

August 25, 2020

The Honorable Stephen Hahn, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to you regarding a topic of critical importance as we fight to contain the global spread of COVID-19. As you are well aware, widespread availability of a safe and efficacious vaccine will play an essential role in slowing transmission of this deadly disease and allowing us to move safely and confidently towards full re-opening of our businesses and schools, helping ease Americans back towards pre-pandemic life. However, public polling suggests that vaccine hesitancy is at an all-time high, which could hobble efforts to ensure widespread vaccination when one or more vaccine candidates are made available. **With COVID-19 vaccine development moving at a rapid pace, it is critical that we ensure physicians are continuously informed of the U.S. Food and Drug Administration's (FDA) plans for review and that they are provided with the utmost level of transparency regarding the process for authorization or licensure, standards for review, and safety and efficacy data as soon as possible.**

Physicians have come to rely on the FDA's rigorous review process and stringent oversight of medical products to ensure safety and efficacy of the products granted the agency's clearance, authorization, licensure, or approval. However, the unprecedented circumstances presented by COVID-19, including the need to rapidly bring to market an effective vaccine, have raised a number of questions from not only the general public, but from physicians as well. While vaccine hesitancy among the public has been rapidly increasing in recent years, it appears to be reaching unprecedented levels due to a number of factors including concerns about the rapid pace of vaccine development and significant spread of misinformation through channels such as social media. We are also beginning to field increasing numbers of questions and concerns from our physician members, mostly due to the pace of development for a type of vaccine yet to be successfully brought to market for use in humans, as well as what has been perceived as very little available information about the vaccines in development and the planned FDA review process.

The AMA and our members are strongly committed to ending this global pandemic and to fighting medical misinformation. However, our members need to feel confident in the safety and efficacy of the COVID-19 vaccine candidates. To help physicians promote vaccine confidence among their patients and the general public, we must start now to provide information, education, and transparency around the FDA's process for authorization or licensure, as well as the standards by which FDA will review vaccine candidates and the clinical endpoints which the FDA hopes to achieve. New processes for continuous updates for physicians about the review process and any available safety and efficacy data must be in place as soon as possible so that we can ensure widespread education about vaccine candidates and promptly address questions or concerns raised by physicians. These efforts will be critical to ensure

The Honorable Stephen Hahn, MD

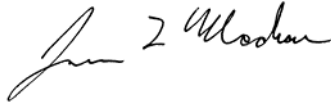
August 25, 2020

Page 2

vaccine literacy and acceptance amongst all demographics, and will be especially important to ensure vaccine education and acceptance among communities hardest hit by COVID-19, such as Black, Latinx, and Indigenous communities.

The AMA recognizes the difficulty of these unprecedented circumstances for federal regulators. We are exceedingly appreciative of the exceptional efforts of the agency towards transparency and communication in this space to date, as well as efforts to continuously engage with stakeholders throughout the course of this pandemic. **However, we strongly urge the FDA to work more closely with the physician community starting now to develop a plan for further education and transparency surrounding COVID-19 vaccine candidates.** We welcome the opportunity for further discussion on this critical issue and would like to request a conversation about how best to work together as soon as possible. Please do not hesitate to contact Shannon Curtis, Assistant Director, Federal Affairs at Shannon.Curtis@ama-assn.org, to schedule a time for further discussion or with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD