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**"Vaccines are exempt from pre-licensure placebo-controlled trials," says Robert F. Kennedy Jr.**

Coffee Beans

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Robert Francis Kennedy Jr. (b. 1954), American politician, environmental lawyer and member of the famous Kennedy clan, in other words, says that vaccines against serious diseases are not adequately tested. This erroneous belief of R. F. Kennedy Jr. was presented in his interview with Jesse Watters on Fox News on July 10, 2023 [1] and is repeated by a number of vaccine misinformation websites [2-4]. Kennedy claimed that vaccines "should have the same kind of testing - placebo-controlled trials - that exist for every other drug." In doing so, he presented a fundamental misunderstanding of some of the generally applicable rules in constructing a system for testing new vaccines. The article "No vaccines have been tested in placebo-controlled clinical trials" [1] contains a polemic by Professor Paul Offit on the false claim made by Mr Kennedy. Prof. Offit states that this is a misunderstanding of what a placebo is and why some vaccine testing schemes are placebo-free.

First on the placebo issue. According to the Food and Drug Administration (FDA), a placebo is "an inert treatment or procedure used in clinical trials to determine whether changes in participants result from actual treatment or occur by chance. Placebos contain no active ingredients or have no therapeutic value but are used to deceive participants" [5]. According to the US CDC, a placebo is "a substance or treatment that has no effect on living beings, usually used as a comparison to a vaccine or drug in clinical trials" [6]. And to make it not so simple, there are two types of placebos, called A "pure" placebo refers to an inert substance such as starch, dextromaltose, lactose, talc, mentholated water and saline, and an "impure" placebo refers to substances with known pharmacological activity such as vitamins, minerals, antibacterial and psychotropic agents used in subtherapeutic doses or in the wrong indication, for example the use of antibacterial agents in uncomplicated viral infections [7]. However, the anti-vaccine group Informed Consent Action Network, for which R. F. Kennedy Jr. was the legal counsel, demanded that only saline containing no other substance be recognized as an acceptable placebo in vaccine testing [8]. However, the question of placebo use and its possible effects is very broad [9]; thus, placebos cannot be limited to saline alone. Thus, R. F. Kennedy Jr. and the entire Informed Consent Action Network group developed their own definition of placebo.

And now to the question of test schemes. Vaccines are among the most cost-effective interventions against infectious diseases, and their development and testing are subject to strict controls. Thus, there are also rules for the use of placebos in their testing and approval. The problem with the use of placebos is that the placebo group is not protected against a given infection and its use puts the proband's health at risk. This is particularly relevant for testing new vaccines where an effective vaccine

against the disease already exists. Therefore, recommendations have been made as to when a placebo can or cannot be used in large-scale clinical trials [10]. Thus, testing a new vaccine against a placebo is scientifically and ethically difficult to justify, especially when its efficacy is tested against an already approved and used vaccine against the disease in question [11]. This is the case with the Prevenar 13 vaccine, which is a redesign of the Prevenar 7 vaccine licensed in 2000 [12, 13].

The misinformation that R. F. Kennedy started with his speech last year is based on true information but interpreted according to his own false definitions. Such misinformation is extremely dangerous and very difficult to refute. The rule must therefore always be to draw information on a given issue from multiple independent sources.

## References

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