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Legal Sidebar

CDC's Updated Childhood Vaccine Schedule: Litigation and Potential Implications for Vaccine Injury Compensation Program

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In December 2025, President Trump issued an executive memorandum in which he instructed the Secretary of the U.S. Department of Health and Human Services (HHS) to "review best practices from peer, developed countries for core childhood vaccine recommendations," to determine if updates to the childhood immunization schedule were warranted. The memorandum stated that "[p]eer, developed countries recommend fewer childhood vaccinations" than the United States, and it characterized the then-current schedule as "depart[ing] from [vaccine] policies in the majority of developed countries." In January 2026, HHS released an assessment comparing vaccine recommendations in the United States with 20 peer nations, concluding that the Centers for Disease Control and Prevention (CDC), a division of HHS, should update the childhood vaccination schedule to recommend fewer vaccines for children. The assessment found that the United States "is a global outlier among developed nations in both the number of diseases addressed in its routine childhood vaccination schedule and the total number of recommended doses." A few days later, CDC announced a new childhood vaccine schedule, which modified the recommendation types of six vaccines. While the previous schedule recommended these six vaccines for administration to all children, the new schedule recommends that they be received only by certain risk-based groups and/or based on an individual decision process between the child's parent(s) or guardian(s) and their health care provider (a process known as "shared clinical decision-making" (SCDM)).

In creating the new schedule, CDC did not consult with the Advisory Committee on Immunization Practices (ACIP), the federal advisory committee that has made both childhood and adult vaccine recommendations to the HHS Secretary for more than 60 years. When the new schedule was announced in January 2026, the agency did not involve ACIP or explain why it had not followed CDC's typical process of having ACIP vote to recommend any changes made to the childhood schedule.

On February 17, 2026, the American Academy of Pediatrics (AAP), joined by several other stakeholder associations as well as a few individual plaintiffs, filed a lawsuit to challenge the new schedule as a violation of the Administrative Procedure Act (APA). The plaintiffs argue that the new schedule was a "final agency action" that was arbitrary, capricious, and not in accordance with law. The case had initially been filed in the U.S. District Court for the District of Massachusetts in late 2025 to challenge other CDC

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actions related to vaccines, and the plaintiffs subsequently amended their complaint in February 2026 to include a challenge to the new schedule. On March 16, 2026, the district court preliminarily stayed the implementation of the new schedule, along with several other CDC actions, in response to the plaintiffs' motion for a preliminary injunction.

This Legal Sidebar discusses the district court's preliminary stay of the new vaccine schedule in *American Academy of Pediatrics v. Kennedy* and explores potential implications for the Vaccine Injury Compensation Program (VICP) if the new schedule were allowed to take effect. It concludes by offering considerations for the 119th Congress.

Background

Advisory Committee on Immunization Practices

CDC has annually published a recommended immunization schedule for both children and adults for many years. While this process is not subject to specific statutory provisions, it has evolved over the years to be led by ACIP. ACIP is a federal advisory committee, established by the U.S. Surgeon General in 1964, that develops recommendations for the use of vaccines in the United States. ACIP was created under a general authority in the Public Health Service Act that allows the HHS Secretary to appoint an advisory council "for the purpose of advising him in connection with any of his functions." Although Congress did not create ACIP by statute, both federal and state laws refer to ACIP and its vaccine recommendations. For example, in the 21st Century Cures Act, Congress required ACIP to "consider the use of" any new, FDA-approved vaccines at the committee's next, regularly scheduled meeting. If the committee decides not to make a recommendation for use of a new vaccine, it is required to update the HHS Secretary as to the status of the vaccine's review.

In addition to reviewing new vaccines, ACIP establishes and periodically reviews vaccines eligible for the Vaccines for Children Program. The committee also regularly reviews the pediatric vaccine schedule, which includes listing the appropriate dose and dosage interval for each vaccine, as well as any contraindications. ACIP's recommendations inform CDC and the HHS Secretary's decisionmaking about which vaccines are placed on the CDC-recommended schedule for children.

Vaccine Injury Compensation Program

While some federal statutory frameworks mention ACIP directly, others instead refer to CDC's vaccine recommendations, which have generally been based on ACIP's recommendations. For example, Congress requires the HHS Secretary to add to the VICP vaccines that CDC "recommend[s] for routine administration" to children. Congress created the VICP in 1986 when it enacted the National Childhood Vaccine Injury Act. The VICP is a no-fault compensation program that allows individuals to file a petition for compensation against the HHS Secretary for a "vaccine-related injury or death," which is defined as an injury or death related to a vaccine that is listed on the Vaccine Injury Table (the Table). Congress created VICP to limit the liability of vaccine manufacturers and administrators and to provide a process by which individuals injured by certain vaccines could receive compensation. The statute shields manufacturers and administrators from liability for vaccine-related injuries or deaths by generally barring individuals from filing civil claims in excess of $1,000 against a vaccine manufacturer or administrator for damages arising from such injuries or deaths until after a VICP petition has been filed and judgment entered through the program. The statute also limits the types of civil actions that can be brought against vaccine manufacturers and administrators even after the VICP process is exhausted. The U.S. Department of Justice (DOJ) defends the HHS Secretary in the cases, and Congress created the Office of Special Masters (OSM), situated within the U.S. Court of Federal Claims, to adjudicate VICP petitions.

The VICP's liability shield and the compensation it provides are both tied to the Table, which currently includes sixteen vaccine types. Some of these vaccines were added by Congress when the program was initially created, and some were added by HHS later, after the CDC considered them to be "recommended for routine administration" to children. Thus, a newly approved vaccine can be added to the Table either by Congress via statute, or by the HHS Secretary via rulemaking.

While the statute does not explicitly authorize the HHS Secretary to remove a vaccine from the Table, it empowers the Secretary to make two types of changes to the Table. First, the Secretary may initiate a rulemaking proceeding to make certain administrative revisions to the Table, including adding to or deleting from the list of injuries associated with particular vaccines and the onset periods for those injuries. Second, when CDC recommends a new vaccine "for routine administration to children," the Secretary must promulgate a rule adding that vaccine to the Table within two years of the recommendation. In order for the Table change adding the new vaccine to be legally effective, however, Congress must enact an excise tax on the vaccine. The funds from the excise tax paid by vaccine manufacturers are placed into a trust fund from which VICP awards are made to entitled petitioners. In other words, when a new vaccine is "recommended for routine administration" by CDC, in order for that vaccine to be covered by the VICP, not only must the Secretary add the new vaccine to the Table via rulemaking, but Congress must also enact a tax on it.

The VICP statute does not define what it means for a vaccine to be "recommend[ed] for routine administration," and a court has never interpreted this provision of the statute. CDC and ACIP also have not used consistent terminology in their vaccine recommendations, and HHS has not always been consistent with the types of vaccine recommendations that have led to inclusion on the Table. For example, the VICP already includes the meningococcal B vaccine, which CDC recommends only for SCDM, and HHS added the hepatitis A vaccine before it was universally recommended. (The hepatitis A vaccine was first recommended only for children in areas with high rates of the virus, but the recommendation was later updated.) Moreover, CDC appears to contrast routine recommendations with SCDM in guidance on its website, which was updated shortly after the new schedule was released in January 2026. The agency states, "Unlike *routine*, catch-up, and risk-based recommendations, [SCDM] vaccinations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian" (emphasis added). The ACIP Handbook similarly refers to a "routine recommendation" as one that "appl[ies] to all persons in an age group." In light of these examples, it is unclear whether all of the changed vaccine recommendations, were they not stayed, would be considered "recommended for routine administration" to children.

American Academy of Pediatrics v. Kennedy

In 2025, plaintiffs filed a lawsuit in the U.S. District Court for the District of Massachusetts, challenging several of CDC's recent actions making changes to vaccine recommendations and to ACIP, including the HHS Secretary's decision to remove all seventeen ACIP members and replace them with new members. The plaintiffs subsequently amended the complaint to challenge the January 2026 new childhood vaccine schedule. Plaintiffs contend that the agency's actions were arbitrary and capricious under the APA. Plaintiffs also claim that the new ACIP members lack the relevant credentials to serve on the committee and render it unfairly balanced in violation of the Federal Advisory Committee Act. This Legal Sidebar focuses on plaintiffs' challenge to the new childhood immunization schedule released by CDC in January 2026 and the court's subsequent stay of that new schedule.

In February 2026, plaintiffs filed a motion for a preliminary injunction, requesting that the court prohibit the new vaccine schedule from taking effect until the lawsuit is resolved. In support of the motion, plaintiffs argued that HHS "downgraded" six vaccine recommendations and made other substantive changes to the schedule without providing any "new data that calls into question the safety or efficacy of

any of the downgraded immunizations." In March 2026, the district court stayed the implementation of the new schedule, holding that it was a "final agency action" for purposes of the APA and that plaintiffs were likely to succeed on the merits of their APA claim that the new schedule was arbitrary and capricious.

The Supreme Court has held that an agency action is "final" for purposes of APA review when it represents the "consummation of the agency's decision-making process" from which "legal consequences will flow." The district court held that while CDC's vaccine schedules are characterized as "recommendations," legal consequences still flow from them and thus they are final agency actions. The court pointed to several federal laws that reference both ACIP and CDC's vaccine schedules, including the Vaccines for Children Program statute. The court also observed that changing which vaccines are recommended for children could expose health care providers to civil liability, citing the HHS Secretary's claim that vaccine administrators who do not follow the recommendations as listed on the new schedule would not be covered by the VICP's liability shield. Finally, the court found that states also rely on the recommendations made by CDC, which sets "nationwide industry standards." The court was also unpersuaded by the government's argument that CDC's vaccine schedules were not reviewable under the APA because they were "committed to the agency's discretion by law," finding that Congress requires CDC to "at least[] consider ACIP's recommendations before adopting an immunization schedule." The court pointed to several laws referencing ACIP's role in reviewing and establishing the schedules, reasoning that "Congress's mention of ACIP [in these laws] would be rendered pure surplusage if the CDC Director were empowered to act entirely apart from [them]." The court further observed that the government did not cite any case law in support of its point that vaccine recommendations were committed to agency discretion.

The court further concluded that the plaintiffs were likely to succeed on the merits of their APA claim because the CDC director "lacked authority to issue [the new schedule]" without ACIP's involvement, given the statutory provisions that "directly contemplate ACIP as, at least, a meaningful participant in any changes to the CDC's immunizations schedules." When the CDC director issued the new schedule without "sufficiently consulting ACIP," the court held that he "acted contrary to law." The court further found that the new schedule was also arbitrary and capricious, "because it abandoned the agency's longstanding practice of getting recommendations from ACIP before changing the immunization schedules without sufficient explanation." The court said that HHS did not sufficiently explain why it "circumvented [the] decades-old practice" of receiving recommendations from ACIP, other than citing to the December 2025 executive memorandum. The court noted, however, that "Defendants cannot disregard the APA's requirements simply because they are following the President's orders."

The court also concluded that the plaintiffs had demonstrated sufficient irreparable harm for which interim relief was appropriate. The court agreed with the plaintiffs that both the professional organization plaintiffs themselves, as well as their members individually, would suffer financial harm in the form of uncompensated work and diverted resources expended to address the new schedule. This includes increased time spent counseling patients and physicians regarding the schedule's implementation. The court also held that the balancing of equities supported granting the stay. On April 29, 2026, the government appealed the ruling to the U.S Court of Appeals for the First Circuit.

Potential Implications for the Vaccine Injury Compensation Program

Amidst ongoing litigation challenging various CDC actions to alter the childhood vaccine schedules, public health organizations such as AAP have released their own childhood and adolescent vaccine schedules, which differ from the CDC's guidelines. As the Massachusetts District Court noted in its stay

of the new schedule, Secretary Kennedy has claimed that providers who diverge from CDC recommendations for vaccines "are not shielded from liability under the 1986 Vaccine Injury Act." The HHS Secretary did not further explain this statement, and HHS has not taken any action to officially change the Table since releasing the new schedule. If the new schedule were to take effect, it is possible that the HHS Secretary could propose changes to the Table in accordance with it, which could include removing vaccines that are recommended for SCDM. If the Secretary were to undertake such an action, legal questions would likely arise, including what it means for a vaccine to be "recommended for routine administration" by the CDC, whether a vaccine recommended for SCDM is still "recommended for routine administration," whether the HHS Secretary has the authority to remove a vaccine from the Table, and what that would mean for drug manufacturers who are still obligated to pay the excise tax.

For example, the seasonal flu vaccine is recommended only for SCDM under the new schedule, so if the new schedule were to take effect, the HHS Secretary could undertake rulemaking to remove the flu vaccine from the Table. The Secretary might argue that such an action was warranted because the flu vaccine would no longer meet the criteria for being added to the Table, based on an interpretation of "recommended for routine administration" that excluded SCDM. If the flu vaccine were no longer listed on the Table, then it could not be covered by the VICP, because it would no longer meet the definition of a "vaccine-related injury or death." In that scenario, a person allegedly injured by the flu vaccine would not qualify to seek VICP compensation and could sue the manufacturer directly. In addition, the injured person or the vaccine manufacturer being sued might challenge the Secretary's authority to remove the vaccine from the Table. If such a case were to be brought challenging the Secretary's authority to remove a vaccine from the Table, a court may have an opportunity to interpret what it means for a vaccine to be "recommended for routine administration" to children under the VICP statute.

If a court were to determine that vaccines that are recommended for SCDM are not "recommended for routine administration," legal questions might then arise about the HHS Secretary's treatment of SCDM vaccines that are listed on the Table. It is unclear whether the HHS Secretary has unilateral authority to remove a vaccine from the Table altogether, as such authority is not explicitly laid out in the VICP statute. Even if the statute were interpreted to give the Secretary this authority, only Congress could amend the tax code to remove the excise tax on a vaccine. Thus, even if the Secretary has the authority to remove a SCDM vaccine from the Table, if Congress does not act, the manufacturer would potentially remain legally obligated to pay the tax.

Considerations for Congress

To the extent that Congress determines it is appropriate to do so, Congress could clarify the questions raised by the new schedule and related litigation. For example, Congress could specify which vaccines it wants the VICP to cover and how the liability shield should function for vaccines that CDC recommends for SCDM. Alternatively, Congress could consider clarifying what it means for a vaccine to be "recommended for routine administration," by defining the term, further specifying which kinds of CDC vaccine recommendations are included within it, or by giving the HHS Secretary the authority to define the term via rulemaking. Congress could also amend the VICP statute to clarify what should happen in the event that a vaccine listed on the Table is no longer considered to be "recommended for routine administration."

In addition to potential uncertainty regarding ACIP and a new CDC schedule's effect on vaccines covered by the VICP, attorneys and other vaccine interest groups are urging HHS to make further changes to the VICP. For example, a group of attorneys recently sent a letter to Secretary Kennedy requesting that the Secretary immediately amend the Table to add a list of injuries that they claim are "associated with" certain Table vaccines. The authors argue that the VICP statute requires the Secretary to amend the Table to add injuries "associated with" certain vaccines, and that because there are studies demonstrating that

particular injuries are associated with certain vaccines, the Secretary is legally obligated to add those injuries to the Table. The authors, all of whom represent VICP petitioners, have threatened to sue HHS if the Secretary does not exercise his authority under the statute to add additional injuries to the Table. Any changes that the Secretary makes to the Table would likely be considered "final agency actions" and would thus be reviewable under the APA.

In April 2026, HHS posted a *Federal Register* Notice announcing a renewal of ACIP's charter through April 2028. When compared with the previous committee charter from 2025, the new charter omits language requiring members to have "expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety." The new charter retains a statement that the committee should be "fairly balanced" in terms of the perspectives represented. It also contains broader categories of expertise, including individuals with knowledge of "medicine, vaccines, immunization practices, immunology, toxicology, pediatric neurodevelopment, epidemiology, data science, statistical analysis, health economics, recovery from serious vaccine injuries, or public health." In the event that stakeholders such as AAP have concerns about the changes made to the ACIP charter, it is possible that these changes could be harder to challenge under the APA. For example, if AAP sought to challenge the changes made to the ACIP charter, the organization would need to articulate a concrete, particularized harm that stems directly from the agency's actions in order to have standing. Congress could exert more control over the committee by statute, if it sought to do so. For example, Congress could authorize ACIP in statute and require committee members to have specific expertise, which would limit some of the HHS Secretary's authority over the committee.

Author Information

Hannah-Alise Rogers
Legislative Attorney

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