

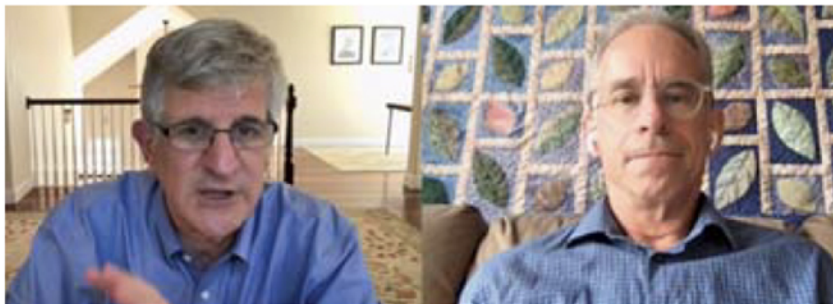
Dr. Offit discusses managing expectations for a COVID-19 vaccine

December 1, 2020

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Article type: [AAP National Conference & Exhibition](#)

Topics: [COVID-19](#), [Infectious Diseases](#), [Vaccine/Immunization](#)



Paul A. Offit, M.D., FAAP (left), said he is confident proper safeguards are in place for new COVID-19 vaccines. His comments came during an AAP Virtual National Conference session with Douglas S. Diekema, M.D., M.P.H., FAAP, of the conference planning group.

Editor's note: For more coverage of the 2020 AAP Virtual National Conference & Exhibition, visit <http://bit.ly/AAPNationalConference2020>. For the latest news on COVID-19, visit <https://www.aapublications.org/news/2020/01/28/coronavirus>.

Operation Warp Speed. Race for a vaccine. Crossing the finish line first.

The language that surrounds a vaccine for COVID-19 does sound a bit alarming, said Paul A. Offit, M.D., FAAP, noting a sizable number of Americans have indicated they would not take the vaccine if offered today. Still, he is confident that proper safeguards are in place despite the fact that this will be the fastest vaccine ever produced.

An attending physician in the Division of Infectious Diseases at Children's Hospital of Philadelphia, Dr. Offit also directs its Vaccine Education Center. He offered an inside look at "The Path to a SARS-CoV-2 Vaccine: Managing Expectations" during the 2020 AAP Virtual National Conference & Exhibition.

It is unprecedented, Dr. Offit said, that more than 180 COVID-19 vaccines are in clinical development — based on various technologies and platforms — and more than 100 companies around the world have an interest in them. Billions of dollars have been donated by the Biomedical Advanced Research and Development Authority, the World Health Organization and the Bill & Melinda Gates Foundation. In addition, because of the urgent need, the government is paying for mass production of the vaccines for a number of pharmaceutical companies while the phase 3 trials are underway.

Dr. Offit, a member of the Food and Drug Administration's (FDA's) Vaccines and Related Biological Products Advisory Committee and a National Institutes of Health working group on vaccines, reviewed how vaccines are developed, approved and manufactured; characteristics of coronaviruses; the need for wide representation of groups in the trials, including children; and the COVID-19 vaccine strategies being pursued.

The platforms are as follows:

- messenger ribonucleic acid,
- DNA,
- replicating viral vectors,
- whole killed virus,
- live, attenuated virus and
- purified viral protein.

While not everything will be known about the effects of a vaccine when it is released, Dr. Offit expressed confidence about the review processes and monitoring systems in place. He cited the Vaccine Safety Datalink, the Vaccine Adverse Event Reporting System and the Post-Licensure Rapid Immunization Safety Monitoring system run by the FDA.

"I think the data safety monitoring board for these vaccines have been charged with the same thing that they are always charged with, which is: Make sure this vaccine is safe and effective — as you would any vaccine," he said.

"As long as we don't truncate the phase 3 trials, which currently are being planned for roughly 30,000 people, then you're basically getting the catchment that you need. The phase 3 trial is the catchment, and 30,000 participants is reasonable."

It is understandable that some people are skeptical, Dr. Offit added. But the way you convince skeptics is with data presented in a "clear, passionate, compassionate, compelling way." That does not include the group he calls vaccine cynics, who are "basically conspiracy theorists.

"There is no talking them out of it," he said. "They believe that the pharmaceutical companies control the world, they control the government, they control the medical establishment."

Even with a COVID-19 vaccine, hygienic precautions still will be needed, he said, including masking and social distancing.

"What worries me and keeps me up at night is that vaccines are going to be sold as some sort of magic powder we're going to sprinkle across the land and make this virus go away," he said. "And that's not true."

Registered attendees can access the session through Jan. 31, 2021, at <https://www.eventscribe.net/2020/AAPexperience/>.