FDA recommends vaccines for kids under 5: Suggested talking points

- **Kids under 5 could get vaccinated as soon as this weekend.**
  - Today, the FDA's outside experts recommended the Pfizer vaccine for kids under 5 and the Moderna vaccine for kids under 6.
  - Pfizer's three-shot pediatric vaccine appeared to be 80 percent effective at preventing symptomatic COVID-19.
  - Moderna's two-shot pediatric vaccine was about 40 to 50 percent effective at preventing milder infections. The company is also testing a booster shot for this age group.
  - The vaccines must now receive FDA authorization and CDC recommendation. The CDC's advisory committee is meeting Friday and Saturday to discuss use of the vaccines.

- **There were no concerns about myocarditis in the pediatric vaccine clinical trials.**
  - Pfizer's and Moderna's vaccines for older kids and adults have been linked to rare cases of myocarditis, a type of heart inflammation.
  - The clinical trials for vaccines for kids under 5 did not document any myocarditis cases among the few thousand participants who received the vaccines.
  - But the FDA notes that there is currently not enough data on the pediatric vaccines to assess the risk of myocarditis.
  - Common side effects of the vaccine for this age group include pain at the injection site, irritability, and sleepiness.

- **Vaccines help protect kids under 5 against the worst outcomes of COVID-19.**
  - Kids are less likely than adults to become seriously ill from COVID-19, but some do suffer from complications.
  - More than 30,000 kids under 5 have been hospitalized with COVID-19, and nearly 500 have died.
  - An infected child can also spread the virus to more vulnerable members of their family or community.
  - Pfizer's and Moderna's pediatric vaccines do not target the new Omicron variants BA.4 and BA.5, but they produce antibodies that help defend against the worst outcomes of COVID-19.

FDA recommends vaccines for kids under 5: Frequently asked questions

1. **When will kids under 5 be able to get vaccinated?**

Kids under 5 could become eligible to receive COVID-19 vaccines in the next few days. Both Pfizer's and Moderna's vaccines for this age group received recommendation from the FDA's outside experts this week. The next step is to receive official FDA authorization. The vaccines will then need to obtain recommendation from the CDC's advisory committee as well as CDC Director Dr. Rochelle Walensky. The CDC's advisory committee is expected to meet June 17 and 18 to discuss the use of the pediatric vaccines. If all goes well, kids under 5 could start getting vaccinated as soon as this weekend.

2. **Why is it important for this youngest age group to get a COVID-19 vaccine?**

The benefits of getting kids vaccinated against COVID-19 outweigh the risks. Vaccines are especially important in protecting kids from the worst outcomes of COVID-19. Kids are less likely than adults to become seriously ill from COVID-19, but they can still experience complications from the virus. More than 30,000 kids under 5 have been hospitalized with COVID-19, and nearly 500 have died. In terms of the risks of vaccination, common side effects for this age group include pain at the injection site, irritability, and sleepiness. There were no concerns about myocarditis in the pediatric vaccine clinical trials, but the FDA does note that there was not enough data to adequately assess the risk of the condition. However, myocarditis cases were extremely rare among older kids and adults.

3. **Should we wait for an Omicron-specific vaccine?**

Some experts believe that everyone will eventually need to receive updated COVID-19 vaccines that are designed to target specific variants. The FDA's advisory committee is scheduled to meet on June 28 to discuss which strains should be included in COVID-19 boosters for the fall. It's still unclear if and when an updated vaccine will be available, especially for kids under 5. Parents should use the tools at hand to protect their kids from the virus.