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Uncertainty reigns as ACIP remains on court hold

By Mari Serebrov

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For the second time this year, the U.S. CDC's Advisory Committee on Immunization Practices (ACIP) canceled a scheduled meeting due to a federal judge's stay that keeps the panel from meeting with its current membership.

Typically, ACIP meets three times a year – in February, June and October. The 2026 June meeting was slated for June 23-25. Whether the adcom meets in October will be up to the courts and how far Health and Human Services (HHS) Secretary Robert Kennedy digs in his heels to maintain a hand-picked committee tilted toward his view of vaccines.

Judge Brian Murphy, of the U.S. District Court for the District of Massachusetts, granted the stay in *American Academy of Pediatrics v. Kennedy* earlier this year based on his determination that 13 of the 15 adcom members in place at the time didn't meet the qualifications laid out in the ACIP charter. While Kennedy could have replaced those members with individuals who met the qualifications or convened the ACIP as scheduled with the committee's ex officio members, he instead tried to change the charter and appealed Murphy's stay to the U.S. Court of Appeals for the First Circuit.

HHS ignored those options in its June 17 opening brief to the appellate court, as it blamed the current paralysis of the ACIP on the lower court. "The stay order below transferred vaccine policy authority from the executive branch to a single district judge," the brief said. "By staying 13 of 15 ACIP appointments while simultaneously holding that the CDC director cannot change the immunization schedule without ACIP's involvement, the court ensured that no one could make vaccine policy: the director needs the ACIP, the ACIP lacks a quorum, and the government cannot reconvene it without judicial permission. Should a pathogen emerge tomorrow, the government's only path to respond would run through the district court."

Politics aside, the turmoil that's encased the ACIP since Kennedy dismantled the existing panel last year continues to undermine public trust and has vaccine makers looking for glimmers of predictability amid the uncertainty.

"Vaccine innovation requires scientific predictability," David Dodd, chairman, president and CEO of Geovax Inc., told *BioWorld*. "Companies can adapt to changing policies, but prolonged uncertainty around recommendation pathways ultimately increases risk, slows investment decisions and may delay the availability of future vaccines that strengthen national preparedness." Industry needs "a stable ecosystem that allows vaccine innovation to continue," he added.

Because of the ACIP's role in recommending when and who should get a particular vaccine, FDA approval isn't the final hurdle for a new vaccine candidate. If the CDC adopts the committee's recommendations, which can narrow the FDA's approved indications, the recommendations become part of the agency's vaccine schedule, assuring reimbursement for the specified populations. Vaccines, or uses, that aren't on the schedule may still get coverage, but there could be more hoops to jump through, including prior authorization, Dodd said.

Undermining confidence

In addition to coverage, the ACIP recommendations play a big role in public confidence in a vaccine, the formation of state vaccine programs, physician adoption, commercial market demand and long-term investment decisions, Dodd noted. "ACIP is not simply an advisory body," he

added. “It is one of the key signals that helps translate scientific innovation into public health implementation."

Given ACIP’s importance, sponsors of innovative vaccines often start discussing their product with the CDC and ACIP within at least 18 months of potential FDA approval. But in the current situation, sponsors are left to wonder whether reaching out is a waste of time, Dodd said.

That’s a pertinent question right now for Geovax, which plans to begin a phase III trial of its mpox vaccine later this year. While Dodd received guidance from an mpox expert at the CDC in 2024, there’s no guarantee that advice will hold under the current administration or that the same expert, or any expert for that matter, will be in a position to act on that guidance.

Dodd also stressed the importance of the ACIP meeting at its scheduled times. Even if a company doesn’t have a vaccine on the agenda, he said the meetings are of interest to people in the vaccine industry, as well as other stakeholders, including payers and investors.

At the same time, it’s discouraging when ACIP members are publicly discussing vaccines without the expertise or the necessary context. In meetings last year, some ACIP members went beyond their remit to question FDA approvals and rip apart FDA-approved trial designs used to demonstrate a product’s safety and efficacy. Such discussions further undermine public confidence in vaccines and the FDA itself.

The irony is that Kennedy used the need to rebuild public trust as justification for gutting the ACIP last year.

Another concern is the impact the continuing controversies around the ACIP has had on investment for vaccines. “Investors evaluate risk carefully,” Dodd said. “If uncertainty persists around how vaccines ultimately reach populations, capital may become more selective. That could disproportionately affect smaller biotechnology companies that are often responsible for much of the innovation in infectious disease.”

When evaluating risk, investors have to consider the likelihood that vaccines will be recommended, adopted and reimbursed, as well as whether there will be a sustainable demand. “Regulatory uncertainty inevitably becomes part of those discussions,” Dodd said.

“Vaccine development is already high-risk,” he said, but because of the additional regulatory uncertainty, vaccine developers are reassessing their risk profiles. As a result, some companies could delay investment decisions, narrow their portfolios, prioritize lower-risk programs, seek alternative markets or rely more heavily on government partnerships rather than investors.

However, it’s not all doom and gloom on the vaccine front. Dodd cited Eli Lilly and Co.’s offer last month to buy three vaccine companies for a total of about $4 billion as the “first positive news” the vaccine space has seen since January 2025. The announcement signaled that investing in vaccines “is a smart move,” Dodd said, adding that it also may be a sign “that things may be settling down” for the sector.

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