

**Testimony Before FDA's Vaccines and Related Biological  
Products Advisory Committee**

**Discussion of Emergency Use Authorization  
of Moderna Vaccine to Prevent COVID-19  
in Adolescents Aged 12-17 Years**

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**I have no financial conflicts of interest**

# CDC Statement About Recent Adolescent Surge

“Recent increases in COVID-19-associated hospitalization rates and the potential for severe disease requiring ICU admission, including invasive mechanical ventilation, among adolescents indicate an urgent need for vaccination in combination with correct and consistent mask wearing by persons not yet fully vaccinated..”\*

\*CDC, *MMWR*, June 4, 2021, page 5

# **Adolescents Aged 12–17 Years with Laboratory-Confirmed COVID-19 Patients Hospitalized in 14 States from January 1, 2021–March 31, 2021**

- **204 hospitalizations**
- **64 required intensive care unit admissions**
- **10 required mechanical ventilation**
- **0 died**

# Public Information about Moderna Vaccine Efficacy in Adolescents Aged 12–17 Years\*

- **Confirmed COVID cases in placebo group**      **4/1000+**
- **Confirmed COVID cases in vaccine group**      **0/2000+**
- **Moderna calculated efficacy of vaccine**      **100%**

\*5/25/21 <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-teencove-study-its-covid-19-vaccine>

# **Why use placebos in future COVID-19 randomized trials?**

**“If another COVID-19 vaccine is licensed or authorized for use in the age group(s) enrolled in the trial, recommended by public health authorities, and widely available such that it is unethical to use a placebo control, the licensed or authorized COVID-19 vaccine could serve as a control.”**

# Reasons for such comparator studies

- **A placebo would be unethical once there is an authorized vaccine for that age group**
- **Parents would be much more willing to enroll their child since they would always get some treatment, not a placebo**
- **Clinical trials for subsequent vaccines for that age group would therefore have less difficulty with enrollment**

### **3. Please discuss studies following licensure and/or issuance of an EUA to further evaluate safety and effectiveness of COVID-19 vaccines in different pediatric age groups.**

- Since FDA has not yet [publicly] authorized the Moderna vaccine for 12- to 17-year-old adolescents, why were these EUA data not provided for this meeting?
- A much more evidence-based discussion of question 3 (above) could have thereby occurred. *Further evaluation* of any vaccine for any age group needs to be predicated on what is already known.