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Pharma and government health officials are luring parents and teens into getting the vaccine by promising a return to social events and normal life — while ignoring potential harms and the "miniscule" risk COVID poses to children.

by <u>Children's Health Defense Team</u>, <u>The Defender</u> May 21, 2021

A decade ago, Ohio researchers bemoaned the difficulty of recruiting children for clinical trials. In the-article, "Pediatric Drug-Trial Recruitment: Enticement Without Coercion," published in the journal Pediatrics, researchers identified barriers such as "the challenge of determining appropriate payments for participation that are not coercive," "the need to obtain consent from parents" and "ethical concerns."

With <u>COVID-19</u>, it appears the government and <u>pharma</u> may have determined they can simply leapfrog over these pesky obstacles.

On May 10, the U.S. Food and Drug Administration (FDA) <u>extended</u> the FDA's <u>Emergency Use Authorization</u> (EUA) for the <u>Pfizer/BioNTech</u> COVID vaccine to adolescents 12 through 15 years of age.

The <u>FDA committee</u> that steered the decision chose to ignore <u>urgent warnings</u> from around the world about the vaccine's risks for children, including a letter by 93 Israeli doctors who wrote in April that "<u>not even a handful</u> of children should be endangered through mass vaccination against a disease that is not dangerous to them."

According to a recent New York Times <u>article</u>, "For children, the evidence so far does not offer much reason for alarm about COVID-19's long-term effects." Conversely, the Israeli doctors and <u>other experts</u> have emphasized that "it cannot be ruled out that the vaccine will have <u>long-term adverse effects</u> that have not yet been discovered at this time, including on growth, reproductive system or fertility."

Warnings ignored

Notwithstanding warnings about COVID vaccine risks for children, the Centers for Disease Control and Prevention (CDC) followed up with an immediate endorsement of FDA's EUA expansion, and CDC director Rochelle Walensky called on healthcare providers to begin administering the still-investigational vaccine to younger adolescents "right away."

Incredibly, a CDC committee* also gave providers <u>permission</u> to administer the COVID vaccines with other childhood and adolescent vaccines "without regard to timing" — including "simultaneous administration of COVID-19 and other vaccines on the same day, as well as co-administration within 14 days."

The CDC is basing this incautious advice on the unproven assumption that "adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone," even though the <u>agency also admits</u> that it does not know "whether so-called 'reactogenicity' increases with [vaccine] co-administration."

The shockingly cavalier promotion of a no-holds-barred approach to COVID vaccination for America's children flies in

the face of global vaccine experts' collective opinion (expressed at a World Health Organization meeting in December 2019) that vaccine safety science and safety monitoring are flawed and utterly inadequate.

No less an entity than the Institute of Medicine has <u>stated</u> that systematic research on "key elements of the entire [childhood vaccine] schedule — the number, frequency, timing, order, and age at administration of vaccines" — has never been done.

Bypassing payment

Returning to the <u>recruitment obstacles</u> outlined in the 2011 Pediatrics article, it appears that in lieu of "payment" for participation in Pfizer's mass vaccine trial, the strategy deployed by <u>Walensky</u> and others is to entice adolescents with sunny assurances of a "faster return to social activities."

Pfizer CEO <u>Albert Bourla</u> and FDA Commissioner <u>Janet</u> <u>Woodcock</u> have likewise promised youngsters that COVID vaccination equals a return to a "sense of normalcy."

These pledges seem to be just the ticket for <u>socially</u> <u>starved</u> teens who profess to be "all ready to get [the vaccine]" and "excited to get things going again" after being "locked up for a year."

Six hundred thousand 12- to 15-year-olds rushed to get COVID jabs within the first week of the EUA expansion. Counting the 16- and 17-year-olds who had previously received Pfizer's vaccine, the total number of injected adolescents (ages 12-17) now numbers 4.1 million, Walensky announced.

These teens and families were likely unaware of the serious adverse events — such as <u>blood clots</u> and <u>Guillain-Barré syndrome</u> — already being experienced by those 16 and older. After a 17-year-old Utah athlete <u>developed blood clots</u> in his brain one day after receiving his first Pfizer injection, the

basketball player's mother tearfully aired her <u>buyer's</u> <u>remorse</u>, <u>stating</u> her son was "healthy and well before" and "the hardest thing was, I let him get that shot."

Nor are most parents and teens focusing on the fact that accepting one COVID injection will not be the end of the story. COVID <u>booster shots</u> are already in the offing – introducing the prospect of recurrent and cumulative risks.

Bypassing parents

As the above-cited numbers suggest, a significant proportion of parents seem to be on board with their kids' swift compliance. In April, just prior to the EUA expansion, a Kaiser Family Foundation poll tested the waters and <u>found</u> 30% of parents with children in the 12-15 age group were themselves chomping at the bit — ready to "get their child vaccinated as soon as a vaccine is available" — and another 18% were willing to do so if schools required it.

On the other hand, <u>about half</u> of Kaiser's parent respondents stated that they either planned to wait or "definitely" would not be getting their child COVID-vaccinated. This is the group of parents that prompted the Ohio researchers in 2011 to scratch their heads and <u>characterize</u> "the need to obtain consent from parents" as a barrier to pediatric medical experimentation.

The "solution" seems to be to bypass troublesome parents altogether. Five states, heedless of the injections' <u>investigational status</u>, are allowing healthcare providers and medical practices to dispense with <u>parental</u> consent requirements for COVID vaccines.

In <u>North Carolina</u>, adolescents who are 12 and up can provide their own consent if deemed able to understand and make decisions about their health. A representative of the state's heavyweight health group UNC Health <u>stated</u>, "COVID vaccination is one of those medical treatments that North Carolina says

that a child is able to consent for on their own."

Three other states — Alabama, Oregon and Tennessee — are permitting adolescents 14 or 15 years of age and older to do the same, and Iowa is leaving consent requirements to the discretion of "each individual healthcare provider/health system."

In March, in the face of heated public opposition, the <u>District of Columbia</u> enacted legislation enabling children as young as 11 to get CDC-recommended vaccines without parental consent or even knowledge.

Bypassing ethics

At the close of 2020, New York University (NYU) and Tulane researchers <u>wrote</u> in the International Journal of Clinical Practice about COVID vaccines and the "serious mechanistic concern" of antibody-dependent enhancement (ADE) — the phenomenon whereby vaccination worsens subsequent disease.

The <u>conclusion</u> reached by the researchers (not specific to, but certainly germane to adolescents) was that the risk of ADE "is sufficiently obscured in clinical trial protocols and consent forms for ongoing COVID-19 vaccine trials that adequate patient comprehension of this risk is unlikely to occur, obviating truly informed consent by subjects in these trials."

Independent of the topic of ADE, the NYU/Tulane authors' study demonstrated how difficult it is for the average adult — much less adolescent — to penetrate the risks "obscured" in consent forms and thus to achieve "truly informed consent."

And if this is the case, how likely are teens (or their parents) to understand the distinction between relative and absolute risk when they consent to COVID vaccination? How many young persons can grasp that Pfizer's relative-risk-based claim of a "100% effective" vaccine for 12-15 year-olds

translates into an absolute risk reduction ("the <u>difference</u> between attack rates with and without a vaccine") that is "<u>teensy-tiny</u>"?

Using relative risk calculations, Pfizer declared its injection "100% effective" on the basis of trials with 2,260 younger adolescents. According to the company's press release, 18 cases of COVID occurred in the placebo group versus zero in the vaccine group. Nowhere does Pfizer spell out that these numbers equate to a reduction in absolute risk of 1.59% (obtained by dividing 18 by the 1,129 teens allocated to the placebo group).

Moreover, in the analyses for its clinical trials with adults, Pfizer doctored its results by <u>excluding</u> thousands of participants who had symptoms identical to COVID but not confirmed by <u>PCR testing</u>. Did similar sleight of hand produce the magic "100%" result for adolescents? Access to "full datasets and <u>independent scrutiny and analyses</u>" are needed to answer that question.

Even assuming a straightforward analysis on Pfizer's part, European scientists writing in The Lancet in April emphasized the importance of putting vaccine trial results "in context and not just looking at one summary measure." When researchers omit information about absolute risk reduction and communicate only relative risk reduction numbers, "reporting bias is introduced, which affects the interpretation of vaccine efficacy" — raising questions about the investigators' intent and integrity.

The lead author of the Lancet commentary <u>admitted</u> to Wired, "One of the main reasons why absolute risk reduction is not shown is because of the numbers. If you say, 'It's 95% effective' — Wow! ...But if your absolute risk reduction is like 0.8%..., so what?"

The Lancet authors also noted relative risks "should be seen

against the background risk of being infected and becoming ill with COVID-19, which varies between populations and over time."

This is a particularly crucial observation for children, whose "background risk" of developing serious COVID illness is minuscule, as evidenced by the fact that the CDC uses 5-17 year-olds as its "reference group" (the group with the lowest risk) when presenting risks of COVID infection, hospitalization and death for other age groups.

There are 74 million children in the U.S. So far, 282 have died from conditions "involving COVID," producing a mortality rate of 0.00038%. At the May 12 meeting of the CDC's Advisory Committee on Immunization Practices (ACIP), CDC <u>estimated</u> 22.2 million children aged 5-17 had had COVID, and 127 had died – or 0.00057%.

As a University of Pennsylvania infectious disease specialist <u>told</u> the New York Times, "For the average kid, Covid is a negligible risk."

By way of comparison, in 2019 (the most recent year for which data are available), 847 children in the 5-14 age group died in car accidents and 233 perished by drowning. In 15-24 year-olds, 2019 witnessed another 6,031 car accident deaths, 415 fatal drownings and 4,346 poisoning deaths.

In 2017, drowning deaths claimed nearly 1000 young people <u>under age 20</u>. From February 2020 through mid-February of this year, 5,738 children aged 5-14 and 36,900 adolescents and young adults aged 15-24 died from <u>causes other than COVID-19</u>.

In 1- to 17-year-olds, COVID ranks behind <u>nine other causes of death</u> (injury, suicide, cancer, homicide, congenital anomalies, heart disease, influenza, chronic lower respiratory disease and cerebrovascular causes).

Outsized risks

When announcing the expansion of its Pfizer EUA for 12- to 15-year-olds, FDA head Janet Woodcock told parents they "can rest assured that the agency undertook a rigorous and thorough review of all available data."

However, as of May 7 (that is, just prior to the EUA expansion to younger adolescents), the <u>Vaccine Adverse Event Reporting System</u> (VAERS) was already showing 694 post-COVID-vaccine adverse events in the 12-17 age group, including 14 rated as "serious" and three deaths.

The VAERS data released one week later, on May 14 (just after the 12-15 go-ahead), showed a sharp bump up in COVID-vaccine-related adverse events in the 12-17 age group: 943 total adverse events, including 23 rated as serious and the three deaths.

Two of the deaths reported before May 10 were in 15-year-olds, one after receiving the Pfizer vaccine and the other after receiving the Moderna vaccine. These adolescents must have been enrolled in the clinical trials, as their ages would have precluded them getting the vaccines legally under the EUAs in effect at the time.

With about 1,000 children in Pfizer's clinical trial vaccine group in the 12-15 age group — and probably about the same number in Moderna's trial — the death rate following either vaccination in this age group (assuming the two teens were trial enrollees) is approximately two in 2,000, or 0.1%. Available evidence strongly suggests, therefore, that COVID vaccines are much more dangerous to children than the disease.

Across all age groups, VAERS had received reports of almost 228,000 total adverse events between Dec. 14, 2020, and May 14, including more than 4,200 deaths. That this unprecedented trail of destruction was not cause for concern among the FDA and CDC committee members who enthusiastically recommended

Pfizer's experimental vaccine for young people is baffling.

Tragically, it is a virtual certainty that VAERS reports for children will rise in the coming weeks — leaving many parents as <u>regretful</u> as the Utah mom who let her son "get that shot."

*Footnote: The 14 members of the CDC's Advisory Committee on Immunization Practices (ACIP) who unanimously voted to recommend COVID vaccines for 12- to 15-year-olds and also endorsed simultaneous administration of COVID and other vaccines are: Jose Romero (Arkansas Secretary of Health); Kevin Ault (University of Kansas); Lynn Bahta (Minnesota Department of Health); Beth Bell (University of Washington School of Public Health); Henry Bernstein (Cohen Children's Medical Center); Wilbur Chen (University of Maryland); Matthew Daley (Kaiser Permanente Colorado); Sharon Frey (St. Louis University); Camille Kotton (Massachusetts General Hospital); Grace Lee (Stanford University); Sarah Long (Drexel University); Veronica McNally (Franny Strong Foundation); Katherine Poehling (Wake Forest University); Pablo Sanchez (Nationwide Children's Hospital and Ohio State University); and Helen Talbot (Vanderbilt University). Consider reaching out to these individuals to ask them how they reached their reckless decisions.

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