ACMT Supports a COVID-19 Vaccine Approval Decision Based on Establishment of Safety and Efficacy, Not Political Considerations

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As physicians with expertise in pharmacology, adverse drug effects, and public health we are familiar with the many benefits and rare risks of vaccination. A COVID-19 vaccine, when and if available, promises to become a key part of our multifaceted approach to address the current public health crisis. Vaccination has proven to be one of the most effective public health strategies in the United States and worldwide. The safety, efficacy, and cost effectiveness of our current vaccine regimen has contributed to the reduction of child mortality, near eradication of polio, and overall improvement of health and life expectancy. Our record of vaccine safety is a result of our methodical, stepwise vaccine development process.

The severity of the COVID-19 pandemic has resulted in unprecedented investment to accelerate the development, manufacture, and distribution of therapeutics, including vaccines. The major initiative, named “Operation Warp Speed”, is a multibillion-dollar public-private partnership to rapidly produce effective vaccines for COVID-19. Although vaccines have historically required many years for development, testing, and distribution, several vaccine candidates are already in late stages of clinical testing and seemingly poised for release.

The pace of vaccine development has raised global concern that the usual regulatory and safety regulatory mechanisms may be abbreviated or bypassed. Indeed, in China and Russia, COVID-19 vaccines have already been released despite limited safety and efficacy data. At the same time, several trials have been placed on hold as a result of safety concerns. There are ongoing concerns about how political considerations could influence regulatory decisions regarding a COVID-19 vaccine approval.

In order to expedite access, FDA has already signaled that a vaccine will initially be supported by issuance of an Emergency Use Authorization (EUA) rather than a formal approval.[1] The EUA has been used to provide access to hydroxychloroquine, which was ultimately demonstrated to be ineffective or even harmful for treatment of COVID-19. The decision to authorize hydroxychloroquine was largely perceived to be a result of political interference and had limited supportive data.[2] Although not as rigorous as a

formal approval standard, the guidance issued by FDA describes requirements exceeding what is typically needed for an EUA. For example, FDA has requested that before an EUA will be issued, COVID-19 vaccine studies should include a median follow-up duration of two months after completion of the vaccine regimen. FDA will also review cases of severe COVID-19 in trial participants to identify signs of enhanced disease severity associated with the vaccine and determine the appropriateness of continued study.

There is already substantial resistance to established vaccines in some populations, regardless of effectiveness and proven safety.[3] Because vaccination is voluntary, success of a COVID-19 vaccine program will depend on public trust and willingness to receive it. Therefore, it is imperative that the vaccine approval process is based on principles of medical science and free from political interference, both of which could affect the scientific integrity of and public confidence in the vaccine. The safety and efficacy of a vaccine to protect against COVID-19 must be established in clinical trials, with adequate post-marketing data prior to widespread use, and ongoing surveillance once released.

ACMT supports FDA authorization of a COVID-19 vaccine based on a prespecified threshold of efficacy in placebo-controlled clinical trials and sufficient follow-up data available to establish safety and efficacy.

American College of Medical Toxicology (ACMT)

Board of Directors

References

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