TuSalud

RFK Jr's Vaccine Policies Could Undermine Coverage — and Trust

A series of recent changes could have significant implications for how Americans receive and pay for their shots.

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In June, the Department of Health and Human Services Secretary, Robert F. Kennedy Jr., ousted all 17 members of a panel that makes vaccine recommendations to the U.S. government. "A clean sweep is necessary to reestablish public confidence in vaccine science," said Kennedy, who accused the panel members of, among other things, having conflicts of interest due to ties with pharmaceutical companies.

Many vaccine experts were dismayed. Members of the panel, known as the Advisory Committee on Immunization Practices, or ACIP, must follow strict rules regarding conflicts. Further, some of Kennedy's hand-picked replacements have made false claims about vaccine safety and efficacy. One panel member, for example, stated that the Covid mRNA shots — credited with saving millions of lives — instead caused "unprecedented" harm.

This change in the composition of the panel, which advises the Centers for Disease Control and Prevention, could have a direct impact on insurance coverage, said Charlotte Moser, a former ACIP member who co-directs the Vaccine Education Center at Children's Hospital of Philadelphia. ACIP recommendations are linked to specific legislation, she wrote in an email to Undark. The Affordable Care Act, for example, requires that nearly all insurers cover the ACIP-recommended vaccines, and the Vaccines for Children Program, created by Congress in the 1993 in the wake of a measles epidemic, provides these vaccines free of charge for children who are uninsured or whose families may be unable to afford them.

Beyond the ACIP, Kennedy unilaterally announced that the CDC's recommendation to routinely vaccinate healthy children and pregnant women against Covid-19 would end (a move that has since been called into question). Kennedy's announcement coincided with a major policy shift at the Food and Drug Administration, which in May stopped recommending Covid-19 boosters for healthy people under 65, citing uncertain benefits from the shots. All of this could have significant implications for how Americans receive and pay for vaccines.

This includes people like me: I'm 60 and relatively healthy. Without the FDA recommendation, insurers may no longer cover products for groups deemed low-risk, so I may have to pay the full

price, around $240 or more, when I get vaccinated this fall. If more changes are ahead, the cost to individuals could quickly add up. According to the CDC, the out-of-pocket cost for a pediatric hepatitis B vaccine can run you $28, while a measles, mumps, and rubella jab is around $95. Meningococcal shots are between roughly $166 and $237, and human papilloma virus immunization tops $300.

Insurers are monitoring changes in guidance and have not confirmed that they will maintain or cut coverage. Camm Epstein — an expert on payers and health policy — emailed Undark that some payers may still cover a vaccine even when it isn't recommended any longer. They may see it as a "medical necessity, believe it aligns with customer or member preferences, or doing so yields a positive ROI" — referring to return on investment — he wrote. "While ACIP sets the floor, it doesn't set the ceiling."

The pivot away from a universal Covid-19 vaccine recommendation wasn't entirely unique or unexpected. Many other countries no longer recommend boosters for younger adults and children unless they belong to high-risk groups. And at the April meeting, now-ousted ACIP panel members discussed the possibility of transitioning the U.S. to targeted recommendations aimed at high-risk individuals. (Notably, the panel was presented slides designating pregnancy as increasing risk of severe Covid-19, presumably meaning pregnant people ought to get vaccinated.)

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FDA officials will now require new clinical trial research on the effectiveness of Covid-19 vaccines in lower-risk populations before issuing approvals of new Covid-19 vaccines. Correspondingly, the agency decided to limit the approval of the nation's only non-mRNA coronavirus vaccine, made by Novavax, for use in adults 65 and older, or for those 12 to 64 who have at least one underlying health condition that puts them at increased risk from Covid-19. Moderna won approval for its latest mRNA Covid-19 vaccine less than two weeks later with the same set of limits.

In a commentary published in the New England Journal of Medicine, FDA commissioner Martin Makary and Center for Biologics Evaluation and Research director Vinay Prasad wrote that 100 to 200 million Americans will retain access to Covid-19 vaccines because individuals with a wide range of health conditions will qualify, including people with asthma, cancer, cardiovascular disease, diabetes, and obesity. This move implies not only new approval standards for the Covid-19 vaccines but also a more targeted approach to vaccinating the population. It's usually ACIP's advice, however, and CDC's decisions that determine vaccination strategies, not the FDA's.

It's unknown if Kennedy, the FDA, or the newly formed ACIP will recommend other changes. But ACIP's June meeting gives pause. Panelists called for investigating childhood vaccines, which came a few months after an announcement that the CDC would launch a study on possible links

between autism and vaccines, in spite of extensive scientific research over many years having found no such connections.

And the new members voted 5 to 1 (with one abstention) against recommending scheduling flu vaccines containing the preservative thimerosal. In the U.S., thimerosal was removed from childhood vaccines in 2001 as a precautionary measure, and since then, studies have consistently found that the preservative is not linked to autism. Nevertheless, at the ACIP meeting, Lyn Redwood, a nurse and noted vaccine skeptic, claimed in a presentation to the committee that thimerosal is toxic. Redwood will soon join the CDC in its vaccine safety office. The lone committee member to vote "no," Cody Meissner, a professor of pediatrics, said that "no study has ever indicated any harm from thimerosal." But just yesterday, HHS announced it would adopt ACIP's recommendation to remove thimerosol from flu vaccines.

In a separate vote at the June meeting, ACIP unanimously recommended yearly flu shots for all people without contraindications over the age of 6 months, though the committee didn't end up voting on the Covid-19 vaccine. But panelist statements suggest the direction it may take at future meetings. For example, ACIP chair Martin Kulldorff referred to "inflated promises" about the Covid-19 vaccines. Investor analysts observing the meeting suggest that ACIP wants to look closer at safety and not overvalue benefits.

While Kulldorff implied that Covid-19 vaccines had underperformed, a CDC presentation at the June meeting made the case they had succeeded in their core goal across all sub-groups in the population: preventing severe disease, hospitalization, and death. The agency's website still encourages adults under 65 and children ages six months to 17 years to receive vaccinations, though it has qualified its advice to accommodate the concept of informed consent and shared clinical decision-making. And a note at the top of the page warns that Covid-19 vaccine recommendations have recently changed, and "this page will be updated."

Kulldorff also noted ACIP would establish a new workgroup to evaluate the current vaccine schedule, including the "interaction effects between different vaccines" and their "relative timing." Here, Kulldorff wants to review the total number of vaccines American children receive and the possible cumulative burden of vaccine ingredients. The vaccines Kulldorff referred to are still on CDC's schedule. But for how long?

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In an email to Undark, Peter Hotez, a vaccine scientist and pediatrician at Baylor College of Medicine, wrote that there are now vaccines for 16 preventable diseases, several of which he's seen the devastating effects of as a doctor. "Which disease does he want to bring back?" Hotez asked.

Inconsistencies between CDC and the perspectives of the new ACIP panelists suggest the potential for more division. “If families hear competing messages, the confusion that follows may result in decreased vaccine uptake,” Moser noted.

And though the implication of removing thimerosal from vaccines is largely inconsequential, as only a small percentage of flu shots in the U.S. contain the preservative, questioning safety by resurrecting debunked theories could lead to further distrust by the public in a broad array of vaccines.

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