Dear Ms Kyriakides,

In the name of our organization associating experts from the fields of medicine, science and law from the Czech Republic, we would hereby like to draw your attention to the problems of the study submitted recently to the FDA by Pfizer, which will, presumably, be soon submitted (if not submitted already) to EMA as well; namely, the subject of our concern is the study supporting the request to approve the use of the Comirnaty vaccine in the youngest children (6 months to <5 years of age). Unfortunately, the study shows significant shortcomings, while, most importantly, not sufficiently proving the vaccine efficacy. We have already sent our Letter of concern including the analysis prepared by our experts to EMA.

As the European Commission grants marketing authorizations for medicines in the EU and you are the Commissioner responsible for Health and Food Safety, we would like to bring your attention to some serious concerns about the Pfizer study regarding the COVID-19 mRNA vaccines for children of 6 months to <5 years of age. As Pfizer submitted (or is about to submit) this study (probably in a slightly altered version) also to EMA, we would like to kindly ask you to consider our serious concerns shown in this letter and attached analysis when this issue is discussed.

Among other things, we would like to emphasize the following facts (the attached analysis is more detailed):

1) The efficacy of the vaccines against infection, hospitalization or death was not proved by the Pfizer study for any of the groups. The approximately 80% efficacy of the vaccine against infection declared in the Executive Summary is based just on a subgroup containing a small number of patients, which resulted in the confidence interval for this value ranging virtually from -370% to 100%; in other subgroups, the protective effect of the vaccine has not been demonstrated, either.
2) During the study, changes were made to the protocol to support the efficacy assessment of the 3rd dose (it should be noted that no positive vaccine effect was observed following 2 doses of the original protocol). This, in itself, would not have posed a major problem; however, as a result of these changes, an unprecedentedly high number of subjects were „unblinded“ and the data presented as the main results come from only a small subset of patients.
3) Due to unblinding, it is very difficult to discern the actual length of follow-up of the safety profile after the Dose 3. For example, Tables 19 and 20 report a follow-up time after Dose 3 of less than 7 days for the majority of participants; on page 13, for example, for the 6-23 months group, only 461 subjects out of 1178 vaccinated are reported to have a follow-up time of more than 2 months (i.e. a minority, but presented as 60.8%). However, the median follow-up times after the Dose 3 stated in the report (e.g. page 23) are longer than one month (for both the blinded and combined populations), which is impossible – given the fact that the majority of subjects were vaccinated with Dose 3 for less than one week, the median should be less than a week.
4) The only endpoint showing certain beneficial effects of the vaccine was the production of antibodies. However, this criterion is very „soft“, among other things because the immunobridging included a comparison to a group of young adults whose immune system works very differently from the youngest children. Added to this, we should also point out the dichotomy in the official position that antibodies cannot be considered proof of protection from COVID-19 as no „safe“ level of antibodies can be established (while it is

apparently sufficient for vaccine approval) or the fact that virus neutralization test was performed using the original Wu-han strain, from which the vaccine was constructed while against the Omicron variant, the effectiveness is approximately 5-6 times lower.

5) COVID-19 is a far less dangerous disease for children under five than for the adult population, and severe course in this age group is rare, occurring most often in children with other underlying conditions. The death of a healthy child is exceedingly rare. To the best of our knowledge, there was not a single fatality following reinfection with COVID-19 in a previously healthy child from this age group. It is likely that most children have already encountered the infection and acquired post-infection immunity. Administering the vaccine to these children may increase the risk of adverse events while providing no benefit (as demonstrated by the Pfizer study itself) to such children and hence, the risk associated with vaccine administration may significantly outweigh the benefit.
6) In addition, the mRNA vaccines have, so far, been always approved in a simplified way, i.e., an emergency mode (FDA) or conditional authorization (EMA) and we assume that the current request to EMA would be also for conditional authorization, the regulations for which are much less strict than for standard authorization. This is, however, only applicable and justifiable if the population in question is at grave risk of serious health impacts of the disease, which is not the case here.

We would like to kindly ask you to evaluate the information stated in this letter and look at the study objectively, without prejudice, and to ask yourself the crucial questions: Does the Pfizer study prove the effectiveness of their vaccine for the youngest age group and does it offer good protection (and from what)? And as so many statements presented to us with great certainty over the last year and a half about these vaccines (such as „they are 100% effective, their effectiveness is long-term, whoever gets vaccinated, cannot die of COVID," etc.) have already turned out to be false, can we indeed be 100% certain that the vaccines based on this novel technology are completely free of any adverse effects that would develop over years? And once we answered these two questions, can we really approve the administration of these vaccines to our children based on this study or should we rather apply the precautionary principle?

Thank you very much for your kind understanding and thorough evaluation of the submitted materials. Should you wish to call on our expertise, for example, to give an opinion on the version of the Pfizer study presented to EMA, we will be happy to help and are open to any discussion.

Yours sincerely (in alphabetical order),

Prof. MUDr. Jiri Benes, CSc., specialist in infectious diseases
Prof. MUDr. Jiri Beran, CSc., epidemiologist and vaccinologist
MUDr. Emil Berta, Ph.D., anaesthetist and ICU doctor
MUDr. Mgr. Jan Brodnicek, general practitioner and pneumologist
Mgr. Zuzana Candigliota, attorney-at-law
MUDr. Vladimir Cizek, angiologist, chairman of an ethics committee
MUDr. Alena Dernerova, pediatric neurologist, senator
Prof. RNDr. Gejza Dohnal, CSc., expert in applied statistics
MVDr. Vaclav Fejt, immunologist
RNDr. Tomas Furst, Ph.D., university teacher, data analyst
MUDr. Martin Gabrys, neurosurgeon
MUDr. Jana Gandalovicova, cardiologist
MUDr. Radan Gocal, specialist in internal medicine

MUDr. Jan Hnizdil, specialist in internal medicine and psychosomatics
MUDr. Jitka Chalankova, physician, senator
RNDr. Jaroslav Janosek, Ph.D., university teacher, editor of medical texts
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MUDr. Mgr. Jana Kralova, general practitioner for children and adolescents
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Prague, August 5th, 2022