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Written statement* submitted by Planetary Association for Clean Energy, Inc., The, a non-governmental organization in special consultative status

The Secretary-General has received the following written statement which is circulated in accordance with Economic and Social Council resolution 1996/31.

[22 August 2022]

* Issued as received, in the language of submission only.

Covid-19 and Vaccines, Indefensible FDA decision to Grant Emergency Use Authorisation for Pfizer in under Five Year Olds

The Food and Drug Administration (FDA) were presented with data from Pfizer that did not demonstrate either effectiveness or safety for its use in children under the age of five. Despite this and despite the still total, inevitable, lack of data on long-term harms, they unanimously voted to give the drug Emergency Use Authorisation (EUA), on 15th June 2022.

The FDA's own criteria for granting an EUA include:

1. the treatment is for a serious or life threatening disease or condition;
2. the product may be effective to prevent, diagnose or treat the condition;
3. the potential benefits of the proposed product outweigh the known and potential risks.

None of these criteria have been met and yet the FDA committee approved the EUA unanimously. Young children are not at significant risk of serious or life threatening disease with a 99.995% recovery rate. The product has not been shown to be effective at prevention. The known risks outweigh this lack of benefit let alone the potential risk.

The Pfizer submission must be the most extreme case of data manipulation and bad science ever presented to the FDA. The study was approved on the basis of 4,500 participants but 3,000 of them had not completed the trial when the evidence was presented to the FDA.

The trial was designed with the aim of demonstrating that the product would result in raised antibody levels in these children. Pfizer said, "no specific neutralizing antibody titer has been established to predict protection against COVID-19." Therefore, demonstration of raised antibodies is meaningless even as a surrogate marker. Young children have a different more efficient, robust immune response with superior innate immunity, and fast viral clearance. It should not be assumed that training children's immune systems to respond in a more specific and adult way to SARS-CoV-2 will benefit them.

After two doses there were no detectable antibodies to the Omicron variant so a third dose was added. Antibodies to Omicron were detected after this third dose but only in 225 children and at levels around half of those to the Wuhan variant after the second dose.

Three weeks after the first dose there were 30% more cases in the mRNA arm. This increased risk period has been noted before. These cases and all those that occurred before one week after the third dose, in total 97% of the covid cases in the trial, were ignored. The protocol was to wait for 21 cases before analysis yet the analysis was carried out on the basis of 10 cases. Pfizer commented on this limitation. The evidence was so weak that it could mean the children were at substantially higher risk of covid as reflected by the wide confidence intervals. The FDA specified requirements for an EUA for covid products were at least 50% efficacy and a lower confidence interval of more than 30%. The last criteria was not met. Furthermore, 12 children had two episodes of covid (11 after mRNA), not included in these results.

The Pfizer data on the sample for antibody testing showed that 37.9% of 6-23 month olds had evidence of infection during the trial, a 30.2% increase on the 7.6% that had evidence of prior infection at the outset. For 2-4 year olds, 29.9% had evidence of infection during the trial compared to 12.7% at the outset, a 17.2% increase. These figures are far higher than the 8.7% and 8.0% who were described as 'cases' by Pfizer and calls into question the accuracy of the study.

Children have a negligible risk of dying with covid. CDC estimates of deaths and hospitalisations have been overcounted.

For this trial Pfizer defined serious disease such that any child with a raised respiratory rate or heart rate would be considered to have severe disease. By this definition, in the 2-4 year age group there were 6 'severe' covid cases in the mRNA group (although 2 were injected with mRNA after completing their placebo course) and only 1 in the placebo group. Although

these numbers are small they suggest that it was more likely that mRNA increased the risk of severe covid than reduced it. No child died or was hospitalised because of a covid infection.

The CDC estimated that 75% of the children and adolescents had had a covid infection by February 2022 and more will have been infected subsequently. Immunity acquired by infection is superior to drug-induced immunity such that injecting the already immune is treating a problem that does not exist. Pfizer failed to present evidence of a benefit in these young children.

Any hypothetical benefit would only be of relevance if there were subsequent waves of covid. The trial began in June 2021 when the Delta variant was dominant. The mRNA is based on the Wuhan variant and it is well established that the Omicron is significantly milder in children under 5 years old.

It is now accepted that the risk from mRNA products of myocarditis is much higher in younger age groups and estimates of up to 337, 377, 378 per million in 12-17 year old males. Active surveillance resulted in a several fold higher cases. When heart cells are killed they cannot be replaced. The CDC data shows that 39% of those with myocarditis had restricted activity after 3 months and half remained symptomatic. Long term outcomes remain unmeasured for mRNA induced myocarditis. Other causes of myocarditis result in a 3-4% rate for heart transplantation and a mortality rate at five year of 44-56%. Injecting those previously infected appears to increase this risk of myocarditis and there is no evidence that mRNA reduces harm from myocarditis caused by covid. Rates of myocarditis in young children remain unquantified.

Just because a drug has been labelled with the word ‘vaccine’ does not make it safe. The FDA’s own criteria for safety of 6 months follow-up of 500-3000 children were not met. Pfizer described their study as limited due to “The median blinded follow-up time post Dose 3 in the analyses was only 35 days for participants 6-23 months of age and 40 days for participants 2-4 years of age.”

The trial was far too small and short to assess safety. Six children had a fever of more than 40 degrees in the mRNA group compared to a single child in the smaller placebo group. From this it appears the mRNA may have caused more illness than it managed to prevent.

Children should be given the opportunity to develop a full natural immune response such that in later life, when they are at more risk from covid, they can rely on this earlier training of the immune system to protect them.

In the original Moderna trial 93% of the unvaccinated controls had an immune response resulting in nucleocapsid antibodies after infection compared to only 40% after mRNA. The immune response to infection had therefore been interfered with such that a spike protein antibody response was the dominant feature. Spike protein is the part of the virus with the most frequent mutations.

The variants that have resulted from mutation have resulted from the virus evading the mRNA induced immune response and the impact of altering the immune response in this way therefore has potential risks for the individual and for wider society. The European Medicines Agency has also warned that frequent booster shots could adversely affect the immune response. Yet Pfizer’s own submission included comments about boosters for these children, “it is likely that a booster dose will be needed in addition to the three-dose primary series to increase robustness, breadth, and duration of protection against currently circulating and emerging SARS-CoV-2 variants in children 6 months through 4 years of age.”

Any medical intervention in children should be taken only on a precautionary basis. Long term, as yet unassessed impacts would have the biggest effect on those with the most life left to live.

Despite the woefully inadequate data presented, Pfizer had the audacity to suggest that for any future research the use of a placebo group would be “unethical” and their product should be used instead. It is unbelievable that this study ever achieved ethical approval given the lack of long term safety data with these novel treatments in an age group that is at no risk of serious disease or death. The FDA’s Vaccines and Related Biological Products Advisory

Committee voted unanimously to recommend the products for Emergency Use Authorisation. This is a designation used to prevent serious injury or death – how can they claim it is any way relevant to children under 5 years of age?

On August 11 2022, the World Health Organization (WHO) published a statement titled: “Interim statement on COVID-19 vaccination for children”, which covered-up for all these blatant lies.