccination from 95.2% to 92.7%. In the 2024-2025 academic year, 16 states had MMR vaccination rates below 90%, which is below the critical threshold for herd immunity for measles. Consequently, in 2025 there were nearly 50 measles outbreaks and over 1,800 measles cases attributed to those outbreaks. Finally, although the CDC still recommended the COVID-19 booster for all children in 2023, the uptake was less than 10%.

Robust immunization programs are an essential public health tool, but those tools are only effective when there is public trust. Unscientific belief that vaccine-acquired immunity was superior to infection-acquired immunity combined with inaccurate CDC claims that the COVID-19 vaccine would prevent infection and transmission eroded public trust in the COVID-19 vaccine.

The loss of trust in the COVID vaccines coincided with less adherence to the full CDC childhood vaccine schedule, which has resulted in lower immunization rates of well-established vaccines, such as those for measles, rubella, pertussis, and polio.

Current Problem: Knowledge Gaps Concerning Safety

The Institute of Medicine (IOM) stated in a report that "vaccines—like all drugs or medical interventions—are neither 100 percent risk-free nor 100 percent effective." The United States administers significantly more doses of childhood immunizations than its peer nations, yet there is a significant knowledge gap due to a dearth of randomized vaccine trials and limited post-licensure infrastructure for monitoring potential adverse reactions and long-term chronic events.

The U.S. has a limited post-licensure infrastructure focused on monitoring potential adverse reactions that occur within a few days or weeks after vaccination. This includes the Vaccine Adverse Event Reporting System (VAERS), but the two key components are CDC's Vaccine Safety Datalink (VSD) and FDA's Biologics Effectiveness and Safety (BEST) System. These systems typically conduct limited safety review using risk windows after vaccination which inject significant bias and severely limits the potential to detect serious harms, but despite this and other serious limitation, these systems within a year of vaccine approval have confirmed serious harm, including intussusception after rotavirus

vaccines, febrile seizures after the MMRV vaccine, and anaphylaxis and myocarditis after the mRNA COVID-19 vaccines. Additionally, current surveillance systems are underutilized to detect long-term harms.

International Comparison of Childhood Vaccine Schedules

As illustrated in Table 2 on page 15 of TAB 1, the United States currently recommends more childhood vaccines than any peer nation, and more than twice as many vaccine doses as some European nations.

While a set of consensus vaccines is consistently recommended in all peer countries, several vaccines included in the current CDC childhood and adolescent immunization schedule (e.g., hepatitis A, varicella, influenza, rotavirus and meningococcal vaccines) are limited in their recommendation or excluded in some other developed countries. Each disease addressed by the U.S. child immunization schedule poses a health risk, but the level of threat varies widely by disease and sometimes by individual underlying risk factors. The mere existence of a vaccine does not automatically make it appropriate for every child, nor does it necessarily justify universal vaccination.

There is global variation in the universal use and timing of numerous childhood vaccines. Although these differences sometimes reflect the unique epidemiology of diseases in each region, they more often arise from uncertain science and knowledge gaps, which lead to inadequately informed assessments of risks and benefits that are subject to differing interpretations. Disagreement among states and professional societies in the U.S. further underscores the need and opportunity for a more adaptable childhood immunization schedule.

Broad-based insurance coverage of both consensus and non-consensus immunizations should remain in effect following the updates to the vaccine schedule. Identifying the consensus vaccines on the schedule would help Americans follow the schedule while making all vaccines available for parents also wanting non-consensus immunizations. Through proper vaccine research, it is important to improve our understanding of populations who are most likely to benefit from individual vaccines as well as situations where vaccination may not be needed.

Recommended Immunization Schedule Based on Assessment of Peer Nations and Scientific Evidence

Immunizations Recommended for All Children: These are immunizations that are important for all children to receive. They include measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib and pneumococcal disease vaccines. These are consensus vaccines that are part of the recommended childhood immunization schedules for all 20 peer nations, with the exception of mumps in Japan. While the safety/risk profile is not fully understood, and in need of further study, there is consensus among peer nations that they provide material benefits against the target disease. Focusing on these vaccines is more likely to reverse the declining uptake of these vaccines.

In addition to the vaccines listed above for which there is nearly unanimous peer nation agreement, HPV and varicella vaccines should also be included.

The scientific evidence for the HPV vaccine—increasingly recognized by peer nations in their own recommendations—supports one dose instead of two when given to children. Australia, parts of Canada, Ireland, Spain, and the United Kingdom have already changed their recommendations to one dose.

The varicella zoster virus causes chickenpox (typically in children) and, for those infected, can reemerge as shingles (typically in adults). The uncertainty of its long-term consequences on adults is one reason why some countries have been cautious about adding the varicella vaccine to the childhood schedule, but similar caution may be warranted regarding a removal once there has been widespread use of this vaccine. The rate of two dose vaccination for varicella among American children is estimated at 92%. Partial population varicella vaccination (60-80% for two doses) could increase the average age at which the population naturally gets chickenpox when this disease could cause more complications, and hence there is a consensus among peer nations that once vaccination for chicken pox has become widespread, stopping use of this vaccine could cause certain complications. For these reasons, the varicella vaccine should remain a consensus vaccine.

Immunizations Recommended for Certain High-Risk Groups or Populations: Like all medical products, vaccines have different risk-benefit profiles for different people. This can either be because of underlying comorbidities, unusual exposure to the disease, or the risk of disease transmission to others. For example, the hepatitis A vaccine when children travel internationally to an endemic area or the birth dose of the hepatitis B vaccine for infants born to mothers that are hepatitis B positive. TAB 1 does not propose any changes in immunization recommendations for high-risk populations.

Immunizations Based on Shared Clinical Decision-Making: Shared clinical decision-making recommendations are individually based and informed by a discussion between the health care provider and the patient or parent/guardian, something that should occur for all vaccines. It is not always possible or pragmatic for public health officials to clearly define who will benefit from a vaccine, who has the relevant risk factors, or who are at risk of exposure. Parents and physicians, who know the child, may be better placed to make that judgement. With shared clinical decision-making, the characteristics of the individual are considered, including their likelihood of being exposed to the diseases, their risks of morbidity and mortality if contracting the diseases, their likelihood of benefitting from the vaccine, their likelihood of vaccine adverse reactions, and their risk of transmitting the disease to others. Sometimes, it is also important to consider personal and family preferences, beliefs, and knowledge, including when a patient presents specific information regarding the pre-and-post licensure safety data of a vaccine or presents specific familial experience with a vaccine. While non-consensus immunizations are not routinely recommended for all children, all these vaccines will continue to be available for anyone who wants them and will be covered by Medicaid, CHIP, the Vaccines for Children Program, and private health insurance.

- Hepatitis A: When hepatitis A vaccines were approved in the 1990s, the primary candidates for vaccination were "travelers to regions of endemic disease, children living in high prevalence areas, homosexual males, users of illicit intravenous drugs, persons working directly with nonhuman primates or hepatitis A virus, patients older than 30 years of age with chronic liver disease, and persons who have received a liver transplant or are awaiting one." Those had disappeared in the U.S. by 2006, at which time a 2-dose regiment at age 12 to 23 months was added to the universally recommended childhood immunization schedule. In 2006, the annual incidence rate of hepatitis A

was very low at around 1 per 100,000 and it remains similarly low. The annual mortality rate is 1 per 10 million, with the highest rate among older men.

Among peer nations, Greece is the only one with a routine childhood vaccine recommendation. Given the low U.S. incidence and mortality, and the lack of randomized placebo-controlled safety data, the benefit-risk ratio is at best very low for most children. There is a clear benefit, but still undefined risk, for children travelling to high endemic countries in the developing world.

- Hepatitis B: Together with hepatitis B immune globulin, it is important that infants are administered the hepatitis B vaccine at birth if the mother is HBsAg-positive or status is unknown. If the mother tests negative, only two of the 20 peer nations recommend routine vaccination at birth: Australia and Portugal, while two countries do not recommend it at all. At their December 2025 meeting, the ACIP followed the majority of peer nations and voted to no longer recommend the birth dose if the mother tested negative. Instead, it recommended shared clinical decision-making, taking the risk profile of each unique child into account.

- Rotavirus: Rotavirus is a common infection, and prior to the rotavirus vaccine, nearly every child would be infected, both in the U.S. and abroad. In the developing world, many children die from dehydration after catching the virus, and there is a greater opportunity for benefit from vaccination. In the U.S., it can cause hospitalization for gastroenteritis, but the virus poses almost no risk of either mortality or chronic morbidity.

  Data from CDC indicate that among all U.S. children <15 years of age, there were an average of 3.3 deaths per year with the rotavirus diagnostic code listed on the death certificate between 1999 and 2005. This was after the RotaShield vaccine was withdrawn from the market in 1999 and before the RotaTeq vaccine was approved in 2006. Another vaccine, Rotarix, was approved in 2008. After these vaccines were recommended for all children, there were 1.6 deaths per year from 2009 to 2020. There may be many reasons for this very small decrease in mortality that are unrelated to the vaccine, including improved medical care, changes in diagnostic practices, or random fluctuations.

  RotaShield was removed from the market due to an excess risk of intussusception. The newer current vaccines have a lower intussusception risk, at around 1 or 2 per 100,000 vaccinated children. Reasonable people can reach different conclusions about recommending the rotavirus vaccine for all children. Among peer nations, Belgium, Denmark and Portugal do not recommend it. Denmark has cited the very low risk of mortality and chronic morbidity to nearly all children in their rationale for not adding the vaccine to their childhood immunization schedule.

- Meningococcal disease: Among peer nations, 15 recommend meningococcal vaccination for all children while five limit it to high-risk groups. The incidence of meningococcal disease has declined during the past decades, both in countries with and without the routine vaccine recommendations for children, and the magnitude of the decline appears to be independent of vaccination policy. The current incidence in the U.S. is 0.12/100,000 or about one case per million per year.

  In a 2011 position paper, the World Health Organization (WHO) recommended that countries with more than 2 cases per 100,000 population/year maintain a "large scale meningococcal vaccination program," while only vaccinating the high-risk population in countries with lower rates. In the

United States, the current incidence rate is around 0.1 per 100,000 is much lower than the WHO suggested cut-off.

The current meningococcal vaccines recommended for all children (Menveo, Menquadfi, and Penbraya) were not evaluated in large-scale double-blind placebo-controlled randomized trials before FDA approval.

Considering the low incidence rates of meningococcal disease in the U.S., the meningococcal vaccine should not be part of the consensus recommended vaccine schedule. High-risk children and adolescents, such as children with certain types of immune deficiencies, may have a greater chance of benefiting from the vaccine.

- Influenza: The primary purpose of the childhood influenza vaccine in children is to reduce hospitalizations and mortality in children, as well as transmission to the elderly, who are of higher risk for death but there are no randomized controlled trials demonstrating these benefits. There are a few post-licensure randomized placebo-controlled trials for the influenza vaccine. The most comprehensive review was done in 2018 by the Cochrane Collaboration. They found that "in children aged between 3 and 16 years, live influenza vaccines probably reduce influenza (moderate-certainty evidence)" infections while "inactivated vaccines also reduce influenza (high certainty evidence)." Only a few of the trials evaluated school and parental work absenteeism, not finding a statistically significant reduction. There was no evidence about reduced transmission. The trials could not evaluate differences in hospitalizations or mortality, as there were none or few in either group, so they provide no evidence that the vaccines reduce hospitalization or deaths. There was not much information about children under 2 years old.

  The conclusion of the Cochrane systematic review of randomized trials in children was that "Decision-makers' attention to the vaccination of very young children is not supported by the evidence summarised in our review. Although there is a growing body of evidence showing the impact of influenza on hospitalisations and deaths of children, at present we could find no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, or community transmission of influenza."

  There have been some observational studies with mixed results. A test-negative case-control study claimed to show that childhood influenza vaccine reduces hospitalization, but that is a notoriously biased study design with highly implausible results.

  While there is a scarcity of reliable safety data, the influenza vaccines are not without risk. The seasonal vaccine has been linked to Guillain Barré syndrome. During the 2009/2010 H1N1 influenza pandemic, the Pandemrix pandemic vaccine was found to cause narcolepsy among vaccinated children and adolescents. The Cochrane systematic review, noted that "the lack of safety data for inactive vaccines in younger children is particularly surprising given that the inactive vaccine is now recommended for healthy children six months and older in the USA and Canada" and that "the manufacturers' refusal to release all safety outcome data from trials carried out in young children, together with obvious reporting bias and inconsistencies in the primary studies, does not bode well for a fair assessment of the safety of live attenuated vaccines."

Considering the evidence, and lack of evidence, it is understandable that public health agencies in different countries have come to different conclusions about the influenza vaccine for children. Among the 20 peer countries, only Austria and Canada recommend an annual influenza vaccine for all children >6 months and all adolescents. Another six recommend the shot for all children in selected age ranges. The remaining twelve peer nations do not recommend the influenza vaccine for all children in any age group.

Based on both the evidence and uncertainties, the influenza vaccine should not be recommended for all children, but it should be available through insurance for all children >6 months old, through shared-clinical decision making.

- COVID-19: In 2022, Denmark became the first peer nation to remove its universal recommendation of the COVID-19 vaccine for children, with the director of its public health authority recognizing that there was little benefit in giving this vaccine to children. Since then, all other peer nations have followed. At their September 2025 meeting, the ACIP voted that shared clinical decision-making should be applied to the COVID-19 vaccine for U.S. children and adolescents.

Finally, if you approve the revised schedule, you should also later recommend to the Secretary that HHS agencies fund and conduct gold standard medical research to assess overall health outcomes related to all immunizations on the revised schedule (i.e., immunizations recommended for all children, immunizations recommended for high-risk groups, and immunizations based on shared clinical decision making), the interaction effects between different immunizations as well as other aspects of the immunization schedule—something that is needed to close the knowledge gap.

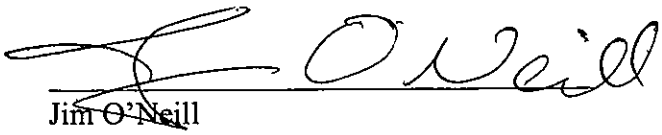
EXECUTION

If approved, the revised childhood and adolescent immunization schedule will be published in an upcoming *Morbidity and Mortality Weekly Report*. CDC will also publish the CDC-adopted recommendation on the applicable CDC website and also update the childhood and adolescent schedule in alignment with this decision.

DECISION

After thoroughly reviewing the assessment in TAB 1 and further considering the childhood immunization recommendations based on my discussions with CDC, FDA, and peer, developed nation health officials, I have determined that the CDC will adopt the revised childhood and adolescent immunization schedule, as stated in Figure 1 of TAB 1. Specifically, the CDC immediately recommends: (1) immunization for the measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib, pneumococcal disease, HPV, and varicella for all children; (2) specified immunizations for high-risk groups (Respiratory syncytial virus (RSV) monoclonal antibodies, and hepatitis A, hepatitis B, meningococcal B, meningococcal ACWY, and dengue); and (3) immunization for hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and COVID-19 based on shared clinical decision making, as stated in Figure 1 of TAB 1.

Approved: ✓ **Disapproved:** _____ **Would like briefing:** _____



Jim O'Neill
Acting Director, CDC

January 5, 2025
Date

TABS

1. "Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries"
2. Current CDC Recommended Childhood and Adolescent Immunization Schedule