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October 2, 2020

The Honorable Alex M. Azar, II
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

On behalf of our physician and medical student members of the American Medical Association (AMA), I am writing to share our concern with recent comments from the White House regarding the Food and Drug Administration's (FDA) planned process for review and authorization of potential COVID-19 vaccine candidates. The AMA and its members are optimistic that a safe and efficacious vaccine will be available in the near future. However, we are also aware of significant and growing vaccine hesitancy both in members of the public and, for the first time, in physicians and other clinicians. **At a time when trust in our regulatory review process is of critical importance, it is essential that the Administration fully support the work of the career scientists at the FDA and that there not be attempts to override the FDA process for evidence-based review of these critically important vaccine candidates.**

The United States has unfortunately seen increasing vaccine refusal and hesitancy over the past several years. In many cases, this lack of confidence has surrounded established vaccines despite long track records of safe and effective use in the population. With vaccine hesitancy on the rise, as well as the ongoing spread of medical misinformation related to COVID-19, it should be of no surprise that there is even greater concern regarding the safety and efficacy of a vaccine developed through "Operation Warp Speed" in a much shorter time frame than we are used to seeing. While this reaction may not be completely unexpected from the general public, the AMA is concerned to see that many physicians are also beginning to have doubts about a potential COVID-19 vaccine. The speed at which the vaccines have been developed, along with a lack of currently available information about the safety and efficacy data, as well as comments from the White House suggesting they may seek to override FDA decision making on vaccine authorization, has physicians tremendously concerned that available vaccines may ultimately not meet our standards.

The AMA and its members remain incredibly hopeful that we will see one or more vaccine candidates licensed or authorized over the coming months. We have long trusted the FDA's dedicated career scientists and rigorous process for review to ensure the safety of the medical products we offer our patients. However, continued threats to prioritize speed to market over a thorough, evidence-based review with rigorous standards for safety and efficacy do nothing to ensure confidence in the vaccine candidates, even among physicians. If we are to start working towards putting an end to this global pandemic, we must have a safe and efficacious vaccine that enjoys broad uptake among the population. If our physicians

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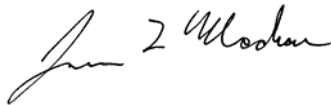
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are unwilling to recommend a vaccine and the general public is unwilling to seek out vaccination over concerns the process has been rushed, then we will have ultimately made no progress at all.

As we work towards availability of a COVID-19 vaccine that is safe and effective, **we strongly urge you to support the decision-making and review process of the career scientists and leaders at the FDA, however long that process make take, and to reassure the American people that any decision regarding authorization of a COVID-19 vaccine will ultimately be based on the results of the well-established process at the FDA.** We must ensure that our regulatory review process remains based on science and continues its long tradition of engendering trust in the products it approves. Without that trust, we will have nothing, and we will lose one of the best possible tools we may have to put an end to this terrible disease.

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 written in a cursive, flowing style.

James L. Madara, MD