WHOLISTIC PEDIATRICS
& FAMILY CARE

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Docket No. FDA-2020-N-2242 - Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

December 9, 2020

Dear CBER Vaccines and Related Biological Products Advisory Committee,

I am writing to formally request an oral presentation slot at the VRBPAC meeting to discuss Emergency Use Authorization (EUA) of the Moderna, Inc., COVID-19 Vaccine on December 17, 2020. I will be the only presenter in my slot.

The information I will present at the December 17th meeting will differ substantially from what I am addressing at the December 10th meeting regarding the Pfizer-BioNTech COVID-19 Vaccine. During that meeting I will discuss issues related to transparency and widespread public hesitancy regarding the vaccine.

I am in the process of reviewing the data released December 8, 2020 related to the Pfizer COVID-19 vaccine. I have initial concerns about some of the reported effects seen in subjects who received the Pfizer vaccine, such as the four cases of Bell's palsy in the vaccine group compared to zero in the control group; the ten-fold increase in lymphadenopathy in the treatment group; and, the doubled incidence of appendicitis.

It is disconcerting that on the first day the United Kingdom made the Pfizer vaccine available to its population, two recipients of the vaccine suffered significant allergic reactions. The subsequent level of concern resulted in the Medicines and Healthcare Products Regulatory Agency (MHRA) issuing advice to hospitals, cautioning them to not administer the vaccine to anyone with a history of allergic reactions or those advised to carry an adrenaline auto-injector, and recommending resuscitation facilities should be available at all times for vaccinations.

Due to the short turn-around time between receiving the Pfizer data and the December 10th committee meeting, I will be unable to incorporate a more detailed analysis of that data into my December 10th presentation materials, which I have already prepared and submitted. I presume similar data pertaining to the Moderna COVID-19 vaccine will be released not much in advance

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of the December 17th committee meeting, at which time I would be prepared to discuss both the Pfizer and the Moderna reports to your committee.

If patterns of allergic and hyperinflammatory reactions after COVID-19 vaccinations continue to indicate prevalence may be higher than previously reported in the manufacturer's press releases, it would be wise for the Committee to adequately evaluate and address these findings. This action will be crucial if the FDA wants to help alleviate concerns and hesitations about the COVID-19 vaccine, and reassure the American people it has adopted rigorous safety and transparency mechanisms related to the COVID-19 vaccines.

Thank you for the opportunity to speak to your committee again.

Sincerely,

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