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AAP to feds: Children must be included in SARS-CoV-2 vaccine trials

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Carla Kemp, Senior Editor

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The Academy is calling on federal officials to ensure that children are included in SARS-CoV-2 vaccine trials and that a transparent, deliberate approach is taken so that Americans have confidence that the vaccines are safe and effective.

“Children must be included in vaccine trials to best understand any potential unique immune responses and/or unique safety concerns,” AAP President Sara “Sally” H. Goza, M.D., FAAP, said in a letter to U.S. Department of Health and Human Services (HHS) Secretary Alex Azar, J.D., and Food and Drug Administration (FDA) Commissioner Steven M. Hahn, M.D.

“It would also be less than desirable to have one or more SARS-CoV-2 vaccines licensed or available under Emergency Use Authorization (EUA) at a time when no data have been collected on the safety, tolerability, dose, and regimen for children,” she said.

The letter also states that study subjects should reflect the racial and ethnic diversity of the U.S. population and include pregnant women and those with underlying comorbidities.

Dr. Goza expressed concerns that the anti-vaccine movement is spreading misinformation about a potential SARS-CoV-2 vaccine, which could discourage people from getting the vaccine and decrease confidence in all vaccines.

“The nation’s pediatricians are critically important to the provision of pediatric vaccines, which prevent morbidity and mortality from vaccine preventable diseases,” Dr. Goza said. “As such, the Academy strongly encourages HHS and FDA to ensure that the national approach to the coronavirus pandemic not compromise the trust that American parents have in our existing safe and effective approach to the vaccination of children.”

The letter laid out the following principles that should be followed to ensure the same methodical steps that are used to assess other vaccine candidates are applied to the SARS-CoV-2 vaccines in development:

- Assessment of vaccine candidates must include stringent, well-defined metrics for safety. Such assessment requires adequate numbers of study subjects receiving the vaccine and appropriate time to determine whether a safety signal exists.

- SARS-CoV-2 vaccines studied for use in the U.S. should have publicly available, peer-reviewed data supporting their licensure based on efficacy in prevention of SARS-CoV-2 infection or COVID-19 disease.
- A priori sample sizes providing rigorously powered outcomes should be utilized in the assessment of safety, immunogenicity and efficacy endpoints.
- Data serving as the basis for authorization of any coronavirus vaccine must be based upon studies that include Americans subjects and must reflect the racial and ethnic diversity of the US population.

“In summary, we understand that these undoubtedly are difficult times in which to conduct these historically important vaccine trials,” Dr. Goza said. “We urge you to follow the principles outlined above, as they have been tested and designed to protect the lives of the Americans that the medical community serves.”