# Robert F. Kennedy Jr. proposes placebo-controlled trials for all new vaccines, sparking expert backlash



The Boston Globe is reporting that Robert F. Kennedy Jr., the Secretary of the US Department of Health and Human Services (HHS), plans to implement significant changes to vaccine testing protocols that could impact the approval and availability of vaccines. The proposed policy would require all new vaccines to undergo placebo-controlled trials before licensure, a method where some participants receive the vaccine and others an inert substance, such as a saline shot. This marks a major departure from past practices, especially for vaccines targeting well-studied diseases such as measles and polio.

An HHS spokesperson told The Washington Post that this shift aims to increase transparency in vaccine safety testing. However, the specifics around the implementation remain unclear, including which vaccines would be subject to this protocol and what exactly defines a “new vaccine.” The department indicated that the annual flu vaccine, which has been in use for over 80 years, would not be affected by these new testing requirements. While HHS focused much of the discussion on coronavirus vaccines, it did not elaborate on the status of other vaccines.

Kennedy has a history of questioning vaccine safety and calling for placebo testing even for vaccines already approved. The HHS issued a statement defending his approach, claiming, “Secretary Kennedy is not anti-vaccine - he is pro-safety, pro-transparency, and pro-accountability.” However, this perspective has raised alarm among medical experts and public health officials who warn that adding placebo-controlled trials for established vaccines could be unethical and impractical. Many believe such requirements would delay vaccine approval, increase costs, limit vaccine production, and ultimately restrict access, potentially putting more people at risk of preventable diseases.

Paul Offit, director of the Vaccine Education Center at Children’s Hospital of Philadelphia, expressed concern over the changes, stating, “You are watching the gradual dissolution of the vaccine infrastructure in this country. The goal is to make vaccines less available and less affordable.” The medical community also fears that the approach could lead to public mistrust amid ongoing outbreaks such as measles and could impact the rollout of COVID-19 vaccines.

Current vaccine testing standards, experts argue, already include placebo-controlled trials when introducing vaccines for new diseases, such as the coronavirus vaccines developed in large-scale clinical trials. But for long-established vaccines, testing generally relies on identifying biological markers known to correlate with protection, not necessarily placebo trials. Stanley Plotkin, a vaccine pioneer, highlighted the ethical considerations, stating, “Can I ethically agree to having people acquire the disease because they receive a placebo?” This question underscores the reluctance to use placebo groups when effective vaccines already exist.

The potential change has also revived debates regarding the coronavirus vaccine approval process. FDA Commissioner Marty Makary suggested the agency is reviewing its approach to approving updated COVID-19 shots, citing a “void of data” and a need to restore public trust. HHS indicated that the COVID-19 pandemic would no longer justify blanket approvals for new products without sufficient evidence. The Trump administration is reportedly pushing for the vaccine manufacturer Novavax to conduct a new clinical trial for its COVID-19 vaccine before full approval, a move seen by some as political interference, as the vaccine has been available under emergency use and uses a traditional protein platform, differing from mRNA vaccines.

Senator Bill Cassidy (R-Louisiana) previously secured commitments from Kennedy to work within existing vaccine approval frameworks and to notify Senate health committees ahead of any changes, indicating some oversight in the process. However, experts like Dorit Reiss from the University of California stress that overstating vaccine risks under the guise of “transparency” can amount to misinformation that undermines informed consent.

The ongoing debates and proposed shifts in vaccine policy under Kennedy’s leadership have fostered uncertainty among public health officials, clinicians, and vaccine manufacturers. Experts warn that altering longstanding vaccine development practices could hamper innovation and reduce the availability of vaccines crucial for public health.

The Boston Globe reports that these developments are unfolding amid a broader decline in public trust towards vaccines and growing concern over measles outbreaks and COVID-19 vaccination efforts. The evolving situation continues to draw scrutiny from both within the health community and the government.

Source: [Noah Wire Services](https://www.noahwire.com)

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