MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

DECEMBER 04-05, 2025
MEETING SUMMARY

Trade names are used for identification purposes only and do not indicate endorsement.

THURSDAY: DECEMBER 04, 2025

WELCOME AND ROLL CALL

Roll Call/Opening Statement

Dr. Mina Zadeh, ACIP Executive Secretary, convened the meeting at 8:00 a.m. on December 4, 2025, and welcomed participants to the December 4-5 session of the Advisory Committee on Immunization Practices (ACIP). She provided general logistical information and noted that presentation slides were available on the ACIP website. Dr. Zadeh reviewed the public comment process, explaining that one oral comment session was scheduled, with 10 speakers selected in advance through a blinded lottery, and that written comments were accepted through regulations.gov (Docket No. CDC-2025-0783). She reaffirmed ACIP's commitment to transparency and reviewed conflict-of-interest policies, noting that members must disclose relevant conflicts and may receive limited waivers for activities that enhance expertise but may not vote on related matters.

Dr. Zadeh then shared that Dr. Martin Kulldorff has accepted the position as Chief Science Officer within the Department of Health and Human Services and, as a result, has stepped down from his role as an ACIP member and chair. ACIP expressed its appreciation for Dr. Kulldorff's contributions and leadership and noted that the committee looks forward to continuing collaboration with him in his new role. She then welcomed the new ACIP chair, Dr. Kirk Milhoan. Due to Dr. Milhoan's remote participation, ACIP Vice Chair Dr. Robert Malone served as the meeting facilitator.

Dr. Zadeh proceeded with the roll call of ACIP members, Ex Officio members, and liaison representatives. A complete list of participants is provided in the appendix at the end of this summary. No conflicts of interest were identified.

Dr. Malone gave the opening statement and reminded everyone that he would be the meeting chair for the next two days. He thanked ACIP members, working group members, and support staff for their preparation and participation, acknowledging the significant effort required to support the meeting. He stated that this was his third meeting as an ACIP member and expressed his appreciation for the opportunity to open the session. Dr. Malone highlighted the full agenda for the meeting and specifically recognized the childhood immunization schedule working group, led by Dr. Vicky Pebsworth, for their contributions, including expertise on hepatitis B vaccines, adjuvants, and related clinical and public health policy considerations. He noted that working group discussions informed the work presented and would form the basis for the recommendations provided to the CDC Acting Director.

Dr. Malone concluded by outlining the principles guiding ACIP's work, emphasizing evidence, transparency, and thorough data review to ensure recommendations are grounded in evidence-based science and best medical practice. He reaffirmed that ACIP's mission is to provide independent advice to the CDC Director. He emphasized the importance of evaluating the totality of the evidence with scientific rigor, intellectual honesty, and a willingness to address challenging questions. He also noted ACIP's responsibility to clearly communicate its recommendations and the rationale behind them to both the CDC Director and the American public.

HEPATITIS B VACCINES - RECAP

Dr. Robert Malone, ACIP Vice Chair, noted that ACIP deferred a vote on proposed changes to the hepatitis B vaccination schedule at the September meeting due to incomplete data and the need for clearer evidence. He explained that pausing to review the evidence is consistent with ACIP's responsibility to provide accurate, objective advice to the CDC director. Since that meeting, the CDC established a hepatitis B work group to examine the remaining issues in greater depth. He stated that the Childhood and Adolescent Immunization Schedule Work Group includes diverse perspectives and has helped sharpen the key questions guiding the current discussions. Dr. Malone emphasized ACIP's commitment to a transparent, structured, and evidence-based process and thanked CDC staff and external experts for their essential technical contributions supporting the committee's work.

Policy Context and Schedule Comparison

On behalf of the ACIP Childhood and Adolescent Immunization Schedule Work Group, Dr. Vicky Pebsworth, Chair, reviewed the policy context and presented a comparison of hepatitis B immunization schedules. Dr. Pebsworth thanked CDC staff for their support, noting that the work could not have been completed without their assistance. She explained that the Childhood and Adolescent Immunization Schedule Work Group serves as the umbrella work group and that a hepatitis B sub-work group was formed in response to a specific question. She identified Dr. Evelyn Griffin, Dr. Kirk Milhoan, and Dr. Tracy Beth Hoeg as members of the hepatitis B work group who attended the meeting.

The work group was asked to focus on infants born to mothers who tested negative for hepatitis B surface antigen during pregnancy. The review focused on the hepatitis B birth dose administered within hours of birth and primarily reviewed the two United States-licensed single-antigen hepatitis B vaccines, excluding combination vaccines administered later in infancy.

In accordance with ACIP's charter, vaccines are reviewed periodically. The work group was tasked with reassessing the current recommended schedule, given the length of time since the last review and concerns raised by external groups that the current U.S. policy may be misaligned with recommendations in other developed countries.

Several developments shaped the current hepatitis B policy landscape. Reported acute hepatitis B cases in the U.S. increased significantly over 25 years due to bloodborne and sexual transmission, including exposures associated with unscreened blood transfusions, dialysis, men who have sex with men, persons with multiple sexual partners, and injection drug use. During this time, increased immigration from hepatitis B-endemic regions in Southeast Asia expanded the population of individuals with chronic infection.

Factors affecting policy shifts included major developments in vaccine technology and liability protections. In 1981, the FDA approved the first plasma-derived hepatitis B vaccine in response to the growing hepatitis B crisis, and the vaccine was considered highly effective. However, concerns emerged about the safety of donor plasma. Six years later, the FDA licensed a recombinant hepatitis B vaccine manufactured in yeast, addressing these safety concerns. Liability concerns for pediatricians and manufacturers related to the recombinant vaccine were discussed further with the passage of the 1986 National Childhood Vaccine Injury Act.

A 1989 *JAMA* editorial titled "Worldwide Elimination of Hepatitis B Transmission: We Have the Way, We Have the Will," written by Dr. Hal Morgan and Dr. Donald Francis of the CDC, argued

that universal vaccination at birth in settings with high rates of perinatal transmission, combined with childhood immunization elsewhere, could establish a globally protected cohort against long-term hepatitis B infection. The authors noted that in the U.S., selective vaccination of high-risk groups had not effectively reduced overall disease incidence and suggested that immunization strategies targeting both infants and adolescents should be considered. This editorial helped establish the rationale for expanding hepatitis B vaccination to infants not traditionally considered at high risk.

ACIP hepatitis B vaccination recommendations have evolved. In 1982, only infants born to hepatitis B surface antigen–positive mothers were recommended to receive hepatitis B immune globulin (HBIG) at birth, followed by vaccination at three months of age. In 1984, the recommended timing for immunization was changed from 3 months to 7 days after birth, and in 1985, both HBIG and the hepatitis B vaccine were recommended within 12 hours of birth. In 1987, the first recombinant hepatitis B vaccine was licensed. In 1991, ACIP recommended vaccination for all infants, including those born to hepatitis B surface antigen–negative mothers, before hospital discharge or by two months of age. In 2005, the two-month option was removed, and vaccination of all infants was recommended within 12–24 hours of birth.

The objectives of the session included addressing stakeholder and parental concerns, summarizing the hepatitis B work group's review, and considering whether alternative immunization policies might better align with practices in comparable countries while remaining evidence-based, responsive to the needs of higher-risk populations, and informed by public health and vaccination ethics. The work group was asked to assess the use of a universal birth dose for infants born to mothers who were hepatitis B surface antigen-negative. As outlined in the work group's terms of reference, the scope included reviewing the efficacy and safety of the immunization schedule for children and adolescents, identifying potential safety concerns, and responding to stakeholder input. In support of this work, the group cited Institute of Medicine (IOM) reports from 2002 and 2013 that address parental concerns about the number and safety of childhood immunizations and recommend that the overall immunization schedule be incorporated into research prioritization based on epidemiologic evidence, biological plausibility, and feasibility.

Dr. Pebsworth reviewed stakeholder concerns and discussed findings from two relevant surveys identified through the literature. A 2014 survey of Oregon parents of hospitalized newborns found that 5% refused the hepatitis B birth dose, 8% preferred to delay vaccination, and 6% were undecided. Common reasons cited included beliefs that the infant was too young, concerns about vaccine safety, and perceptions of low risk for infection. She also summarized results from an October survey conducted by the Kaiser Family Foundation and *The Washington Post*, which found that 13% of parents reported skipping or delaying the hepatitis B vaccine and 16% reported skipping or delaying other vaccines. Reported reasons included concerns about side effects and safety, beliefs that vaccines were unnecessary, reluctance to administer multiple vaccines at one visit, preferences to space out vaccinations, questions about safety testing, and limited confidence in federal agencies.

Dr. Pebsworth compared hepatitis B policies across countries with varying prevalence of chronic hepatitis B infection. She noted that the U.S. has a relatively low prevalence of chronic hepatitis B, approximately 0.5%, compared with higher-prevalence countries such as South Korea, Bulgaria, and Romania, where prevalence ranges from approximately 3% to 4.5%. She explained that countries with higher prevalence generally recommend a universal hepatitis B birth dose, while many lower-prevalence countries do not, instead using alternative or delayed vaccination approaches, including initiation later in infancy. She stated that, relative to other

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countries with very low endemicity, the U.S. is an outlier in routinely vaccinating all infants at birth.

She emphasized that ethical considerations were incorporated into the work group's review. She referenced a framework described by Markman that calls for public health policymakers to consider expected health benefits for target populations, potential harm and burdens for stakeholders, implications for individual autonomy, impacts on equity, and efficiency considerations. She also described a more recent framework that emphasizes the preservation of health by weighing both individual and population-level benefits of vaccination, including herd immunity, against potential harms from disease and vaccine-related adverse events. Additional ethical principles discussed included proportionality of interventions, careful consideration of evidence quality and generalizability, acknowledgement of uncertainty, and the exercise of restraint by limiting vaccine dosing, adjuvant exposure, and the number of vaccines administered simultaneously to what is necessary.

Dr. Pebsworth summarized that current conditions reflect persistent, and in some cases increasing, stakeholder dissatisfaction with vaccination policy in general and hepatitis B policy in particular. She stated that this level of dissatisfaction is of societal significance and continues to pose challenges for immunization policymaking. She noted that, as highlighted in prior IOM reports, public health leaders previously endorsed the belief that universal vaccination, supported by emerging technologies, could eradicate hepatitis B, and this perspective shaped public policy. As a result, ACIP recommendations between 1983 and 1991 shifted from targeting only high-risk infants to recommending vaccination for all infants.

She summarized that 35 years have passed since the implementation of the universal hepatitis B birth dose policy. The work group was asked to assess the use of a universal birth dose for infants born to mothers who are hepatitis B surface antigen-negative and to review current evidence and context. She explained that factors contributing to hepatitis B increases in the 1970s and 1980s have since diminished through targeted interventions, while the universal birth dose was intended to eliminate transmission more broadly. She added that some countries with similar hepatitis B incidence and prevalence use selective vaccination approaches rather than a universal birth dose and that stakeholder groups have expressed interest in greater flexibility in vaccination decisions. She concluded that ongoing stakeholder dissatisfaction, documented for more than two decades, remains a relevant consideration as ACIP evaluates current hepatitis B vaccination policy considering evolving evidence, technologies, and liability considerations.

<u>Burden of Disease</u>

Dr. Cynthia Nevison, a CDC contractor with Vortex LLC, presented data on the burden of hepatitis B disease and framed her presentation around three topics relevant to the rationale for universal hepatitis B vaccination of newborns in the U.S. These included morbidity trends and the relative impact of universal versus targeted interventions, perinatal transmission risk and prevention strategies, and evidence regarding horizontal transmission during childhood. Across these topics, she emphasized a recurring contrast between surveillance data, which suggests relatively low disease burden, and modeling approaches, which project higher levels of risk.

She first reviewed age-stratified data on acute hepatitis B cases from 1983 to the present using the National Notifiable Diseases Surveillance System (NNDSS). Historical data provided by the CDC's Division of Viral Hepatitis extended beyond what is publicly available. Acute cases declined substantially from a peak in 1985 to approximately 2,000–3,000 cases annually over the past decade, with the largest reductions observed among adults aged 20–39 years. She

noted that declines began well before implementation of the universal hepatitis B birth dose recommendation in the early 1990s and that reductions among adolescents and young adults occurred earlier than would be expected if driven by newborn vaccination, suggesting a greater role for targeted interventions.

Factors contributing to declines in acute hepatitis B cases before and after implementation of the birth dose were then discussed. These included improved screening of the blood supply, which reduced transfusion- and dialysis-associated transmission, adoption of safer sexual practices during the HIV/AIDS epidemic, implementation of needle exchange programs, and screening and case management of hepatitis B surface antigen-positive pregnant women with targeted vaccination of their infants. Based on the timing and age distribution of observed declines, Dr. Nevison stated that the universal birth dose appeared to contribute only modestly to reductions in acute hepatitis B cases.

Attention then turned to chronic hepatitis B. Dr. Nevison noted that chronic cases were first reported to NNDSS in 2003, with early increases likely reflecting expanded reporting. Case counts remained relatively stable from approximately 2015 to 2020, followed by an increase after 2020, most pronounced among adults aged 60 years and older, with smaller increases among those aged 30 years and older. She stated that the reasons for this increase were unclear and that universal newborn vaccination would not be expected to directly affect chronic disease trends among older adults.

Infant morbidity data were reviewed next, including acute, chronic, and perinatal hepatitis B cases reported to NNDSS. Acute cases in infants declined sharply to near zero, with reductions observed both before and after implementation of the birth dose, suggesting that early declines may reflect targeted vaccination of at-risk infants. Reported chronic hepatitis B cases in infants remained low, and perinatal infections were rare. Surveillance data indicated 36 reported cases of perinatal chronic infections in 2015 and 7 in 2023. These figures were compared with CDC modeling estimates projecting substantially higher numbers, including 952 cases in 2015 and approximately 601 cases in 2023. Dr. Nevison highlighted this discrepancy and noted that the reasons for the difference warrant careful consideration.

She then summarized overall hepatitis B morbidity trends, noting that acute cases declined sharply for multiple reasons, many of which were unrelated to the universal birth dose. Newly reported chronic cases were relatively stable until recent increases among older adults, emphasizing the long-term health implications of chronic infection. Perinatal infections documented through surveillance remained uncommon, while modeling approaches continued to project higher case counts.

Dr. Nevison transitioned to a detailed discussion of CDC modeling for perinatal hepatitis B infections. She explained that the model uses a bottom-up approach beginning with estimates of the number of hepatitis B surface antigen-positive women giving birth in the U.S. She cited estimates indicating that approximately 21,000 such women gave birth in 2015, representing about 0.5% of all births, with more than half not born in the U.S. The largest proportions originated from East Asia, Southeast Asia, and Africa.

The structure of the CDC model was then described. In the absence of postexposure prophylaxis (PEP), all infants born to hepatitis B surface antigen-positive mothers are assumed to be susceptible to infection. Mothers who are hepatitis B e antigen-positive are estimated to have a 90% transmission risk, while e antigen-negative mothers have an estimated 5%–20%

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risk. Infants infected at birth are estimated to have a 90% risk of developing chronic infection, compared with approximately 5% among those infected after age 5 years.

Dr. Nevison reviewed the role of PEP, which includes hepatitis B vaccine and hepatitis B immune globulin administered within 12 hours of birth, and emphasized the importance of maternal screening. Updated model estimates indicate that approximately 88% of pregnant women are screened and that nearly all infants born to identified carrier mothers receive timely PEP. Among the approximately 12% of mothers who are not screened, the model assumes that just under 80% of infants receive PEP, while the remaining 20% are categorized as susceptible.

She restated that the model estimated approximately 601 infants with chronic hepatitis B infection in 2023, compared with 7 cases reported through NNDSS. Factors contributing to this discrepancy were discussed, including uncertainty about the assumed 8% PEP failure rate, questions about the estimate of 88% screening coverage, and assumptions regarding infants born to unscreened mothers. She noted that the model may not fully account for informed parental decision-making among mothers aware of their hepatitis B-negative status. She concluded that several assumptions may contribute to overestimation.

Summarizing perinatal findings, Dr. Nevison stated that infection risk is concentrated in approximately 0.5% of pregnancies, mainly among women from regions with higher hepatitis B endemicity. She suggested that enhanced screening strategies, including integration into immigration-related medical examinations, and improvements in prenatal and delivery screening could support more targeted prevention approaches and reduce reliance on universal newborn vaccination. She emphasized that worst-case assumptions may inflate model-based estimates and should be interpreted cautiously.

The presentation then turned to the horizontal transmission of hepatitis B during childhood. Dr. Nevison stated that limited documented evidence exists for such transmission in the U.S. CDC staff provided a single modeling study by Armstrong et al., which estimated approximately 16,000 cases annually among children aged 0–9 years in the pre-vaccine era. About half were estimated to occur among Asian immigrant populations and half in the general U.S. population. The study used a serocatalytic modeling approach, interpreting a linear increase in age-specific seropositivity as evidence of horizontal transmission.

She noted that the study analyzed multiple populations and relied on assumptions regarding perinatal infection rates, including an assumed rate of 0.07% in the general U.S. population based on unpublished data. Dr. Nevison explained that these assumptions influenced the model estimates and were difficult to assess independently.

The underlying serosurvey data were then reanalyzed without anchoring the model to an assumed perinatal infection rate. When observed data points were analyzed directly, three of four populations did not show a statistically significant linear increase in seropositivity with age. In NHANES data representing the general U.S. pediatric population, the estimated slope was statistically indistinguishable from a flat line, indicating no clear evidence of horizontal transmission.

A statistically significant increase was observed only in the Southeast Asian subgroup, where approximately 16% of children were seropositive by age 9 years. This finding was based on studies documenting transmission within specific refugee communities characterized by high

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background prevalence and transmission from older siblings. Dr. Nevison emphasized that these circumstances may not be generalizable to the broader U.S. pediatric population.

Summarizing horizontal transmission findings, she stated that such transmission has been documented in certain high-risk immigrant communities but that evidence for transmission among most U.S. children is limited. She noted that prior modeling estimates were not supported by surveillance data, citing that before implementation of the birth dose, approximately 400 acute cases per year were reported among children aged 0–9 years, many likely attributable to perinatal transmission. She also referenced a prior request for documentation of school-based transmission, noting that the CDC reported no records identifying such cases.

Dr. Nevison then summarized the hepatitis B burden approximately 34 years after the implementation of the universal birth dose. Acute cases declined for multiple reasons, largely by age group and period, suggesting a limited association with newborn vaccination. Chronic cases increased after 2020, particularly among adults aged 30 years and older, with the largest increase among those aged ≥60 years, highlighting current public health concerns. Surveillance continued to document low perinatal infection counts, while modeling approaches frequently projected higher estimates.

The presentation concluded with a discussion of vaccine efficacy and waning immunity. Dr. Nevison reviewed studies examining antibody persistence and reported that antibody levels declined over time, with more rapid waning observed among individuals who initiated vaccination earlier in life. Long-term studies among Alaska Native populations showed higher antibody persistence among those vaccinated at ages 5–19 years compared with those vaccinated before age 5 years. Although most participants demonstrated an anamnestic response to a booster dose, a subset did not achieve protective antibody levels.

Similar patterns were reported in studies of U.S. children vaccinated during infancy. Individuals who initiated vaccination at birth were less likely to retain protective antibody levels in adolescence compared with those who initiated vaccination at age ≥4 weeks, and a small proportion did not respond adequately to boosting. NHANES data further illustrated lower antibody persistence among cohorts likely vaccinated as newborns compared with earlier cohorts vaccinated at older ages.

In summarizing findings on waning immunity, Dr. Nevison stated that antibody levels declined most rapidly among individuals vaccinated during infancy, particularly at birth. While most vaccinated individuals demonstrated immune memory, a subset did not respond to booster doses, raising questions about long-term protection during later periods of increased risk.

HBV Vaccine Safety

Mr. Mark Blaxill (CDC) presented a review of safety evidence related to the hepatitis B birth dose, drawing on findings from clinical trials, post-licensure safety studies, Institute of Medicine (IOM) assessments, and data from the Vaccine Injury Compensation Program (VICP). He also noted that animal model studies were reviewed to provide insight into safety questions that cannot be directly evaluated in human infants.

He summarized overarching themes from the safety evidence, noting that the quantity and quality of available data varied across evidence sources. Clinical trial evidence cited in prior

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ACIP deliberations was reviewed, with Mr. Blaxill stating that these studies did not include randomized, placebo-controlled trials using inert placebos in infants and generally involved short follow-up periods. As a result, evaluation of chronic or late-onset outcomes was limited, and safety concerns may not have been comprehensively assessed.

He referenced a rapid systematic review of post-licensure safety studies conducted by CDC's Immunization Safety Office (ISO) and presented at the past September meeting, describing it as a valuable resource. His review of this literature identified findings related to potential chronic or late-onset outcomes that were not previously highlighted. He also discussed conclusions from IOM vaccine safety reports, noting that for many health outcomes, evidence was insufficient to assess potential associations with hepatitis B vaccination. In addition, he summarized information on hepatitis B vaccine claims processed through the VICP and briefly addressed mechanistic findings from animal studies, noting that some studies have examined immune activation in experimental models.

Turning to the clinical trials supporting the universal hepatitis B birth dose recommendation adopted in 1991, Mr. Blaxill noted that the three cited studies were published in the 1980s. Two did not include control groups, and one used another vaccine as a comparator. Sample sizes were small, and some studies focused on infants born to hepatitis B surface antigen-negative mothers within Asian American populations at higher risk for perinatal transmission. Follow-up periods were short, with a maximum duration of 7 days, limiting the ability to assess chronic or late-onset outcomes. While the studies generally reported the vaccine to be safe and well tolerated, one documented systemic complaint in approximately 18% of vaccinated infants, and another reported a death that was determined not to be related to vaccination.

Among these trials, the Zajac study was described as providing the most detailed safety data, although it evaluated infants under 1 year of age rather than the birth dose specifically. Mr. Blaxill reported that the study documented systemic complaints in approximately 18% of vaccinated infants, defined as fatigue or weakness, diarrhea, or irritability, and described in the publication as nonspecific or transient. He noted that some of these symptoms overlap with clinical signs monitored for neurologic conditions, citing definitions from the National Institute of Neurological Disorders and Stroke. He emphasized that the findings were not conclusive but were presented as part of the broader safety evidence.

Post-licensure safety evidence was then reviewed in greater detail. The ISO rapid systematic review screened nearly 2,000 publications and identified 20 studies relevant to hepatitis B vaccination administered during the first 30 days of life. Of these, nine specifically evaluated the birth dose administered within 1 day or up to 8 days after birth, while 11 included vaccinations during the first month of life.

Mr. Blaxill explained that he organized these 20 studies according to ISO's categorization by vaccination timing and reviewed whether studies used another vaccine or an unvaccinated comparison group. He stated that studies using another vaccine as the comparator were less informative for safety assessment. Four studies using unvaccinated or no-vaccine comparison groups were identified across the ISO categories and reviewed in detail.

One such study, published by Linder et al. in 1999, examined neonatal outcomes before and after the introduction of the hepatitis B birth dose in a hospital in Israel. Among approximately 5,000 infants born before vaccine implementation, 14 cases of unexplained neonatal fever were observed. Following the introduction of the birth dose, the study documented an increase in unexplained fever, with an associated odds ratio of 2.2. Mr. Blaxill reported that the authors concluded the increase, which led to sepsis evaluations, intravenous antibiotic use, and prolonged hospital stays, may be associated with vaccination on the first day of life and prompted subsequent follow-up evaluations.

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Findings from three additional studies using unvaccinated comparison groups were summarized. The Lewis et al. study, conducted to evaluate concerns regarding neonatal fever and sepsis, found no significant differences between vaccinated and unvaccinated infants. However, the authors acknowledged the potential influence of a healthy-vaccinee effect. A 2004 study by Eriksen et al. examined mortality outcomes using Vaccine Safety Datalink (VSD) data and reported lower mortality among vaccinated infants, while noting methodological considerations related to confounding. A more recent Australian study evaluating a specific adverse event among preterm infants reported a lower risk among vaccinated infants. Still, it also acknowledged the potential impact of a healthy-vaccinee effect.

The Eriksen et al. study was reviewed in greater detail. Mr. Blaxill noted substantial differences between vaccinated and unvaccinated infants, with vaccinated infants generally being healthier, born at term, and having higher birth weights. In contrast, unvaccinated infants were often medically fragile, including premature and very low birth weight infants, with those of extremely low birth weight excluded from analysis. The study compared mortality among 72 vaccinated infants with matched unvaccinated infants drawn from two California health maintenance organizations. Deaths in the unvaccinated group were more frequent and often occurred early in life, complicating comparisons. While sudden infant death syndrome (SIDS) accounted for the most frequent cause of death among vaccinated infants in the matched analysis, the authors identified additional SIDS cases among a larger pool of unvaccinated infant deaths. They concluded that SIDS rates were similar between groups.

Mr. Blaxill stated that the study illustrates challenges in post-licensure safety evaluation, particularly the influence of confounding due to the healthy-vaccinee effect when comparing vaccinated and unvaccinated infant populations.

Additional post-licensure studies not highlighted in the September presentation were briefly addressed, including vaccine effectiveness studies and those examining longer-term outcomes with extended follow-up periods. Mr. Blaxill summarized four VSD-based studies evaluating outcomes such as tic disorders, developmental delay, childhood emotional disturbances, and premature puberty. He reported that these studies identified statistically significant associations with hepatitis B vaccination exposure in the first month of life, noting that the findings are subject to the limitations inherent in observational research.

Mr. Blaxill concluded that the available evidence for the hepatitis B birth dose is limited and varies across sources. He referenced IOM reviews conducted over the past 2–3 decades, which generally concluded that evidence was insufficient to accept or reject causal associations for most chronic or late-onset outcomes. He also reviewed VICP data, noting that compensation has been awarded for hepatitis B vaccine–related injuries, including claims involving sudden infant death syndrome, seizures, encephalopathy, and other causes of death.

He further noted that animal studies, while limited and mixed, have reported immune activation following early-life hepatitis B vaccination in some experimental models, with associated neurologic and behavioral findings. Mr. Blaxill concluded that gaps remain in the evidence base due to the lack of randomized trials with inert placebo controls and limited long-term follow-up, and that animal model findings raise theoretical considerations relevant to overall safety assessment.

Discussion

Dr. Pollak asked whether the CDC has 2025 data on the seroprevalence rate of anti-hepatitis B antibodies among women of childbearing age. He noted that if these women have existing antibodies, they could transfer passive immunity to their infants, providing reassurance to mothers hesitant about newborn vaccination. He referenced earlier 2017 data showing that up

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to 50% of the U.S. population had hepatitis B antibodies and asked whether newer data are available.

Dr. Nevison responded that most available data focus on hepatitis B surface antigen positivity rather than antibody prevalence. However, based on findings on waning immunity, many individuals vaccinated at birth may no longer have detectable antibody levels. She emphasized, though, that the absence of detectable antibodies does not necessarily mean loss of protection, as immune memory cells may remain present and ready to respond if exposed to infection.

Dr. Meissner stated that he strongly disagreed with several points made during the prior presentations and focused his comments on the hepatitis B discussion. He said that antibodies should not be conflated with protection, emphasizing that while hepatitis B surface antibody levels may wane over time, durable cellular immunity persists and is not easily measured. He stated that, to his knowledge, there have been no documented cases of symptomatic or chronic hepatitis B infection in otherwise healthy individuals, including neonates, who completed the recommended vaccination series. He highlighted that hepatitis B remains a major global health problem and noted that, although U.S. prevalence is relatively low, the absolute number of chronically infected individuals remains substantial. He described the neonatal hepatitis B birth dose as a critical safety net, particularly for infants born to mothers with undiagnosed infection, given real-world limitations in testing and follow-up. Dr. Meissner concluded by asking whether there is any credible evidence of harm associated with administering the hepatitis B vaccine to neonates, stating that reported symptoms such as irritability or fatigue should not be mischaracterized as serious neurologic injury, and emphasizing that the benefits of neonatal vaccination are clear.

Mr. Blaxill responded that the available safety evidence for universal neonatal hepatitis B vaccination is limited and said he would not speculate about specific harms, noting that the Institute of Medicine has concluded there is insufficient evidence to establish or reject causality for a wide range of conditions. He expressed concern that the universal birth dose administered to all infants, including those at low risk, requires robust, definitive safety data.

Dr. Meissner replied that he was not aware of any evidence demonstrating harm from neonatal hepatitis B vaccination. He stated that without concrete examples or data showing adverse outcomes, he does not accept that claim and emphasized that the benefits of birth dose are well established.

Dr. Levi responded that he did not believe the question of whether evidence of harm exists was the most appropriate framing. Instead, he argued that the key question is whether the current monitoring and surveillance systems can detect harm if it were present at a certain rate. He stated that based on the data presented, including very small sample sizes, short follow-up periods, and a lack of placebo comparisons, significant safety signals could exist without being detected. He emphasized that the absence of detected harm cannot be separated from the limitations of what was measured and monitored. He said this issue reflects a broader problem in vaccine safety assessment, where conclusions about safety are drawn without adequately considering whether existing systems can identify meaningful risks.

Dr. Meissner stated that there is clear evidence of benefit from neonatal hepatitis B vaccination and that, based on the available data, there is no evidence of harm.

Dr. Levi questioned how vaccine benefit is being quantified and asked what the number needed to vaccinate would be for infants born to mothers who test hepatitis B surface antigen negative to prevent one case of chronic hepatitis B. He said he suspects no such estimate exists and that the number would likely be extremely high, given the very low baseline risk in this population. He argued that without this information, it is challenging to justify universal vaccination and said

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that recommending such an intervention would require confidence that the number needed to harm is far greater than the number needed to vaccinate, a threshold he does not believe has been demonstrated.

Dr. Malone stated that Dr. Meissner's comments were directed toward CDC subject matter experts and sought clarification on vaccine safety. He reframed the question as an inquiry into what data or evidence exists regarding risks associated with COVID-19 vaccines, noting that these are multiple distinct products rather than a single vaccine. He then asked CDC experts to describe, based on currently available information, what is known about the risks associated with these products, independent of the Institute of Medicine's conclusions.

SME, Dr. Su, acting director of the CDC Immunization Safety Office, provided additional context on the rapid systematic reviews referenced earlier. He explained that these reviews were conducted in September at the request of the ACIP chair and focused on the hepatitis B vaccine administered within the first 24 hours of birth. This narrow scope led to the exclusion of several studies discussed during the meeting. He noted that the reviews followed a standardized, reproducible methodology using GRADE criteria to assess the quality and confidence of evidence, and that many excluded studies were omitted due to low confidence ratings. He also explained that some studies were excluded because they evaluated vaccines no longer in use, including products containing thimerosal, which has not been included in hepatitis B vaccines since 1999–2000. Dr. Su stated that among the studies meeting the inclusion criteria, the identified adverse events were consistent with those observed in pre-licensure clinical trials.

Dr. Meissner clarified his question by asking whether there has been any documented case of active or chronic hepatitis B in an otherwise healthy individual who had completed the recommended hepatitis B vaccination series. He stated that he is not aware of any such cases.

Dr. Su responded that the question relates more to breakthrough infection than to an adverse event. He said answering it would require a more detailed review of the data. To his knowledge, such cases have not been identified, but he noted that the issue has not been examined in depth and said the CDC could provide a more definitive answer.

Dr. Langer added that Dr. Meissner's question concerns breakthrough infections rather than adverse events. He stated that available data indicate breakthrough hepatitis B infections have occurred only among individuals with significant comorbidities, such as immunocompromising conditions. He said there are no known instances of a healthy individual, vaccinated adequately against hepatitis B and without significant comorbidities, subsequently developing hepatitis B infection.

Dr. Griffin raised concerns about gaps in prenatal hepatitis B screening and questioned whether responsibility is being shifted to infants rather than addressing shortcomings in adult prenatal care. She noted that ACOG recommends early pregnancy hepatitis B screening. Yet work group data showed that only 84% to 87% of women were tested or had results available before delivery, compared with 96.5% reported in 2002 MMWR data. She asked how this decline occurred and whether it reflects missed opportunities in prenatal care. Dr. Griffin questioned whether the neonatal birth dose is being used as a safety net for systemic failures in adult screening and whether it is fair to place that burden on infants. She emphasized that nearly all births occur in hospital labor and delivery units, most of which already perform routine serologic testing, and pointed out that hepatitis B surface antigen testing can return results within 30 to 90 minutes, with point-of-care testing becoming increasingly available. She suggested that universal or repeat testing at delivery, like existing practices for syphilis and HIV, could help close the screening gap and allow for targeted infant prophylaxis. Dr. Griffin concluded by asking whether the CDC is considering or developing guidance or programmatic efforts to

strengthen prenatal or delivery-based hepatitis B screening to identify at-risk infants better and reduce reliance on universal neonatal vaccination as the primary safeguard.

Dr. Su responded that the question raised relates to standards of obstetric and gynecologic care rather than vaccine safety. He noted that while vaccine safety experts were present, obstetrics and gynecology experts were not, and said the CDC would defer questions about prenatal screening practices and standards of care to specialists in those fields.

Dr. Langer thanked Dr. Griffin and asked her to restate the question to ensure he was addressing it accurately.

Dr. Griffin explained that she was concerned about the widening gap in hepatitis B screening during pregnancy, noting that screening rates reported in 2002 were 96.5%, while more recent data suggest substantially lower rates. She asked where this change may come from and what opportunities exist to close the gap.

Dr. Langer responded that closing the hepatitis B screening gap in pregnancy is now a CDC strategic priority, with dedicated efforts and resources focused on improving prenatal testing. He said the causes of the screening gap are likely multifactorial, including issues related to access to healthcare and the availability and timeliness of testing, mostly in lower-resource settings. He noted that discussions with obstetric clinicians at the CDC indicated that timely hepatitis B testing can be challenging in some facilities, even if this is not the case in higher-resource hospitals. Dr. Langer said these challenges underscore why the neonatal hepatitis B birth dose remains an important safety net while broader efforts are underway to improve screening practices.

Dr. Hibbeln emphasized the need for clear, reproducible, and non-speculative data to inform committee decisions and agreed with earlier comments about rigorously quantifying risks and benefits. He noted that hepatitis B vaccination has been cited as one of the major public health accomplishments in U.S. medical science. He said that any changes to existing recommendations require a high burden of proof. He observed that earlier in the discussion, questions were raised about documented rates of harm, but he had not heard evidence presented. Dr. Hibbeln then asked whether there is any actual evidence of harm associated with hepatitis B vaccination and, more specifically, whether there is evidence of harm when vaccination is given before 30 days of age compared with after 30 days, or whether concerns about earlier vaccination are based on speculation.

Mr. Blaxill stated that a concern was raised in an observational study documenting unexplained fever in infants following the hepatitis B birth dose. He noted that while this finding was published and documented, there is limited evidence regarding any long-term risk associated with it.

Dr. Hibbeln stated that the concerns raised were speculative, supported by limited evidence, and emphasized the importance of grounding decisions in clear, reproducible data.

Dr. Nevison cited figures from the U.S. Vaccine Injury Compensation Program, noting that millions of dollars have been awarded for neurologic and autoimmune conditions, including Guillain-Barré syndrome, transverse myelitis, multiple sclerosis, rheumatoid arthritis, and other neuropathies, in both children and adults. She argued that because the program is adversarial, compensated claims likely reflect cases with strong supporting evidence, and that these risks, even if rare, should be weighed against benefits, especially for infants born to hepatitis B surface antigen–negative mothers.

Dr. Malone summarized Dr. Nevison's point by stating that these compensated cases represent documented harms that should be considered in any risk–benefit assessment alongside expected benefits.

Dr. Meissner responded that compensation payouts do not establish causality, explaining that, based on his experience as a former chair of the Vaccine Injury Compensation Program, settlements explicitly state that they are not admissions that a vaccine caused the condition and therefore should not be interpreted as confirming associations.

Dr. Malone requested that CDC subject matter experts and Reed Grimes from HHS and HRSA address the specific question regarding documented adverse events associated with products labeled for hepatitis B vaccination.

SME, Dr. Su explained that hepatitis B vaccines, particularly the birth dose, have been in use for decades and have been monitored through multiple vaccine safety surveillance systems, including the Vaccine Adverse Event Reporting System, which he described as the most sensitive. He noted that reports involving children largely reflect adverse events identified during pre-licensure trials. He added that safety reviews summarizing these findings have been published in the peer-reviewed literature and in reviews conducted by the Institute of Medicine. According to Dr. Su, post-licensure adverse events following hepatitis B vaccination have generally been consistent with what was observed in pre-licensure trials, and additional data could be shared with the work group or full committee if needed.

Dr. Grimes, Director of the Division of Injury Compensation Programs within the Health Resources and Services Administration, explained that the National Vaccine Injury Compensation Program provides compensation through several pathways, including HHS concession of a table injury or causation, decisions by special masters in the U.S. Court of Federal Claims, or negotiated settlements without formal determinations of causality. He noted that since 1988, just under 50% of claims have been compensated overall, while in the most recent five fiscal years, approximately 77–78% of claims have resulted in compensation.

Dr. Middleman thanked the committee for the opportunity to speak and emphasized that antibody levels alone do not define protection. She clarified that her study focused on the anamnestic response, which reflects immune memory and is a stronger indicator of lasting protection. The study showed preserved immune memory regardless of when the first hepatitis B dose was given, with no statistically significant differences between groups. Even participants with no detectable antibodies demonstrated protective immune responses upon challenge, reinforcing that immune memory, not circulating antibodies, is the critical factor.

Dr. Malone acknowledged and endorsed Dr. Middleman's explanation regarding recall responses and immune memory. He noted that broader discussions of risk-based versus universal strategies were outside the scope of the current agenda and redirected the conversation back to questions about the data presented during the session.

Dr. Middleman then emphasized the importance of reviewing vaccine policy using a structured, evidence-based methodology, such as an evidence-to-recommendation framework. She cautioned against relying on isolated findings and stressed the need to consider the full body of scientific and historical evidence. She requested more organized input from CDC subject matter experts. She asked for clarification on the professional roles and areas of expertise of the presenters, noting the importance of hearing directly from experts whose primary work focuses on immunization science and policy.

Dr. Malone responded to Dr. Middleman's question about presenter backgrounds. He clarified that both Nevison and Blaxill currently hold roles connected to the CDC, noting that Nevison serves as a CDC contractor, and stated that this had been disclosed. He acknowledged Dr.

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Middleman's points regarding immune recall responses and broader process concerns. Dr. Malone then asked whether the GRADE framework had been used in establishing the original hepatitis B birth dose policy.

Dr. Middleman replied that the policy was created before her tenure as a liaison. She noted her 21 years of experience in that role and stated that, to her knowledge, GRADE was not used in developing the policy. She added that, as evidence evaluation methods have evolved, applying such frameworks is now appropriate.

Dr. Malone confirmed that GRADE was not the basis for the current birth dose recommendations.

Dr. Goldman stated that the committee failed to use an evidence-to-recommendation framework and did not adequately consider the totality of evidence, risks, benefits, harms, equity, and implementation impacts. He criticized what he described as the selective use of data, the lack of transparency around work group composition, and insufficient clinical and scientific expertise among presenters. He emphasized that vaccine recommendations are not mandates, that medical decisions are individualized between physicians and patients, and that waning immunity and passive immunity were not appropriately contextualized. He expressed concern that the discussion created public confusion, did not accurately reflect available data, and risked undermining patient care. He urged the committee to prioritize rigorous scientific processes, transparency, and public trust.

Dr. Malone responded that work group activities are governed by the Federal Advisory Committee Act, which requires confidentiality of work group proceedings. He stated that this limits the ability of the chair and members to publicly disclose work group deliberations or membership details, despite the concerns raised about transparency.

Dr. Goldman replied that he had served as a liaison on prior ACIP work groups for many years and noted that, historically, the names, affiliations, and roles of work group members were publicly listed even though deliberations themselves were confidential. He clarified that his request was for disclosure of who served on the work group and their roles, not for disclosure of confidential discussions. He expressed concern that the subject-matter-expert physician liaisons had been removed.

Dr. Malone acknowledged the concern and stated that the requested information would be addressed in a slide deck scheduled for later in the meeting.

Dr. Fryhofer explained that as a practicing physician and American Medical Association liaison, she strongly supports maintaining the hepatitis B birth dose. She noted that maternal–infant transmission of hepatitis B results in chronic infection in approximately 90% of infected infants. She emphasized that screening of pregnant women is not 100%, leaving gaps that place newborns at risk. She described severe outcomes she has personally treated, including cirrhosis, liver cancer, and death due to hepatitis B. She also raised concerns about early postnatal and nonsexual transmission, noting that hepatitis B is highly contagious and that it is not feasible to test every individual who may have contact with a newborn during the period if vaccination is delayed. On behalf of the American Medical Association, she urged ACIP to maintain the recommendation for a hepatitis B vaccine dose at birth to protect infants during this vulnerable window.

Dr. Munoz-Rivas, speaking as an infectious disease specialist on behalf of the Infectious Diseases Society of America, expressed strong concern about proposals to remove the hepatitis B birth dose. She emphasized that this vaccine is a well-established, safe, and successful prevention strategy that protects the most vulnerable infants. She noted that current systems do not reliably identify all infants at risk because prenatal screening and follow-up are

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imperfect. Given these gaps, she argued that removing the birth dose would be irresponsible and damaging to both the health care community and infants who depend on this safety net. She framed infant protection as a collective duty when risk cannot be eliminated through maternal testing alone.

Dr. Levi responded that the U.S. policy differs from approaches used in many other countries that also prioritize child health and may view the balance of risks and benefits differently. He questioned the level of confidence expressed regarding both safety and necessity, noting that similar certainty had previously been asserted for other vaccines and later challenged by emerging evidence. He encouraged humility, careful comparison with international practices, and respectful scientific debate, cautioning against characterizing differing views as irresponsible rather than part of legitimate evidence-based discussion.

Dr. Hoeg stated that the U.S. is an outlier among high-income countries in recommending a universal hepatitis B birth dose. She noted that the original approval data for infant hepatitis B vaccines relied on short-term observational studies without control groups, evidence that would not meet current regulatory standards. She also referenced several short-term randomized trials that compared the hepatitis B vaccine to other vaccines rather than a placebo, emphasizing that these provided low-confidence safety data. She said known adverse events include rare anaphylaxis, fever, and reactogenicity. She argued that, given the low baseline risk for infants born to surface-antigen-negative mothers, greater humility is needed when asserting that benefits outweigh harms without stronger evidence.

Dr. Malone asked about the size of trials needed to detect rare adverse events, noting that detecting an event occurring at a rate of 1 in 1,000 would require thousands of participants, and substantially more to detect rarer events.

Dr. Hoeg responded that such detection would require trials with tens of thousands of participants and confirmed that no placebo-controlled randomized trials of that size exist for hepatitis B birth dose vaccines.

Dr. Malone clarified that without trials of sufficient size, current data cannot reliably detect adverse events occurring at rates such as 1 in 1,000 or even 1 in 100.

Dr. Hoeg agreed, reiterating that the absence of large placebo-controlled randomized trials limits confidence in safety conclusions. She emphasized that because the benefit for most low-risk infants is extremely small, identifying rare but serious safety signals would require extensive studies. She questioned why a universal birth dose is considered necessary, given that many peer nations do not recommend it for infants born to hepatitis B surface-antigen-negative mothers and urged a more cautious, evidence-proportionate approach.

Dr. Pebsworth drew attention to the Linder et al. 1999 study from Israel, which examined unexplained neonatal fever before and after the introduction of the hepatitis B birth dose. She stated that the study found a 100% increase in unexplained neonatal fever following implementation of the birth dose, leading to more sepsis evaluations, antibiotic use, and longer hospital stays, and offered this as an example of published evidence suggesting potential harm.

Dr. Malone clarified work group transparency, stating that the Federal Advisory Committee Act allows disclosure of work group membership but does not require it. He noted that a decision had been made to disclose the work group members in a later slide.

Dr. Buchanan questioned why the hepatitis B vaccination policy is being revisited in the absence of evidence showing widespread safety signals or adverse events. She noted that no clear data have been presented demonstrating harm to infants from the birth dose and asked why the issue is being brought forward now. Dr. Buchanan emphasized that, while humility in

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reviewing evidence is important, she remains concerned that reconsidering the policy without evidence of harm overlooks the known and significant risks to infants who are not protected against hepatitis B.

Dr. Griffin raised concerns about the strength and duration of the pre-licensure safety evidence for the hepatitis B birth dose, noting that the original studies involved only four to five days of follow-up and lacked placebo controls, which would be insufficient to detect rare or long-latency adverse events. She emphasized that while these trials were underpowered and underfunded, there are signals in the literature suggesting associations with autoimmune conditions, including multiple sclerosis, that may take years or decades to emerge. Dr. Griffin clarified that the intent is not to discontinue protection for infants born to hepatitis B surface antigen–positive mothers, but to reassess risk in infants born to hepatitis B-negative mothers who are at low risk. She argued that safety evaluation should extend beyond short-term seroconversion outcomes and consider long-term effects after decades of widespread use. As an example, she referenced research on macrophagic myofasciitis, where aluminum adjuvant has been identified at injection-site granulomas and associated with systemic symptoms such as fatigue, brain fog, and functional impairment. While she acknowledged that these findings demonstrate association rather than causation, she stressed that inadequate funding and study design have limited the ability to investigate these potential risks properly. She urged caution in continuing universal birth dosing for low-risk infants until these questions are more thoroughly examined.

Dr. Malone offered a closing comment encouraging participants to focus on the actual proposed voting language rather than speculating based on media reports or prior commentary. He noted that the draft language was available. He suggested that reviewing the text directly would provide a clearer and more accurate understanding of what was being considered, which may have differed from what some had anticipated.

HEPATITIS B VACCINE MANUFACTURERS

GlaxoSmithKline (GSK)

Dr. Candice Robinson, representing GSK Vaccines, stated that GSK submitted a formal letter to the docket and emphasized long-standing evidence supporting the hepatitis B birth dose. She noted that without vaccination, 80% to 90% of infants infected at birth develop chronic hepatitis B, with increased risk of cirrhosis and liver cancer later in life. She cited a 2023 peer-reviewed analysis indicating that up to 500,000 women giving birth annually in the U.S. were not tested for hepatitis B during pregnancy between 2015 and 2020, despite guidelines. Dr. Robinson explained that GSK's recombinant hepatitis B vaccine has been FDA-approved since 1989, with approximately 1.4 billion doses administered globally and more than 35 years of postmarketing safety data supporting an acceptable safety profile, including use at birth. She also referenced GSK's combination pediatric vaccines containing hepatitis B, which have undergone rigorous regulatory review and ongoing safety monitoring. She stated that the evidence base is extensive and offered GSK's willingness to participate in a future session for more detailed scientific discussion.

Merck

Dr. Michelle Goveia, a pediatrician from Merck's global medical and scientific affairs team, stated that Merck supports maintaining the current hepatitis B birth dose recommendation based on nearly 40 years of evidence. She emphasized that the risk of progressing to chronic hepatitis B is strongly age dependent, with up to 90% of infants infected at birth developing

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chronic infection, which can result from maternal transmission or close contact with infected family members who may be unaware of their status. She noted that the hepatitis B virus can survive on surfaces for up to a week, making exposure possible through parents, caregivers, or others. Dr. Goveia explained that Recombivax HB, first FDA-approved in 1986, has been a cornerstone of hepatitis B prevention in the U.S. and globally, with more than 330 million doses distributed. She argued that limiting vaccination to newborns of infected mothers would result in missed opportunities to prevent transmission, disease, cancer, and death, particularly given challenges within the U.S. health system related to screening gaps, false negative results, and the potential for maternal infection after prenatal testing. She also cautioned that removing, delaying, or weakening the birth dose recommendation could disrupt the use of hepatitis B-containing combination vaccines, potentially affecting protection against multiple diseases, creating supply and access challenges, reducing parental choice, lowering coverage rates, and diminishing overall disease prevention.

Sanofi

Dr. Ayman Chit, head of medical affairs for Sanofi Vaccines in North America, stated that Sanofi supports maintaining access to FDA-approved and CDC-recommended immunizations as a core public health strategy grounded in transparency and evidence-based medicine. He emphasized that Sanofi vaccines are developed, tested, evaluated, approved, and monitored under rigorous scientific and regulatory standards across their full life cycle, from pre-licensure through post-licensure. He noted that each vaccine ingredient serves a specific purpose and is used at the lowest effective amount to maximize protection while minimizing risk. Dr. Chit highlighted that the U.S. childhood immunization schedule is based on robust safety data and is designed to protect infants when they are most vulnerable, explaining that delaying vaccination increases susceptibility to preventable diseases. He underscored the importance of combination vaccines, which are used by approximately 80% of U.S. infants, for reducing the number of injections, improving provider workflow, and being generally preferred by parents. He cautioned that changes to recommendations for any vaccine component could disrupt supply, limit access for years, and affect protection against multiple diseases. Dr. Chit stated there is no credible evidence indicating safety risks with current immunizations and that removing or altering recommendations would require extensive research, regulatory review, and long manufacturing lead times, potentially leaving patients without protection. He concluded by reaffirming Sanofi's support for informed consent, parental choice, and continued partnership to preserve vaccine access and protect infants early in life.

Dr. Griffin asked the manufacturers to briefly clarify whether the hepatitis B vaccine antigen is still produced using yeast-based fermentation. Specifically, she wondered whether each manufacturer continues to use recombinant strains of *Saccharomyces cerevisiae* as the host organism for antigen production, and whether this production method has remained consistent since the original approvals in the mid to late 1980s, approximately 1986 onward.

Dr. Goveia confirmed that this was correct.

Dr. Chit stated that Sanofi uses a hepatitis B vaccine component manufactured by Merck.

Dr. Griffin thanked the manufacturers for confirming continued yeast-based production since the original approvals in the 1980s. She expressed concern about anti-Saccharomyces cerevisiae antibodies, which are recognized markers of inflammatory bowel disease, particularly Crohn's disease. She cited published literature showing a substantial global rise in inflammatory bowel disease from 1990 to 2021. She noted that while yeast is commonly found in the environment,

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hepatitis B vaccination is one of the few contexts in which yeast-derived antigens are injected, potentially bypassing natural immune barriers.

Dr. Malone paraphrased Dr. Griffin's concern as a question about whether hepatitis B vaccines induce antibodies to yeast antigens and whether such antibodies could be associated with immune-mediated conditions such as inflammatory bowel disease.

Dr. Griffin clarified that her question to manufacturers was whether studies have evaluated associations or causality between hepatitis B vaccination, development of adaptive antibody responses to yeast antigens, and subsequent inflammatory bowel disease.

Dr. Malone asked whether pharmacovigilance systems evaluate the risk of developing acquired adaptive immune responses to antigens introduced during vaccine manufacturing.

Dr. Chit responded that all serious adverse events are closely monitored through robust post-licensure safety surveillance systems and that no safety signals have been identified to date that raise concern in this area.

HEPATITIS B VACCINES (CONTINUED)

Summary of the Information & Presentation of the Vote Language

Dr. Pebsworth opened by summarizing the Childhood and Adolescent Immunization Schedule Work Group's charge, scope, and findings. She explained that the work group was tasked with assessing the use of a universal hepatitis B birth dose for infants born to mothers who test negative for hepatitis B surface antigen. While the request focused on the birth dose, related issues affecting subsequent doses were also considered. She noted that the work group included current ACIP members, outside experts, and an ex officio participant, and operated under terms of reference that included reviewing schedule efficacy and safety, identifying evidence gaps, and addressing stakeholder concerns.

Following the September meeting, the work group undertook an intensive review process. Dr. Pebsworth described how 16 questions were submitted to the CDC requesting additional data and clarification. Between October 17 and November 24, the group met seven times and reviewed 12 presentations from CDC staff, work group members, and invited ad hoc experts. Topics included clinical ethics, nonspecific effects of vaccination, exposure to aluminum adjuvants, clinical practice challenges and solutions, and the Alaska hepatitis B vaccine trials.

Polling of work group members identified several areas of complete or near-full agreement. Dr. Pebsworth reported consensus that hepatitis B can be transmitted vertically and horizontally, is a serious disease, and is preventable through vaccination, including the use of hepatitis B vaccine and immune globulin in specific populations. At the same time, members identified uncertainty regarding U.S. incidence, prevalence, and horizontal transmission rates, as well as uncertainty about whether all three doses are required to achieve protection. Gaps and limitations in the evidence base were noted, and the available safety evidence was characterized as poor according to GRADE criteria.

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Strong agreement was also reported regarding the protection of infants born to mothers who test positive for hepatitis B surface antigen. Dr. Pebsworth stated that the work group agreed these infants should continue to receive hepatitis B vaccine and immune globulin soon after birth. Members further agreed that gaps in prenatal screening should be eliminated, that rescreening at the time of delivery should be considered to avoid unknown maternal status, and that screening failures represent a serious quality-of-care issue with implications for newborn management and follow-up.

With respect to infants born to mothers who test negative for hepatitis B surface antigen, Dr. Pebsworth summarized agreement that the risk of horizontal infection during childhood is extremely low, particularly in the first month of life. Based on this assessment, the work group concluded that routine hepatitis B vaccination at birth is not required for this population. She highlighted several recurring themes, including the need to improve the quality and appropriateness of hepatitis B preventive care, reduce unnecessary early-life exposures in vulnerable infants, support individualized decision-making and parental autonomy, strengthen safety monitoring and research, and consider U.S. policy in relation to approaches used in other low-endemicity countries.

Dr. Pebsworth then outlined the voting options considered by the work group. One option was to continue universal hepatitis B vaccination for all infants, which two members preferred. A second option was to make no recommendation for this population, which one member preferred. The majority favored an option centered on individual-based decision-making. She noted that approximately half of the work group ranked making no recommendation as their second-preferred option, but concerns about acceptability prevented it from becoming the preferred approach.

The rationale for favoring individual-based decision-making was then described. Dr. Pebsworth stated that most infants born to mothers who test negative for hepatitis B surface antigen are at very low risk of infection, particularly during the first months of life. She noted that vaccine safety risks in this context are not well characterized and that a risk-based approach would allow vaccination decisions to be tailored through informed consent, considering individual risk factors and parental preferences.

She explained that this approach would allow families to choose vaccination timing closer to periods of higher risk, such as adolescence, and to use existing catch-up vaccination options, including initiation at age 11 years. Delaying vaccination could reduce exposures during early infancy and adolescence, which were described as periods of biologic vulnerability. It could allow for the use of serologic testing to assess whether additional doses are needed.

Additional advantages of an individual-based approach were discussed. Dr. Pebsworth noted that it would support shared decision-making between parents and health care providers, permit more flexible schedules, and allow care to be tailored to individual needs. She also referenced discussion of initiating the vaccine series at age 2 months, citing physiologic maturation, alignment with international policies, use of combination vaccines, fewer injections, and availability of lower-aluminum-containing products.

Factors limiting full support for an individual-based option were also reviewed. Dr. Pebsworth reported concerns about rare exposures that could result in infection or chronic disease, acceptability within medical and public health communities, and challenges associated with modifying existing systems. Additional issues included the time required for parental counseling, limited availability of clear educational materials, potential liability and reimbursement concerns, and increased administrative burden. She noted that some members viewed potential safety concerns as theoretical rather than reflective of demonstrated risk.

Implementation considerations were then addressed. These included ensuring continued effective use of postexposure prophylaxis for infants born to hepatitis B surface antigen–positive mothers, strengthening maternal screening programs, and improving screening during immigrant medical examinations. Dr. Pebsworth noted that delaying initiation of the vaccine series could also increase flexibility in vaccine selection, including the use of monovalent and combination products.

She further noted that even under the current universal birth dose policy, not all infants receive hepatitis B vaccination at birth, and available data have not shown a corresponding increase in hepatitis B incidence. CMS newborn data from 2016 through 2021 were cited in support of this observation.

Dr. Pebsworth then described an analysis of coded pregnancy and live birth data. Approximately 90% of infants received a first dose of hepatitis B vaccine by age 2 years, while approximately 70% received a birth dose, indicating delayed uptake for a portion of the population. Although many infants initiated vaccination later, no corresponding increase in hepatitis B incidence was observed.

In closing, Dr. Pebsworth stated that the work group's review underscored the need to balance disease prevention, vaccine safety, ethical considerations, and implementation feasibility. She emphasized substantial evidence gaps, particularly related to safety and risk stratification. She highlighted the importance of aligning preventive strategies with individual risk, informed decision-making, and high-quality maternal screening. She noted that the proposed voting options were intended to reflect these considerations and support further ACIP deliberation.

Following the work group presentation, Dr. Malone summarized areas of agreement and ongoing discussion. He stated that there was a broad consensus that hepatitis B is a serious disease, that infants born to hepatitis B surface antigen–positive mothers should receive hepatitis B vaccine and immune globulin, and that strengthening maternal screening during pregnancy, including consideration of repeat screening at delivery, is essential.

He then identified areas of divergence, including whether evidence supports population-level benefits of the universal birth dose for infants born to mothers who are hepatitis B surface antigen–negative, the risk and significance of horizontal transmission, and the adequacy of existing preventive systems. He also noted differing views regarding potential harms and confidence in available safety data, stating that these issues remain unresolved and would benefit from additional evidence, while acknowledging that clinical decisions are often made in the context of imperfect data.

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Dr. Malone then read the drafted voting language for consideration:

Vote 1:

ACIP recommends a birth dose of Hepatitis B virus (HBV) vaccine and Hepatitis B immunoglobulin for infants born to women who test HBsAg-positive. ACIP recommends individual-based decision-making, in consultation with a health care provider, for parents deciding whether to give the HBV vaccine birth dose to infants born to women who are HBsAg-negative or whose HBsAg status is unknown. Parents should consult with health care providers and decide when or if their child will begin the HBV vaccine series.[1] Parents and health care providers should consider vaccine benefits, vaccine risks, and infection risks. For those not receiving the HBV birth dose, it is suggested that the initial dose is administered no earlier than 2 months of age.

[1] Parents and health care providers should also consider whether there are risks, for example, when a household member is HBsAG-positive or when there is frequent contact with persons who have emigrated from areas where Hepatitis B is common.

Vote 2:
ACIP reaffirms the current standard of care: a birth dose of hepatitis B vaccine and hepatitis B immune globulin are administered to infants born to women whose hepatitis B surface antigen status is unknown.

Vote 3:
When evaluating the need for subsequent hepatitis B vaccine doses in children, parents should consult with health care providers to determine whether post-vaccination anti–hepatitis B surface antigen serologic testing should be offered before administration of the next dose. Serologic results should be used to determine whether the established protective anti–hepatitis B surface antibody threshold of ≥10 mIU/mL has been achieved. The cost of this testing should be covered by insurance.

CMS Comment:

Dr. Andrew Johnson provided comments from a Centers for Medicare & Medicaid Services (CMS) perspective, stating that the proposed hepatitis B vaccine language would not affect insurance coverage or access. He explained that infants born to mothers who are HBsAg-positive, HBsAg-negative, or of unknown status would continue to have access to the vaccine without cost sharing, regardless of testing status or the timing of parental decision-making.

Dr. Malone summarized the discussion, stating that the revised language would not impact the availability of covered vaccines for parents and children.

Mr. Johnson confirmed that this interpretation was correct, noting that coverage would remain available if vaccination decisions are made in consultation with a health care provider.

Vote Discussion

Dr. Blackburn asked whether data exist on the risk of hepatitis B infection in infants considered low risk when the mother tests HBsAg-negative, including any known perinatal transmission rate specific to this group. She also asked about the rate of false-negative maternal screenings, whether safety profiles differ between administering the birth dose at birth versus later, and whether parents receive adequate guidance on symptoms to monitor after vaccination.

Dr. Malone asked Blackburn to restate her first question and sought clarification on which experts should address it.

Dr. Blackburn clarified that she was asking about the risk of an infant born to an HBsAg-negative mother if the birth dose is delayed.

Dr. Malone asked whether her question pertained to the risk of horizontal transmission and referenced the working group's previous discussion about risk being dependent on social context.

Dr. Pebsworth stated that horizontal transmission among infants of HBsAg-negative mothers is sporadic in the United States and that available data are limited. She noted that risk may be higher in specific social or household contexts, but evidence is sparse and primarily based on case studies.

Dr. Malone asked CDC subject matter experts to provide any additional data on horizontal transmission in the United States.

Dr. Langer explained that defining infants as low-, medium-, or high-risk at birth is challenging because risk is influenced primarily by social context. He noted that recent U.S. data reflect the protective effect of high birth-dose vaccination coverage and that limited contemporary evidence does not indicate the absence of risk, but rather that the vaccine prevents horizontal transmission. He added that historical pre-1991 data confirm that horizontal transmission did occur, though recent population-level surveillance to quantify current risk is not available.

Dr. Malone acknowledged this information and noted that practicing pediatricians typically assess social context during routine history-taking.

Dr. Levi commented that evidence for horizontal transmission risk is minimal and often anecdotal. He noted that other countries without universal birth-dose vaccination policies have not documented widespread issues and that earlier U.S. data did not show a substantial burden in young children. He emphasized that models used to estimate this risk often do not align with observed data and stated that the totality of evidence suggests the risk is very low, making broader assumptions about its frequency largely speculative.

Dr. Meissner commented on Dr. Blackburn's question, stating that relying on maternal history alone to identify hepatitis B surface antigen–positive or chronically infected mothers is unreliable. He noted that experience with HIV screening has shown that patients may report no risk, yet testing later reveals infection.

Dr. Malone responded that his understanding of Blackburn's question focused on the risk of horizontal transmission from households or broader social contacts rather than on maternal transmission. He stated that, based on working group discussions, practicing pediatricians in higher-risk communities, including economically disadvantaged and specific immigrant populations, routinely assess social and household context to evaluate potential horizontal transmission risk to newborns.

Dr. Blackburn confirmed that this interpretation of her question was correct.

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Dr. Meissner clarified his earlier comment, stating that he had understood the question to relate to situations in which a mother is incorrectly classified with respect to hepatitis B surface antigen status and the infant is not immediately identified for vaccination. He asked whether administering the hepatitis B vaccine after the first month of life would have a limited impact on preventing transmission to the infant.

Dr. Langer responded that hepatitis B vaccine efficacy as postexposure prophylaxis declines rapidly over time, decreasing significantly within hours after birth. He explained that this is why current recommendations call for vaccination within 12 hours of birth for infants born to mothers who are HBsAg-positive or whose status is unknown. He noted that even short delays reduce the likelihood of preventing infection and emphasized that the timing of administration is critical.

Dr. Malone explained that vote two was separated from vote one because some committee members were not comfortable incorporating both topics into a single vote. He stated that dividing the votes allows members the opportunity to indicate whether they align with both clauses or only one. He then opened the floor for the committee members to vote to amend the language.

Dr. Stein raised a question about discrepancies between the written language she had and statements she heard during the discussion, specifically regarding references to mothers of unknown hepatitis B status. She stated that, as written, the language appeared to address vaccination for mothers who are hepatitis B positive and did not seem to include language related to mothers of unknown status. She asked for clarification.

Dr. Malone clarified that language regarding mothers of unknown status was included in vote two, not vote one, and acknowledged that this distinction may have been confusing.

Dr. Pollak indicated his intent to make a motion to amend vote one and explained that sentence three was redundant because its content was already addressed in the preceding sentence. He also stated that sentence five was problematic because it was not supported by data presented during the meeting or in the literature reviewed.

Dr. Malone restated the proposed amendment, confirming that the motion was to strike sentence three, beginning with “Parents should consult,” and sentence five, starting with “For those not receiving.”

Dr. Pollak confirmed the wording of the amendment and formally moved to strike both sentences from vote one.

Dr. Malone then asked whether there was a second to the motion.

Dr. Malone noted that no second had been offered for the proposed amendment and thanked Dr. Pollak for the motion. He then asked whether there were any additional motions to amend vote one.

Dr. Meissner asked Dr. Pollak how he would prefer the language to be revised.

Dr. Pollak explained that sentence three of vote one was redundant because its content was already addressed in sentence two. He further stated that sentence five was problematic

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because no data had been presented to support the suggested timing of administering the first dose at two months of age. He noted that no evidence was cited indicating why two months, rather than one, three, or four months, would be preferable. He also raised concerns that adopting this language could create unintended legal implications for pediatricians and other providers if the guidance were later used as a standard of care. Based on these concerns, he reiterated his proposed amendments to strike sentences three and five and indicated that he was seeking a second to the motion.

Dr. Meissner added that the content of sentence four applies broadly to all vaccines and questioned whether it was necessary to include it in this specific vote language.

Dr. Meissner then proposed deferring voting on all three items until the following session for further consideration.

Dr. Hibbeln seconded the motion.

Dr. Hoeg requested to comment and stated that adding language about hepatitis B immunoglobulin to both votes one and two was unnecessary and could create problems, particularly in vote two. She noted that recommendations for administering hepatitis B immunoglobulin vary based on the infant's weight when the mother's hepatitis B surface antigen status is unknown or pending. She suggested that including uniform language across both votes may not accurately reflect those distinctions.

Dr. Malone called for a vote on the motion to delay all three votes until the following session, anticipated to occur the next day.

Vote: Defer Vote until 12/5/25

Vote: Defer Vote

A vote was held to defer votes 1–3 on hepatitis B vaccines to the next meeting day, 12/5/25. The motion carried with 7 votes in favor, 3 votes opposed, and 1 abstention. The disposition of the vote was as follows:

7 Favored: Pollak, Stein, Levi, Griffin, Blackburn, Meissner, Hibbeln
3 Opposed: Pebsworth, Malone, Pagano,
1 Abstained: Milhoan

Vote Discussion

Dr. Stein revisited a question raised earlier regarding the false-negative rate of hepatitis B testing in pregnant women. She noted that she had identified literature suggesting an approximate 2% false-negative rate and asked CDC experts to confirm whether this estimate, corresponding to about 98% specificity, was accurate.

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Dr. Langer responded that while he did not have exact figures available, the false-negative rate for hepatitis B testing is low, and that an estimate of approximately 2% appeared reasonable. He explained that even a low false-negative rate can translate into infants who would benefit from the birth dose as a safety net, particularly when combined with additional risks such as potential horizontal transmission within households or communities.

Dr. Malone summarized the response, stating that a specificity of approximately 98% appeared to be a reasonable interpretation based on the discussion.

Dr. Stein offered an additional comment regarding informed consent, stating that she did not believe a universal vaccination policy fully aligns with informed consent principles. She noted that some mothers have reported feeling their consent was violated. She stated that the revised language under discussion better supports informed consent than a universal policy.

Dr. Griffin provided extensive comments related to informed consent and safety considerations for the hepatitis B birth dose. She noted that, in practice, parents often receive multiple consents during labor and delivery and may be unaware of interventions administered to their newborn in the first hours after birth. She stated that some parents report not recalling discussions about the hepatitis B vaccine beforehand and that, in some cases, infants receive the birth dose despite parents wishing to decline it. She emphasized that clearer communication during prenatal care and at delivery could help address these concerns and that the updated language under discussion may better support informed consent. Dr. Griffin also noted that logistical gaps may occur during the handoff between obstetric and pediatric care, suggesting opportunities for improved counseling and testing during pregnancy and upon admission for delivery.

Dr. Levi shared personal experience indicating that informed consent discussions regarding the hepatitis B birth dose did not occur for his children born in the United States. He stated this reflects broader gaps in how informed consent is implemented in practice. He discussed policy considerations related to universal versus risk-based vaccination approaches. He referenced earlier data showing declines in hepatitis B incidence associated with targeting higher-risk populations before implementation of the universal birth-dose recommendation. Dr. Levi expressed concerns about the evidence base supporting the universal birth dose, noting that early recommendations predated frameworks such as GRADE and that some safety studies lacked comparator groups and included potential conflicts of interest. He also noted that school and practice-level vaccination requirements may limit individualized decision-making. He emphasized the importance of allowing parents and clinicians to assess risks and benefits and make informed decisions, stating that differing parental preferences regarding vaccination timing are reasonable and consistent with personalized, risk-based public health approaches.

Dr. Mahmoudi, representing the American Osteopathic Association, asked whether there is a mechanism to reassess the committee's vote over time, including monitoring potential harms and benefits and revisiting the policy if new data emerge.

Dr. Malone responded that ACIP policy includes provisions for periodic review and revision of recommendations, though there is no fixed timeline for such re-evaluation. He asked Dr. Pebsworth to confirm this interpretation of the ACIP charter.

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Dr. Pebsworth confirmed that the ACIP charter requires periodic re-review of policies.

Dr. Malone concluded that, while no specific timeline is defined, ACIP has a formal policy to revisit and revise recommendations as necessary.

Dr. Grant Paulsen, representing the Pediatric Infectious Diseases Society, asked why there is a need to change the current hepatitis B birth-dose policy, noting that it has been effective in preventing infection in children. He questioned whether the pressure to revise the recommendation is driven by safety concerns that may be theoretical rather than evidence-based. Paulsen also noted that the draft vote language had not been made available to liaison organizations in advance, making it difficult to assess the proposal fully, and expressed concern that the addition of a second vote mid-process appeared ad hoc. He emphasized that vaccines have known side effects, that universal maternal screening has become inconsistent, and that the overarching goal remains to provide the best protection against lifelong infection in pediatric populations.

Dr. Pebsworth stated that the discussion was part of ACIP's periodic review process and noted that there had also been pressure from stakeholder groups to revisit the hepatitis B policy.

Dr. Sonja Hutchins referenced earlier discussion comparing surveillance data with CDC modeling and emphasized that national surveillance systems are known to underestimate hepatitis B incidence due to underdiagnosis and underreporting. She asked about the rationale for using the CDC modeling and whether adjustments were made to account for these limitations to more accurately estimate the true impact of acute and chronic hepatitis B in the U.S. population.

Dr. Langer responded to the question regarding the CDC modeling, explaining that modeling was used because reported acute hepatitis B case counts substantially underestimate the true burden of disease. He noted that acute hepatitis B is often underdiagnosed, may present with mild or no symptoms, and may not be reported even when diagnosed. He explained that CDC surveillance programs routinely apply modeling to adjust reported case counts upward using additional data sources to better estimate true disease burden and avoid misinterpretation of raw surveillance data.

Dr. Malone asked whether part of the discrepancy between reported surveillance data and modeled estimates reflects differences between documented clinical cases and infections that do not result in medical evaluation.

Dr. Langer explained that the CDC distinguishes between reported cases and actual infections and that population-level estimates rely on adjusting reported data to account for underdiagnosis and underreporting. He noted that prevalence data are derived from surveys such as NHANES, while incidence estimates are modeled using reported case data combined with adjustment factors. He confirmed that asymptomatic or undiagnosed infections contribute to the gap between reported and actual disease burden.

Vaccines for Children (VFC) Presentation

Note: Text enclosed in [brackets] was added following the meeting, per the presenter's request.

Dr. Jeanne Santoli (CDC) introduced a draft Vaccines for Children (VFC) resolution intended to align with the hepatitis B voting language currently under discussion. She noted that the resolution could change pending further committee deliberation and explained that proposed updates were shown in red, while existing language remained in black.
She then described the purpose of the draft resolution, which was to update recommended vaccination schedules and intervals to reflect revised ACIP recommendations for hepatitis B vaccination. She emphasized that eligibility criteria under the VFC program would remain unchanged.

Dr. Santoli next reviewed proposed changes to the schedule for infants born weighing 2,000 grams or more and those weighing less than 2,000 grams. She noted that these revisions applied only to infants born to mothers who are hepatitis B surface antigen–negative and that schedules for infants born to mothers who are hepatitis B surface antigen–positive or of unknown status were unchanged.

She also reviewed updates to the table notes. This included clarifying language stating that only the single-antigen hepatitis B vaccine may be administered before 6 weeks of age, as well as adding a new footnote addressing individual- or shared-based clinical decision-making for infants born to mothers who are hepatitis B surface antigen–negative.

Dr. Santoli noted that under the draft resolution, infants vaccinated before 2 months of age through individual-based decision-making could receive up to four doses of the hepatitis B vaccine. She emphasized that no changes were proposed to vaccination schedules for children and adolescents, dosage, contraindications, revaccination guidance, minimum intervals, or other sections of the resolution.

She concluded by stating that the remainder of the resolution was unchanged and thanked the committee for its patience during the presentation.

PERSPECTIVES FROM PEOPLE WITH LIVED EXPERIENCE

Dr. Sue Wang, a physician living with hepatitis B, shared a personal and professional perspective emphasizing the human impact of hepatitis B infection and the importance of universal birth-dose vaccination. She described how she likely acquired hepatitis B as an infant through household exposure before birth-dose vaccination was routine, noting that a universal birth dose could have prevented lifelong infection. Dr. Wang highlighted that infants are uniquely vulnerable, as approximately 90% infected at birth develop chronic disease, compared with about 10% of older children and adults.

Drawing from her clinical experience, Dr. Wang highlighted the long-term consequences of hepatitis B, including liver disease and cancer, and shared patient stories illustrating the lasting physical, emotional, and family impacts. She emphasized that preventing infant infection has been central to national and global hepatitis B elimination efforts. Dr. Wang noted significant gaps and complexity in risk-based approaches, including incomplete maternal screening, missed testing at delivery, challenges in follow-up testing of infants, and the fragmented nature of the U.S. health care system.

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She cited estimates indicating that delaying the birth dose to two months could result in additional infections, deaths, and health care costs annually. Dr. Wang compared U.S. conditions with those of countries using selective vaccination strategies, noting differences in population size, diversity, health system structure, and hepatitis B incidence. While expressing support for shared clinical decision-making when options are equally reasonable, she stated that the evidence supports the hepatitis B birth dose as best practice for preventing lifelong infection. She emphasized that families retain the option to decline vaccination and concluded by urging the committee to maintain universal birth-dose vaccination to protect all infants, particularly given unpredictable future risk.

Michael Belkin provided his experience related to the hepatitis B vaccine birth dose. He shared his professional background in business and statistics. He described the death of his infant daughter at five weeks of age, which occurred approximately 15 hours after she received a second hepatitis B vaccine dose. He stated that his daughter had been healthy before vaccination and outlined events surrounding her death, including autopsy findings and his concerns about the cause of death and its classification as sudden infant death syndrome.

Mr. Belkin described steps he took following his daughter’s death, including reviewing hepatitis B vaccine safety information, analyzing Vaccine Adverse Event Reporting System data, attending immunization meetings, and consulting with pathologists. He expressed concerns about how adverse events following hepatitis B vaccination are identified, investigated, and communicated, as well as about data transparency, safety monitoring, and potential conflicts of interest in vaccine policy development. He questioned the risk-benefit balance of universal hepatitis B birth-dose vaccination, particularly for infants born to mothers without hepatitis B infection, and urged the Committee to reconsider the universal birth-dose recommendation.

PUBLIC COMMENT

The floor was opened for public comment on December 4, 2025. The comments made during the meeting are summarized in this document. Members of the public were also invited to submit written public comments to ACIP through the Federal eRulemaking Portal under Docket Number ID CDC-2025-0783. Visit regulations.gov for access to read the comments received.

Miss Kayla Inthabandith
Asian Health Coalition

Ms. Inthabandith spoke in support of maintaining the universal hepatitis B birth dose, emphasizing its long-standing public health success and projected prevention of millions of acute and chronic infections. She noted gaps in prenatal screening, risks of false negatives and later pregnancy infections, and the inability of screening alone to prevent horizontal transmission in early childhood. She expressed concern about declining newborn vaccination rates and increased parental safety concerns due to unclear messaging, warning that changes to the recommendation could undermine public confidence and place infants at risk. She emphasized that universal recommendations provide clarity and equitable protection and are critical to preventing liver cancer, a preventable outcome through timely vaccination.

Mr. Noah Louis-Ferdinand
Voices for Vaccines

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Mr. Louis-Ferdinand described the hepatitis B birth dose as a public health success that has reduced infections among children and adolescents by 99% since its routine adoption in 1991. He cautioned against replacing universal recommendations with shared clinical decision-making, noting that ACIP guidance informs clinical decisions and serves as a safety net when screening or documentation fails. He highlighted risks associated with delayed vaccination, including high rates of chronic infection when transmission occurs at birth, and emphasized that immediate vaccination is necessary to prevent lifelong disease. He urged ACIP to maintain current recommendations to support hepatitis B elimination efforts.

Mrs. Katrin Werner-Perez
Alliance for Aging Research

Mrs. Werner-Perez expressed support for continued universal hepatitis B vaccination, citing decades of evidence showing effectiveness in preventing early childhood infections. She noted failures of prior risk-based strategies and emphasized that universal vaccination has led to a 99% reduction in cases among children under age 19. She also addressed vaccine safety, referencing large-scale studies demonstrating no association between aluminum-containing adjuvants and chronic health conditions. She urged the committee to rely on established scientific evidence, maintain the current schedule, and avoid actions that could restrict access or create barriers for patients and providers.

Dr. Vivian Huang, MD, MPH
Hepatitis B Free Arizona

Dr. Huang shared both professional and personal perspectives, describing her work in domestic and global public health responses and vaccination campaigns. She recounted her own hepatitis B infection before universal birth dose implementation and the lasting consequences it has had on her life. Dr. Huang emphasized the success of the birth dose program in nearly eliminating hepatitis B among younger generations and warned against reversing progress. She urged ACIP to continue the birth dose recommendation to protect future generations and prevent preventable disease and suffering.

Dr. Allison Grady, DNP
University of Wisconsin–Milwaukee

Dr. Grady, a pediatric oncology nurse practitioner, urged the committee to maintain the current evidence-based immunization schedule. She described clinicians' concerns about potential changes to vaccine timing, formulation, or dosing, particularly for immunocompromised children. Dr. Grady emphasized the importance of herd immunity for pediatric cancer patients and described the impact of declining immunization rates on patient safety and quality of life. She encouraged the committee to rely on decades of scientific evidence and to send a clear message in support of vaccination to protect vulnerable children.

Ms. Chloe Humbert
Private citizen

Ms. Humbert spoke in favor of universal vaccination, citing expert commentary on household transmission risks and the high contagiousness of hepatitis B. She shared a personal reflection on HIV/AIDS advocacy and emphasized that infectious diseases can affect any family. She underscored that vaccines are a collective public health responsibility and expressed concern

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that weakening vaccine recommendations could erode trust and protection. She stated that public health agencies have a responsibility to safeguard communities through science-based interventions.

Serese Marotta
Vaccinate Your Family

Ms. Marotta spoke as a bereaved parent, scientist, and advocate, emphasizing the safety and effectiveness of routine childhood vaccinations. She questioned why ACIP was revisiting settled vaccine science while outbreaks of measles, pertussis, and influenza continue amid declining vaccination rates. She shared the loss of her five-year-old son to influenza and warned that reduced access to vaccines would lead to preventable deaths and further family loss. She urged the committee to prioritize evidence-based decisions that protect children and communities.

Dr. Rita Kuwahara, MD, MIH, FACP
Association of Asian Pacific Community Health Organizations

Dr. Kuwahara highlighted the hepatitis B vaccine as the first anti-cancer vaccine and emphasized its role in preventing thousands of infections and deaths since universal childhood vaccination began. She noted that most infants infected at birth develop chronic disease with serious long-term consequences. Dr. Kuwahara stressed that universal recommendations preserve parental choice and reduce administrative barriers that could limit access, particularly for high-risk populations. She urged ACIP to maintain universal birth dose recommendations to ensure equitable protection for all newborns.

Joanna Colbourne
National Foundation for Infectious Diseases

Ms. Colbourne emphasized NFID's support for evidence-based immunization policy and the continued use of the hepatitis B birth dose. She noted that many adults with chronic hepatitis B are unaware of their infection and that infants infected at birth face the greatest risk of severe outcomes. She stated that delaying the birth dose could result in additional infections and deaths and that decades of data show no benefit to altering current timing. Ms. Colbourne also expressed concern about weakening the childhood immunization schedule amid rising outbreaks and urged ACIP to maintain rigorous scientific review processes.

Dr. Toby Rogers, Ph.D., M.P.P.
Brownstone Institute for Social and Economic Research

Dr. Rogers opposed hepatitis B vaccination, asserting that clinical trial designs were inadequate and alleging links between the birth dose and autism and other adverse outcomes. He cited analyses of vaccine safety data and called for removing hepatitis B vaccines from the childhood schedule. He stated that proposed changes to vaccine timing did not sufficiently address his concerns and argued that hepatitis B vaccines lack adequate safety evidence.

Dr. Griffin thanked all contributors and expressed sympathy for the harms and losses described. She acknowledged the bravery of individuals who shared their experiences. She emphasized that the committee's responsibility is to balance risks and benefits for all patients, grounded in the principle of first doing no harm. She noted that any harm is tragic, whether resulting from hepatitis B infection or from a vaccine-related injury. Dr. Griffin stated that a universal birth dose changes the risk calculus by exposing all infants, including those at low risk, to potential

vaccine-related risks. She highlighted concerns about rising rates of chronic disease in children over recent decades. She stated that, while vaccines are not definitively implicated, the committee is tasked with examining vaccine-related questions and must address them with seriousness. She referenced prior comments about adjuvants and aluminum. She reiterated information on macrophagic myofasciitis, aluminum found in injection-site granulomas, and studies reporting aluminum in the brains of individuals with neurologic conditions. She raised questions about administering aluminum-containing vaccines within hours of birth, given the immaturity of neonatal physiologic systems, and encouraged continued research into whether a causal relationship exists between aluminum exposure and autoimmune or neurologic conditions. She concluded by underscoring the need for caution and reaffirming that the committee's obligation is to ensure safety and avoid harm.

COVERAGE IMPLICATIONS

Dr. Georgina Peacock, Director of the Immunization Services Division, provided an overview of implementation considerations related to the Vaccines for Children (VFC) program. She reminded the committee that the VFC program, established in 1994, ensures access to vaccines for eligible children ages 0–18 years regardless of ability to pay, including children who are Medicaid-eligible, uninsured, American Indian or Alaska Native, or underinsured. Dr. Peacock explained that vaccine coverage under the VFC program is determined by language included in the VFC resolution approved by ACIP. She noted that when shared clinical decision-making language is included in a VFC resolution, vaccines recommended under that approach are covered for VFC-eligible children. She provided current examples of vaccines with shared clinical decision-making recommendations under VFC, including meningococcal B vaccination for adolescents and young adults and COVID-19 vaccination for children.

Mr. Andrew Johnson provided an overview on behalf of CMS on how ACIP recommendations influence vaccine coverage across Medicaid, the Children's Health Insurance Program (CHIP), and private and employer-sponsored health insurance plans. He explained that Medicaid and CHIP coverage are anchored to ACIP recommendations and the pediatric and adult immunization schedules, and that states are required to cover all ACIP-recommended vaccines without cost sharing for most beneficiaries. He noted that recommendations involving shared clinical decision-making (also referred to as individual-based decision-making) are also mandatorily covered under Medicaid and CHIP.

He stated that while states must cover all ACIP-recommended vaccines, they may expand coverage beyond the immunization schedule. Under Medicaid's EPSDT provisions, coverage for individuals up to age 21 may include additional vaccines based on medical necessity. CHIP programs may also elect to cover vaccines beyond those contained in ACIP schedules and receive federal matching funds for doing so. He noted that states generally do not require CMS approval to expand vaccine coverage, as state plans do not specify this level of detail.

Mr. Johnson also summarized coverage requirements for non-grandfathered employer-sponsored and individual health plans, which must cover ACIP-recommended vaccines for routine use without cost sharing. He clarified that these requirements do not apply to self-insured ERISA plans regulated by the Department of Labor. He concluded by stating that CMS uses these statutory and regulatory frameworks to review ACIP vote language and determine potential coverage implications.

Discussion Continued

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Dr. Meissner questioned the slide language that referenced hepatitis B vaccination at less than 6 weeks of age, noting concern that it could be misinterpreted as implying that monovalent vaccines cannot be used after 6 weeks. He emphasized that this was not the intended meaning.

Dr. Santoli responded by reading the exact slide language, which stated that only a single-antigen hepatitis B vaccine, such as Engerix B or Recombivax HB, can be given at less than 6 weeks of age.

Dr. Meissner clarified that his concern was potential misinterpretation and then asked whether combination vaccines can be used after six weeks of age. He asked specifically whether, if an infant does not receive the hepatitis B vaccine before six weeks, the initial dose in the three-dose series can be given as a combination vaccine or if it must be monovalent.

Dr. Santoli stated that she did not believe there was an immediate answer to that question and indicated that it would need to be addressed by hepatitis B subject matter experts, asking whether additional expertise was available to respond.

Dr. Meissner clarified his question and asked whether data was available.

Dr. Levi said that the committee had seen earlier that about 30% of Medicaid-insured infants do not receive the birth dose, and many receive hepatitis B vaccination up to two years of age, yet all are ultimately vaccinated. He suggested that, in practice, combination vaccines are already being used for initial doses in a substantial number of infants, though he did not have the precise numbers immediately available.

Dr. Meissner asked whether those combination vaccines provide an equivalent immune response to that of the monovalent vaccines.

Dr. Hoeg said that, from a European perspective, several countries administer the hexavalent combination vaccine as the initial hepatitis B dose at two to three months of age. She noted that Germany and Japan both use this approach. She did not have direct comparative immunogenicity data,v but confirmed that this is standard practice in those countries.

Dr. Meissner thanked her, and she provided additional information on hepatitis B surface antigen testing, noting that the sensitivity of tests used in the United States and Europe is consistently listed as 100%.

Dr. Malone said this indicated that false negatives were not occurring in meaningful numbers.

Dr. Hoeg confirmed that false negatives were not seen in practice.

Dr. Robert Schechter, speaking as a pediatrician and an official with the U.S. public health vaccination program, noted that limitations in surveillance and gaps in the U.S. health care system help explain discrepancies between modeling estimates and reported hepatitis B cases. He emphasized that, despite extensive public health and clinical follow-up efforts, surveillance and case ascertainment remain incomplete, particularly because many hepatitis B infections in young children are asymptomatic or mildly symptomatic, and children are not routinely screened. He highlighted that in California, infections among exposed infants declined from about 20 cases per year two decades ago to zero or one per year after a universal birth dose recommendation, while acknowledging that it remains challenging to determine how many cases may still be missed. Dr. Schechter then raised two questions for CDC experts: whether there is evidence that seropositivity alone represents a correlate of protection in individuals who have not completed a full hepatitis B vaccine series, noting concern that transient antibody positivity, such as after immune globulin, could falsely reassure parents; and what surveillance systems would be used to detect the effects of relaxing or reducing the birth dose recommendation, including how quickly potential impacts would be identified given that many pediatric infections are asymptomatic.

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Dr. Langer responded by explaining that serologic testing has only been studied as a correlate of protection in the context of a complete hepatitis B vaccination series. He stated that there is no data to support using serology to determine whether subsequent doses in the series should be administered, and that clinical trials indicate the full series is necessary. He added that the most serious consequences of hepatitis B infection, such as cirrhosis, liver cancer, and reduced life expectancy, may not appear for many years or even decades. Because childhood infections can be asymptomatic or mild, he said it would be difficult to confidently detect the impact of any change to the birth dose policy over a long period.

Dr. Levi thanked Dr. Langer and shared additional observations, noting an imbalance in how long-term risks are considered for diseases versus vaccines. He stated that if chronic disease outcomes from hepatitis B were occurring at meaningful rates under a universal birth dose policy, they should already be visible after decades of implementation. He argued that long-term effects should be considered for vaccines as well as diseases, since vaccines are designed to induce lasting immune changes that may not always be fully understood. Dr. Levi suggested that if the hepatitis B birth dose were considered as a new policy today, current evidence might not meet modern regulatory thresholds for safety and efficacy in infants born to hepatitis B surface antigen-negative mothers. He stated that large, long-term clinical trials examining dose number and timing in this low-risk population would be ethically feasible and scientifically appropriate and urged regulatory agencies to pursue such studies so parents can be provided with more robust and transparent information.

Dr. Hibbeln stated that there is evidence of efficacy for universal hepatitis B vaccination based on long-term national trends. He referenced charts presented earlier showing declining illness rates from 1985 to 1991, noting that reductions before 1991 were attributed to both increased vaccine use and public health measures. He explained that once universal vaccination was implemented, it allowed for comparison with a single major variable change. Under universal vaccination, reported hepatitis B cases declined from approximately 17,500 in 1991 to about 601 by 2025, which he cited as evidence supporting the effectiveness of universal vaccination.

Dr. Laura Morris stated that she was speaking on behalf of the American Academy of Family Physicians and from her perspective as a rural family physician providing full-scope care, including prenatal care. She expressed concern about shifting away from a clear recommendation, particularly moving to a schedule that delays vaccination until after two months of age without additional supporting evidence. She emphasized that moving to shared clinical decision-making would significantly affect clinical implementation in primary care, increasing documentation requirements, administrative burden, and workflow complexity, as occurred with COVID-19 vaccine recommendations. She noted that such changes could eliminate standing orders, require prescriptions, and consume substantial clinician time, despite insufficient evidence of harm to justify undoing a program that has been effective in preventing chronic disease and serious outcomes.

Dr. Malone asked Dr. Morris to elaborate on the practical impact of these changes from a frontline clinical perspective.

Dr. Morris explained that a blanket recommendation supported by evidence allows clinicians to efficiently vaccinate most patients for whom the benefits outweigh the risks. She said that shifting to shared clinical decision-making introduces additional documentation, messaging, and prescribing requirements, particularly in states where pharmacists and health systems are closely aligned with ACIP recommendations. She emphasized that the current recommendation already allows parents to decline vaccination, noting that only about 80% of infants receive the birth dose, demonstrating that it is not a mandate. She stressed that increasing administrative

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barriers would undermine a successful prevention program without evidence to support alternative timing or models.

Dr. Malone then asked about the implications for parents seeking more latitude in decision-making under informed consent.

Dr. Morris responded that informed consent is already part of routine practice. She described counseling parents thoroughly, both prenatally and at birth, and strongly recommending vaccination while respecting parental autonomy. She stated that parents who trust their clinician and choose vaccination benefit from streamlined workflows such as standing orders. Parents with concerns are provided with counseling and written information, and those who decline are respected. She emphasized that the current recommendation supports both groups while maximizing protection for infants.

Dr. Malone asked specifically about her experience with vaccine-hesitant parents.

Dr. Morris said she frequently works with vaccine-hesitant families and that the current birth dose recommendation does not prevent parents from declining vaccination at any point. She stated that she listens to concerns, partners with families, honors their decisions, and supports bodily autonomy. At the same time, she explained that maintaining the current recommendation enables clinicians to best serve families who want vaccination and understand that early protection reduces the risk of rare but catastrophic illness in infants.

Dr. Malone acknowledged and expressed appreciation for Dr. Morris's frontline experience and perspective.

Dr. Judith Shlay raised several concerns relevant to the discussion of changing the hepatitis B birth dose recommendation. She referenced a recently published economic evaluation by Eric Hall et al. that examined the consequences of delaying infant hepatitis B vaccination from birth to two months and found that such a delay would result in an estimated 238 additional infections among children, including those born to mothers who tested hepatitis B surface antigen negative. She emphasized that this analysis assessed both economic impacts and preventable infections and should be reviewed before considering any policy change. Dr. Shlay also agreed that improvements in obstetric practice, such as hepatitis B surface antigen testing at the time of delivery, are important but cautioned that the birth dose should not be altered until those clinical changes are fully implemented, given the time required to change practice patterns. She further noted that relying on assumptions of declining risk may be problematic, citing recent increases in syphilis and congenital syphilis as evidence that infectious disease risks can rise rapidly and unexpectedly. She concluded by stressing that even a single preventable hepatitis B infection resulting from a policy change would be unacceptable. She stated that, from a public health immunization program perspective, the goal should be to prevent every possible case of hepatitis B infection in children.

Dr. Levi stated that he appreciated the reference to the recent economic analysis and noted that, in his view, a comprehensive cost-benefit analysis of the hepatitis B birth dose has never been adequately conducted. He suggested that if the substantial resources used to vaccinate millions of low-risk infants were instead redirected toward improved screening and targeted interventions for higher-risk populations, overall public health outcomes might improve. He emphasized that his comments were not a criticism of frontline clinicians, whom he expressed strong respect for, but rather a concern that both clinicians and parents are often given high-confidence assurances about vaccine safety that are not fully supported by robust long-term evidence. He argued that because near-universal vaccination has eliminated meaningful control groups, it is difficult to assess long-term risks retrospectively, and that early clinical trials were insufficient by modern standards to support absolute claims of safety.

Dr. Griffin agreed and reflected on medical training, noting that clinicians are typically taught to memorize and follow the pediatric vaccine schedule, assuming it has been exhaustively vetted. She described a disconnect between that assumption and the underlying evidence base, recalling that a safety study presented to the committee contained minimal methodological detail regarding adverse event assessment. She stated that this experience highlighted a broader, systematic issue in medical education and vaccine evaluation, and acknowledged that the safety data were less rigorous than she had previously believed.

Dr. Hoeg added a perspective on health economics, citing a detailed cost-benefit analysis conducted by the Danish government that evaluated universal hepatitis B vaccination in children. He explained that Denmark concluded the strategy did not make economic or public health sense and cited this analysis as the primary reason the country does not recommend universal hepatitis B vaccination at birth or in childhood. Instead, Denmark focuses on clearly defined high-risk groups and targeted, informed decision-making. He noted that this approach reflects broader differences in how peer nations evaluate vaccine policy and that he planned to discuss this issue further in a subsequent session.

Dr. Hoeg provided a health economics perspective, citing a comprehensive cost-benefit analysis conducted by the Danish government that evaluated whether to introduce universal hepatitis B vaccination in children. She explained that Denmark determined universal childhood hepatitis B vaccination did not make economic or public health sense and identified this analysis as the primary justification for not recommending a universal birth dose or routine childhood vaccination. Instead, Denmark focuses on clearly defined high-risk populations and targeted, informed decision-making. Dr. Hoeg emphasized that this comparison is particularly relevant because Denmark has hepatitis B prevalence levels very similar to those of the U.S., including comparable rates of chronic hepatitis B and of mothers who are hepatitis B surface antigen-positive, yet has reached a different policy conclusion.

Blackburn raised concerns about access to pediatric care for parents who choose alternative vaccination approaches. She noted hearing from multiple parents who reported being dismissed from pediatric practices due to differing views on vaccination. While acknowledging the lack of national data quantifying this issue, she emphasized concern that some families may be left without care options when they are not supported in pursuing individualized approaches.

Dr. Malone invited Dr. Langer from the CDC to address long-term evidence on hepatitis B vaccination, including the Kedong intervention study.

Dr. Langer described a large, long-term study conducted in China during a hepatitis B vaccine shortage in the 1980s, which effectively created three comparison groups: individuals vaccinated in early childhood, those vaccinated later in adolescence, and those never vaccinated. These cohorts have now been followed for approximately 35 to 40 years. One primary outcome examined was hepatocellular carcinoma associated with hepatitis B infection, and findings show substantially lower rates of liver cancer in vaccinated groups, particularly those vaccinated early in life, compared with unvaccinated individuals. Dr. Langer noted that this study represents rare, randomized evidence addressing long-term vaccine efficacy. He also addressed concerns about long-term safety, stating that investigators continue to monitor all groups for adverse events and have not observed higher rates of adverse outcomes among vaccinated individuals compared with unvaccinated controls. While acknowledging that the data are not from the U.S., he emphasized they provide valuable long-term evidence from another large, industrialized country.

Dr. Malone raised a follow-up question about whether there could be selection bias in the group that remained unvaccinated, specifically asking whether individuals who were negative at the

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initial vaccination and follow-up might represent noncompliant individuals once vaccination became available.

Dr. Langer explained that, based on his understanding of the study, the assignment was done at the village level rather than the individual level. Entire villages were randomized to receive vaccination early in childhood or not, which would be expected to minimize selection bias and reduce the likelihood that differences were due to individual refusal or noncompliance with vaccine availability.

UPDATE ON WORK GROUPS

Dr. Malone provided an update on ACIP work groups and clarified their role and structure. He explained that the primary analytical and investigative work of ACIP occurs within formally chartered work groups, as required under the Federal Advisory Committee Act. These groups operate with confidentiality constraints established by congressional statute, not by CDC discretion, which limits what information can be publicly shared.

He reported that current ACIP work groups have updated several Terms of Reference, which function as the formal scope of work documents for each group. These updated Terms of Reference have been developed under new work group leadership, reviewed through legal and policy channels, and will be posted on the ACIP website. Topics include influenza, respiratory syncytial virus, and human papillomavirus. In addition, CDC leadership and ACIP are initiating a new work group focused on vaccination and pregnancy, for which Terms of Reference are still under development. Dr. Malone emphasized that establishing these documents is a rigorous process that requires legal review and approval by the CDC and the Department of Health and Human Services.

AGENCY UPDATES

The Centers for Disease Control and Prevention (CDC)

Dr. Renata Ellington, Acting Director of CDC's National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), provided an update on an ongoing HIV and hepatitis C outbreak in Penobscot County, Maine. The county typically reports two new HIV diagnoses per year; however, 14 cases linked to injection drug use were identified in 2024, followed by an accelerated increase in 2025. As of October 2025, 30 new HIV cases had been reported, nearly all with hepatitis C co-infection.

The Maine CDC is leading the outbreak investigation, with the CDC providing sustained support. The CDC deployed a five-person team in August 2025 to deliver on-site technical assistance, including strengthening surveillance, expanding access to testing and treatment, and supporting outbreak response operations. After returning to Atlanta, the CDC continued to provide virtual assistance by developing data collection protocols, educational materials, and tools for community partners, while engaging in ongoing coordination calls with Maine CDC and local organizations.

As of December 1, 2025, a team of six CDC staff is on the ground in Bangor to conduct a formal field-based assessment scheduled to continue through December 19. The team is interviewing individuals affected by the outbreak to understand barriers and facilitators to HIV and hepatitis C testing, prevention, and treatment, and to assess knowledge and practices that may contribute

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to ongoing transmission. Findings will inform educational materials for providers, response partners, and the community. Ellington emphasized that identifying the drivers of these increases is essential to protecting public health and preventing future outbreaks.

Dr. Brandi Limbago, Acting Director of CDC's National Center for Immunization and Respiratory Diseases, provided updates on measles, avian influenza, and the current respiratory virus season. As of December 2, 2025, 1,828 measles cases had been reported across 43 U.S. jurisdictions, linked to 46 outbreaks, with 87% of cases outbreak-associated. This represents a substantial increase compared to 2024. In most cases (92%), individuals were unvaccinated or had unknown vaccination status. Three deaths were reported, including two among children. Despite these increases, the overall risk to the U.S. population remains low due to existing vaccination coverage.

Regarding avian influenza, since April 2024, there have been 71 confirmed human H5 infections in the U.S., primarily H5N1 associated with cattle and generally resulting in mild illness. In November, the first human infection with H5N5 was identified in Washington state; this case involved an older adult with underlying conditions and was fatal, marking the second avian influenza–related death this year. The general population risk remains low, though individuals with direct exposure to infected animals face a higher risk. No human-to-human transmission has been identified, and the CDC continues close surveillance.

As of December 1, 2025, during the respiratory virus season, overall acute respiratory illness activity remained low nationwide. RSV activity is increasing in southeastern and southern regions, particularly among children ages 0–4 years. COVID-19 activity remains low nationally, and seasonal influenza activity is also low but rising, especially among children and young adults. Dr. Limbago emphasized that it is still appropriate for eligible individuals to receive influenza, COVID-19, and RSV vaccinations.

Dr. Malone asked a follow-up question regarding a potential mismatch between the circulating H3N2 influenza strain and the strain included in the current seasonal influenza vaccine.

Dr. Limbago confirmed that the currently circulating H3N2 virus has drifted somewhat from the vaccine strain; however, the seasonal influenza vaccine continues to protect against other strains included in the formulation and remains protective against severe influenza outcomes. She further explained that the CDC is monitoring vaccine effectiveness against the circulating H3N2 subclade, but because influenza activity remains low at this time, sufficient data are not yet available to conduct meaningful analyses of vaccine effectiveness.

Dr. Chris Braden, Acting Director of the CDC's National Center for Emerging and Zoonotic Infectious Diseases (NCEID), provided an update on several domestic and international public health threats. He reported that the Ebola outbreak in the Democratic Republic of Congo had been successfully controlled and was declared over on November 30, with a total of 64 cases and 45 deaths. CDC is currently supporting a 90-day enhanced surveillance period and an Ebola survivor monitoring program to address potential persistent infections. Dr. Braden also reported a new outbreak of Marburg disease in Ethiopia, announced on November 14, with 13 confirmed cases and eight deaths as of December 2. CDC staff are supporting Ethiopia's response through epidemiology, laboratory support, outbreak coordination, and border health guidance. He noted that the risk to the U.S. population remains low and that the CDC is prepared to respond if needed.

Domestically, Dr. Braden updated the committee on a multistate outbreak of infant botulism linked to contaminated commercial infant formula, the first such outbreak reported to CDC. As of November 26, 37 cases have been identified across 17 states, all requiring hospitalization, with no deaths reported. CDC is continuing the investigation in partnership with state health departments and the FDA, including retrospective case identification before August 2025, and emphasized that updated information is available on the CDC website.

Dr. Malone asked whether currently licensed Ebola vaccines remain well-matched to circulating Ebola virus strains.

Dr. Braden responded that the CDC continues to monitor for strain mismatch and, to date, no mismatch has been identified between licensed Ebola vaccines and circulating viruses. He added that a similar assessment is ongoing for Marburg virus vaccines, noting that an investigational vaccine exists and no mismatch concerns have been identified so far.

Dr. Malone clarified that he was referring to the Serum Institute adenovirus-based product, which remains experimental.

Dr. Meissner then asked Dr. Limbago to clarify her earlier statement that no person-to-person transmission of H5 influenza has occurred, noting that such transmission has been reported internationally.

Dr. Limbago clarified that her comments were specific to the situation in the U.S., where no human-to-human transmission of H5 influenza has been identified.

Food and Drug Administration (FDA)

Dr. Tracy Beth Hoeg (FDA) reported that the FDA is revising its vaccine safety surveillance framework to broaden the scope of monitored adverse outcomes and to incorporate additional methodologies to reduce the likelihood of missing potential safety signals. She noted that some new methods are already being implemented. Dr. Hoeg also referenced an internal memo regarding COVID-19 vaccine–associated deaths reported to VAERS, explaining that a full investigation was conducted several years ago but not publicly released at that time. She stated that analyses performed by FDA staff are now expected to be released publicly in the near term, underscoring the need for greater transparency in how VAERS data are evaluated and communicated to the public. Finally, she noted that FDA is planning changes to evidentiary requirements for expanding vaccine indications to additional populations, such as pregnant individuals and young children, and that these expansions will require randomized controlled trial data to ensure greater certainty regarding safety in those populations.

Dr. Malone asked whether newly developed and more advanced data analysis tools would be applied to existing safety databases and whether ACIP should consider the implications of FDA policy changes for its obligation to re-evaluate recommendations for existing products periodically. He sought the FDA's perspective on whether ACIP should proactively assess or mitigate potential impacts of these changes.

Dr. Hoeg responded that it would be appropriate for ACIP members to remain aware of FDA activities, noting that updated surveillance approaches could lead to more frequent label changes. She indicated that improved evidence generation on safety and efficacy may result in more rapid changes to ACIP recommendations. Still, she did not suggest a need for immediate proactive action by ACIP beyond staying informed.

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Dr. Malone summarized his understanding that ACIP should monitor developments and be prepared to respond to specific modifications in current and future recommendations, without taking proactive measures at this time. He asked whether the proposed changes would require updated guidance to the industry and what the expected timeline might be.

Dr. Hoeg confirmed that such changes would typically involve guidance to industry but stated that timelines were still to be determined.

Dr. Malone concluded that future briefings would be needed to keep ACIP updated, which Dr. Hoeg affirmed.

Dr. Hoeg also noted that reports of deaths potentially attributable to COVID-19 vaccines in VAERS were not unexpected, referencing acknowledgments from multiple countries and peer-reviewed studies. She emphasized that the key issue had been the timing and transparency of releasing and communicating this information, rather than the existence of such reports.

Indian Health Services (HIS)

Dr. Matthew Clark, representing the Indian Health Service (IHS), stated that IHS continues to work closely with federal, tribal, and urban Indian organization partners to mitigate the risk of vaccine-preventable illnesses among its service population. He emphasized IHS's commitment to improving health outcomes for American Indian and Alaska Native communities through a comprehensive approach that includes health promotion, screening and prevention, support for traditional culture and healing, and management of acute and chronic diseases.

Dr. Clark noted that vaccination is a key component of IHS's strategy as a comprehensive health care system serving more than two million American Indian and Alaska Native beneficiaries. He highlighted ongoing efforts to advance immunization across the age spectrum through proactive education, improved access, and respect for patient, family, and community values and priorities.

He also acknowledged that tribal communities face unique challenges that affect access to preventive, clinical, and public health interventions. Dr. Clark concluded that IHS seeks to continue collaborating with tribal and tribal health partners to identify vaccine-prevention priorities and promote immunization best practices that meet current needs in Indian Country.

Dr. Malone asked Dr. Clark to comment on the availability of hepatitis B surface antigen testing within IHS communities, noting its relevance to the current discussion.

Dr. Clark responded that hepatitis B surface antigen testing is widely available across IHS facilities. However, he noted that turnaround times for results can be limited in some settings, particularly at IHS sites in rural and remote areas.

Dr. Malone asked for clarification on whether turnaround times may be several days in many cases.

Dr. Clark clarified that longer turnaround times may occur in ambulatory care settings but not in hospital-based sites.

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Dr. Malone then asked whether hospital sites generally near-real-time have testing available for expectant mothers.

Dr. Clark confirmed that near real-time testing is available at hospital sites.

Dr. Malone acknowledged the information and thanked Dr. Clark for sharing it.

Dr. Meissner asked Dr. Clark to comment on the uptake of monoclonal antibodies for RSV, specifically nirsevimab and clesrovimab, among newborns and young children in American Indian and Alaska Native communities.

Dr. Clark reported that IHS has taken a highly proactive approach to promoting RSV monoclonal antibody immunization in this vulnerable population. He noted that ACIP recommends RSV monoclonal antibodies for all infants in their first RSV season and universally for American Indian and Alaska Native children up to 19 months of age entering their second season. Dr. Clark acknowledged logistical challenges in rural and remote areas but highlighted a successful model implemented by the Yukon-Kuskokwim Health Corporation, which used Bush plane flights to deliver immunizations to remote villages. He reported strong real-world effectiveness in preventing RSV-related hospitalizations in one of the highest-risk regions globally. He stated that implementation varies by location but that, in collaboration with CDC, IHS has prioritized proactive communication and support, with generally positive responses from tribal communities.

Dr. Meissner asked whether adequate supplies were available.

Dr. Clark confirmed that while there were supply limitations for nirsevimab during the first season and to some extent the second, IHS has prioritized nirsevimab due to strong real-world effectiveness data in tribal communities. He emphasized that all American Indian and Alaska Native children up to age 19 are eligible for the Vaccines for Children program and that IHS has worked closely with CDC partners to ensure access to ACIP-recommended immunizations.

Dr. Meissner thanked Dr. Clark for the update.

Discussion Continued

Dr. Middleman offered two related comments emphasizing the importance of historical context and a structured policy review process. She clarified that declines in hepatitis B rates among adolescents and young adults following implementation of the universal birth dose should not be interpreted as diminishing the effectiveness of the birth dose, noting that in the 1990s risk-based recommendations for adolescent vaccination proved insufficient and ultimately led to universal adolescent hepatitis B vaccination in 1995 with catch-up through age 18 in 1997. She stressed that this policy history is essential when interpreting current data. She also noted that earlier ACIP recommendations predated the use of GRADE and the Evidence to Recommendation (EtR) framework, and that vaccine policy development has become more rigorous over the past two decades. Dr. Middleman observed that the volume of material presented during the meeting felt disorganized and occasionally included misinformation. She recommended a comprehensive, well-structured presentation that clearly evaluates the proposed voting language, including risks and benefits, the public health problem being addressed, the feasibility of any changes, acceptability, resource implications, and stakeholder values. She concluded by

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emphasizing that ACIP has an obligation to approach vaccine policy decisions through a systematic and organized process rather than concluding fragmented or incomplete information.

Dr. Levi stated that the slide being discussed reflected CDC data and not misinformation. He argued that the decline in acute hepatitis B cases following implementation of the universal birth dose in 1991 could not be attributed to that policy because the reductions occurred primarily in age groups that were too old to have received the birth dose at that time. He maintained that the data instead pointed to interventions targeting higher-risk populations as the drivers of reduced incidence and suggested that several countries, reviewing similar evidence, concluded that universal infant hepatitis B vaccination was not cost-effective and could introduce unnecessary risk.

Dr. Middleman responded that she disagreed with this interpretation and cautioned against using declines in older adolescents and young adults to question the effectiveness of the universal birth dose. She explained that the historical context of vaccine policy is critical, noting that early risk-based adolescent hepatitis B vaccination strategies in the 1990s failed due to access barriers and inequities, leading to the adoption of universal adolescent vaccination in 1995, with catch-up through age 18 in 1997. She emphasized that multiple coordinated interventions contributed to population-level declines and urged the use of a comprehensive, organized Evidence-to-Recommendation approach rather than selective data points.

Dr. Levi replied that while he respected Dr. Middleman's perspective, he maintained that the CDC data showed declines driven by age groups not impacted by the birth dose at the time the decrease occurred. He reiterated that other targeted public health interventions explained the reductions, characterized the universal birth dose as a response driven by impatience rather than evidence, and stated that conclusions should be based on data rather than beliefs or anecdote.

Dr. Middleman restated that her position was grounded in evidence and historical policy experience, not beliefs, and again stressed that risk-based adolescent strategies were unsuccessful. She emphasized the importance of reviewing all available data in an organized and systematic manner to assess risks and benefits before making policy decisions that affect millions of people.

Dr. Hibbeln asked Dr. Middleman to clarify what she meant by stating that risk-based adolescent vaccination did not work, noting that this issue was central to the committee's deliberations about potentially shifting toward risk-based strategies.

Dr. Middleman explained that early risk-based recommendations focused on adolescents identified through behaviors or socioeconomic factors but failed to substantially increase coverage because the populations at highest risk also had the least access to care and were least likely to be reached. She stated that this led to persistent inequities and informed the decision to move to universal adolescent vaccination, adding that similar patterns have been observed with other vaccines and that CDC subject matter experts could provide additional supporting evidence.

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Dr. Sandra Fryhofer, serving as the American Medical Association liaison, spoke on behalf of the AMA in strong support of maintaining the hepatitis B birth dose recommendation. She stated that a birth dose is crucial for protecting infants from perinatal and early postnatal hepatitis B transmission. She noted that maternal–infant transmission results in chronic infection in approximately 90% of infected infants, which can later lead to liver disease, cirrhosis, liver cancer, and death. She emphasized that the birth dose provides universal protection, including for infants with incomplete prenatal records or cases where maternal screening was missed. Dr. Fryhofer stated that the hepatitis B birth dose has prevented more than six million hepatitis B infections and nearly one million hospitalizations related to hepatitis B-associated disease. She concluded by noting that the American Medical Association strongly urges ACIP to maintain the birth dose recommendation. She also shared a personal perspective as a mother and grandmother, stating that her twin children recently had newborns who received the hepatitis B birth dose, reflecting what she supports for her own family.

Dr. Malone asked Dr. Fryhofer to clarify the source of the data she referenced regarding infections prevented, specifically whether those figures were derived from modeling studies or other analyses.

Dr. Fryhofer responded that the data she cited came from the American Medical Association.

Ms. Carol Hayes, representing the American College of Nurse-Midwives, stated that ACNM fully supports Dr. Fryhofer's comments and strongly supports the hepatitis B birth dose as critically important for newborns in the United States. Drawing on nearly 39 years of experience as a certified nurse-midwife, she noted that she practiced before many current vaccines were available. She referenced a study she conducted in 1987 on pregnant women's self-assessment of HIV risk, which demonstrated that perceived risk is often inaccurate. Ms. Hayes cited the resurgence of congenital syphilis as a clear example of the limitations and failures of risk-based approaches, stating that such strategies are not in the best interest of pregnant women or their newborns. She also highlighted practical clinical challenges, noting that she has repeatedly observed clinicians and office staff confuse antibodies with antigens, underscoring the risks of relying on nuanced interpretations in real-world settings. She concluded by reiterating her strong support for the birth dose recommendation.

Dr. Meissner emphasized that transmission of hepatitis B from a chronically infected mother occurs almost entirely at the time of birth, with only about 1 to 2% of cases acquired in utero. He stressed that intervention immediately after birth is therefore critical, as there is a brief and narrow window to prevent mother-to-infant transmission.

Dr. Malone stated that there is a broad consensus on this point and that it is not an area of disagreement within the committee. He noted that for hepatitis B surface antigen-positive mothers, there is an established and widely accepted recommendation to administer both hepatitis B immune globulin and hepatitis B vaccine at the time of delivery.

Dr. Meissner reiterated that his reason for raising the issue was to underscore the importance of that brief postnatal window in preventing transmission from mother to infant.

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Dr. Malone again affirmed that there is no disagreement on this issue, emphasizing that prompt treatment of infants born to hepatitis B surface antigen-positive mothers is standard, effective, and not under debate.

Dr. Judith Shlay noted that data presented showing higher hepatitis B rates in older adults may be relevant to newborn risk, as older family members, such as grandparents, often have close contact with infants, creating potential for horizontal transmission if a baby does not receive the hepatitis B birth dose. She stated that she is both a practicing physician and an immunization program director and emphasized that informed consent is routinely conducted for vaccines, including those recommended by the CDC. She also highlighted that despite high health care spending; the U.S. has poorer health outcomes than other developed nations and argued that hepatitis B vaccination is a highly cost-effective program that effectively reduces harm and protects the broader population.

Dr. Malone acknowledged her comments and agreed on the importance of informed consent. He asked for clarification regarding her first point, seeking to understand whether she was attributing higher hepatitis B rates in older populations to immigration.

Dr. Shlay clarified that she was not referring to immigration. She explained that she was responding to earlier remarks about increasing rates among older populations and pointed out that older adults, including grandparents, may unknowingly transmit hepatitis B to infants through close contact.

Dr. Malone stated that he had misunderstood her earlier wording and confirmed that she was referring to family members visiting newborns rather than immigration. He noted that this clarification was helpful.

Dr. Shlay expanded on the point by drawing a parallel to Tdap cocooning strategies, where mothers and close family members are vaccinated to protect infants from pertussis before they are fully immunized. She indicated that a similar concept could apply to hepatitis B, given potential transmission from older adults to infants.

Dr. Malone responded that the clarification raised an important issue and suggested that cocooning strategies and adult vaccination recommendations related to protecting neonates could be an appropriate topic for future ACIP consideration.

Phyllis Arthur requested two process-related considerations regarding ACIP working groups. She noted that in prior years, although the content of working group deliberations was not shared publicly, the names of working group members were posted on the CDC website. She asked that, once the terms of reference are finalized for all current and future work groups, the member lists be posted publicly again. Hence, stakeholders understand who is participating in these closed discussions. She also requested that ACIP consider reinstating participation by industry representatives in closed working group meetings so that companies can respond to proprietary or product-specific questions that may arise.

Dr. Malone acknowledged her comments and stated that the Federal Advisory Committee Act allows discretion regarding the disclosure of working group membership. He indicated that ACIP

would likely need to establish a process to obtain authorization from individual working group members before their names can be publicly posted.

Mike Ybarra stated that he is the Chief Medical Officer at PhRMA and an emergency physician practicing at a liver transplant center. He emphasized that the public may not fully appreciate how severe advanced liver disease can be. He noted that patients with complications of liver failure are often among the sickest seen in emergency departments and hospitals. He aligned with comments from other liaison representatives, including Ms. Arthur, and highlighted that PhRMA had submitted formal comments to the docket. He encouraged ACIP to continue sharing the composition of working groups and to explore ways to broaden expertise and stakeholder participation in future work group discussions.

Dr. Malone thanked Mr. Ybarra for his remarks, noting appreciation for the collegial tone and observing that approaching difficult policy questions collaboratively is preferable to unnecessary confrontation.

Dr. Jason Goldman stated that he is President of the American College of Physicians, representing more than 160,000 internal medicine physicians worldwide, and that he also practices as a primary care internist who routinely vaccinates patients and conducts informed consent discussions. He thanked the Chair for allowing additional comments despite time constraints. Dr. Goldman raised several questions for the Committee to consider ahead of the vote. First, he questioned how changing long-standing recommendations based on concerns about informed consent would address a process issue, rather than correcting consent practices themselves. Second, he asked whether analyses had been conducted on the projected impact of the proposed changes, including effects on disease burden, health care costs, access to care, equity, and disease recurrence. Third, he asked which stakeholders requested the change, how they were surveyed, what data supported their position, and whether conflicts of interest were assessed. Fourth, he questioned why liaison representatives were no longer participating in work groups. He emphasized that these questions are typically addressed through the Evidence to Recommendation framework. He urged the Committee to return to that structured process to avoid unintended harm and protect patients, noting the hepatitis B birth dose's historical success in reducing liver disease.

Dr. Malone thanked Dr. Goldman for his remarks and responded to questions related to liaison participation in work groups. He explained that under the Federal Advisory Committee Act, work group members may serve in their individual capacity but may not formally represent outside organizations, including professional societies or industry groups. He stated that this requirement comes from federal statute rather than discretionary decisions by the Committee or the Secretary and noted that this distinction has been widely misunderstood. Dr. Malone indicated that individuals with relevant expertise may still participate in work groups as independent experts, consistent with FACA requirements.

Dr. Levi stated that the earlier patient surveys showed dissatisfaction with the current policy, including families facing barriers such as daycare exclusion or difficulty obtaining clinical care. He noted that these concerns represent stakeholders whose perspectives may not be prioritized by others. He emphasized that the work group's process was extensive and diverse, relying on

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all data provided by the CDC and additional analyses. Dr. Levi expressed concern about overreliance on the Evidence to Recommendation (ETR) and GRADE frameworks, stating that, in his view, these methods can be misapplied to justify recommendations based on limited evidence. He argued that the work group conducted a deeper analysis than previous ACIP processes and rejected the implication that the work lacked rigor.

Dr. Goldman responded that the discussion concerns hepatitis B and that the ETR framework is a standard tool applied to all vaccine policy decisions. He stated that the purpose of the framework is to ensure consistent evaluation of evidence, outcomes, and population impacts.

Dr. Malone interjected to clarify that ACIP members have received formal training in GRADE and ETR from methodological specialists. He noted that both systems depend heavily on the quality and completeness of available data and that poor data inevitably limits decision-making. Dr. Malone then provided updated information regarding liaison participation in work groups. He explained that the CDC began removing liaison positions from all Federal Advisory Committee Act (FACA) committees in 2010 and that ACIP had previously been an exception. In June 2025, the CDC implemented changes to bring ACIP into full compliance with FACA requirements. Under these rules, individuals may participate in work groups only in a personal capacity and not as representatives of outside stakeholder organizations. He emphasized that the changes are procedural, not targeted at any specific group.

Dr. Hibbeln added that the use of a scientific decision framework is fundamental to ACIP's work. He noted that for several weeks, he has advocated that the Committee organize its deliberations around a structured methodology to avoid confusion about key decision questions. He reported that the Committee explored whether an alternative evidence framework might be superior to GRADE or ETR, but none was proposed. Members subsequently received training in both systems. Dr. Hibbeln stated that although any framework can be misapplied, a structured and transparent approach is preferable to no framework at all, and the committee intends to use ETR to guide future deliberations.

Due to the deferment of the hepatitis B vote, discussions and any related votes regarding hepatitis B vaccines were scheduled to continue Friday, December 5, 2025. Summaries of those discussions and votes will be included in the Day 2 section of the report. The meeting was recessed until December 5, 2025, at 8:00 a.m. EST.

FRIDAY: DECEMBER 05, 2025

WELCOME AND ROLL CALL

Call to Order/Roll Call

Dr. Robert Malone, ACIP Vice Chair, convened the meeting at 8:00 a.m. on December 5, 2025, and welcomed participants to the December 4-5 session of the Advisory Committee on Immunization Practices (ACIP). Dr. Zadeh proceeded with the roll call of ACIP members, Ex Officio members, and liaison representatives. A complete list of participants is provided in the appendix at the end of this summary. No conflicts of interest were identified.

Dr. Robert Malone delivered opening remarks to begin the second day of the ACIP meeting. He noted that the prior day's discussions were constructive and reflected careful analysis. He summarized that the committee reviewed the evidence on the hepatitis B vaccine in depth and voted 7–3 to defer the vote on vaccine language until the morning session, emphasizing that deliberation and transparency are essential to maintaining public trust.

Dr. Malone outlined the agenda for Day 2, which would proceed after completion of the hepatitis B vote. The agenda included a discussion of the childhood and adolescent immunization schedule, with a presentation by Aaron Siri. He noted that Drs. Paul Offit and Peter Hotez had been invited to present their perspectives but declined. The presentation would include a comparison of the U.S. childhood immunization schedule with those of other countries. If time permitted, a limited discussion would also address vaccine aluminum adjuvants, clarifying that no voting language had been prepared for those topics and that further discussion and evaluation within working groups would be required.

Dr. Malone reiterated that ACIP's role is to rigorously evaluate available information, including recognition of both the strengths and limitations of the data. He stated that credibility depends on careful analysis rather than speed and emphasized ACIP's responsibility to scrutinize evidence, identify gaps and uncertainties, and clearly articulate the rationale for recommendations. He noted that scientific deliberation is inherently challenging and sometimes contentious, and that robust debate is a necessary component of evidence-based decision making.

Dr. Malone then acknowledged the broader public context, noting that public confidence in vaccine policy has been affected by experiences during the COVID period. He stated that he has worked in vaccine research and development for more than 30 years and does not consider himself opposed to vaccines, while clarifying that he opposes vaccine mandates. He emphasized his continued commitment to advancing safer and more effective vaccine technologies. He referenced concerns about coercion and compulsion in prior public health practices and underscored the importance of informed consent as a foundational ethical principle.

Dr. Malone referenced published reports indicating that some pediatric practices do not accept patients who decline full adherence to vaccine schedules, which he characterized as concerning in the context of informed consent. He also addressed comments from the previous day regarding CDC data presented on hepatitis B trends, stating that the data were official CDC data and should not be characterized as misinformation. He urged the committee to engage openly with differing interpretations of data and to avoid dismissing information that may be inconvenient to viewpoints.

Dr. Malone concluded by encouraging respectful dialogue, open consideration of alternative perspectives, and reliance on shared data to guide decisions. He noted that his final remarks reflected personal views and thanked the committee for their engagement as the meeting continued.

Dr. Meissner added that the American Academy of Pediatrics appeared not to be participating in the ACIP deliberations. He noted that the academy has a longstanding history of working closely with ACIP and that vaccine recommendations are improved through discussion that includes a variety of perspectives. He expressed concern that the academy's absence could be perceived as prioritizing a political statement over children's health. He further noted that, along with major public health advances such as clean drinking water and pasteurization,

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immunizations are among the most important medical interventions available. He stated that vaccines are a standard of care and that pediatricians should be part of these discussions. He concluded that refusal to participate in ACIP meetings does not appear to be in the best interest of children.

HEPATITIS B VACCINES (CONTINUED)

Dr. Vicky Pebsworth provided a recap of Day 1, explaining that her presentation the previous afternoon summarized the work group's charge, process, findings, and the themes that informed its recommendations. The work group was tasked with evaluating the use of a universal birth dose of hepatitis B vaccine in infants born to mothers who are hepatitis B surface antigen-negative. Under its terms of reference, the group reviewed available evidence on the efficacy and safety of the immunization schedule, identified gaps or problems, and assessed stakeholder concerns.

She noted that the work group met multiple times and identified several areas of full or near-full agreement. This included recognition that hepatitis B can be transmitted vertically and horizontally, is a serious disease, and is preventable through vaccination. Members agreed that there is uncertainty regarding the true incidence and prevalence, the horizontal transmission rates, and whether all three recommended doses are required for protection. They also agreed that evidence gaps and safety limitations exist.

There was a strong consensus that infants born to mothers who test positive for hepatitis B surface antigen should continue to receive hepatitis B vaccine and hepatitis B immunoglobulin soon after birth. There was also strong agreement that pregnant women must be screened without exception, that gaps in screening should be eliminated, and that unknown maternal status at delivery should be treated as a serious quality-of-care issue. Additionally, members agreed that infants born to mothers who test negative do not need routine hepatitis B vaccination at birth.

Based on these areas of agreement, the work group evaluated three policy options: universal birth dose, no recommendation, or an individual-based decision-making approach. The group most strongly favored the individual-based option.

Preamble to voting language: There will be no change to the vaccination recommendation for infants born to women who test HBsAg-positive or have an unknown HBsAg status; the existing recommendation remains the same.

Vote 1. Recommendation for Infants Born to Hepatitis B Surface Antigen–Negative Mothers.

For infants born to HBsAg-negative women: ACIP recommends individual-based decision-making, in consultation with a health care provider, for parents deciding when or if to give the HBV vaccine, including the birth dose.[1] Parents and health care providers should consider vaccine benefits, vaccine risks, and infection risks. For those not receiving the HBV birth dose, it is suggested that the initial dose is administered no earlier than 2 months of age. Y/N

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[1]Parents and health care providers should also consider whether there are risks, for example, such as a household member is HBsAg-positive or when there is frequent contact with persons who have emigrated from areas where Hepatitis B is common.

Vote 2. Post-Vaccination Serologic Testing for Children.
When evaluating the need for a subsequent HBV vaccine dose in children, parents should consult with health care providers to determine if a post-vaccination anti-HBs serology testing should be offered. Serology results should determine whether the established protective anti-HBs titer threshold of ≥10 mIU/mL has been achieved. The cost of this testing should be covered by insurance. Y/N

<u>Discussion</u>

Dr. Blackburn stated that she supports the intent of maintaining strong protection against hepatitis B while also empowering parents to work with their pediatricians. She offered clarification regarding Vote 1, recommending that, for infants born to hepatitis B surface antigen–negative mothers who do not receive the birth dose, the hepatitis B series should explicitly begin at 2 months as part of the existing routine immunization schedule. She noted that many infants already receive combination vaccines at two, four, and six months that include hepatitis B, and aligning the start of the series with this schedule would simplify implementation and support adherence. Regarding Vote 2, Dr. Blackburn acknowledged the intent behind evaluating the need for additional doses but expressed concern about the feasibility of introducing serologic testing in young children, noting that this would be a new practice and that evidence is limited on how well children achieve protective titers after one or two doses. She requested additional information before moving forward.

Dr. Malone responded by confirming that any changes to the proposed wording would require motion, a second, and specific revised language.

Dr. Levi commented on the implications of the proposed policy change. He stated that the new recommendation moves away from the assumption that all infants face comparable hepatitis B risk and instead distinguishes clearly between infants born to hepatitis B surface antigen–positive mothers and those born to mothers who test negative. He emphasized that vaccination remains essential for infants at high risk, where the intervention is highly effective against severe disease. For infants born to mothers who test negative, he noted that the risk of infection in early life is extremely low and that this supports an individualized, clinician-guided approach rather than routine administration at birth. He added that the recommendation reinforces the need to address health system gaps, such as inconsistent maternal screening, rather than relying on universal vaccination as a compensatory measure. He also stated that the proposal rejects the use of routine infant vaccination as a basis for mandates in educational or clinical settings. Dr. Levi concluded that although the discussion may be complex, the proposed approach better aligns vaccination decisions with actual risk levels and encourages careful evaluation of benefits, risks, and evidence when determining the timing and necessity of vaccination for infants born to mothers who are hepatitis B surface antigen negative.

Dr. Stein commented on the proposed voting language and emphasized that the recommendation does not change vaccination guidance for infants born to mothers who are

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hepatitis B surface antigen positive or whose status is unknown. She noted that these infants must continue to receive timely intervention and that addressing gaps in screening remains essential. She explained that the proposal applies only to infants born to mothers who test negative, a group at exceedingly low risk. She reiterated that the central issue is informed consent. She noted that some families who decline the birth dose have experienced denial of medical care, dismissal from pediatric practices, or exclusion from school, which she described as inconsistent with informed consent. She referenced affiliate comments from the previous day, affirming the importance of informed discussion with parents, and stated that this policy supports that principle. Dr. Stein added that individual-based decision-making does not limit access to vaccination, since vaccines will remain available to any parent who chooses them, including in settings with limited access to maternal testing. She also noted that, as confirmed by the Vaccines for Children program and CMS, insurance coverage and access to care will not be affected by this language.

Dr. Pollak thanked the work group for their fortitude and willingness to revise the voting language based on the prior day's discussions. He noted that he would reserve additional comments until a formal motion was introduced.

Dr. Hibbeln noted that the preamble was illogical because infants with unknown maternal status are not included in the current recommendations, rendering the claim that existing recommendations remain unchanged inaccurate. He added that the committee is not being allowed to vote on, agree with, or disagree with the preamble. Regarding vote one, he highlighted that the final sentence, suggesting that the initial dose be administered no earlier than two months for infants not receiving the birth dose, is the unresolved issue that prompted tabling the vote for further discussion three months ago. He stated that the committee has still not received evidence or scientific discussion supporting a decision before or after two months of age and described this as unacceptable. Regarding vote two, he emphasized that introducing P serology testing after a first dose is a completely new concept. He noted that this idea has not been debated, that no data supporting its efficacy have been presented, and that the standard three-dose series is known to provide 95 percent efficacy. He stated that the proposal lacks scientific grounding, adds administrative burden, and could create new barriers to protection. He concluded that the current fourth iteration of the voting language, within 96 hours, remains highly problematic.

Dr. Meissner stated that thoughtful inquiry is always commendable but should not be confused with unwarranted doubt, which he believes occurs in the current discussion. He reiterated that when any vaccine is administered, healthcare providers must weigh the benefits and harms, and he found it difficult to accept the proposals in both votes. He noted that opposition to the neonatal birth dose appears to assume that harm outweighs benefits, and he questioned why the risk would be any different at 2 months of age, stating that he is unaware of evidence supporting reduced harm at that time. He emphasized that delaying the start of the series by two months would likely result in reduced protection for some infants, with no demonstrated reduction in vaccine risk. Regarding vote two, he stated that the proposed use of P serology is unsupported, calling it an idea being created without a scientific basis. He explained that titers above 10 milli-international units after one dose do not indicate that no further doses are

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needed, and that P serology is recommended only to verify that infants born to hepatitis B surface antigen-positive mothers were protected after receiving vaccine and immune globulin. He added that testing before three months is also not evidence-based. He addressed comments suggesting that children are being used to protect society, clarifying that vaccination is intended to protect infants themselves from a potentially fatal disease and not to shield others. He reiterated that no clinician claims that infants of surface antigen-negative mothers are "high risk." Still, the vaccine is given because exposure is unpredictable and the three-dose series provides durable protection. He rejected analogies comparing vaccination to airplane safety, arguing that hepatitis B vaccines are well-established, safe, and effective. He concluded that adopting the proposed changes would lead to increased hepatitis B infections among children, adolescents, and adults.

Dr. Milhoan explained that neonates must be considered a highly protected population because their blood-brain barrier, kidney function, and overall physiology differ significantly from those of older infants. He stated that this requires an approach rooted in caution and ensuring that any intervention is truly necessary. He noted that the suggested start at two months is intended to move vaccination out of the neonatal period and allow a practical option for families who may choose to begin the series later or use combination vaccines. He then addressed P serology, stating that work group presentations showed seropositivity in neonates at approximately 26%, which he described as low. He added that three doses are currently recommended not only for efficacy but also for achieving herd immunity targets of around 95%. He explained that even at that level, one in twenty children may not demonstrate a measurable antibody response, although cell-mediated immunity may still be present. He said the purpose of P serology testing is to provide a more scientific and individualized assessment of whether a child has mounted an immune response, noting that adults who do not meet a titer of 10 milli international units are typically advised to receive a booster. He acknowledged that the concept is novel but argued that it could increase confidence by confirming protection and avoiding unnecessary doses, particularly given that injections carry some risk. He concluded by emphasizing that decisions should prioritize the child's benefit, adhere to the principle of first do no harm, and distinguish between vaccination for individual protection and vaccination for herd immunity.

Dr. Hoeg stated that she agreed with Dr. Levi and viewed vote one as a positive step that aligns the U.S. with peer nations that do not routinely administer the hepatitis B vaccine at birth for infants who are not high risk. She emphasized the importance of the burden of proof, noting that a vaccine should not be given to an infant unless benefits outweigh potential harms. She said this standard has not been met in low-risk situations, given limitations in the available randomized trials, which are not large or long enough to rule out rare but serious safety issues. She noted that this low baseline risk would require tens of thousands of participants followed over time to establish the benefit fully. She acknowledged questions raised about whether there is a meaningful difference between administering the vaccine at birth or at two months. She agreed that the evidence to distinguish between the two is limited. She also said that informed consent is more complex immediately after delivery and that this supports not recommending routine administration at birth. She encouraged the committee to conduct a careful risk–benefit assessment, considering both known and unknown risks. She recommended examining why Denmark, which has a hepatitis B prevalence like that of the U.S., has chosen not to

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recommend universal childhood vaccination and instead uses an individualized approach for higher-risk children. She concluded by stating that she has not seen evidence validating P serology as a correlate of protection in infants and encouraged ACIP to ensure supporting data are available if the committee chooses to move forward with vote two.

Dr. Malone noted that the concept of a validated correlate of protection is often referenced but not always well understood, and he emphasized that it is complex. He stated that this issue is central to new recommendations from the Center for Biologics Evaluation and Research, which stress that antibody titers should not automatically be assumed to equate to clinical protection. He added that the emerging standard is to verify that assumptions linking antibody responses to protection are supported by evidence. He further remarked that although a threshold of 10 units has been historically used, he is not aware of any validation confirming that this threshold is meaningful. He then asked Dr. Hoeg if that understanding was correct.

Dr. Hoeg responded that she was not aware of evidence validating the threshold and had not seen data presented confirming that it is a correlate of protection. She stated she would welcome clarification.

Dr. Johnson stated that CMS reviewed the updated language from the work group and determined that, for Medicaid, the Children's Health Insurance Program, private insurance, and employer-sponsored insurance, there would be no coverage gaps. He added that CMS does not believe the proposed language would restrict access to hepatitis B vaccination.

Dr. Malone asked whether, in practical terms, the proposed votes would have any predictable impact on equity, availability, or federally supported distribution and administration of FDA-approved hepatitis B vaccines.

Dr. Johnson confirmed that they would not and reiterated that these vaccines would remain covered by insurance without an out-of-pocket cost.

Dr. Meissner stated that although he is not a hepatitis expert, he understands that a level of 10 milli-international units is considered an appropriate immune response to the hepatitis B vaccine. He explained that, as recommended, if a person's level exceeds this threshold within three months after completing the three-dose series, that individual is regarded as reliably protected. He noted that the CDC confirmed the previous day that there have been no documented cases of acute or chronic hepatitis B in individuals who achieved that level after vaccination. He then addressed a point raised earlier regarding booster doses. He clarified that if a health care worker has a titer below 10 milli-international units within 3 months of the third dose, a booster is recommended due to the risk of occupational exposure. However, for members of the public who are not at increased risk, this recommendation does not apply. He added that although antibody levels may decline over time, an anamnestic response will occur if a booster is administered years later to someone who initially responded and is otherwise healthy. He concluded that the absence of hepatitis B cases among individuals who completed the vaccine series is strong evidence of the vaccine's effectiveness.

Dr. Malone asked for clarification, noting that although there is no documented evidence of hepatitis B in fully immunized individuals who achieved the protective titer, the absence of evidence does not necessarily rule out the event.

Dr. Meissner responded that if a case of acute hepatitis B occurred in an otherwise healthy person who was fully vaccinated, it would be notable enough to appear as a lead report in the New England Journal of Medicine.

Dr. Milhoan stated that he agreed with Dr. Hoeg's point but noted an inconsistency in the use of serology thresholds. He observed that the committee accepts the standard serology threshold for determining seroconversion, yet there is little data on whether one dose or two doses is sufficient when seroconversion occurs. He added that when he was trained in medical school in 1992, the series was explained primarily as a strategy to achieve herd immunity rather than individual immunity. He emphasized that the committee appears to rely on the serology number when it is convenient and discount it when it does not support the desired conclusion. Regarding healthcare workers, he asked whether the same logic would apply to individuals with high-risk household contacts. He reiterated that the committee lacks rigorous evidence demonstrating whether one dose is insufficient and whether three doses are superior, and that efforts to obtain such data have not yielded answers. He concluded by highlighting the overall lack of data and stating that he prefers to err on the side of protecting children from potential harm.

Dr. Meissner stated that the committee is conflating what is known with what is unknown. He noted that a titer of 10 million international units within three months after the third dose is known to be protective, but the committee does not know whether a higher titer, such as 15 million international units, after a single dose would provide sufficient protection. He explained that it is possible but unproven, and he is not aware of CDC data that answers this question. He added that when considering harm, the greater risk is allowing a child to remain susceptible in later years because it is unknown whether a single dose provides adequate cellular immunity. In his view, the harm arises from failing to administer the full three-dose series.

Dr. Malone then responded that Dr. Milhoan's remarks effectively requested clarification from CDC experts regarding any existing data on protection conferred by one or more doses that reach the historic antibody threshold, and he asked the CDC to comment.

Dr. Langer from the Hepatitis Center explained that historical data from the original controlled trials show that approximately 25% of infant recipients develop a protective titer after the first dose, and that a larger proportion do so after the second dose, with levels exceeding 90% after the third dose. He emphasized that although these early serologic responses occur, all efficacy studies demonstrating clinical protection were conducted after completion of the full three-dose series. Therefore, if a single dose yielding a titer above 10 would provide lifelong protection is a major, unsupported assumption. He added that there is no evidence supporting reduced risk from giving only one or two doses, and no evidence of significant long-term adverse events associated with the full series. Dr. Langer also addressed comparisons to other countries, noting that the U.S. does not have true peer nations. He explained that Denmark, often cited in discussions, has substantial structural differences, including a population of 6 million, universal

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and free prenatal care, hepatitis B screening rates above 95%, a national health registry with unique identifiers, and near-complete follow-up for infants born to mothers who are hepatitis B surface antigen-positive. By contrast, many infants in the U.S. are lost to follow-up after hospital discharge. He added that even Canada, the country most like the U.S., has recent studies indicating that a universal hepatitis B birth dose will be necessary to achieve elimination and that economic analyses have found the birth dose to be cost-effective. Multiple Canadian medical societies have already advocated for adopting a universal birth dose. He concluded that comparisons should be made using true equivalents rather than structurally incomparable systems.

Dr. Malon noted that, from an immunology perspective, a measurable titer after dose one indicates activation of effector and memory cells and stated that there is no theoretical reason to assume these immune cells would behave differently over time than those generated after subsequent doses. He asked whether this aligns with fundamental immunology.

Dr. Langer responded that while the hypothesis is reasonable, no data demonstrate this for hepatitis B vaccination. He emphasized that controlled randomized trials would be needed to support any change to the dosing schedule. He noted that the committee could recommend a shorter series if it wished, along with a recommendation that appropriate studies be performed. Manufacturers could then decide whether to pursue trials and seek FDA label changes. At present, however, no data support the use of P serology to predict long-term protection.

Dr. Malone commented that fewer doses could create competitive advantages for manufacturers, as has historically occurred. He stated that the broader dilemma is the inadequate data available to frontline physicians, who must make clinical decisions despite gaps in evidence. He observed that the discussion reflects a fundamental tension between public health objectives, which focus on maximizing benefits for the largest number of people, and individuals' and caregivers' rights to exercise medical decision-making. He noted that, in his view, individual decision-making should be prioritized and that this issue sits at the center of differing perspectives on the role of public health versus individualized medical care.

Dr. Langer stated that he believes the committee and public commenters are largely aligned regarding personal autonomy, informed consent, and the doctor–patient relationship. He emphasized that U.S. policy and law give licensed medical providers substantial discretion to deviate from guidelines and product labeling, noting that off-label use is common in clinical practice. He clarified that ACIP and CDC recommendations represent the best available guidance at the population level and cannot account for every individual circumstance. Individual practitioners, in consultation with parents or adult patients, are responsible for determining what is best for their specific patients. Dr. Langer stressed that he would not want to remove that decision-making ability from parents or providers. Dr. Langer encouraged the committee to consider adding language that vaccine recommendations are recommendations and should not be interpreted as mandates. He noted that mandates are typically established by state and local jurisdictions rather than the CDC or the federal government. He acknowledged the cultural challenges in the U.S. around prescriptive requirements. He reiterated that ACIP provides guidance based on what science shows to be best practice for most of the population. If a clinician, in discussion with a patient's parents, determines that a recommendation is not

appropriate for a specific patient, that judgment is within the scope of their medical training and licensure. If providers can justify their decisions, Dr. Langer stated that CDC would not criticize them.

Dr. Malone expressed sincere appreciation for Dr. Langer's remarks, noting that he was deeply moved and grateful for the honest and open-hearted commentary.

Dr. Levi agreed with Dr. Langer's earlier remarks regarding vaccine mandates, stating that it was encouraging to see consensus on that issue. He then offered several reactions to the discussion about serology testing between doses. He noted that the original clinical trial defined success as seroconversion, as demonstrated by serology testing, and that three doses were historically selected because most recipients converted after the third dose. He explained that parents and physicians are now faced with decisions about whether a child who demonstrates seroconversion after one or two doses should accept the small remaining risk of incomplete protection or proceed with additional doses. He stated that this returns to a fundamental difference among committee members regarding the strength and sufficiency of existing safety data, and he acknowledged that such differences are fair and expected in this setting. Dr. Levi also addressed earlier comments from Dr. Hibbeln. He emphasized that the committee is composed of members who will inevitably hold differing views. He stated that disagreements about voting outcomes should not be interpreted as evidence that the work group failed to perform rigorous review or that relevant information was overlooked. As an example, he referenced his dissenting vote on RSV products during a previous meeting, despite the majority's approval, noting that although he continues to have concerns, he respects the integrity of the process and the work conducted by the work group and CDC experts. He encouraged all members to separate dissatisfaction with an outcome from assumptions about the quality or completeness of the group's work.

Dr. Milhoan commented that he did not believe it was scientifically supportable to declare that there is no difference between receiving one dose and three doses, particularly during the infant period, when issues such as aluminum and other adjuvants would soon be discussed. He noted that adequate data does not exist to make such a determination. He suggested that the CDC should have information on breakthrough hepatitis B infections in individuals who received incomplete versus full vaccine series, and he asked whether any such data are available. He stated that if breakthrough infections occur, understanding the vaccination history would be essential. Dr. Milhoan also raised concerns about autonomy and informed decision-making. He said that if serology testing is used to demonstrate seroconversion, then clinicians must be able to tell parents whether additional doses are necessary even after seroconversion. He questioned whether the data exist to support such guidance. He emphasized that this uncertainty is directly relevant to shared decision-making, since parents must be informed of the implications of choosing one, two, or three doses. He concluded by noting that much of the committee's debate reflects two distinct perspectives. Some members prioritize individual patient and physician decision-making, while others focus on public health goals. Both perspectives, he noted, influence how members interpret the available evidence and the implications of proposed recommendations.

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Dr. Meissner stated that while parents hold the primary authority in vaccine decision-making, society also has a responsibility to issue recommendations for infants who are too young to decide for themselves. He emphasized that recommendations must be grounded in what is known and unknown, and current evidence shows that three doses administered on the existing schedule are safe and effective in preventing hepatitis B. He noted that parents retain the right to decline vaccination, but the committee also has an obligation to consider the infant's welfare. He acknowledged the stress surrounding childbirth but stated that this alone does not justify removing a safe and effective intervention. Dr. Meissner reiterated that strong evidence supports efficacy, and there is no evidence indicating a lack of safety. He agreed that fewer doses might ultimately prove sufficient and noted emerging data suggesting a single dose may be adequate, observing that the field originally began with three doses. He described this as an important scientific question and supported Dr. Langer's earlier suggestion that vaccine manufacturers could pursue studies to evaluate shortened series.

Dr. Hibbeln responded by addressing Dr. Levi's earlier remarks, clarifying that his concerns were not about liking or disliking a proposed decision but about whether adequate data had been presented to evaluate the issues under consideration. He emphasized that after four months of discussion, no data were provided regarding the question of administering vaccines before or after three months of age. Therefore, the distinction was not about preference but about the absence of evidence. He then noted his agreement with Dr. Malone that the committee does not have all the data it would ideally want, acknowledging that this is inherent to scientific work. He stated that decisions must be made using the available data and rely on credible evidence rather than speculation or hypotheses. He cited examples such as assumptions about neonatal blood–brain barrier development or possible unknown harms, stating that these points represent untested hypotheses rather than data-driven conclusions.

Dr. Malone stated that changes in pediatric blood–brain barrier function and overall physiology are well documented in the scientific literature.

Dr. Hibbeln responded that while infants' physiological systems are still developing, the assertion that these developmental factors justify administering or withholding a vaccine before or after three months of age remains a hypothesis rather than evidence-based guidance. He emphasized the need to distinguish clearly between hypotheses or speculation and actual data, noting that this principle aligns with the chair's own admonition at the start of both days of the meeting.

Dr. Hoeg responded to Dr. Langer's earlier comments by emphasizing that differences in health care systems between the U.S. and Denmark do not, in her view, provide a scientific rationale for recommending hepatitis B vaccination for low-risk infants in one country but not the other when the underlying disease risk is comparable. She noted that her own children were considered low risk in Denmark and remained low risk after moving to the U.S. She stated that American parents question why vaccination would be used to compensate for perceived gaps in the U.S. health system. She suggested that both the U.S. and Canada appear to rely on universal vaccination in this context. In contrast, Denmark bases its recommendations on scientific assessment of known and unknown risks while maintaining higher public trust. She indicated that she would expand on this point in her later presentation.

Dr. Malone acknowledged what he described as a central unresolved issue: the possibility of cumulative risk across the entire childhood vaccine schedule. He noted that FDA and CDC safety evaluations traditionally focus on single products, while children often receive multiple vaccines in close succession, sometimes containing shared components. He stated that this raises the question of whether biologically active ingredients common to several vaccines, such as aluminum-based adjuvants, could pose cumulative risks even if each product shows no identifiable safety concerns. He added that the lack of cumulative toxicology data has long been a concern raised by various communities and is one reason the childhood vaccine schedule working group was formed.

Dr. Blackburn noted that, as a parent of two young children, she views the discussion of individual-based decision making through the lens of practical experience. She emphasized that for many families who wish to delay or decline the birth dose, true choice has often not existed in practice. She stated that numerous parents have been dismissed from pediatric practices for requesting alternative timing or spacing for vaccines, and that this reality must be acknowledged if the committee intends to promote informed and collaborative decision-making. She stressed that recommendations encouraging parental choice and clinician consultation only function when families retain access to clinicians willing to care for them, and that no child should lose their medical home for engaging in the individualized decision-making being discussed. She added that as the committee proceeds, it will be important to consider implementation in real-world settings and to ensure families are not left without care.

Dr. Middleman began by thanking the chair and stating that she wanted to clarify her use of the term “misinformation.” She explained that misinformation refers to false or inaccurate information spread without any intent to deceive. She believed this clarification was necessary because her previous comment had been interpreted differently. She emphasized that she does not question the committee members' intentions and believes everyone is working in the best interests of children.

Dr. Malone responded that he believed he had misheard her earlier comment and had thought she said “disinformation.” He apologized for the misunderstanding.

Dr. Middleman continued by explaining that, as a health services researcher, she observed significant misinformation during the meeting. She noted that the surveillance system referenced in discussions about acute hepatitis B incidence likely does not capture infant infections because infants are rarely symptomatic. She stated that conclusions drawn from her own study had been misinterpreted. She also identified misinformation about serology, its meaning, and its relationship to cellular immunity. She pointed out that several committee members had acknowledged they are not hepatitis B experts and urged the group to rely more heavily on CDC subject-matter experts who work with these data regularly and could have vetted questionable claims before they were shared publicly. She closed by stressing the importance of responsible communication and urged the committee to evaluate the proposed vote using a systematic, rigorous process.

Dr. Shlay, representing NIHO, commented that the proposed requirement to delay vaccination until two months of age is inappropriate. She noted that some parents may decline the birth

dose but still wish to have their infant vaccinated within the first days or weeks after delivery, such as during a routine nurse visit. She stated that the language should not restrict administration for two months and recommended striking that requirement if the committee proceeds with a vote. She also said that she does not believe the committee should vote on changes to the birth dose at all. She added that before adopting any recommendation involving post-dose serology testing, rigorous studies are needed to determine whether a single dose provides protection. She noted that similar evidence-based reductions in dose schedules have occurred for other vaccines, such as HPV. She emphasized that comparable data are necessary before proposing changes to hepatitis B vaccination practices.

Dr. Malone clarified that the wording in vote one is not prescriptive. He noted that the language states, “for those not receiving the hepatitis B birth dose, it is suggested that the initial dose be administered no earlier than two months of age,” emphasizing that the term “suggested” does not function as a strict requirement.

Dr. Shlay responded that she appreciates the clarification but still recommends removing the two-month suggestion entirely. She stated that if the committee proceeds with vote one, the recommendation should not include any suggested timing and should instead allow vaccination at any point agreed upon by the parent and provider.

Dr. Goldman stated that while he agrees with the principles of scientific rigor highlighted at the start of the meeting, he has not seen those principles applied in the committee’s deliberations. He urged members to allow liaison representatives to speak for an adequate amount of time and not use member comment periods to limit liaison input. He questioned why concerns about COVID-19 mandates were being used to justify changes to the hepatitis B schedule and noted that universal recommendations are not mandates. If informed consent is the concern, he asked why the committee is pursuing changes not supported by evidence. He requested detailed information on which stakeholders want the recommendations changed and whether they represent broad public sentiment or a small group opposed to the birth dose on ideological rather than scientific grounds. He also questioned the absence of cost analyses for P serology testing, the feasibility challenges of bringing infants back for blood draws, and the implications for families without insurance. He asked where the data are showing that serology after a single dose provides lifelong protection and emphasized that public health recommendations should be based on evidence, not anecdotal impressions. He added that school mandates are irrelevant to a birth-dose policy and argued that the proposed changes present an unnecessary solution in search of a problem. He stated that altering the recommendations will not address concerns about informed consent but will increase the risk of harm and death for children. As a practicing physician and representative of the American College of Physicians, he urged the committee to uphold its responsibility to population health, adhere to the principle of doing no harm, and reject all proposed votes.

Dr. Munoz-Rivas, speaking on behalf of IDSA, expressed significant concern regarding the proposed voting language. She voiced support for the points raised by Drs. Hibbeln and Meissner noted that professional societies, practicing physicians, and members of the public who provided input share similar concerns. She said that the primary issue is the absence of a scientific framework or sufficient data to justify the changes reflected in the proposed votes. She

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further expressed concern that some committee members rely on personal assumptions rather than evidence, and that there are instances of incorrect or incomplete interpretation of existing data, including misunderstandings of basic immunologic principles. She reminded the committee that CDC's remit is U.S. public health and that the purpose of ACIP recommendations is to protect the health of the broader U.S. population; recommendations are not mandates. She added that changes to the hepatitis B recommendations would not resolve concerns about informed consent and may instead undermine public trust by introducing confusion and casting doubt on the substantial body of safety and efficacy data accumulated over the past 30 years. Dr. Munoz-Rivas voiced full agreement with Dr. Langer's explanation of why comparisons with other countries are not directly applicable and reiterated that recommendations must reflect the specific needs and realities of the U.S. She concluded by urging the committee to act responsibly and dismiss the proposed votes if their priority is truly the best interest of public health.

Dr. Bagdasarian, speaking on behalf of ASTHO, stated that as a practicing infectious disease physician, she has seen firsthand the consequences of hepatitis B. She explained that in her role as a state health official, she regularly engages with health care providers across her state and wanted to share the real-world implications of the proposed voting language. She noted that when a vaccine recommendation includes extensive language about shared clinical decision-making, many providers interpret this as indicating that the vaccine is controversial, that additional steps are required, or that they may face increased liability. She acknowledged that multiple committee members have expressed a commitment to ensuring vaccine choice and believes this commitment is sincere. However, she emphasized that informed consent is already a foundational component of medical care and should apply broadly rather than being highlighted for specific vaccines in a way that suggests uncertainty. She added that clinicians depend on clear, population-level vaccine guidance, and that adding ambiguous shared decision-making language to routine vaccines creates confusion, suggests unwarranted scientific uncertainty, and imposes unnecessary burdens on providers and families. She also referenced the committee's discussions about improving hepatitis B screening for pregnant women. She agreed that this would be ideal but cautioned that real-world experience demonstrates how difficult this is to achieve. She cited congenital syphilis as an example, noting that in her state, every maternal case with missed screening reflects a complete lack of prenatal care or fragmented, inconsistent care. She stated that weakening or removing the universal birth dose recommendation would widen existing gaps in the system. She urged the committee to consider not only theoretical implications but also the real-world consequences for the children the recommendations are intended to protect.

Dr. Middleman stated that, historically, the risk of disease acquisition decreases when an immunization program is effective, as with hepatitis B vaccination. She noted that in her 21 years as a liaison to ACIP, this would be the first time the committee would vote on a policy that, based on all available and credible evidence regarding benefits and harms, would increase risk to children rather than reduce it. She emphasized that data show the universal hepatitis B birth dose recommendation improves adherence to the full vaccination series. Any policy change that weakens this recommendation and allows children to fall through gaps in an imperfect U.S.

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medical system would, in her view, lead to preventable harm. She concluded that ACIP must create policies that recognize these realities and protect children in the U.S.

Dr. Malone provided a procedural clarification before the vote. He stated that, according to ACIP rules, Dr. Milhoan is the official committee chair and, in the event of a tie vote, would serve as the tiebreaker. Dr. Malone noted that he is only acting in the chair's place because Dr. Milhoan is attending virtually, and that Dr. Milhoan retains full authority to break ties if he is present.

Dr. Pollak opened the discussion and referenced his earlier comments on Vote 1. He noted that informed consent is inherent to the practice of medicine. He expressed concern that the proposed language implies that obstetricians and other clinicians caring for pregnant women and newborns are not providing appropriate informed consent. He stated that portions of the language appear redundant. Dr. Pollak also raised concerns about the suggestion to delay vaccination until no earlier than 2 months of age, commenting that such language could constrain pediatric practice. He requested input from Dr. Meissner and other committee members on how this recommendation might affect pediatricians, stating that many would continue vaccinating according to the current schedule. He further noted a tension between the proposed two-month timing and the statement at the top of the page, which he characterized as conflicting with current CDC infant vaccination guidelines.

Dr. Meissner responded to Dr. Pollak's question, stating that he remains hopeful that pediatricians will continue to administer the hepatitis B birth dose within 24 hours of delivery and before hospital discharge. He cautioned that delaying the dose is not in the infant's best interest, noting there is no evidence of harm from administering the vaccine at birth and no reason to assume outcomes would differ if given later, except that more children would be at risk of infection. He clarified that a previous statement suggesting the policy change would increase the risk of death for millions of children was hyperbolic. While he does not expect impacts at that scale, he emphasized that relaxing the recommendation would increase the risk of hepatocellular carcinoma, cirrhosis, and premature death for some children, whether in the low or high thousands. He reiterated that hepatitis B has become "a victim of its own success" because declining disease rates reflect the vaccine's effectiveness, not the disappearance of the virus. He cautioned that altering the dose, timing, or schedule would lead to a resurgence of infections. Dr. Meissner concluded that, for these reasons, he is uncomfortable with the wording in vote number one.

Dr. Hibbeln noted that many of his key concerns had already been raised by Dr. Meissner. He stated that, in preparing for this meeting, he developed responses to 11 questions in the evidence-to-recommendation framework but would not address all of them due to time constraints. He expressed concern that the preamble does not allow members to agree or disagree and is not logical, noting that the status of mothers with unknown hepatitis B infection is not part of the current recommendation. He added that vote number one remains problematic, as issues related to the two-month data were not discussed or presented during the three months since the previous meeting.

Dr. Milhoan stated that the work group has made significant efforts to avoid decreasing access to vaccination and emphasized the need to avoid hypothetical concerns when the committee

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has been asked to focus on what is being made available. He noted that the group has followed the available data as closely as possible and has ensured that both clinicians and patients retain freedom of choice, including maintaining coverage of the vaccine. He characterized hepatitis B in this context as a very low-risk disease and stated that offering shared clinical decision-making is appropriate. As a practicing pediatrician and pediatric cardiologist with more than 20 years of experience counseling families, he said he does not view the proposal as problematic. He added that the vote preserves the option to administer the vaccine at birth or at another time through shared decision-making, which he does not find burdensome in clinical practice.

Dr. Levi stated that the use of individual decision-making reflects an intention to signal that the current broad recommendation may no longer be appropriate for all infants born to mothers who test hepatitis B surface antigen negative. He added that the shift to a two-month starting point implicitly encourages parents to consider whether they want to assume the perceived risk of giving another dose of vaccine, and that many may choose to delay far beyond two months, potentially for years or into adulthood, in consultation with their physician. He emphasized that this language represents a fundamental change in approach to this vaccine and perhaps to vaccination more broadly, rather than a reinforcement of existing concepts, and concluded that although no language is perfect, the proposed wording accomplishes its purpose.

Dr. Malone stated that any action taken by the committee will be reflected in the CDC's published immunization schedule, which is widely used and not merely advisory. He noted that many states adopt CDC policy directly as their own, meaning the committee's decisions have real implications for a portion of the U.S. population. He clarified that ACIP does not set policy but provides recommendations to the CDC director, who holds final authority. He stated that the committee is therefore debating the advice it will give the director on whether to make changes to current CDC communications and public recommendations, contingent on the director's concurrence.

Dr. Pagano clarified that the preamble was included only for informational purposes and is not part of what the committee is being asked to vote on; therefore, it should not be conflated with the actual vote language. He stated that although some have commented on redundancy in the language of vote one, he does not find those elements objectionable and believes they add clarity to the committee's intent. He noted that while the language suggests the first dose may be delayed to the two-month range, it still allows parents and physicians to administer the vaccine earlier if they determine it is appropriate.

Dr. Griffin stated that, building on Dr. Pagano's comments, redundancy in the language is not problematic because language matters and repetition helps reinforce core ethical obligations such as "first, do no harm." She noted that informed consent serves as a continual reminder of this principle in every clinician–patient interaction, and she will support even more redundancy if it strengthens that reminder. She then referenced prior discussions from 2005 about the origins of the infant hepatitis B program and the rationale for moving the birth dose to within the first 24 hours. She explained that at that time, a key consideration was establishing a "safety net" for infants born to hepatitis B surface antigen–positive mothers who were not identified due to testing errors or failures in reporting results. She noted that medical errors contribute significantly to adverse outcomes, making this safety-net function a real and serious concern.

However, she expressed discomfort with treating infants themselves as the safety net, emphasizing that although she does not want any infants to be missed or infected, the original framing of the safety net was rooted in a different context than the way it is being applied in current discussions.

Vote: Hepatitis B Vaccines Vote #1

> For infants born to HBsAg-negative women: ACIP recommends individual-based decision-making, in consultation with a health care provider, for parents deciding when or if to give the HBV vaccine, including the birth dose.[1] Parents and health care providers should consider vaccine benefits, vaccine risks, and infection risks. For those not receiving the HBV birth dose, it is suggested that the initial dose is administered no earlier than 2 months of age. Y/N
>
> [1]Parents and health care providers should also consider whether there are risks, for example, such as a household member is HBsAg-positive or when there is frequent contact with persons who have emigrated from areas where Hepatitis B is common.

Motion/Vote: Hepatitis B Vaccines

Dr. Levi motioned to approve the recommended voting language, stating,
"For infants born to HBsAg-negative women: ACIP recommends individual-based decision-making, in consultation with a health care provider, for parents deciding when or if to give the HBV vaccine, including the birth dose.[1] Parents and health care providers should consider vaccine benefits, vaccine risks, and infection risks. For those not receiving the HBV birth dose, it is suggested that the initial dose is administered no earlier than 2 months of age.
[1]Parents and health care providers should also consider whether there are risks, for example, such as a household member is HBsAg-positive or when there is frequent contact with persons who have emigrated from areas where Hepatitis B is common."
Dr. Griffin seconded the motion. No COIs were declared. The motion carried with 8 votes in favor, 3 votes opposed, and 0 abstentions. The disposition of the vote was as follows:

8 Favored: Stein, Levi, Pebsworth, Malone, Griffin, Blackburn, Pagano, Milhoan
3 Opposed: Pollak, Meissner, Hibbeln
0 Abstained:

Vote Discussion

Dr. Pollak stated that there are several problems with the language in vote two. He first questioned the meaning of the term "children," noting that it is unclear whether it refers to ages

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0 to 18, neonates, or another group, and emphasized that the definition needs clarification. He then expressed concern that the sentence “parents should consult with health care providers” places the burden on parents to initiate the discussion and assumes they understand a complex practice-management issue. He noted that in the U.S., many parents are not well-versed in vaccination biology or immunology and suggested that the wording should instead indicate that physicians consult with parents. He also stated that although the proposal attempts to mirror management strategies used for other viral diseases, such as cytomegalovirus or hepatitis C, this situation is not comparable. He emphasized that there is no evidence that serologic monitoring indicates immunity, regardless of whether one or three doses are given. He added that, in practical terms, most pediatricians will likely continue using the current three-dose protocol because CDC data show that three doses provide 95% protection, and data for fewer doses are lacking. Given that the committee is intended to be data-driven, he urged a “no” vote on vote two until these concerns about the language are adequately addressed.

Dr. Levi stated that he understood the arguments raised but encouraged the committee to view the vote through the lens of supporting patient choice and empowerment. He noted that patients should not be underestimated in their ability to participate in decision-making. He explained that the underlying dilemma stems from clinical trial data in which additional doses were treated as having minimal incremental effects. Because serology testing captures a conversion metric, the goal has been to ensure that nearly all individuals seroconvert. However, he emphasized that this does not mean every patient would prefer to receive three doses. He stated that it is reasonable to hypothesize that individuals who convert after one or two doses may have adequate protection. Dr. Levi observed that patients and providers must balance the potential risks of taking an additional vaccine dose against the possibility that this hypothesis may be incorrect. He stated that the evidence does not fully resolve this uncertainty. In situations of uncertainty, he concluded that patients and their providers should be allowed to choose the level of uncertainty they are willing to accept.

Dr. Griffin stated that definitions of “children” vary across global institutions, but noted that the CDC defines children as individuals under age 19. In contrast, the legal perspective typically defines them as under age 18. She then asked Dr. Pollak whether he would consider rephrasing the language to say, “parents may consult with healthcare providers,” and invited his opinion on that suggested wording.

Dr. Pollak responded that “may” would be acceptable and that although “should” is more explicit, “may” is preferable in this context.

Dr. Pagano stated that “may” works in the revised language but suggested that “when possible” may be preferable because it accounts for challenges families face in returning for multiple visits, such as obtaining lab work and then returning for vaccination. He added that although additional data would be valuable, the language should not create burdens that discourage follow-up.

Dr. Malone stated that the proposed recommendation raises intriguing research opportunities. He then responded to Dr. Levi’s earlier comment, emphasizing that no data support the idea that one dose is as effective as three. He noted that achieving a serologic titer above 10 after

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one dose does not equate to the immune response achieved with the three-dose series, and that failing to complete the full hepatitis B schedule poses meaningful risk.

Dr. Meissner reiterated that there is no evidence of harm from the current schedule. He noted that differences in the blood–brain barrier between infants and older individuals do not relate to vaccine reactions. He stated that concerns raised about deviating from the established schedule are unsupported, given the CDC's demonstrated benefits and the absence of harm.

Dr. Malone asked whether there were specific comments Dr. Meissner wished to make regarding the wording in vote two.

Dr. Meissner responded that no data show that fewer than three doses provide protection. He emphasized that risks extend beyond the neonatal period, noting that hepatitis B transmission later in life can occur through intravenous drug use and sexual exposure, and that high-risk behaviors cannot be reliably predicted. He stated that the safest approach to protect children is to administer the recommended hepatitis B vaccine series beginning within the first 24 hours of life.

Dr. Milhoan stated that the discussion appears inconsistent: seroconversion was considered sufficient for vaccine approval, yet it is now being questioned as a basis for assessing effectiveness. He noted that in other contexts, such as yellow fever vaccination for travel to endemic areas, a single dose is accepted and suggested that it may be time to formally study whether a single dose of hepatitis B vaccine provides meaningful protection. He emphasized that many questions could be answered if the CDC presented any available data on breakthrough infections among individuals with incomplete vaccine series, which he has never seen. He stated that assuming all individuals require three doses is a significant assumption, given that the three-dose standard was based on seroconversion rather than clinical efficacy. He questioned whether concern about the estimated 1 in 20 who may not seroconvert should apply uniformly. He added that existing data, including that presented by Dr. Nevison, suggest variability based on timing of the first dose, which may warrant closer examination. He framed his perspective as an effort to provide families with additional information about whether they appear covered rather than imposing burdens. He concluded that he has no issues with the current language and would also not object to changing the phrasing to "may."

Dr. Malone asked Dr. Pebsworth for clarification on the intent of the proposed language. He stated that his understanding was that serologic testing would identify approximately 1 in 20, or 5%, who do not seroconvert after three doses, and that the recommendation would allow those individuals to receive a fourth dose. He emphasized that this approach "cuts both ways," as it provides information not only about whether fewer doses may be sufficient but also about whether an additional dose may be warranted for those who do not respond. He noted that Dr. Milhoan appeared to agree and concluded that this was the clarification he wished to highlight.

Dr. Meissner stated that the comparison to the yellow fever vaccine is not appropriate because yellow fever is an RNA flavivirus. In contrast, hepatitis B is a DNA virus, and the two are immunologically distinct. He noted that achieving a titer of 10 mIU after three doses, measured within three months of series completion, correlates with lifelong protection. However, no evidence exists that achieving 10 mIU after a single dose confers lifelong immunity, making the

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two situations fundamentally different. He agreed it would be valuable to have additional data, but emphasized that none currently exists. In the absence of such evidence and given the lack of harm associated with the three-dose series, he stated that he does not understand how the committee could recommend a change. He warned that altering the schedule would lead to increased hepatitis B infection rates and concluded that doing so would not be the right course of action.

Dr. Hibbeln stated that his comments were directed toward the wording of vote two. He noted that the hepatitis B vaccine program is recognized as one of the greatest global achievements in protecting children and emphasized that any changes to the current program should meet a very high threshold. He stated that the language for vote two has been confusing, the scientific basis behind it has been unclear, and the committee has had limited time to address the question, resulting in considerable discord. He proposed removing the entire block of language for vote two, stating that decisions must be based on data rather than speculation and that a careful, data-driven evaluation has not occurred for this issue.

Dr. Malone asked for clarification on Dr. Hibbeln's suggestion, noting that eliminating the text of vote two would effectively be equivalent to voting no.

Dr. Hibbeln responded that the committee was only discussing potential text modifications at this stage. He reiterated his view that the language should be removed entirely and stated that others may interpret that position as a no vote, but no vote has yet occurred.

Dr. Milhoan stated that he had just received an email from a pediatrician in the work group who noted that parents frequently ask how they can know whether additional doses are needed. He said he would support a vote to recommend that this issue be formally studied, given the lack of data and the amount of speculation being presented as science. He stated that assumptions about lifelong immunity remain unproven and that adults are managed differently based on seroprevalence and risk. He emphasized that although population-level risk may be low, it is inaccurate to say that the vaccine carries zero risk for any individual. He expressed support for language requesting comprehensive studies to determine dose requirements and how to assess when a child is truly immune, noting that current reliance on seroconversion would need reassessment if it does not reflect true protection.

Vote: Hepatitis B Vaccines Vote #2

> When evaluating the need for a subsequent HBV vaccine dose in children, parents should consult with health care providers to determine if a post-vaccination anti-HBs serology testing should be offered. Serology results should determine whether the established protective anti-HBs titer threshold of ≥10 mIU/mL has been achieved. The cost of this testing should be covered by insurance. Y/N

Motion/Vote: Hepatitis B Vaccines

Dr. Levi motioned to approve the recommended voting language, stating,

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"When evaluating the need for a subsequent HBV vaccine dose in children, parents should consult with health care providers to determine if a post-vaccination anti-HBs serology testing should be offered. Serology results should determine whether the established protective anti-HBs titer threshold of ≥10 mIU/mL has been achieved. The cost of this testing should be covered by insurance." Dr. Pagano seconded the motion. No COIs were declared. The motion carried with 6 votes in favor, 4 votes opposed, and 1 abstention. The disposition of the vote was as follows:

6 Favored: Levi, Pebsworth, Malone, Griffin, Pagano, Milhoan
4 Opposed: Pollak, Blackburn, Meissner, Hibbeln
1 Abstained: Stein

Vote: VFC Resolution Vote

Dr. Santoli briefly summarized the issue before the committee. She stated that the purpose of the resolution was to update the hepatitis B recommendations, including the revised schedule for infants born to mothers who test negative, in which vaccination would begin at two months of age. She noted that the resolution also included a footnote indicating that infants born to negative mothers could, under individual-based or shared clinical decision making, receive the vaccine before two months of age.

Motion/Vote: VFC Resolution Vote

Dr. Levi motioned to approve the updated Vaccines for Children (VFC) resolution for prevention of hepatitis B. Dr. Stein seconded the motion. While Dr. Malone objected to proceeding to a vote, others did not share that objection, and the motion to vote passed. No COIs were declared. The motion carried with 8 votes in favor, 0 votes opposed, and 3 abstentions. The disposition of the vote was as follows:

8 Favored: Blackburn, Griffin, Malone, Pebsworth, Levi, Stein, Pollak, Milhoan
0 Opposed:
3 Abstained: Pagano, Meissner, Hibbeln

CHILDHOOD/ADOLESCENT VACCINATION SCHEDULE

Aaron Siri presented on the historical development of the U.S. childhood vaccine schedule. He identified himself as an attorney and managing partner of Siri & Glimstad LLP, a law firm with more than 100 professionals that handles civil rights, employment, immigration, exemption, and

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injury-related claims involving vaccination. He disclosed that for nearly a decade, he has engaged in litigation with federal and state health agencies regarding vaccination policy and has deposed and cross-examined vaccinologists.

As part of his disclosure, Mr. Siri stated that his firm is currently involved in multiple lawsuits against the U.S. Department of Health and Human Services and related agencies, including approximately 93 Freedom of Information Act lawsuits, many of which involve vaccination. He also disclosed ongoing litigation challenging the constitutionality of the PREP Act related to COVID-19 vaccine injury immunity, lawsuits involving COVID-19 vaccine exemptions in the U.S. Air Force and U.S. Army, representation of clients with claims in the National Vaccine Injury Compensation Program, and representation of clients in the Countermeasures Injury Compensation Program. He noted that he would not discuss the substance of any pending litigation.

Providing historical context, Mr. Siri reviewed the development of the U.S. childhood vaccine schedule. He noted that ACIP was established in 1964 and issued recommendations for many years, but that the first formally published vaccination schedule appeared in 1983. He referenced CDC archival materials indicating that the 1983 childhood schedule included three routine vaccines: DTP, oral polio vaccine, and MMR.

He compared the 1983 schedule with the current childhood vaccination schedule, highlighting the substantial expansion in the number of recommended vaccines and dosing intervals over time. He clarified that his remarks focused exclusively on the childhood schedule.

Mr. Siri presented data comparing vaccine uptake rates between 1983 and 2020. Coverage was measured at age 2 years for most vaccines and at ages 13–17 years for Tdap, HPV, and meningococcal ACWY due to later administration. He reported substantial increases in coverage across vaccines, including increases in MMR, DTP/DTaP, and polio vaccination rates. Vaccines not included in the 1983 schedule had near-zero uptake at that time and demonstrated coverage rates ranging from approximately 60% to over 90% by 2020.

Turning to pre-licensure safety considerations, Mr. Siri reviewed clinical trial designs supporting vaccines included in the childhood schedule. He described a comparative analysis of standalone childhood vaccines and the control products used in their licensing trials, noting that ACIP recommendations for routine use often followed [very] shortly after FDA licensure, leaving clinical trial data as the primary evidence available at the time of recommendation. He noted that hepatitis B, hepatitis A, and inactivated polio vaccines were exceptions, with longer periods between licensure and routine recommendation.

Mr. Siri emphasized the importance of robust pre-licensure clinical trial data, particularly given the difficulty of revising recommendations once implemented. He outlined criteria for evaluating trial quality, including use of appropriate controls,, adequate follow-up duration to assess developmental neurologic, [and other health] outcomes, sufficient sample size to detect safety signals, and proper randomization and blinding. He stated that pediatric trials may require longer follow-up than adult trials.

He compared vaccine trials with those for other pharmaceutical products, citing examples of drugs licensed based on placebo-controlled trials with multi-year safety follow-up. He referenced

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commentary by Drs. Plotkin and Orenstein noting that public confidence increasingly depends on more comprehensive pre- and post-authorization safety data.

Mr. Siri reviewed the types of control groups used in vaccine licensure trials. He stated that the two standalone hepatitis B vaccines were licensed [for children] without control groups, that DTaP vaccines were licensed using DTP as a comparator, and that subsequent vaccines were often tested against earlier vaccines rather than against placebos. He described this as a chain of active comparators extending across multiple vaccine classes, including Hib, pneumococcal conjugate, influenza, HPV, and meningococcal vaccines.

Specific examples of trial designs were then reviewed. Mr. Siri stated that MMR II was licensed based on trials involving fewer than 1,000 children, short safety follow-up, and no control group, and that the later licensed measles-containing vaccine used MMR II as a comparator. He reported that varicella, hepatitis A, Tdap, HPV, and meningococcal vaccines were similarly licensed using non-inert controls.

He concluded that none of the standalone routine-injected childhood vaccines, nor the vaccines used as controls in their licensing trials, were licensed based on placebo-controlled clinical trials.

Mr. Siri emphasized that FDA regulatory documents should be consulted when evaluating evidence on vaccine licensure and stated that he would submit a supplemental memorandum with citations. He argued that reliance on active comparators results in layered assumptions of safety rather than an established baseline.

He further stated that safety follow-up durations in pediatric trials were often insufficient to detect long-term outcomes and that many trials were underpowered. As examples, he cited Recombivax HB and Engerix-B, noting limited sample sizes and safety monitoring periods of four to five days [after injection].

Mr. Siri addressed IOM reviews of vaccine safety, stating that across multiple reports published in 1991, 1994, and 2012, the IOM frequently concluded that evidence was insufficient to accept or reject causality for many serious outcomes. He emphasized that these conclusions reflected a lack of adequate studies rather than evidence [to support safety or] disprove causation.

He then discussed pneumococcal conjugate vaccines, describing licensure and recommendation timelines for PCV7, PCV13, and PCV15, and noting the continued use of investigational vaccines as comparators. He cited FDA documentation reporting similar rates of serious adverse events between vaccine and comparator groups and stated that these findings did not preclude safety concerns.

Mr. Siri provided additional examples involving diphtheria-tetanus-pertussis vaccines. He referenced international studies examining associations with all-cause mortality, while noting methodological limitations and differences from current U.S. vaccine use.

He compared vaccine trials [for routinely recommended vaccines] with those for the dengue vaccine, which underwent a large placebo-controlled trial with extended follow-up, identifying

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age- and serostatus-specific risks. He stated that these findings were possible due to the trial design and duration.

Mr. Siri attributed differences in trial rigor between routine childhood vaccines and other products to liability protections under the National Childhood Vaccine Injury Act of 1986, arguing that this framework alters incentives for conducting extensive pre-licensure trials. He cited ethical concerns regarding inadequately designed studies and recommended stronger requirements for pre- and post-licensure safety evidence.

He then addressed post-licensure safety monitoring, summarizing IOM reviews commissioned by HHS and highlighting persistent evidence gaps. He referenced [a published, peer-reviewed study containing] commentary by Drs. Plotkin and Orenstein noting limited funding for post-authorization safety studies.

[To highlight what he represented as the lack of adequate post-licensure safety,] Mr. Siri discussed autism as a commonly claimed vaccine-related outcome, stating that IOM reviews concluded that evidence was insufficient to accept or reject causality for pertussis-containing vaccines. He described FOIA requests and subsequent litigation that resulted in the CDC identifying studies [which it stated supported the statement that "vaccines do not cause autism" but that" he stated did not evaluate vaccines administered in the first six months of life.

He noted that the CDC website language was updated to reflect the absence of studies demonstrating that vaccines administered in the first six months of life do not cause autism and emphasized the importance of this issue to parents [of children with autism].

Mr. Siri raised concerns about post-licensure surveillance systems, including VAERS, VSD, and V-safe, citing limitations in automation, access, and study design. He stated that although unvaccinated comparison groups exist within available datasets, comparative outcome studies have not been published.

He further discussed aluminum-based adjuvants, citing studies reporting tissue distribution and immune activation in animal models and noting unresolved questions regarding [aluminum-related] labeling accuracy.

Turning to vaccine effectiveness, Mr. Siri distinguished between vaccines that prevent transmission and those that primarily prevent disease [in only the recipient]. He cited IPV and acellular pertussis vaccines as examples [of vaccines] that do not prevent infection or transmission and stated that licensure standards do not require demonstration of transmission prevention.

He also reviewed mortality estimates attributed to childhood vaccination, raising concerns about modeling assumptions and the lack of adjustment for confounding factors. He discussed historical disease trends for diphtheria, measles, and hepatitis B and stated that observed declines in mortality predated vaccine introduction.

Mr. Siri concluded by emphasizing [the importance of and need for] informed consent, transparency, and individualized decision-making. He stated that acknowledging vaccine injuries, strengthening safety evidence, and balancing risks and benefits are essential to

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maintaining public trust. He urged the committee to prioritize robust safety data, transparency, and respect for informed consent in vaccine policy deliberations.

Discussion

Dr. Zadeh clarified that, to provide a broad perspective on the U.S. vaccine schedule, ACIP invited several individuals to discuss how the schedule developed and its current state. She noted that three experts were invited, including Dr. Paul Offit, a former ACIP member, and Dr. Peter Hotez, a vaccine developer at Texas Children's Hospital; however, she stated that they declined the invitation.

Dr. Levi thanked Mr. Siri for the presentation and noted that many of the issues raised aligned with topics discussed during the meeting. He referenced Mr. Siri's comments on mandates and how other entities may leverage recommendations from ACIP, the CDC, and professional organizations to impose mandates. Dr. Levi stated that he personally shares the view that mandates are ethically problematic and ineffective as public health policy. He observed that evidence from other countries suggests that education, empowerment, and informed choice are more successful approaches. Dr. Levi asked, from a legal perspective, what actions ACIP or the CDC could take at the federal level to make vaccine mandates less feasible.

Mr. Siri responded that public or private entities below the federal level that engage in conduct violating individual civil rights, such as the right to religious exemption, should not receive federal funding. He stated that the federal government has an obligation to uphold the U.S. Constitution, including First Amendment protections for religious freedom, and that government funding should not support entities that violate those rights.

Dr. Levi asked whether Mr. Siri believed existing legislation already allows such actions or whether additional legislative changes would be required.

Mr. Siri responded that addressing the issue would require a combination of statutory changes, regulatory action, and policy decisions at multiple levels. He cited, as an example, statements by the American Academy of Pediatrics calling for the elimination of non-medical exemptions for school attendance, noting that such positions influence downstream policy decisions.

Dr. Meissner stated that he found Mr. Siri's presentation difficult to respond to within the available time and characterized it as a distortion of the scientific evidence, noting that while Mr. Siri is entitled to express his views under the First Amendment, he strongly disagreed with the conclusions presented. He expressed regret that Dr. Paul Offit was not present, stating that Dr. Offit would have been better positioned to address the presentation in detail. Dr. Meissner emphasized that the expansion of the U.S. childhood vaccine schedule represents a major public health achievement that has contributed to historically low rates of infectious disease in the United States and cautioned that reduced vaccine uptake would likely result in increased disease incidence, including hepatitis B. He stressed the importance of distinguishing temporal association from causation, noting that adverse events occurring after vaccination do not necessarily indicate a causal relationship, and stated that conflating the two is misleading. He objected to references made to Drs. Stanley Plotkin and Walter Orenstein, stating that they are strong proponents of vaccination who have made substantial contributions to child health and

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vaccine science, and that portraying them otherwise was inaccurate. Dr. Meissner addressed specific examples raised during the presentation, explaining that the U.S. transition from oral to inactivated polio vaccine reflected a deliberate risk-benefit decision to prevent vaccine-associated paralytic polio, even though the inactivated vaccine is less effective at preventing transmission. He similarly noted that acellular pertussis vaccines were adopted to reduce adverse events associated with whole-cell vaccines, accepting reduced transmission prevention in exchange for improved safety. He referenced recent diphtheria cases among unvaccinated populations in Europe to underscore that vaccine-preventable pathogens remain present and that decreased vaccination can lead to disease resurgence. Dr. Meissner described pneumococcal conjugate vaccines as highly effective, stating that their public health benefits extend beyond vaccinated children to unvaccinated adults through indirect protection, and rejected implications that their safety had not been adequately evaluated. He stated that immunologic correlates of protection are a valid and necessary approach when diseases are rare, and that the close timing between FDA licensure and ACIP recommendation is appropriate for preventing disease. He concluded that the presentation focused disproportionately on rare or poorly defined adverse events while discounting the substantial and well-established benefits of vaccination, expressing strong disagreement with its conclusions.

Mr. Siri responded that his slide showing the increase in the number of vaccines was included because he was asked to discuss the development of the U.S. childhood vaccine schedule, and that illustrating its expansion over time was directly responsive to that request. He stated that he did not characterize this expansion as positive or negative. Still, he noted that, despite high vaccine uptake, the U.S. has comparatively poor overall health outcomes among developed countries, which he argued should be considered in broader discussions of public health. He said he welcomed a detailed, point-by-point debate with Dr. Meissner at any time and referenced prior public, written exchanges with Dr. Paul Offit regarding vaccine clinical trials, which he encouraged others to review for cited evidence rather than verbal characterizations. He clarified that his references to Drs. Plotkin and Orenstein were cited in their published work, not to portray them as skeptics. Addressing polio vaccines, he acknowledged the rationale for switching from OPV to IPV. Still, he stated that other vaccines have also been associated with severe neurologic injuries, including paralysis. He emphasized that individuals harmed by vaccines are real and should not be dismissed as rare or ill-defined. He stated that denying or minimizing these injuries contributes to vaccine hesitancy. With respect to DTP, he asserted that its safety problems are still underacknowledged. On diphtheria, he argued that environmental and living conditions significantly influence disease expression and clarified that he never advocated stopping [individuals from being to receive] vaccination but instead supported individual freedom to accept or refuse vaccines without coercion. He reiterated his view that licensing pneumococcal conjugate vaccines using other experimental vaccines as controls fails to establish a true safety baseline and that serious adverse event rates in infants should be concerning when no inert comparator exists. He clarified that he does not oppose the use of correlates of protection when appropriate and disputed any suggestion that he rejected that concept. Finally, he objected to characterizing vaccine-injured individuals as insignificant, stating that the conditions reviewed by federal agencies were based on real reports from families, and argued that failure to acknowledge and respectfully treat those families undermines public trust

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and ultimately [caused the very] harm to vaccine confidence [Dr. Meissner expressed concern about].

Dr. Malone stated that dialogue is essential to progressing toward truth and shared understanding. He offered his personal view that the chairperson, Dr. Milhoan, may wish to consider including continued dialogue on future agendas.

U.S. VS. DANISH VACCINE SCHEDULE

Dr. Tracy Beth Hoeg (FDA, ACIP ex officio) presented a comparison of the U.S. childhood vaccination schedule with those of Denmark and other developed countries, highlighting differences in recommendations and the evidence frameworks informing Danish decision-making. She noted that much of Denmark's policy rationale is published in Danish and therefore not widely reviewed in the U.S.

Dr. Hoeg stated that she is currently serving as the Acting Director of the Center for Drug Evaluation and Research at the FDA, has worked as a senior advisor in the Office of the Commissioner and the Office of Biostatistics and Epidemiology since March 2025, and is a dual U.S.-Danish citizen.

She emphasized that differences in vaccination policies across countries do not reflect fundamentally different populations, drawing on her professional experience in both Denmark and the U.S. She referenced the COVID-19 pandemic as an example of how assumptions about national differences influenced divergent public health decisions.

Dr. Hoeg reviewed childhood vaccination schedules used in several developed countries and noted that, as of January 1, 2025, the U.S. differs substantially from its peers. She stated that the U.S. recommends approximately 72 vaccine doses during childhood, including COVID-19 and annual influenza vaccines, whereas many other developed countries recommend fewer than 30 doses. She also noted that the U.S. targets more diseases overall.

According to Dr. Hoeg, these differences raise questions about why the U.S. schedule diverges from those of other developed countries and whether this divergence is supported by scientific and medical evidence. She explained that part of the difference relates to vaccine delivery approaches. In the U.S., some vaccines are given as individual shots, while many European countries more commonly use combination vaccines that protect against multiple diseases in a single injection.

Dr. Hoeg further noted that during her first ACIP meeting as an FDA ex officio member in April 2025, the U.S. was identified as an outlier in recommending COVID-19 vaccination for all children. She stated that this recommendation was later changed and that the revision brought U.S. guidance more in line with practices in other developed countries.

In comparing vaccination schedules by disease, Dr. Hoeg highlighted differences between the U.S. and Denmark. She described the Danish childhood vaccination schedule as more streamlined, with fewer recommended shots and fewer clinic visits, and noted that this simplicity may be easier for families to navigate.

Dr. Hoeg stated that differences in the number of recommended vaccine doses and targeted diseases result in differing cumulative aluminum exposure across childhood vaccination

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schedules. She noted that under the U.S. schedule, children receive approximately 6 milligrams of aluminum by age two and up to 8 milligrams by age 18, compared with approximately 1.4 milligrams by age two and 2.9 milligrams by age 18 in Denmark.

She clarified that she was not asserting specific health harms associated with these exposure levels. Still, she stated that existing data do not establish a clearly defined safe exposure threshold for aluminum administered parenterally throughout childhood. She noted that injected aluminum differs from dietary exposure and may be processed differently by the body.

Dr. Hoeg emphasized the importance of acknowledging uncertainty where data are limited, particularly when making general recommendations for all children, including those at lower risk for severe disease outcomes. She stated that vaccine recommendations should be based on robust evidence, including appropriate randomized trials where feasible, continued post-licensure safety monitoring, and routine reassessment as new data emerge.

She further stated that vaccines, like other medical products, should be evaluated continuously for appropriateness across populations and that recommendations should reflect evolving scientific understanding. She noted the importance of balancing disease prevention with avoidance of unnecessary medicalization and ensuring that each recommended vaccine demonstrates a clear net benefit.

Dr. Hoeg cautioned against the politicization of scientific decision-making and emphasized that public confidence is best maintained through transparent, evidence-based evaluation. She concluded that vaccine policy discussions should focus on minimizing overall harm and developing balanced recommendations that protect children's health.

Dr. Hoeg stated that Denmark's approach to vaccine recommendations may differ in part because vaccine policy discussions there are less politicized. She noted that Denmark's multiparty political system, established culture of public debate, and transparent decision-making processes contribute to how recommendations are developed and reviewed. She described Denmark's reliance on randomized controlled trials, extensive public documentation supporting vaccine decisions, and a willingness to acknowledge uncertainty and revise recommendations when new evidence emerges.

She then turned to child health outcomes in the U.S., noting that, compared with peer high-income nations, the U.S. has experienced less favorable trends in several areas. She referenced higher rates of childhood obesity and certain mental health conditions. She noted that additional outcomes, such as asthma and type 1 diabetes, are also more prevalent in the U.S. She acknowledged that differences in diagnosis, reporting practices, and genetic factors may contribute to these patterns, but stated that the underlying causes are not fully understood.

Dr. Hoeg explained that she raised these observations to question whether having a larger population of children with underlying health risks should necessarily result in a more expansive routine childhood vaccination schedule. She asked whether low-risk children in the U.S. should receive a substantially different set of routine vaccine recommendations compared with low-risk children in Denmark and other high-income countries. She stated that, in her view, differing recommendations for similar low-risk populations across countries warrant careful scientific justification.

Dr. Hoeg addressed the assumption that differences in disease prevalence drive differences in national vaccination schedules. She compared the U.S. and Denmark, noting that rates of

hepatitis B among pregnant women and the prevalence of chronic hepatitis B are similar in both countries. Yet, Denmark does not recommend routine hepatitis B vaccination for children. She made a similar observation for meningococcal disease, stating that incidence rates are comparable and have declined in Denmark despite the absence of routine childhood vaccination, with a similar decline observed in the U.S.

Dr. Hoeg discussed recent increases in measles cases in both the U.S. and Europe, noting that cases are predominantly among unvaccinated individuals and reaffirming that the measles vaccine is effective at preventing disease. She stated that Denmark maintains high and relatively uniform vaccination coverage and has not experienced sustained increases in measles cases.

She noted that overall vaccination coverage at age five for MMR, DTaP, Hib, and IPV was similar in the U.S. and Denmark in 2024. Still, she emphasized that U.S. coverage varies substantially by region, with some areas falling below levels commonly associated with outbreak prevention. She suggested that this regional variability may contribute to outbreaks in the U.S. Dr. Hoeg also addressed rubella, noting that community immunity thresholds are estimated at approximately 83–85% and that vaccination rates in some parts of the U.S. fall below this level. She cautioned that this raises concern for the potential re-emergence of congenital rubella syndrome.

Dr. Hoeg noted that trust in the U.S. health care system declined from about 72% before the COVID-19 pandemic to roughly 40% by 2024, with the steepest drop occurring around 2022. She observed that this decline coincided with ongoing mandates and public health measures in the U.S. at a time when many other high-income countries had moved away from them, while emphasizing that she was not asserting causation. She suggested that reliance on mandates, which is more common in the U.S. than in many European countries, may contribute to reduced trust when people feel coerced rather than informed, and stressed that public trust is essential for effective vaccination policy.

Dr. Hoeg noted that vaccines account for most differences between the U.S. and Danish childhood vaccination schedules, with limited exceptions, such as HPV and meningococcal vaccines. She explained that Denmark has generally been more cautious about adding newer vaccines to its routine schedule and does not routinely recommend vaccines such as hepatitis A, varicella, influenza, rotavirus, meningococcal, COVID-19, or RSV. She stated that, based on the data she reviewed, Denmark has not experienced higher outbreak rates for these diseases than the U.S.

Dr. Hoeg described how Denmark approaches vaccine decision-making and provided examples illustrating its framework. She noted that Denmark was the first high-income country to remove COVID-19 vaccination from the childhood schedule. In June 2022, the Danish Ministry of Health stated that vaccinating children against COVID-19 had not provided sufficient benefit and removed the recommendation for individuals under 18 years of age.

She explained that Denmark also reassessed its influenza vaccination policy. Historically, Denmark, like most European countries, did not recommend influenza vaccination for all children. In 2021, Denmark temporarily recommended influenza vaccination for children aged 2 to 6 years to reduce transmission to older adults. After observing low uptake and no measurable reduction in transmission to the elderly, Denmark withdrew the recommendation in 2023. Dr. Hoeg noted that multiple Cochrane reviews have not demonstrated randomized controlled trial

evidence that influenza vaccination reduces hospitalization, mortality, or transmission in children.

Dr. Hoeg referenced the Pandemrix influenza vaccine experience in Europe, where vaccination of low-risk children was later associated with cases of narcolepsy, with delayed recognition of the adverse outcome. She stated that this experience contributed to greater caution across Europe when considering routine vaccination of low-risk pediatric populations. She noted that most European countries do not recommend routine annual influenza vaccination for children, except for those with specific risk factors.

Turning to hepatitis B, Dr. Hoeg summarized Denmark's published rationale for not including the vaccine in the routine childhood schedule. Danish authorities concluded that adding vaccines perceived as low benefit could reduce confidence in the overall program and lower uptake of other vaccines. Their analyses found a low expected benefit, high costs, and an unfavorable health-economic justification for universal childhood vaccination, leading Denmark to recommend hepatitis B vaccination only for defined high-risk groups.

She reported that similar considerations informed Denmark's decision not to recommend routine meningococcal vaccination. Danish health authorities cited low disease incidence, uncertainty about effectiveness in low-risk populations, and concern that adding vaccines could reduce acceptance of others. Vaccination is recommended only for individuals with specific risk factors, except for students traveling to countries, including the U.S., where vaccination may be required.

Dr. Hoeg explained that Denmark has also declined to include rotavirus vaccination in its routine schedule, stating that the national program prioritizes protection against fatal or long-term-harm-causing infections. In Denmark, rotavirus infection rarely results in death or chronic outcomes, and reviews have not shown an effect on child mortality. She noted that Denmark periodically revisits this decision.

Regarding varicella, she stated that Denmark has not adopted routine vaccination, citing stronger natural immunity, limited long-term safety data, and minimal perceived benefit. However, she noted that Denmark is reconsidering this policy after making the vaccine available for private purchase, which appears to have shifted infections to older ages with more severe disease.

Dr. Hoeg also noted that long-acting monoclonal antibodies for RSV are not included in Denmark's routine schedule and are not widely recommended internationally. She referenced concerns raised at a prior ACIP meeting about higher all-cause mortality observed across multiple phase 3 trials, noting that these warrants continued review.

She concluded by noting that Denmark allows parents to purchase certain vaccines privately when they are not part of the national program, highlighting this as another structural difference from the U.S. approach to childhood vaccination.

Dr. Hoeg summarized several potential benefits of the Danish childhood vaccination schedule. She noted that a more focused schedule may help build public trust and support higher uptake of core vaccines across the population. She emphasized that Denmark's approach relies on transparent, well-documented decision-making that is routinely revisited and openly debated as new evidence emerges. Despite recommending fewer vaccines, Denmark has been effective in preventing outbreaks of the most serious and life-threatening vaccine-preventable diseases.

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Dr. Hoeg also noted that differences between U.S. and Danish recommendations reflect international equipoise, creating opportunities for randomized trials to evaluate further safety and effectiveness where uncertainty remains. She added that fewer routine vaccinations may allow more time during pediatric visits to address overall child health, reduce unnecessary medicalization, and limit the number of health care visits. Finally, she stated that Denmark's non-mandate-based approach supports informed, voluntary decision-making, allows for clearer identification of high-risk groups, and reduces pressure on families while maintaining strong population-level protection.

Discussion

Dr. Pebsworth asked whether Denmark recommends vaccination during pregnancy.

Dr. Hoeg responded that Denmark recently removed its recommendation for the COVID-19 vaccine during pregnancy. She stated that Denmark recommends influenza vaccination during pregnancy and noted that she was uncertain about current RSV recommendations and would need to confirm them.

Dr. Levi identified three elements he considered central to building public trust in vaccine policy: a common-sense approach to risk assessment that prioritizes interventions where the benefit is greatest; avoidance of mandates in favor of education and voluntary decision-making; and respect for individual choice. He then asked how Denmark addresses vaccine injuries and supports individuals who experience adverse outcomes, noting that the failure to acknowledge and adequately address vaccine injuries undermines trust and poses an ethical challenge in the U.S.

Dr. Hoeg stated that vaccine and medication injuries are discussed more openly in Denmark, both publicly and in the media. She acknowledged that recognition and compensation can still be challenging for affected individuals. Still, she indicated that Denmark has generally been more willing than the U.S. to recognize and compensate vaccine-related injuries. She added that compensation programs in the U.S., including the National Vaccine Injury Compensation Program and the Countermeasures Injury Compensation Program, are widely perceived as difficult to access, including for individuals with recognized adverse events following COVID-19 vaccination.

Dr. Levi added that responsibility for addressing vaccine injury extends beyond compensation programs to the scientific, clinical, and media communities and stated that failure to recognize and respond to vaccine injury adequately has contributed to the erosion of public trust and poses a challenge to the long-term success of vaccination programs.

Dr. Reed Grimes (HRSA), Director of the Division of Injury Compensation Programs, provided an overview of the U.S. vaccine injury compensation systems administered by HRSA. He explained that the U.S. operates two programs: the National Vaccine Injury Compensation Program (VICP) and the Countermeasures Injury Compensation Program (CICP).

Dr. Grimes described the VICP as a no-fault, medical-legal alternative to the traditional tort system. The program operates through a tripartite structure involving HHS, the Department of

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Justice representing HHS, and the U.S. Court of Federal Claims, specifically the Office of Special Masters, which works with both government attorneys and petitioner attorneys. He stated that approximately 77–78% of claims filed in the VICP result in compensation. In fiscal year 2024, the VICP paid approximately $23 million in compensation.

He explained that the CICP is an administrative compensation system with a higher evidentiary standard than the VICP. While the VICP applies a "more likely than not" standard, the CICP requires compelling, reliable, valid medical and scientific evidence, as defined by statute.

Dr. Grimes noted that Denmark uses an administrative compensation system for treatment-related injuries and that its universal health care system may facilitate identification of injured individuals and communication with potential claimants. He stated that Denmark's system includes caps on compensation, whereas neither the VICP nor the CICP has statutory caps. Based on his understanding, compensation for vaccine injuries in Denmark may be capped at approximately $1 million U.S. dollars (or 5 million Danish kroner). He further noted that in 2024, Denmark paid approximately $7.5 million in compensation, reflecting its smaller population.

Dr. Hibbeln stated that evaluating and communicating risks and benefits is central to informed policy development and public communication. He asked how the U.S. could improve the generation and communication of data that neutrally evaluates both risks and benefits in clinical trials and public messaging.

Dr. Hoeg responded that vaccine recommendations should be accompanied by formal, transparent risk–benefit analyses developed by a dedicated group of scientists. She suggested this work could occur within HHS and may involve NIH, ACIP members, or other independent experts. She stated that publishing the evidence and rationale behind recommendations, particularly for newly approved vaccines, would allow the public to review the data and better understand the decision-making process. She noted that this level of transparency is standard practice in Denmark and supports public trust. Dr. Hoeg also emphasized that FDA approval alone should not automatically result in inclusion on the childhood vaccination schedule and that additional deliberation is needed to assess appropriateness for all children, particularly given the short timeframes that often separate licensure from recommendation.

Dr. Meissner asked whether data are estimating how many recent measles cases in the U.S. and Europe are occurring among individuals who lack immunity, including immigrants. He also noted that one of the original purposes of the VICP was to provide faster resolution of claims compared with the traditional civil tort system.

Dr. Hoeg responded that available European data indicate the recent increase in measles cases has occurred predominantly among unvaccinated individuals. She stated that she could not determine from the data whether cases were specifically among immigrants but noted that they appeared to lack immunity.

Dr. Malone added that U.S. data indicate that approximately 90% or more of measles cases are occurring among unvaccinated individuals, with the remaining cases likely representing breakthrough infections.

Dr. Hoeg stated that this estimate was consistent with the European data she had reviewed.

Dr. Meissner clarified that his question regarding immigration status would be more appropriately directed to the CDC.

Dr. Grimes explained that the VICP was designed as a no-fault compensation program intended to resolve claims more efficiently than the civil tort system, particularly for table injuries where causation is presumed. He noted that although the process typically takes approximately two to three years from filing to adjudication or payment, it generally operates more quickly than traditional civil litigation.

Dr. Malone asked whether the CDC has data on measles incidence or risk among unvaccinated immigrant populations, noting that individuals who enter the U.S. with authorization may receive vaccinations regardless of their prior history. He asked whether available data distinguish between authorized and unauthorized immigrant populations with respect to measles cases.

Dr. Su stated that this question would be more appropriately addressed by CDC colleagues in immigrant and refugee health or measles surveillance but noted that no subject matter experts from those areas were present at the meeting.

Dr. Malone suggested that the committee follow up on this question later or provide information through a public forum, noting that the issue is of broad interest. He added that while he was aware of anecdotal information about a previous West Texas outbreak, he did not consider it sufficient to draw a conclusion.

Dr. Munoz-Rivas commented on the broader dynamics of vaccine policy development, emphasizing that vaccination recommendations should evolve as new data emerge and be adapted to population needs. She stated that some information presented during the session was misleading or misrepresented the underlying data. She further noted that comparing U.S. vaccine policy with Danish policy is of limited relevance, as recommendations should be based on U.S.-specific data, context, and public health needs. Dr. Munoz-Rivas emphasized that, despite imperfections, the U.S. vaccine safety system has been effective in identifying safety signals and updating guidance accordingly.

Dr. Buchanan noted that comparisons of measles epidemiology in the U.S. and Denmark should account for differences in population size. She emphasized that the U.S. has localized communities with low vaccination coverage, whereas Denmark appears not to have similar pockets. She further noted that Denmark's smaller population size limits direct policy comparisons when considering nationwide recommendations in the U.S.

Dr. Malone stated that changes to measles vaccine policy are not currently under consideration and emphasized that the Secretary of Health has clearly indicated that measles vaccination is effective and recommended.

Dr. Hoeg agreed, noting that the measles vaccine is part of the routine childhood vaccination schedule in both the U.S. and Denmark. She reiterated that measles outbreaks in the U.S. are occurring in areas with low vaccination uptake. She suggested this may reflect broader issues of declining public trust in public health institutions.

VACCINES AND ALUMINUM ADJUVANTS

Dr. Griffin shared that she serves on three ACIP work groups: the Childhood and Adolescent Immunization Schedule Work Group, the Human Papillomavirus Work Group, and the Vaccinations During Pregnancy Work Group. She presented a brief overview focused on aluminum-based vaccine adjuvants.

She explained that the presentation arose from discussions within the Childhood Immunization Schedule Work Group during its review of studies on the hepatitis B birth dose, during which questions about aluminum adjuvants were raised. The group determined that a more in-depth discussion of adjuvants was beyond the scope of its charge.

Dr. Griffin noted that adjuvants are relevant across most ACIP work groups, as many vaccines are adjuvanted. Given the complexity and breadth of the topic, she stated that it would be challenging for any single work group to conduct a comprehensive evaluation.
As a result, she explained that a brief presentation was prepared for the full ACIP committee, with consideration of establishing a dedicated work group to focus on adjuvants and potentially other vaccine ingredients. She noted that a short discussion would follow the presentation, with additional discussion anticipated at a future meeting. No vote was planned.

Dr. Griffin outlined the objectives of the presentation in alignment with the ACIP charter, which directs the committee to provide advice and guidance to the CDC Director on the use of vaccines and related agents. She stated that the presentation had two primary objectives. First, to support ACIP consideration of whether to establish a dedicated adjuvant work group to inform future guidance, or to explore other mechanisms for addressing adjuvants and vaccine ingredients more broadly. Second, to provide an educational overview to improve public understanding of vaccine composition, thereby supporting transparency and informed decision-making. Dr. Griffin emphasized that no current ACIP members are adjuvant researchers and that the presentation was intended as a high-level, introductory overview rather than a comprehensive scientific review.

She provided a brief overview of vaccine categories, noting that vaccines may be live attenuated (e.g., measles, mumps, and rubella), recombinant (e.g., hepatitis B), inactivated, or subunit formulations. Vaccines consist of multiple components, including antigens, adjuvants, preservatives, and other excipients, all of which may contribute to a product's safety, efficacy, and effectiveness. Detailed information on vaccine components is available in FDA-approved package inserts.

Dr. Griffin explained that an adjuvant is a substance added to a vaccine to enhance the immune response to the antigen. Adjuvants stimulate innate and adaptive immune responses and are commonly used in inactivated, subunit, and recombinant vaccines. Adjuvanted vaccines comprise most vaccines in the childhood and adolescent immunization schedules, and some vaccines administered during pregnancy also contain adjuvants. She noted that the FDA approves final vaccine products rather than individual adjuvants, and therefore, no adjuvants are approved as standalone entities.

She stated that aluminum salt–based adjuvants are the most widely used adjuvants in FDA-licensed vaccines and have been used since the 1920s. Common examples include aluminum hydroxide and aluminum phosphate. Dr. Griffin clarified that aluminum salts used in vaccines differ from environmental exposure to aluminum. The mechanisms by which aluminum

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adjuvants enhance immune responses are not fully understood but are known to induce local inflammation, recruit antigen-presenting cells, and preferentially promote antibody-mediated immune responses.

Dr. Griffin summarized available human data on aluminum exposure following vaccination, noting that a small 2013 study measured serum aluminum levels before and 24 hours after vaccination in infants and did not detect a significant increase at that time point. She noted that the study did not assess long-term outcomes.

She discussed existing regulatory benchmarks, explaining that the Agency for Toxic Substances and Disease Registry (ATSDR) has established a minimum risk level for orally ingested aluminum based on animal data, but that ATSDR guidance addresses environmental exposure routes rather than injected substances. She emphasized that injected exposures bypass normal gastrointestinal barriers, warranting careful evaluation.

Dr. Griffin stated that U.S. regulations limit aluminum content in vaccines to no more than 0.85 milligrams per dose, regardless of age. She explained that this limit is based on animal studies conducted in the 1990s and remains the FDA-accepted benchmark, though it has been critiqued regarding its applicability to infants.

She concluded that infants may receive multiple aluminum-containing vaccines during a single visit, resulting in higher aluminum exposure per kilogram of body weight than in adults. She also highlighted that physiologic systems relevant to clearance and distribution, including renal function and the blood–brain barrier, are immature in early infancy and during fetal development, underscoring the importance of continued evaluation of adjuvant exposure across age groups.

Dr. Griffin reviewed the aluminum content in vaccines included in the childhood immunization schedule. She explained that aluminum content varies by vaccine formulation, with per-dose amounts ranging from approximately 0.225 mg to 2.85 mg. She noted that several vaccines, including MMR, varicella, rotavirus, meningococcal A, and influenza vaccines, do not contain aluminum because they are live attenuated or non-adjuvanted.

She described how children may receive multiple aluminum-containing vaccines during a single pediatric visit, resulting in cumulative aluminum exposure at that visit. She noted that certain pneumococcal conjugate, Haemophilus influenzae type b, hepatitis B, and DTaP-containing vaccines are administered repeatedly during infancy, particularly within the first six months of life.

Dr. Griffin stated that the rate at which aluminum migrates from the intramuscular injection site into systemic circulation is not well defined. Given this uncertainty, she noted that tissue accumulation cannot be excluded and warrants consideration. She also explained that aluminum exposure can vary substantially depending on vaccine brand and combination selections, with up to a twofold difference in aluminum exposure despite adherence to the same recommended schedule.

She compared cumulative aluminum exposure in the U.S. and Denmark, noting that by 12 months of age, children in Denmark receive approximately three- to fourfold lower aluminum exposure than children in the U.S., reflecting differences in national vaccination schedules.
Dr. Griffin cited FDA language published in the Federal Register in 2003, acknowledging that infants may be at increased risk from aluminum exposure due to immature renal function, a

developing brain and skeleton, and an immature blood–brain barrier. She clarified that this language addressed environmental exposure to aluminum rather than vaccine adjuvants. Still, she emphasized its relevance to recognizing physiologic immaturity in infancy and to reduced capacity to eliminate xenobiotic substances.

She noted that experimental and clinical data suggest injected aluminum salts may persist at the injection site and migrate via immune cells to organs such as the liver, spleen, and brain. She stated that these considerations support the potential value of further systematic evaluation of aluminum-containing adjuvants in the context of childhood vaccination.

Referencing the Flarend rabbit study, Dr. Griffin stated that aluminum hydroxide and aluminum phosphate showed similar patterns of tissue distribution after intramuscular injection, with the highest concentrations in the kidneys, followed by the spleen, liver, heart, and lymph nodes, and the lowest in the brain. She noted that brain detection was concerning and suggested that additional questions raised by the study would be appropriate for review by an ACIP work group.

Dr. Griffin also referenced research describing macrophagic myofasciitis (MMF), in which muscle biopsies identified aluminum-containing macrophages at prior vaccination injection sites, referred to as MMF lesions. She stated that these findings demonstrate long-term persistence of aluminum in human tissue and noted reported associations with chronic muscle pain, fatigue, and cognitive difficulties, while acknowledging that a causal relationship between injected aluminum adjuvants and systemic symptoms is not universally accepted.

She further stated that the growing body of literature warrants careful evaluation of cumulative aluminum exposure, including studies detecting aluminum in postmortem brain tissue, investigations of autoimmunity, neurotoxicity, and neuroinflammation, and emerging research on aluminum-associated oxidative stress mechanisms, including pathways that may disrupt mitochondrial function and cellular energy metabolism.

Dr. Griffin concluded by outlining questions for ACIP consideration, including how to assess the effectiveness and safety of adjuvants across vaccines used in childhood, adolescence, adulthood, and pregnancy; whether multiple aluminum-containing vaccines should be administered on the same day in early infancy; whether lower-aluminum formulations or alternative spacing strategies should be preferred when feasible; what research is needed to establish an evidence-based safety margin for injected aluminum; and what policy approaches could reduce peak and cumulative aluminum exposure in vulnerable populations while key evidence gaps are addressed.

Dr. Griffin acknowledged the decades of sustained work in vaccinology by pharmaceutical companies, academic and independent researchers, regulatory agencies, public health institutions, manufacturers, and health care providers, noting their shared goal of preventing communicable diseases. She stated that while vaccines play an important role in disease prevention, broader efforts to support immune health should also be considered, emphasizing that vaccines alone cannot address every pathogen. She noted that vaccinology, like all scientific fields, has limitations and that ensuring safety requires ongoing study, monitoring, and open dialogue.

Dr. Griffin addressed the media, encouraging comprehensive and contextual reporting of the full sessions, including areas of debate. She stated that public interest supports long-form, in-depth

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coverage and that transparent access to unedited information can help rebuild trust by enabling informed decision-making.

She recognized the sensitivity surrounding illness and death caused by infectious diseases and stated that these outcomes are appropriately discussed in public health forums. She also noted, however, that vaccine injury has historically received less attention, which may contribute to its prominence in recent discussions.

Dr. Griffin highlighted that families of children with profound developmental conditions, including severe autism, may face barriers to raising safety concerns, including challenges accessing care or requesting modified vaccination approaches. She stated that these dynamics may discourage investigation and dialogue and emphasized the importance of recognizing and supporting affected families within the health care system.

Discussion

Dr. Malone clarified that the purpose of the presentation was to frame whether there is merit for ACIP, or a dedicated work group, to examine further the safety, risks, and benefits of vaccine adjuvants, including aluminum-based adjuvants. He noted that adjuvants are not regulated as standalone products but are ingredients in multiple vaccines. He stated that the central question before the committee was whether ACIP believes additional investigation of this topic is warranted and invited discussion among members regarding the merit of pursuing further review.

Dr. Levi stated that current scientific understanding of how vaccines affect infants, particularly very young babies, remains limited and that greater humility is warranted given the complexity of immune, neurologic, and developmental biology. He noted that infants cannot communicate symptoms and that early immune stimulation, including in utero or early childhood exposures, may interact with neurodevelopment, citing evidence from non-vaccine immune stimulation studies. He observed that aluminum is a common component of many non-live vaccines and referenced prior discussion suggesting that non-live vaccines may have different non-specific effects compared with live vaccines. He noted that this has led to interest in aluminum as a potential unifying topic for review. He cautioned, however, that aluminum may not be the only relevant source of risk and emphasized the tension between evaluating adjuvants as a standalone issue versus assessing risks on a vaccine-by-vaccine basis, with aluminum considered as one component among others. He concluded by encouraging thoughtful consideration of how best to organize further work, whether through a dedicated work group or across existing groups. He emphasized the need for a strategic approach to better understand the biological mechanisms underlying vaccination, including the roles of timing, genetics, and cumulative exposures.

Dr. Milhoan stated that the committee's responsibility is to advise on how to achieve the best possible protection against infectious diseases while minimizing risk. He noted that multiple factors associated with vaccination warrant careful consideration, including age at exposure, dose, timing, year of administration, use of adjuvants, and differences between live and inactivated vaccines. He observed that early vaccine studies often lacked rigorous, long-term safety evaluations focused specifically on adverse outcomes and suggested that safety-related questions may now warrant more systematic review. He indicated that the issue has reached a threshold where it merits focused consideration, potentially through the development of a dedicated work group. He stated that such a group could examine specific questions, including whether aluminum-based adjuvants may play a role in long-term or chronic adverse reactions

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observed in some children. He concluded that, given the committee's role in advising the CDC, it is appropriate to examine these issues closely to support recommendations that prioritize both the effectiveness and the safety of vaccines.

Dr. Hibbeln stated that, as an open-minded scientist, he believes there are plausible hypotheses that aluminum exposure could affect the immune system in ways that may influence neurodevelopmental or psychiatric outcomes. Given aluminum's widespread use in vaccines, he said it is reasonable and prudent to ask whether sufficient human data exist to justify a thorough scientific inquiry. He emphasized the importance of developing and examining underlying biological mechanisms alongside available human data. He noted that rigorous evaluation would raise methodological challenges, including the difficulty of conducting randomized, placebo-controlled trials comparing vaccines with and without aluminum. He cautioned that any investigation would need to acknowledge the limitations of available study designs and data sources. He concluded that the question is scientifically important and that growing public awareness of the issue may increase expectations for a careful, transparent evaluation by the committee.

Dr. Malone stated that, drawing on his background as a clinical trial specialist, there are multiple feasible approaches to gathering epidemiologic data on variable levels of aluminum exposure that could inform future, more rigorous study designs. He noted that comparative population analyses, such as differences between Danish and U.S. vaccine exposure patterns, could function as natural experiments. He also pointed out that within the U.S., populations that do not fully adhere to the recommended schedule create additional opportunities to study variable dosing and timing. He suggested that these populations could be examined for outcomes of interest, including neuropsychiatric conditions, and emphasized that meaningful insights could be gained without relying solely on randomized trials.

Dr. Levi built on these remarks by highlighting that vaccines targeting the same pathogens may contain substantially different amounts of aluminum depending on the brand or formulation. He hypothesized that vaccine brand selection is often not an intentional choice by patients or families, resulting in individuals receiving similar schedules but different aluminum exposures. He suggested that this variability could serve as another form of natural experiment and stated that careful analysis of existing data could help clarify whether these differences are informative.

Dr. Meissner noted that the committee must carefully prioritize how limited time and resources are allocated when considering potential contributors to neurodevelopmental conditions. He referenced the historical impact of the discredited association between measles vaccination and autism, stating that it diverted attention and resources away from investigating genuine causes. He expressed skepticism that additional ACIP or CDC focus on aluminum would be productive, given the challenges of study design and existing evidence. He cited a large Danish study that examined differences in aluminum exposure over time and found no association with adverse outcomes. He questioned whether further assessment would yield different conclusions. He concluded by deferring to the committee on whether pursuing this topic represents an appropriate use of limited resources.

With no additional business to be addressed at the December 2025 ACIP meeting, the meeting was officially adjourned.

APPENDIX: ACIP MEMBERSHIP ROSTER

CHAIR

MILHOAN, Kirk, M.D., Ph.D.
Medical Director
For Hearts and Souls Free Medical Clinic
Term: 12/1/2025-6/30/2029

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Term: 6/13/2025 – 6/30/2029

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Term: 6/13/2025 – 6/30/2029

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Term: 9/11/2025-6/30/2029

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Term: 6/13/2025 – 6/30/2029

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Term: 6/13/2025 – 6/30/2029

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Term: 9/11/2025-6/30/2029

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Note: Text enclosed in [brackets] was added following the meeting, per the presenter's request.

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