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FDA Recommends COVID Vaccine for Children; Assoc. of American Physicians and Surgeons (AAPS) Urges Caution

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A committee of experts advising the Food and Drug Administration met on Oct 26 and voted 17 to 0, with one abstention, to recommend authorizing the Pfizer-BioNTech coronavirus vaccine for children 5 to 11 years old.

In response, Association of American Physicians and Surgeons (AAPS) issued a statement that anyone who administers the shot must first obtain fully informed, completely voluntary consent, without threats or inducements.

AAPS notes that testing in children was limited. Only 1,518 children received the shots, and 750 received a placebo. Follow-up was for only two months in one group and 2.5 weeks in another.

The shots are claimed to be 91% effective against symptomatic COVID in children, based on 16 cases of COVID in the placebo group and three cases in the vaccinated group. AAPS observes that this is an absolute risk reduction of only about 2%.

The Food and Drug Administration (FDA) recognizes a risk of myocarditis (inflammation of the heart) and is requiring after-marketing studies lasting five years in adults in its letter approving the BioNTech Comirnaty vaccine, which is similar to the Pfizer product but not yet available in the U.S. All other products are available only under an Emergency Use Authorization (EUA).

AAPS states: "We do not and cannot know the long-term effects on cancer, fertility, or autoimmune diseases." However, committee member Dr. Eric Rubin states: "We're never going to learn about how safe this vaccine is unless we start giving it. That's just the way it goes."

AAPS concludes that “to give truly informed consent, parents need complete information about possible side effects, even if ‘extremely rare.’”

The Association of American Physicians and Surgeons (AAPS) is a national organization representing physicians in all specialties since 1943. Its motto is *omnia pro aegroto* (everything for the patient).

Complete Text of AAPS statement

A committee of experts advising the Food and Drug Administration met on Oct 26 and voted 17 to 0, with one abstention, to recommend authorizing the Pfizer-BioNTech coronavirus vaccine for children 5 to 11 years old. The committee had received more than 140,000 public comments.

AAPS makes the following observations:

- In the testing, only 1,518 children received the shots, and 750 received a placebo. This is far too few to see uncommon side effects, such as myocarditis/pericarditis, as Pfizer admits.
- Follow-up was for two months in one group and only 2.5 weeks in another. The Pfizer application states that long-term sequelae of post-vaccination myocarditis/pericarditis in participants 5 to 12 years of age will be studied *after* the vaccine is authorized for children.
- The children were not examined for mild, asymptomatic myocarditis, which might cause long-term damage, as by checking troponin levels or echocardiograms, or for blood clotting problems, as by checking platelet counts and D-dimers.
- The only FDA-approved product, BioNTech’s Comirnaty (not yet available in the U.S.) is required to do studies on myocarditis *lasting 5 years*.
- Monthly safety report cards on the three available vaccines, which have different dosages, are supposedly required, but none have been produced or released.
- The claim of 91% relative effectiveness against symptomatic COVID in children is based on 16 cases of COVID in the placebo group and three cases in the vaccinated group over the brief follow-up period. This is an absolute risk reduction of about 2%.
- We do not and cannot know the long-term effects on cancer, fertility, or autoimmune diseases. “But we’re never going to learn about how safe this vaccine is unless we start giving it. That’s just the way it goes,” stated committee member Dr. Eric Rubin, physician at Boston’s Brigham and Women’s Hospital, immunology professor at the Harvard T.H. Chan School of Public Health, and current editor-in-chief of the *New England Journal of Medicine*. The alternative to giving a product to most of an entire generation is animal studies or restricting use to a defined group most likely to benefit, with close follow-up.
- The dosage for children is one-third the adult dose. Dosage in pediatrics is generally determined by weight. Not all children weigh the same, and their weight does not triple between age 11.9 and 12.0 years.
- The COVID products are not shown to interrupt infection and transmission. Masking and distancing are still being recommended or required for adults. Thus, hopes for a return to normalcy once vaccinated are misplaced.

To give truly informed consent, parents need complete information about possible side effects, such as the outcome for Maddy de Garay, a 12-year-old whose public-spirited parents enrolled her in a trial. Post-shot, she experienced excruciating pain and a 2-month hospitalization, and is now in a wheelchair. Pfizer has not acknowledged a connection to the shot. The reaction may be "extremely rare," but many would decline to take even a 1-in-1 million chance of this outcome.

The government has already ordered 68 million doses, so authorization is anticipated, and likely will be followed by mandates.

Several Nordic countries have paused the use of COVID vaccines in persons under the age of 30. Persons at low risk for COVID complications are more likely to die from the shot than from COVID.

Dr. Harvey Risch, Yale epidemiologist, stated that he would home-school his children if public schools mandated this vaccine.

No one should administer a COVID shot to a child unless parents have given fully informed, completely voluntary consent, without threats or inducements.

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