CAPITOL STREET

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Pediatric Vaccine Coverage Remains at Risk with Adjuvants Up Next

ACIP Dec Meeting: Hep B Recommendation Scaled Back

Relevant Companies

Our Take & Next Up

Pediatric vaccine coverage is likely to become increasingly fragmented with the ongoing questioning and dismantling of prior ACIP recommendations (Hep B). The CDC's vaccine advisory committee (ACIP) voted (8-3) to recommend against Hep B vaccination for infants born to pregnant women testing negative for Hep B infection. The panel also voted (6-4 w/ 1 abstention) to recommend children take Hep B immunity tests before considering a second Hep B shot.

The next ACIP meeting will be held Feb. 25-26, 2026, where further changes to the childhood vaccine schedule are likely. The administration continues to pressure vaccine manufacturers with shifting recommendations, claims of autism and other side effects, and a push for individually administered vs. combo vaccines (our take here).

What next? We have said autism could be added to the vaccine injury table (here). *Politico* recently noted HHS is indeed considering adding autism to the vaccine injury table (here), along with a stricter approach to vaccine regulation at FDA (here). Another potential near-term target is reconfiguration of the USPSTF and its priorities (our prior take here).

Key Points

The main headline from ACIP was the Hep B birth dose recommendation, but it also foreshadowed future changes to the immunization schedule and potential removal of aluminum adjuvants.

- An ACIP workgroup presented on potential risks of vaccine adjuvants such as aluminum, signaling further investigation is likely on the horizon.
- This aligns with President Trump's prior statement that we have "already taken out and are in the process of taking out mercury and aluminum now."
- Vaccines can contain small amounts of aluminum salts, which are used as adjuvants to create a stronger immune response.

- Known vaccines with aluminum additives include DTaP vaccines (GSK, SNY), the pneumococcal conjugate vaccine (MRK, PFE), the HPV vaccine (MRK), and Hep B vaccine (GSK, MRK).

ACIP voted against Hep B vaccinations for certain infants, with the President urging quick implementation of a simpler schedule. The reconstituted panel scaled back its Hep B vaccine recommendations and set the stage for future work on vaccine adjuvants (voting results below).

CDC must still endorse the recommendations, but that's a foregone conclusion. This is based on acting CDC Director Jim O'Neill's response (here) to Trump's Dec. 5 Presidential Memo (here) to aligning the US childhood vaccine schedule to that of other countries. Recall, O'Neill previously served at HHS from 2002 to 2008, where he helped launch the Administration for Strategic Preparedness and Response (ASPR) and, as Principal Associate Deputy Secretary, led FDA reforms on food safety and implemented the FDA Amendments Act to strengthen drug and device oversight.

Overall insurance coverage is expected to remain consistent for now, but longer-term coverage for new vaccinations may be harder to achieve. The health insurance industry association, AHIP, on Sept. 16 announced (here) that it would maintain coverage for the vaccines under discussion, despite changes in ACIP recommendations. The questioning of established vaccinations indicates increased vaccine scrutiny. While older vaccines may still see consistent coverage, it will be increasingly difficult for new vaccines to establish consistent recommendations that allow for reimbursement.

DECEMBER ACIP MEETING VOTING RESULTS

Hepatitis B (Hep B) Vaccine

1. **ACIP voted (8-3) to recommend against Hep B vaccination for infants born to pregnant women testing negative for Hep B infection.** 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. 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.
2. **ACIP voted (6-4 w/ 1 abstention) to recommend children take Hep B immunity tests before considering a second Hep B shot.** 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.
3. **ACIP voted (7-0 w/ 4 abstentions) to incorporate the Hep B recommendations into the Vaccines for Children (VFC) program.** The VFC program provides free vaccines to eligible children.

A new ACIP panel chair was announced only days before the meeting: Dr. Kirk Milhoan. Milhoan is known for linking vaccines to heart disease, and was appointed as the new chair. Former ACIP chair Martin Kulldorff was named as the Chief Science Officer for the Office of the Assistant Secretary for Planning and Evaluation (ASPE).

Public scrutiny and the lack of confidence in recent ACIP changes results in fragmented vaccine coverage. Former CDC Director Monarez raised concerns about the new ACIP members in a September Senate Committee hearing (here), claiming they lacked proper skills to evaluate vaccine evidence. Additionally,

the American Academy of Pediatrics (AAP) ended their participation in ACIP, issuing their own guidance (here) that diverges from federal recommendations. The move signals a growing divide between the federal government and major medical organizations.

Vinay Prasad, Director of FDA's Center for Biologics Evaluation and Research (CBER), proposed scrapping long-standing shortcuts in vaccine development like immunobridging studies and requiring full premarketing trials for most new or updated vaccines. In a Dec. 3 *NEJM* article (here), 12 former FDA commissioners, including Scott Gottlieb, warned Prasad's proposal would upend long-standing, science-based vaccine rules, silence internal debate, and rely on questionable safety claims. They say the changes bypass normal transparent processes, threaten staff who disagree, and could slow or block updated vaccines, ultimately weakening the FDA and putting public health at risk.

There's a growing dichotomy between FDA's clinical trial requirements for vaccines and other medicines. According to *STAT* (here), FDA Commissioner Marty Makary is planning to change agency rules so that most non-vaccine products only need one clinical study instead of the usual two. Makary said there will still be times when two trials are required, but going forward, the default will be just one.

Public health experts warn of incremental morbidity and mortality in the US due to recent CDC actions. For example, Dr. Debra Houry, who resigned from her position as CDC's Chief Medical Officer, recently lamented the actions of her former agency (here). Houry noted, "what we have witnessed at the CDC is not reform. It is the hollowing out of an institution Americans rely on in every emergency. The actions since late summer will leave the country less prepared for the next measles outbreak, foodborne illness cluster, maternal mortality crisis, or emerging pandemic. These changes are happening quietly, quickly, and with almost no oversight."

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