# **Referenced Data for Parents Concerning the Pfizer COVID-19 Vaccination for Children Aged 5 through 11 Years**

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On Oct 29, 2021, the Food and Drug Association (FDA) extended its Emergency Use Authorization (EUA) for the Pfizer-BioNTech "vaccine" to be given to reduce serious COVID-19 infections in children aged 5 through 11 years. The FDA provided little evidence for its decision except for a minimal sized "immunobridging" study, which incorrectly considered blood antibody levels to be the same thing as immunity to the SARS-CoV-2 virus, the cause of COVID-19. It is not—especially when using an mRNA "vaccine" that is demonstrably no longer working in the older age groups.

The Pfizer COVID-19 mRNA vaccine is not really a "vaccine" in the true sense of the word. It does not provide longterm immunity like the existing vaccines for measles, polio, chickenpox, and smallpox. Rather, it is an experimental nucleic acid preparation that is associated with rare but catastrophic side effects in individuals aged 12 and older. The administration of the Pfizer-BioNTech and other mRNA "vaccines" for children aged 5–11 should be a decision between physicians and parents. Alternatively, successful early drug treatments for COVID-19 are available.

# The Mass COVID-19 Vaccination of Children Ages 5–11 and Younger Is Not a Safe or Rational Policy

#### Unlike Adults, Children Are Naturally Resistant to Serious COVID-19 Infection

For a variety of infectious diseases, children respond differently than adults. In the 5–11 age group COVID-19 is generally considered to be a self-limiting infection of the upper airway with only mild symptoms of infection, or no symptoms at all.<sup>1</sup>

With respect to fatal outcomes, the infection fatality rate (IFR) of COVID-19 in children is an almost infinitesimal 0.001% to 0.002% in those aged 5–9 years, with a mean increase in the IFR of 0.59% with each five-year increase in age past 10 years.<sup>2</sup> Overwhelmingly, childhood COVID-19 deaths in the 5–11 age group are due to serious pre-existing comorbidities.

Reasons for the resistance of children to severe COVID-19 include a low number of SARS-CoV-2 virus receptor proteins in the nose and mouth and the fact that this age group demonstrates a robust cross-reactive innate immunity to a variety of RNA viral infections.<sup>3,4</sup>

Children are not significant transmitters of the SARS-CoV-2 virus to adults or to each other, further adding to the minimal role they have played in the COVID-19 pandemic.<sup>5,6</sup>

There are currently more than 79 international highquality research papers demonstrating that convalescing COVID-19 patients develop a natural, robust, cross-reactive, and long-lasting immunity superior to that of individuals given the Pfizer COVID mRNA "vaccine."<sup>7</sup> This is how a "herd immunity" develops. It is by triggering an immune response to multiple viral proteins that may be cross-reactive against future "quasi-species" of the COVID-19 virus. It is not created by triggering an immune response to a single, fast-mutating viral protein such as the "spike protein," which forms the basis of all the mRNA COVID-19 vaccines.

In addition, there is evidence that convalescent COVIDrecovered individuals with new natural immunity **may actually be at a higher risk of adverse vaccine effects** if they are then given the Pfizer mRNA "vaccine," when compared to naïve individuals not previously infected.<sup>8-10</sup> **The FDA has absolutely no idea whether this would also be the case for a COVID-recovered and then vaccinated child**).

It would be a formidable task to test all 5–11-year-old American children for a previous COVID-19 infection before administering one of the current mRNA vaccines to them. With the growing unreliability of the mRNA vaccine efficacy in adults and the limited benefit over potential risk of childhood vaccination, this does not appear to be a rational cost-effective public health measure.

As will be discussed, why would we inject an experimental "vaccine" into young children when it does not reliably protect them from infection by the current dominant COVID-19 clades, may make them more prone to hospitalization when they get infected, and is already associated with rare but catastrophic side effects in children 12 and older?

It is important to recognize that a small number of children aged 5–11 with mild or asymptomatic COVID-19 virus exposures may develop a serious generalized inflammatory state a few weeks later. This is termed the multisystem inflammatory syndrome in children (MIS-C). Some scientists are concerned that the Pfizer COVID-19 mRNA "vaccine" may itself trigger MIS-C.<sup>11-12</sup>

To complicate the matter, the FDA has recently acknowledged, in its approval letter for Comirnaty (the parallel European version of the Pfizer vaccine), that it was *incapable of accurately monitoring serious adverse side-effects* associated with "vaccination" using the experimental Pfizer-BioNTech COVID-19 mRNA preparation.<sup>13, p6</sup> Therefore, any tally of the true incidence of MIS-C or other serious side effects linked to the administration of the Pfizer or other mRNA "vaccines" will almost certainly represent a gross undercount with a lack of transparency to parents.

# The Pfizer COVID-19 Injection Is Experimental

The FDA classifies the Pfizer-BioNTech COVID-19 mRNA preparation as a *Biologic Product* created to reduce the severity of COVID-19 once an individual is infected. It is an experimental treatment, which seems to provide roughly a six-month period of whatever protection it gives against the early strains of the COVID-19 virus.<sup>14</sup>

### The mRNA COVID-19 Biological Product Is Not Working as Promised

Unfortunately, the original strains of SARS-CoV-2 are now essentially extinct, having now mutated into other dominant strains such as the widespread Delta variant and its viral quasi-species that are vaccine resistant. Consequently, when considering a childhood vaccination decision, parents should be aware of these related facts:

The Pfizer injection does not reliably protect against COVID-19. Fully vaccinated persons can still be infected with the Delta strain of SARS-CoV-2.<sup>15-17</sup> These fully vaccinated but newly infected persons can transfer their COVID-19 infection to both unvaccinated as well as other fully vaccinated individuals.<sup>18</sup> An Israeli study of 2.5 million patients found that fully vaccinated persons were *6 to 13 times* more likely to later become infected with the Delta variant than those who developed natural immunity from a previous COVID-19 infection.<sup>19</sup>

Additionally, full mRNA "vaccination" did not reliably protect against more severe disease. In the Israeli study, the risk of developing symptomatic COVID-19 was significantly increased among the fully vaccinated, and their risk of hospitalization was eight times higher compared to persons with naturally developed immunity.

This Israeli data is confirmed by Public Health England data published on Sept 3, 2021, which shows that from Feb 1, 2021, to Aug 29, 2021, there were 1,798 deaths within 28 days of a positive test for the Delta Covid-19 variant. The fully vaccinated population accounted for 1,091 of those deaths, with just 536 deaths occurring among the unvaccinated population.<sup>20-21</sup>

Because the Pfizer mRNA COVID-19 Biological Product can no longer reliably prevent infection, re-infection, viral transmission, or death from COVID-19, it is a failed "vaccine." This was reaffirmed on Aug 6, 2021, when Rochelle Walensky, M.D., director of the Centers for Disease Control and Prevention (CDC), stated that there is "concerning evidence of waning vaccine effectiveness over time against the Delta variant." The CDC then inaccurately tried to affirm the remaining efficacy of the mRNA vaccines when it published an earlier deeply flawed and statistically small study claiming that the COVID-19 "vaccines" provide greater protection against reinfection than natural immunity. *To reiterate, there are more than 79 international, peer-reviewed, high-quality studies, which demonstrate that naturally acquired immunity is far superior to that provided by COVID-19 mRNA "vaccination.*"<sup>7</sup>

# The Pfizer Injection Is Associated with Rare but Severe, Crippling Side Effects and Death

In 1990, the FDA and CDC created the Vaccine Adverse Event Reporting System (VAERS) to receive reports about suspected vaccine side effects. This system is grossly antiquated and characterized by the shocking under-reporting of adverse vaccine events. Yet this is the major surveillance system now in use by the FDA and CDC to monitor the safety of the experimental mRNA COVID "vaccines." Despite the underreporting by VAERS, some scientists were calling for a halt to the use of all the mRNA "vaccines" as early as February 2021. At present, the mRNA "vaccines" have accumulated more deaths and adverse events in VAERS than all other types of vaccines combined over the previous decade.<sup>22</sup> Irrespective of the undercounted serious adverse effects being reported, the number of deaths per million administered COVID-19 vaccine doses has increased more than 10-fold when compared to all other vaccines together, as seen in Figure 1.<sup>22</sup>

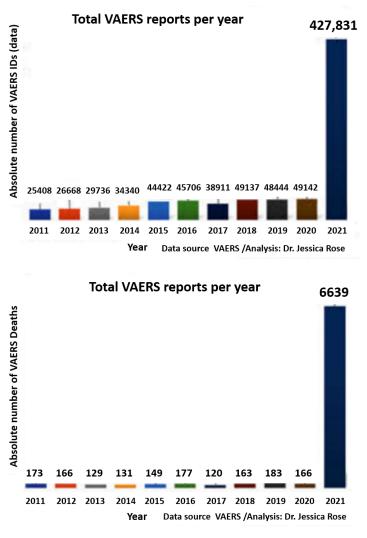


Figure 1. Total VAERS Reports and Reported Deaths

Just as alarming as the deaths are the serious injuries and hospitalizations associated with the mRNA and DNA vaccines. These include vaccine-induced heart damage in young males, precipitation of heart attacks, strokes, and limb amputations due to abnormal blood clotting; a possible phenomenon called antibody-dependent enhancement (ADE); and a spectrum of serious neurological complications including partial paralysis and blindness.<sup>23</sup>

We do not know how to predict who will suffer a deadly vaccine side effect and who will not. All we know is that receiving a second dose of one of the mRNA vaccines seems to be a factor. In addition, the long-term effects caused by the rapid dissemination of mRNA "vaccine" nanoparticles moving from the injection site and deposited in distant tissues remains unknown, as does the likelihood of lethal autoimmune diseases months to years later.<sup>23</sup>

Despite the continuing, repeated calls for caution made by scientists outside government, the dangers of the current COVID-19 mass "vaccination" program have been minimized by senior personnel at the FDA, CDC, and the National Institutes of Health (NIH), who have failed to act on the side of caution.<sup>21-23</sup>

On Sept 22, 2021, FDA amended its authorization for the now unreliable Pfizer-BioNTech COVID-19 "vaccine" to allow the use of a booster dose.<sup>24</sup> Safety concerns over this decision caused a serious conflict between the FDA leadership under Janet Woodcock and two senior FDA scientists who promptly resigned.<sup>25</sup>

This decision is made even more troublesome because of the now overwhelming clinical evidence showing that COVID-19 is a treatable condition, and that early outpatient multidrug-therapy for high-risk infections can cause up to an 85 percent reduction in COVID-19 hospitalizations and death.<sup>26</sup> This involves using the existing FDA-approved drugs that were incorrectly suppressed by Dr. Anthony Fauci at NIH and by Dr. Stephen Hahn and Dr. Janet Woodcock at FDA.<sup>26</sup> (Dr. Woodcock was appointed acting FDA Commissioner after previously recusing herself from all vaccine decisions because of her conflicts of interest.)

# Countries and U.S. States Are Opting-Out of Mass-Vaccination Mandates

Recognizing that their vaccination programs are not working, Britain and Israel are considering dropping vaccine passports and halting the practice of business checks of vaccine status. The U.S. state of Florida has dropped its vaccine mandate as well.

In the first week of October 2021, all the Scandinavian countries simultaneously halted or discouraged the use of Moderna's COVID-19 mRNA vaccine for males under the age of 30. In Denmark this was for everyone younger than 18. This was due to an unacceptably high rate of potentially fatal vaccine-induced inflammation of the heart and/or or the pericardium (the membrane surrounding the heart).<sup>27</sup>

In an unexpected move, on Nov 13, 2021, a three-judge panel on the U.S. Court of Appeals for the Fifth Circuit, sitting in New Orleans, La., issued a ruling temporarily blocking the OSHA requirement for large companies to mandate COVID-19 vaccines for employees or to carry out weekly testing starting in January 2022. The states of Texas, Louisiana, Mississippi, and South Carolina are in the jurisdiction of the Fifth Circuit Court.<sup>28</sup>

### Mass Vaccinations for the Pandemic Control of COVID-19 ls a Failed Doctrine

With all of the approved mRNA "vaccines" now showing clear signs of unreliability,<sup>29</sup> FDA has reversed its previous ban on administering a mRNA booster dose that is different from the type of mRNA vaccine used for the individual's primary vaccination. The FDA justification for this is a recent NIH review of the data from a small volunteer cohort, which is purported to show that the "mix and match" strategy can lead to a stronger immune response.<sup>24</sup> This rushed study for a previously banned procedure suggests a desperate effort by NIH, FDA, and CDC, to broaden the generated antibody epitopes against the COVID "spike protein" in the booster recipients. Some scientists are concerned that might conceivably lead to adverse antibody-dependent-enhancement upon later exposure to future possible COVID-19 viral clades.

Completely ignored is the fact that early outpatient drug treatments continue to show overwhelming evidence

for efficacy, cardiac safety, and for their operational use in controlling COVID-19 community spread. In contrast, the nations with the highest COVID-19 "vaccination" rates, along with the U.S. counties with the highest vaccination rates, are showing the greatest increases in COVID-19 cases.<sup>28</sup> It appears to be the infected vaccinated members of the community who are now driving the pandemic, not the unvaccinated children or adults.

Nevertheless, in October 2021, the FDA vaccine advisory panel voted unanimously 17-0 in favor of vaccinating children aged 5–11 with Pfizer's experimental biological product. In an apparent callous disregard for its potential harm in this age group, one FDA panelist, Dr. Eric Ruben, stated "we're never going to learn about how safe this vaccine is unless we start giving it."<sup>30</sup> The implication is that the FDA has no idea of the short and long-term risks of this "vaccine" in this young age group.

It is time for FDA, NIH, and CDC to face the truth. Mass vaccinations cannot control a pandemic involving a fastmutating RNA virus. Neither can population "lockdowns." Using drugs like remdesivir for exclusive in-hospital treatments will not control a pandemic either.

The only demonstrated method for control of the COVID-19 pandemic is the early use of outpatient drug treatments with the short-term quarantine of infected individuals. This is the precise doctrine that was banned in April 2020 by the efforts of Dr. Janet Woodcock (FDA) and Dr. Anthony Fauci (NIH).

With the present mRNA vaccines, there is no positive benefit-to-risk ratio for vaccinating children aged 5–11 against COVID-19 infection. The unknowns are still too great. There is no way to know whether a vaccinated child with comorbidities will have a higher risk for adverse events if later infected. These comorbidities are expected to include obesity, diabetes, chronic lung disease, sickle cell disease, and immunosuppression. Pediatricians and parents should be making these decisions, not state governors, school boards, or federal bureaucrats and politicians.

# Accountability for This Failed Mass Vaccination Policy Is Necessary

It is past time for the Government Accountability Office as well as a specially designated Senate Committee with a panel of outside advisors to investigate the decisions made from January 2020 to date by Anthony Fauci, M.D., at the National Institute of Allergy and Infectious Diseases (NIAID); 2020 FDA Commissioner Stephen Hahn, M.D.; and Janet Woodcock, M.D., current acting FDA commissioner. All three of these officials, in addition to Rick Bright, Ph.D., formerly at the Biomedical Advanced Research and Development Authority (BARDA), played a fundamental major role in blocking early at-home, safe prescription drug treatments for COVID-19.

In addition, the conflict-of-interest-ridden CDC Advisory Committee on Immunization Practices (ACIP) and some of the 20 members of the FDA Vaccines and Related Biological Products Advisory Committee (FDA/ VRBPAC) need a close examination.

The subversion of proven safe, cheap, and effective early outpatient treatments for COVID-19 was intentional. The replacement of the drug treatment doctrine with an ill-advised mass vaccination program involving highly experimental mRNA and DNA Biological Products *was also intentional*.

A formal investigation is almost a legal mandate now, following the recent release of a paper in the *British Medical Journal* indicating that falsified data may have been used in Pfizer's pivotal phase III trial. This included unblinded patients, inadequately trained vaccinators, and the slow follow-up of adverse vaccination events.<sup>31</sup>

Thousands of Americans have been permanently injured or killed by the experimental mRNA mass vaccination program, and young children are now being placed at risk. Responsible persons must be identified and held accountable.

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**Disclaimer:** This article does not purport to reflect the opinions or views of any organization with which the author is affiliated. This article provides a summary of existing peer-reviewed research with defendable conclusions.

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