WHOLISTIC PEDIATRICS
& FAMILY CARE

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Docket No. FDA-2020-N-1898 for Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

October 15, 2020

To Whom It May Concern:

I am a Board Certified Pediatrician with more than 25 years of clinical experience, and am the founder and medical director of a private pediatric and family medicine practice in Tampa, Florida. As a primary care physician, I specialize in treating a wide-range of patients with neurodevelopmental and immunological conditions, as well as perform standard checkups and sick visit appointments. Throughout my career, I have based my counsel of patients on the notion of informed consent, which at its core requires people be given accurate information from which to make a decision. Likewise, it is imperative the U.S. Food & Drug Administration provides sufficient information from which to assess the potential benefits and risks of any potential SARS-CoV-2 vaccine option.

First, I want to commend the FDA for successfully advocating for stricter vaccine approval guidelines. I strongly believe any publicly available vaccine must be adequately vetted by independent scientists and then approved by the FDA.

Many of my patients/families are expressing hesitancy about potential SARS-CoV-2 vaccines. As you meet to discuss the development, authorization, and/or licensure of vaccines to prevent COVID-19, it is vital that you consider the expertise of practicing physicians who receive direct input from prospective recipients of the vaccine. To increase confidence and, thus, the likelihood of widespread acceptance and participation in a COVID-19 vaccine program, certain verifiable criteria must be met.

The FDA must take certain steps to build public trust, including but not limited to: (1) being fully transparent about clinical trials, (2) providing large scale, ongoing observation and reporting of adverse clinical trial events; (3) ensuring adequate clinical representation of diverse populations; and, (4) transparent reporting of vaccine protective rates.

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1. **Clinical Trial Transparency.** It is highly concerning that AstraZeneca has not fully informed the medical community and general public of the details regarding the AstraZeneca trial participant who reportedly developed transverse myelitis. It is also concerning that AstraZeneca has provided no public information about why it was deemed safe to resume the trial. Also, to date, there has been no information provided about the "unexplained" safety issue that recently resulted in Johnson & Johnson pausing their vaccine trial. For people to trust the FDA, you must provide full transparency, including details of why vaccine trials are paused, and what abnormalities were discovered upon physical examination and from performing diagnostic tests.

2. **Large-scale, Ongoing Observation and Reporting of Adverse Events.** It is known that viruses and vaccines can trigger autoimmune, atopic, and other hyperinflammatory conditions reactions. Furthermore, some of these conditions may take a long time to develop. It is critical that ongoing studies and open reporting include data related to these conditions. It would also be very helpful to track if patients with adverse reactions had prior personal or family history of hyperinflammatory/autoimmune/atopic conditions.

3. **Ensuring Adequate Clinical Representation of Diverse Populations.** Issues of race, ethnicity, and socio-economics must also be considered in terms of who will have access to the vaccines. Data has shown that minority and underprivileged populations are disproportionately contracting and dying from SARS-CoV-2. For the vaccines to be safe and trusted, there must be adequate clinical sample sizes of people of varying races, ethnicities, economic statuses, and health conditions. The FDA should also disclose whether they will be subsidizing the cost of the vaccine for uninsured/underinsured people and those with limited financial resources.

4. **Transparent Reporting of Vaccine Protective Rates.** To make an informed decision about any vaccine, patients must know the likelihood of the vaccine providing immunity, and how long the protective antibodies will persist. For COVID-19 vaccines, it has been reported that a 50% protective rate will be considered a "success" sufficient to warrant approving the vaccine. Based on my clinical interactions, people are expressing concerns about taking a vaccine that may only have a 50% success rate because they question whether the potential benefits outweigh the potential risks.

I would be happy to further discuss the issues raised in this letter, including potential solutions, with anyone on your team.

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Sincerely,

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