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Whopper of the Week: RFK's Obsession with Placebo Controlled Safety Trials is Dangerous

IN SUMMARY:

The United States (US) government does not approve pediatric vaccines unless there is strong data showing that they prevent disease without causing serious side effects. But Robert F. Kennedy, Jr. has been claiming for years that vaccines are not tested for safety. Last June he said on Fox News, "Not one of the vaccines have been safety tested. The only vaccine on the schedule that has gone through placebo-controlled trials prior to licensure was the COVID vaccine. So, nobody has any idea what the risk profiles are on these products." This is nonsense. Childhood vaccines are held to very high standards by the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC). It is their job to evaluate and communicate the risk profile of vaccines. For the Secretary of Health to badmouth his agencies' work on safety is a dereliction of duty.

WHY IS THIS A WHOPPER?
Kennedy is trying to cast doubt on study designs that have been refined over decades to evaluate vaccines. His lies include that: (1) no childhood vaccine has been safety tested; (2) no vaccine was evaluated using placebo controlled clinical trials; and (3) vaccine risk profiles are unknown. These claims are easily debunked:

- Vaccine Development, Testing, and Regulation ref1, ref2, ref3
- Data about vaccine clinical trials ref4, ref5
- Trial comparators and controls ref6, ref7, ref8
- CDC Vaccine Evidence to Recommendations Frameworks ref9

Any pharmaceutical company seeking a license to sell a new vaccine in the US must present randomized clinical trial data to the FDA. The agency mandates what information a pharmaceutical firm provides, including adverse event risks. It then determines whether the vaccine provides sufficient protection against infectious disease and whether there are any serious safety outcomes. FDA approvals balance the data about the vaccine's benefits against data about known or foreseeable risks, taking into account the severity of the disease prevented, and the intended population. Normally, the FDA makes its decisions in an open and transparent way, with input from experts and outside organizations in order to build trust.

Dr. Jake Scott, from Stanford University, says, "essentially every childhood vaccine has been tested in placebo-controlled trials of some sort." In clinical trials, people who receive the study vaccine are compared to those who receive placebo or standard-of-care. Famously, the polio vaccine was tested against a placebo in the 1950s. Mumps, varicella, haemophilus influenza type B, tetanus, diphtheria, pertussis, pneumococcal, meningococcal, human papillomavirus, influenza and COVID vaccines have all been tested against saline placebos. Despite Kennedy's preference for placebos, they are not always appropriate. If there is already an effective vaccine for a disease, it is unethical to deny participants in a clinical trial protection. Instead, the control

arm becomes the standard of care, which also allows researchers to compare the safety and effectiveness of the new and old vaccine.

Dr. Scott is leading an international collaboration that records randomized clinical trials from around the world in a publicly available database. They have compiled over 1,700 trials and have found 398 placebo-controlled safety and efficacy trials for the antigens in childhood vaccines. Kennedy is simply wrong when he says vaccines have not been safety tested in placebo-controlled trials.

Kennedy wants the public to believe that without "gold standard" clinical trials, we won't know the safety profile of vaccines. In medical science, knowledge is cumulative and evidence comes from many sources. Clinical trials have limitations that make them unsuited to study rare or long-term safety outcomes. So, historically, CDC recommendations also took into account epidemiological and biological studies, forecasting models, safety monitoring systems, and health services research. Frameworks were used to balance evidence about the benefits, harms, and public health impacts of vaccines. All that information and supporting documentation about vaccines was made public.

WHY IT MATTERS:

In late April 2025, the FDA told COVID vaccine manufacturers that if they were seeking approval for an updated vaccine for people under 65 years without medical conditions, they would have to conduct new clinical trials. Then, in May 2025, Kennedy said that, “all new vaccines will undergo safety testing in placebo-controlled trials prior to licensure.” Despite the public announcements, no official, agency-wide FDA rule has been enacted for all vaccines yet.

Requiring large scale randomized clinical trials to test for safety signals that are rare or take years to manifest, would greatly delay the approval of vaccines and would make regular updating of flu and COVID vaccines impossible. The danger is that pharmaceutical companies will simply decide not to offer new vaccines. COVID vaccine manufacturers opted to restrict the population eligible for the 2025/2026 vaccines rather than conduct the required new clinical trials for everyone. Kennedy’s abundance of caution will simply deprive the public of new, innovative vaccines, and ultimately lead to more illness and death.

The scariest implication of Kennedy’s actions on vaccine safety is that regulatory decision making has become arbitrary and untrustworthy. The FDA and CDC skip the advisory meetings with expert scientists that review studies; they also skip opportunities for public comment.

Decisions are simply announced in opinion articles, memos, or on social media, with no supporting documentation. Kennedy has killed the processes that build public and professional trust.

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