SIDP | SOCIETY OF INFECTIOUS DISEASES PHARMACISTS

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Stephen M. Hahn, M.D.
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Peter Marks, M.D, Ph.D.
Director
Center for Biologics Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn and Director Marks,

The COVID-19 pandemic has negatively affected nearly all aspects of life in the United States. A vaccine that is effective in preventing COVID-19 infection and is safe across a broad population will be central to protecting the U.S. population from COVID-19 and allowing our country to regain a sense of normalcy.

As pharmacists we are confident in the U.S. Food and Drug Administration's (FDA) career expert scientists and the regulatory approval process for medications and biological products, including vaccines. These processes are in place to ensure the safety and efficacy of approved medications and biological products. Now more than ever, it is imperative these processes are followed to ensure the public's trust in the safety of vaccinations is not undermined, particularly given the reported public reluctance to pursue COVID-19 vaccination should a suitable vaccine become available. We support the recent announcement from nine pharmaceutical company CEO's stating they will submit for approval or emergency use authorization (EUA) only after demonstrating safety and efficacy of a COVID-19 vaccine through Phase-III clinical studies that are designed and conducted to meet requirements of expert regulatory authorities such as the FDA. However, we believe that the EUA process should be used rigorously, judiciously, and sparingly.

If preliminary Phase-III trial data are reviewed by the FDA, the FDA Vaccines and Related Biological Products Advisory Committee, and the Advisory Committee on Immunization Practices (ACIP), these data can be used to support regulatory approval (or an EUA) for COVID-19 vaccine in a limited population with appropriate risk-benefit considerations and labeling. While the FDA and its advisory committee will review the safety and efficacy of COVID-19 vaccine(s), clear guidance from ACIP on vaccine use in diverse populations will be paramount to a successful COVID-19 vaccine(s) launch. As such, we advocate for and offer the following recommendations:

- **A full assessment of COVID-19 vaccine(s) safety and efficacy data by FDA, the FDA Vaccines and Related Biological Products Advisory Committee, and ACIP, and that current efficacy and safety standards are met prior to widespread vaccine use in the U.S.**
- **COVID-19 vaccine safety and efficacy data are made publicly available for review**
- **ACIP recommendations for appropriate COVID-19 vaccine use are based on the data reviewed and included in the EUA guidance**

- **ACIP recommendations align with the COVID-19 vaccine distribution plan – and the distribution plan is sensible and ethical**
- **ACIP recommendations and FDA authorizations should be made based on the available evidence and should not be modified by those external to these public health and science-based agencies.**

Successful deployment of a rigorously studied, safe, and effective COVID-19 vaccine(s) is an opportunity to reduce vaccine hesitancy and counter anti-vaccination theories and disinformation. We cannot afford to prematurely rush regulatory approval of a COVID-19 vaccine. We need widespread confidence in COVID-19 vaccine safety and efficacy to ensure broad uptake by the healthcare community and the public. Failure to secure such confidence will impact not only the pandemic response but also overall faith in vaccines and their role in public health. Additionally, once a vaccine(s) is approved for use, we will need a sound infrastructure to distribute and administer vaccines to the public. To this end, we applaud the recent guidance by HHS to allow qualified pharmacists to vaccinate individuals as young as three years old. **We recommend pharmacists be an integral part of a subsequent mass COVID-19 vaccination program in the U.S.** and support the recent HHS guidance allowing pharmacists to administer COVID-19 vaccines when available.

Sincerely,

The Society of Infectious Diseases Pharmacists

About SIDP

SIDP is an association of pharmacists and allied healthcare professionals dedicated to promoting the appropriate use of antimicrobial agents. SIDP membership is comprised of 1,500 members in hospital, academic, industry, governmental organizations, and other practice settings across all 50 states and throughout the globe. The mission of SIDP is to advance infectious diseases pharmacy and lead antimicrobial stewardship in order to optimize the care of patients.

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