# **Expert statement regarding**

# **Comirnaty – COVID-19-mRNA-Vaccine for children**

## Michael Palmer MD, Sucharit Bhakdi MD, Stefan Hockertz PhD

doctors4covidethics.org

#### Summary

This expertise on the use of the Pfizer COVID-19 vaccine (Comirnaty, BNT162b2) in adolescents is divided into two sections. The arguments presented in Section <u>1</u> pertain to all COVID-19 vaccines, whereas those in Section <u>2</u> apply specifically to the Pfizer vaccine. However, because of the many similarities between the Pfizer vaccine and the Moderna mRNA vaccines, the arguments presented there are also relevant to the latter.

- 1. Is vaccination of adolescents against COVID-19 necessary?
- 2. Is the Pfizer COVID-19 vaccine safe?

We are not including herein the substantial scientific support for the fact that the Pfizer vaccine is ineffective, but we will submit that data should the Court request it. We have proof that the claims of efficacy which Pfizer attaches to its vaccine—namely, 95% efficacy in adults, and 100% in adolescents—are:

- misleading, because these numbers pertain to *relative*, not *absolute* efficacy, the latter being on the order of only 1%;
- specious, because they refer to an arbitrarily defined, clinically meaningless evaluation endpoint, whereas no efficacy at all has been demonstrated against severe disease or mortality;
- most likely altogether fraudulent.

Section <u>1</u> will show that vaccination of adolescents COVID-19 is unnecessary, because

- in this age group the disease is almost always mild and benign;
- for the rare clinical cases that require it, treatment is readily available;
- immunity to the disease is now widespread, due to prior infection with the virus (SARS-CoV-2) or with other coronavirus strains; and
- asymptomatic adolescents will not transmit the disease to other individuals who might be at greater risk of infection.

**Section 2** will show that the safety profile of the Pfizer vaccine is catastrophically bad. It will be discussed that

- Pfizer, the EMA, and the FDA have systematically neglected evidence from preclinical animal trials that clearly pointed to grave dangers of adverse events;
- the Pfizer vaccine is orders of magnitude more dangerous than any other vaccine in history; it has caused thousands of deaths within five months;
- The agencies that granted emergency use authorization for this vaccine committed gross negligence via grave errors and omissions in their assessments of known and possible health risks.

The only possible conclusion from this analysis is that the use of this vaccine in adolescents cannot be permitted.

## 1. Vaccination of adolescents against COVID-19 is unnecessary

#### 1.1. What does the available evidence show?

There are several lines of evidence that show vaccination of adolescents against COVID-19 to be unnecessary.

#### 1.1.1. The case fatality rate of COVID-19 in the general population is low

The vast majority of all persons infected with COVID-19 recovers after minor, often uncharacteristic illness. According to world-leading epidemiologist John Ioannidis [1,2], the infection fatality rate of COVID-19 is on the order of 0.15% to 0.2% across all age groups, with a very strong bias towards old people, particularly those with co-morbidities. This rate does not exceed the range commonly observed with influenza, against which a vaccination of adolescents is not considered urgent or necessary.

## 1.1.2. COVID-19 has a particularly low prevalence and severity in adolescents

In the U.S., persons younger than 18 years accounted for just 1.7% of all COVID-19 cases [3,4]. Essentially no severe cases of COVID-19 were observed in those above aged 10 through 18 years [4]. This group accounted for just 1% of reported cases, almost all of which were very mild. Thus, adolescents are at particularly low risk of harm from COVID-19 infection. Vaccination of this age group is therefore unnecessary.

## 1.1.3. Most people, particularly adolescents, are by now immune to SARS-CoV-2

Due to the many inherent flaws and shortcomings of the diagnostic methods in common use (see Section <u>1.2</u>), it is impossible to accurately determine the proportions of those who have already been infected with SARS-CoV-2 and those who have not. However, there are indications that the proportion of those who have been infected and recovered is high:

- The incidence of multisystem inflammatory syndrome in children (see Section <u>1.1.2</u>) peaked in early to mid 2020, and then receded, with some slight delay after the initial wave of the COVID-19 respiratory disease itself [<u>5</u>].
- Approximately 60% of randomly selected test persons from British Columbia have detectable antibodies against multiple SARS-CoV-2 proteins (personal communication by Stephen Pelech, University of British Columbia), indicating past infection with the virus—as opposed to vaccination, which would induce antibodies to only one (the spike) protein.

Past COVID-19 infection has been found to protect very reliably from reinfection [6], and strong specific humoral and cellular immunity is detected in almost all recovered individuals, and also in those who remained asymptomatic throughout the infection [7]. Thus, a large proportion of individuals in all age groups, including adolescents, already have specific, reliable immunity to COVID-19. As mentioned above, most of those who do not have such specific immunity nevertheless are protected from severe disease by cross-immunity [8,9]. This immunity will be particularly effective in healthy adolescents and young adults. Individuals with specific immunity or sufficient cross-immunity cannot possibly derive any benefit from undergoing an experimental vaccination.

## 1.1.4. Asymptomatic transmission of COVID-19 is a categorical lie

An oft-cited rationale for vaccinating individuals who are not themselves at risk of severe disease is the need to induce "herd immunity:" the few who are at high risk should be protected by preventing the spread of the virus in the general population.

It has been unambiguously determined that such asymptomatic transmission does not occur. In a large-scale study, which involved almost 10 million Chinese residents, no new infections could be traced to persons that had tested positive for SARS-CoV-2 by PCR, but who did not exhibit any other signs of infection [10]. This finding concords with several studies that compared PCR to virus isolation in cell culture among patients with acute COVID-19 disease. In all cases, growth of the virus in cell culture ceased as symptoms subsided, or very shortly thereafter, whereas PCR remained positive for weeks or months afterwards [11,12]. It was accordingly proposed to use cell culture rather than PCR to assess infectiousness and to determine the duration of isolation [12].

These findings indicate that restricting contact of persons at risk with those who show, or very recently showed, symptoms of acute respiratory disease would be effective and sufficient as a protective measure. Indiscriminate mass vaccinations of persons who are not themselves at risk of severe disease are therefore not required to achieve such protection.

## 1.1.5. COVID-19 can be treated

Numerous experienced physicians have collaborated on establishing effective treatment guidelines for clinically manifest COVID-19 [13]. Treatment options are available both for the early stage of the disease, at which emphasis is placed on inhibiting viral replication, and for the later stage, at which anti-inflammatory treatment is paramount. Two drugs that have been used successfully at the early stage are hydroxychloroquine and ivermectin. Both drugs have been, and continue to be, in use against a variety of other diseases. Ivermectin, for example, is considered safe enough to be used not only for treating manifest scabies—a parasite infection of the skin that is unpleasant but not severe—but even prophylactically in asymptomatic contacts of scabies-infected persons [14].

Ivermectin is also widely used in the treatment of tropical parasitic diseases such as onchocerciasis (river blindness), and for this reason it is on the WHO's list of essential medicines. Yet, with COVID-19, the WHO sees fit to warn against the use of this very same well-known and safe drug outside of clinical trials [15]. This policy cannot be rationally justified, and it has quite appropriately been overridden by national or regional health authorities and ignored by individual physicians worldwide.

The availability of effective treatment voids the rationale for the emergency use of vaccines on any and all age groups, including also adolescents.

## 1.2. Missing evidence: use of inaccurate diagnostic methods

A key element that is lacking in the current discussion of the need for vaccination is a reliable diagnostic tool for determining who is or is not currently infected with SARS-CoV-2. The diagnostic procedure most widely used for this purpose is based on the polymerase chain reaction (PCR). The PCR is a powerful method for the *in vitro* amplification of nucleic acids. This permits the very sensitive detection of very small amounts of DNA or, as in the case of SARS-CoV-2, RNA in clinical samples. The amplification occurs in repetitive reaction cycles, which are controlled by periodical shifts in temperature. Each cycle can double the amount of the nucleic acid of interest in the reaction mixture. Therefore, after 10 cycles, the initial amount of nucleic acid will have increased by a factor of approximately one thousand, after 20 cycles by a million, and after 40 cycles by up to one trillion. This consideration already suggests one potential pitfall of the PCR—namely, that it can be too sensitive: excessively high numbers of successive amplification cycles will detect extremely small amounts of viral nucleic acid that do not indicate acute infection or any risk of transmission.

Unfortunately, the number of amplification cycles (the C<sub>t</sub>value) needed to find the genetic material in question is rarely included in the results sent to authorities, doctors and those tested. Most commercially available RT-qPCR tests set the limit of amplification cycles up to which an amplification signal should be

considered positive at 35 or higher. Multiple studies have indicated that  $C_t$  values above 30 have a very low predictive value for positive virus cultures, and thus for infectiousness or the presence of acute disease [11,16–18]. Considering that in many clinical trials—including the ones conducted by Pfizer—a "COVID-19 case", or an "endpoint" amounts to no more than a positive PCR test, regardless of  $C_t$  value, in combination with one or a few non-specific symptoms of respiratory disease, the significance of the use of improperly high  $C_t$  cut-off values cannot be overstated. This systematic and widespread error alone has sufficed to gravely distort the diagnoses conferred on individual patients, as well as the epidemiology of the pandemic as a whole.

Further systematic negligence in connection with PCR testing concerns the verification of the identity of the amplified nucleic acid fragments. While Sanger DNA sequencing of such fragments, the gold standard, is feasible on a large scale in principle, it has not been routinely used in the ongoing mass PCR testing campaigns. The error is compounded by the very low number of independent PCR reactions considered sufficient for a positive test—as few as two, or even only one have been considered sufficient in various jurisdictions—as well as by various other technical faults in the widely adopted and commercialized Corman-Drosten protocol, which have been discussed in detail elsewhere [<u>19</u>].

In summary, a positive RT-qPCR test result cannot be accepted as proof that the person in question is currently infected and infectious—even if there is reasonable clinical plausibility of actual COVID-19 infection, as well as a significant community prevalence of the disease. Firstly, the RNA material containing the target sequences could very well be from nonviable/inactive virus; this is particularly likely if the patient in question has already recovered from the infection. Secondly, there needs to be a minimum amount of viable virus for onward transmission; but tests carried out with excessively high (yet unreported) C<sub>t</sub>values will detect minuscule amounts of genetic material that pose no real risk at all.

## 2. The Pfizer COVID-19 vaccine lacks safety

## 2.1. What does the evidence show?

The clinical trials for Comirnaty (BNT162b2), as well as for the other COVID-19 vaccines, were rushed through in a very short time; this has meant that proper precautions to ensure their safety were not taken. Unfortunately, animal experiments carried out before the start of clinical testing already gave reason to expect severe toxicity, and this expectation has been abundantly borne out in practice since the beginning of mass vaccinations.

## 2.1.1. Preclinical data from animal experiments indicate potential for grave harm

Comirnaty, like all other gene-based COVID-19 vaccines, causes the expression in vivo of one specific protein of SARS-CoV-2—namely, the so-called spike protein, which is located on the surface of the virus particle. The spike protein mediates the virus particle's initial attachment to the host cell and also its subsequent entry into the cell. The key idea behind the Comirnaty vaccine is as follows:

- 1. a synthetic mRNA that encodes the spike protein is complexed with a mixture of neutral and cationic (positively charged) synthetic lipids, which cluster together in lipid nanoparticles (LNPs);
- 2. after injection, the LNPs facilitate the uptake of the mRNA into host cells, where the mRNA will cause the expression (synthesis) of the spike protein;
- 3. the spike protein will appear on the surface of the host cells and induce an immune reaction to itself.

The immune reaction to the spike protein will comprise both antibodies, which may or may not be neutralizing, and T-lymphocytes (T-cells). Some of these T-cells are cytotoxic (also known as T-killer cells);

their function is to kill virus-infected body cells. While this vaccination strategy may look good on paper, it has a number of drawbacks and risks. These arise both from the lipid mixture and from the spike protein, both of which have known toxic activities.

## 2.1.1.1. Toxic and procoagulation activities of the spike protein

Severe clinical COVID-19 disease is often accompanied by a pathological activation of blood clotting [20]. The spike protein is the reason [21]. Notably, there are at least two different mechanisms for triggering blood clots:

- 1. If the spike protein is expressed within vascular endothelial cells—the innermost cell layer of the blood vessels—then an immune reaction to the spike protein can destroy these cells. This will activate blood clotting.
- 2. Spike protein molecules can directly bind to blood platelets and activate them. Platelets cause blood clotting.

The second mechanism is significant because it does not involve an immune reaction; therefore, it can be triggered right away even in those persons who have no pre-existing immunity. The first mechanism will be most effective in those who already have immunity to the spike protein, due to either infection with the virus or a previous injection of vaccine. Note that the underlying mechanism of cell damage will also operate in other tissues—any cell in the body that expresses the spike protein will thereby become a target for the immune system.

Since Comirnaty and other gene-based vaccines induce the synthesis of active spike protein, it is important to understand how this protein with be distributed within the body. Toxicity might be limited if the vaccine remained confined to the site of injection, within the muscle tissue but outside the circulation. On the other hand, if the vaccine were to enter the bloodstream, then one would have to expect expression of the spike protein within the blood vessels and toxicity through the activation of blood clotting.

## 2.1.1.2. Distribution of the vaccine in animal experiments

As it turns out, the vaccine does indeed appear in the bloodstream very rapidly after intramuscular injection. In experiments which Pfizer reported to the Japanese health authorities [22], rats were injected with a mock vaccine sample. This material was was chemically similar to Comirnaty, but it contained an mRNA molecule that encoded an easily traceable, non-toxic model protein (luciferase) rather than the SARS-CoV-2 spike protein. The lipid mixture used to form the LNPs was the exact same as with Comirnaty. One of the lipids in this mixture was radioactively labelled, which permitted the distribution of the sample within the body to be traced and quantified sensitively and accurately. Several remarkable observations were made:

- 1. The radioactive lipid appeared rapidly in the bloodstream. The blood plasma concentration peaked after 2 hours; but even at only 15 minutes into the experiment, the plasma level had already reached 45% of that maximal value.
- 2. Very high levels of the radioactive lipid accumulated in the liver, the spleen, the adrenal glands, and the ovaries.
- 3. Comparatively low levels accumulated in the central nervous system (the brain and the spinal cord).
- 4. Expression of the model protein encoded by the mRNA was studied only in the liver, where it was readily detected.

## 2.1.1.3. Mechanism of vaccine uptake into the bloodstream

Considering that the mRNA with bound LNPs has a rather large molecular size, we must ask how it managed to enter the bloodstream so rapidly. After intramuscular injection, the bulk of the vaccine should end up *outside* the blood vessels. This space is separated from the intravascular space (the circulation) by the

capillary barrier, which permits free passage only to small molecules such as oxygen or glucose (blood sugar) but is normally impermeable to large molecules. The most plausible explanation is that the vaccine has breached the capillary barrier, just like it has breached the even more fortified blood brain barrier. Blood clotting complications must therefore be expected.

## 2.1.1.4. Mechanisms of accumulation in specific organs

Through a FOIA (judicial) demand, the world has learned that Pfizer knew that the vaccine accumulates in a very high amount in the liver, the spleen, adrenal glands, and the ovaries (and due to similar mechanism of action, very likely the placenta and the lactating mammary glands, which were not studied.) These organs will be exposed to the toxicity of the spike protein, and to the immune reaction against it, in proportion to the level of LNP and mRNA uptake – and that uptake was exceedingly high in the ovaries.

## 2.1.1.5. Potential risks to fertility and to the breastfed newborn

An exceedingly high level of expression of spike in the ovaries raises the prospect of significant damage to that organ, with possible consequences for female fertility. Uptake of the vaccine by mammary gland cells opens two possible pathways of toxicity to the breastfed child: firstly, the expression of spike protein and its secretion into the breast milk, and secondly, the wholesale transfer of the vaccine into the milk. The mammary glands are *apocrine*, which means that they pinch off and release fragments of their own cytoplasm into the milk; thus, anything that has reached the cytoplasm might also reach the breast milk. In this connection, we note that both the VAERS database and the EU drug adverse events registry (EudraVigilance) report fatalities in breastfed newborns after vaccination of their mothers.

## 2.1.1.6. Pfizer's failure to investigate risks evident from preclinical investigations

All of the risks discussed above have been substantiated since the vaccines have been rolled out—all are manifest in the reports to the various adverse event registries (see Section <u>2.1.2</u>). We must stress again that each of these risks could readily be inferred from the cited limited preclinical data, but were not followed up with appropriate in-depth investigations. In particular, the clinical trials did not monitor any laboratory parameters that could have provided information on these risks, such as those related to blood coagulation or liver damage.

## 2.1.2. Adverse events after the onset of vaccinations

Since the introduction of the vaccines, numerous adverse events have been reported to registries around the world. We will here focus on two registries, namely, the U.S. vaccine adverse events reporting system (VAERS) and the EU monitoring system for drug adverse events (EudraVigilance). All numbers quoted below are as of May 21<sup>st</sup> unless stated otherwise.

## 2.1.2.1. Fatalities reported in connection with COVID vaccines

Within just five months of the onset of vaccinations, EudraVigilance has accumulated 12,886 deaths in connection with the COVID-19 vaccines, of which the Pfizer vaccine accounted for almost half (6,306). In the same time period, VAERS has run up 4,406 deaths in all; of these, 91% were associated with the mRNA vaccines, with Pfizer accounting for 44% and Moderna for 47% of the total.

It is impossible to know what percentage of all fatalities that occur after vaccination will actually be reported to VAERS or EudraVigilance. However, note that the 4,406 COVID vaccine-related fatalities accrued by VAERS during just the past 5 months exceed the cumulative total of all other vaccines combined, over the entire previous 20 years. It is therefore clear that these vaccines are far and away the most deadly ones in history—quite predictably so, and all for a disease whose case fatality rate does not exceed that of influenza [1,23].

## 2.1.2.2. Severe events related to disrupted blood clotting

The litany of diagnoses in both databases that indicate pathological activation of blood clotting is almost endless—heart attacks, strokes, thromboses in the brain and in other organs, pulmonary embolism; but also thrombocytopenia and bleeding, which result from excessive consumption of thrombocytes and of coagulation factors in disseminated intravascular coagulation. These disease mechanisms caused many of the fatalities summarized above; in other cases, they caused severe acute disease, which will in many cases leave behind severe disability.

#### 2.1.2.4. Severe adverse reactions among adolescents

In the age group of 12-17 years, two deaths likely related to the Pfizer vaccine were already reported to EudraVigilance. Also in this age group, there were 16 cases of myocarditis, all in males, and 28 cases of seizures among both sexes, 3 of them reported as life-threatening. There also were a few cases of stroke, myocardial infarction, and severe inflammatory disease.

While the numbers of adverse events are much lower than those among adults, this is simply due to the hitherto far lower rates of vaccination in this age group. Should systematic vaccination be green-lighted for adolescents, we must expect these numbers to rapidly climb to a level resembling that seen in adults.

## 2.1.2.5. Miscarriages

As of June 21<sup>st</sup>, 2021, EudraVigilance lists 325 cases of miscarriage among vaccinated pregnant women. While it is difficult to ascertain by just how much vaccination will raise the rate of miscarriage, most of these cases were reported by healthcare professionals, who evidently considered a connection to the vaccine at least plausible. This series of cases alone would be reason enough to pause the vaccinations and investigate.

#### 2.2. Missing evidence

We saw above that significant positive indications of risk were neglected in the clinical trials and subsequent rushed emergency approval of the Pfizer vaccine, with unfortunate yet predictable outcomes. Equally damning is the list of omissions—potential risks that should have been investigated in preclinical or clinical trials but never were. We will here discuss only some of these omissions.

## 2.2.1. Drug interactions

The EMA report states (page 110):

Interaction studies with other vaccines have not been performed, which is acceptable given the need to use the vaccine in an emergency situation.

Since it is clear that mortality due to COVID-19 is low (see Section <u>1.1.1</u>) and therefore that no emergency exists, this argument must be rejected as specious.

Immunosuppressive effects of BNT162b2 are apparent from a drop of blood lymphocyte numbers among those vaccinated, as well as from clinical observations of shingles, which arises through the reactivation of persistent varicella-zoster virus [24]. This suggests that the desired immune response to other vaccines simultaneously administered may be impaired.

## 2.2.2. Reproductive toxicity

Reproductive toxicity was assessed using only one species (rats) and on only small numbers of animals (21 litters). A greater than twofold increase in pre-implantation loss of embryos was noted, with a rate of 9.77% in the vaccine group, compared to 4.09% in the control group. Instead of merely stating [25] that the higher value was "within historical control data range," the study should have stated unambiguously whether or not this difference was statistically significant; and if it was not, the number of experiments should have been

increased to ensure the required statistical power. The same applies to the observations of "very low incidence of gastroschisis, mouth/jaw malformations, right sided aortic arch, and cervical vertebrae abnormalities." Overall, these studies are inadequately described and apparently were also inadequately carried out.

#### 2.2.3. Autoimmunity

Exposure to the vaccine will lead to cell damage due to the cationic lipids, and also to the immune attack on cells producing the spike protein. This causes a cascading and cumulative effect in which some cells will be targeted for autoimmune disease. Such an outcome is particularly likely in im mu no compromised people or in those who are genetically predisposed to autoimmune disease (e.g. those with the HLA-B27 allele). The risk of auto immunity induced by BNT162b2 could be adequately addressed only in long-term studies; as with fertility or cancer, the very short period of pre- clinical and clinical testing means that we are flying blind. It should go without saying that all of these risks are particularly grave with children, adolescents, and young adults.

#### 2.2.4. Antibody-dependent enhancement

While antibodies in principle serve to protect us from infections, in some cases they can paradoxically worsen disease. This phenomenon is referred to as antibody-dependent enhancement.

#### 2.2.4.1. The principle

In most cases non-neutralizing antibodies are not harmful, but with some viruses they can actually make matters worse by facilitating entry of these viruses into host cells. This occurs because certain cells of the immune system are supposed to take up antibody-tagged microbes and destroy them. If a virus particle to which antibodies have bound is taken up by such a cell but then manages to evade destruction, then it may instead start to multiply within this cell. Overall, the antibody will then have enhanced the replication of the virus. Clinically, this antibody-dependent enhancement (ADE) can cause a hyperinflammatory response (a "cytokine storm") that will amplify the damage to our lungs, liver and other organs of our body.

ADE can occur both after natural infection and after vaccination, and it has been observed in particular with SARS, whose causative virus (SARS-CoV-1) shares 78% identity with SARS-CoV-2. Attempts to develop vaccines to SARS repeatedly failed due to ADE—when the vaccinated animals were subsequently challenged with the virus, they became severely ill or died—unlike the unvaccinated controls (see e.g. [26]).

## 2.2.4.2. SARS-CoV-2 and ADE

Pfizer and the regulatory bodies (FDA, EMA) are well aware of the risk of ADE. The FDA notes [27]:

Pfizer submitted a Pharmacovigilance Plan (PVP) to monitor safety concerns that could be associated with Pfizer-BioNTech COVID-19 Vaccine. The Sponsor identified vaccine-associated enhanced disease [ADE] including vaccine-associated enhanced respiratory disease as an important potential risk.

EMA has likewise acknowledged that this risk must be investigated further [25]:

Any important potential risks that may be specific to vaccination for COVID-19 (e.g. vaccine associated enhanced respiratory disease) should be taken into account. The Applicant has included VAED/VAERD as an important potential risk and will further investigate it in the ongoing pivotal study and a post-authorization safety study.

Overall, it is clear that the risk of ADE is recognized in theory but is not being addressed in practice. Given the abundant evidence of ADE with experimental SARS vaccines, this is completely irresponsible.

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