

COVID Recommendation FAQ:

What is Secretary Kennedy's Justification for Repealing the Recommendation?

The Secretary is committed to gold standard science as outlined in the President's May 23rd, 2025 executive order. As a result, HHS is reviewing the science of risk and benefit of public health recommendations.

Based on these criteria, the CDC will no longer recommend the COVID-19 vaccine for healthy children or pregnant women. In addition, after two years on the market, the safety and efficacy of the vaccines for healthy children younger than 12 or pregnant mothers has not been established by the manufacturers. There is also information from the COVID-19 manufacturers, FDA, and CDC, detailing serious adverse effects for children between 12 and 17 years of age.

By What Authority Can Secretary Kennedy Amend These Vaccine Recommendations?

The Secretary exercises authority over the CDC and typically acts through the Director of the CDC. There is currently no confirmed CDC Director.

CDC vaccination schedules are typically based on the recommendations of the Advisory Committee on Immunization Practices (ACIP). However, as their name implies, ACIP is an advisory panel. ACIP recommendations are neither required to establish or rescind a recommended vaccination schedule nor are ACIP recommendations to the CDC binding.

The Secretary or the CDC Director may accept, reject, or modify ACIP recommendations. For example, in 2021 former CDC Director Walensky modified an ACIP recommendation regarding COVID-19 boosters by expanding the recommendation for boosters to a broader population than recommended by the ACIP.

Are ACIP Recommendations Law?

ACIP vaccination recommendations are advisory and may be accepted, rejected, or modified by the Secretary or CDC Director. Some laws incorporate ACIP recommendations into various public health or regulatory frameworks, but there is no inherent, stand-alone legal authority vested in ACIP vaccination recommendations.

Will this Prevent Parents from Vaccinating their Children or Pregnant Women from Vaccinating Themselves if They Elect to?

No. Parents and patients are free to consult their health care providers regarding COVID-19 vaccination even if the vaccine is no longer on a recommended schedule for specified populations.

Will VFC Still Pay for the COVID Vaccine?

If a VFC-eligible child presents with a condition that their doctor believes would benefit from a COVID-19 vaccination or booster, the updated recommendation does not prohibit that from happening. In that case the VFC will pay for the vaccination.

Will the Primary Series Still Be Recommended for Children and Pregnant Women Who Are Previously Unvaccinated?

No. The COVID-19 vaccine will only be recommended for children and pregnant women who are immunocompromised, regardless of previous vaccination status.

What Evidence is Secretary Kennedy Using to Repeal This Recommendation?

Information provided by manufacturers for the COVID-19 vaccines state, "[s]afety and efficacy in individuals younger than 12 years of age have not been established," and "[a]vailable data on [COVID-19 vaccine] administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy." iv

Furthermore, post-marketing studies have shown the vaccine to have serious adverse effects, such as an increased risk of myocarditis and pericarditis. This is highest in young males. For instance:

- Myocarditis reports in VAERS after COVID-19 vaccination in 2021 was 223 times higher than the average of all vaccines combined for the past 30 years representing a 2500% increase.
 - a. Demographic data revealed that myocarditis occurred most often in male children, with 76% of cases resulting in emergency care and hospitalization.
- A study from the UK of over 1.7 million children between the ages of 5 and 15 revealed that cases of myo and pericarditis were found exclusively in those that received the COVID-19 vaccine. vi
- A study from Japan showed that COVID-19 vaccination was significantly associated with the onset of myo and pericarditis. These occurred most often in males under 30. vii

A number of studies in pregnant women showed higher rates of **fetal loss** if vaccination was received before 20 weeks of pregnancy. Viii Another showed statistically significant increases in **preterm birth**. Ix Yet another study showed an increase in **placental blood clotting** in pregnant mothers who took the vaccine. X

Will Immunocompromised Individuals Be Able to Access the COVID-19 Vaccination?

Yes, immunocompromised individuals will be able to access the vaccine.

ⁱ Moderna FDA Package Insert (Pgs. 26 & 27)

[&]quot; Pfizer FDA Package Insert (Pgs. 19 & 20)

iii Ibid

iv Ibid

^v J. Rose, N. Hulscher, P. A. McCullough, Determinants of COVID-19 vaccine-induced myocarditis. *Therapeutic Advances in Drug Safety.* **15** (2024), doi:10.1177/20420986241226566.

vi C. D. Andrews et al., OpenSAFELY: Effectiveness of covid-19 vaccination in children and adolescents (2024), doi:10.1101/2024.05.20.24306810.

vii Takada, K., Taguchi, K., Samura, M., Igarashi, Y., Okamoto, Y., Enoki, Y., Tanikawa, K., & Matsumoto, K. (2024). SARS-CoV-2 mRNA vaccine-related myocarditis and pericarditis: An analysis of the Japanese Adverse Drug Event Report database. *Journal of Infection and Chemotherapy*, *31*(1), 102485. https://doi.org/10.1016/i.jiac.2024.07.025

wiii M. P. Velez, D. B. Fell, J. P. Shellenberger, J. C. Kwong, J. G. Ray, Miscarriage after SARS-COV-2 vaccination: A population-based Cohort Study. *BJOG: An International Journal of Obstetrics & Amp; Gynaecology.* **131**, 415–422 (2023). 10.1111/1471-0528.17721.

D. Aharon *et al.*, In vitro fertilization and early pregnancy outcomes after coronavirus disease 2019 (covid-19) vaccination. *Obstetrics & amp; Gynecology.* **139**, 490–497 (2022). <u>10.1186/s12884-022-04505-5</u>.

^{ix} A. Dick *et al.*, Safety of SARS-COV-2 vaccination during pregnancy- obstetric outcomes from a large cohort study. *BMC Pregnancy and Childbirth*. **22** (2022), doi:10.1186/s12884-022-04505-5. <u>10.1186/s12884-022-04505-5</u>.

^x K. Faksova *et al.*, Covid-19 vaccines and adverse events of special interest: A multinational global vaccine data network (GVDN) cohort study of 99 million vaccinated individuals. *Vaccine*. **42**, 2200–2211 (2024). https://doi.org/10.1016/j.vaccine.2024.01.100.