

Health Law & Business

Pharma Industry Watches After RFK Jr.'s Vaccine Policies Paused

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- A federal judge blocked US Health Secretary Robert F. Kennedy Jr.'s changes to the national childhood immunization schedule, handing an indirect win to the pharmaceutical industry.
- The court's decision affirms that US vaccine recommendations must follow a rigorous, science-based process, according to Mike Ybarra, chief medical officer for the Pharmaceutical Research and Manufacturers of America.
- The industry views the decision as a temporary victory, but notes that the damage to public confidence in vaccines may already be done and that the government can still pursue policy changes through different pathways.

A federal judge's decision to block US Health Secretary Robert F. Kennedy Jr.'s changes to the national childhood immunization schedule hands an indirect, if temporary, win to a pharmaceutical industry that's maintained its vaccines are safe and effective.

Kennedy's unprecedented move to shrink the number of recommended shots for children, along with hand-picking members for a federal vaccine committee, was halted by a federal district judge Monday.

"The court's decision affirms that U.S. vaccine recommendations must follow a rigorous, science-based process," said Mike Ybarra, chief medical officer for the Pharmaceutical Research and Manufacturers of America, a leading industry group that represents vaccine makers including Merck & Co., Pfizer Inc., and AstraZeneca Plc.

While the decision hands a temporary victory to the American Academy of Pediatrics and other medical groups that brought the suit, the order also gives a sense of relief to vaccine manufacturers that have been walking a tightrope under Kennedy's agenda that cast doubt on a broad range of shots.

The industry has pushed back on the secretary's various vaccine decisions, questioning the procedures and scientific evidence to implement them.

The Biotechnology Innovation Organization, representing over a thousand biotech companies, similarly said it "supports restoring a trusted, transparent, balanced, and evidence-based Advisory Committee on Immunization Practices to ensure timely vaccine access and protect the nation's ability to prevent deadly infectious diseases."

"It's been a very increasingly challenging environment to raise the necessary capital to be able to advance programs forward," said David Dodd, CEO of GeoVax Labs Inc., a biotechnology company developing vaccines against infectious diseases and cancers. "If we have clarity well defined and know that it's going to be based on the rigor of the science, then we're going to take the risk of pursuing things that will hopefully improve people's lives."

A spokesperson for Sanofi SA said in an email that public health and evidence-based medicine have guided the company's vaccine development in the past and "must continue for the present and future."

Kennedy determined in January that the Centers for Disease Control and Prevention would no longer universally recommend childhood vaccines against Covid-19, influenza, hepatitis B, and other diseases. While some of those vaccines are still recommended for certain high-risk populations, the government now suggests that individuals speak with a doctor before getting them.

The secretary last June also reconstituted the Advisory Committee on Immunization Practices, hand-picking his own selection of advisers for a panel that guides US policy on vaccine safety and effectiveness.

The court order now pauses the implementation of the new vaccine schedule and stays the appointments of the 13 members Kennedy selected for the vaccine committee.

"The tone of the decision should please the vaccine industry to some extent," said Ana Santos Rutschman, an expert in vaccine law in policy and a professor at Villanova University. "The judge opens in a very forceful way, talking about the importance of science and dismissing opinions that pose as scientifically informed."

Damage Already Done

At the same time, any sense of restored normalcy for the industry should be viewed as tentative as the case remains in the preliminary stages and the government is likely to appeal the order, industry watchers say.

"The ruling may temporarily steady expectations, but the longer-term regulatory environment and public health environment remains uncertain," said Brian Dean Abramson, a vaccine law professor at the Florida International University College of Law.

"HHS retains the ability to pursue policy changes through different procedural pathways," he said. "It still has the bullhorn and the ability to damage public confidence in vaccines, and some of its actions such as cutting off funding for avenues of vaccination research are unaffected by this decision."

The judge's order also doesn't necessarily walk back the skepticism that has grown around vaccines, others say.

"I think the concern for industry is that in some ways the damage has already been done in terms of patient uptake, the issue around patient autonomy, and the spreading of a lot of misinformation around vaccines," said Reshma Ramachandran, an assistant professor at Yale School of Medicine.

Ramachandran said the industry should watch for government actions that are upstream of ACIP, such as the US Food and Drug Administration's authorizations of vaccines.

"That's the bigger concern because if there's nothing to authorize, then there's nothing to recommend," she said.

Still, the decision is a "good signal" that the government needs to adhere to established procedures when making major policy changes, said Genevieve Kanter, an associate professor of public policy at the University of Southern California.

"This assurance of stability and backing in the courts will help firms breathe a bit easier, but there will undoubtedly be more skirmishes to come," Kanter said.

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