

Statement from the American Society for Microbiology On the FDA Guidance on EUAs for COVID-19 Vaccines

October 7, 2020

The American Society for Microbiology (ASM) strongly supports the Food and Drug Administration's (FDA) commitment to a science-based, data-driven, and transparent process for approving a COVID-19 vaccine. Adherence to the FDA's October 6 guidance on emergency use authorization for COVID-19 vaccines should be the minimum threshold for an approval process that puts safety and efficacy first, and requires review by experts on the Vaccines and Related Biological Products Advisory Committee. The pressure to bring a vaccine to market through the use of the emergency use authorization designation should not come at the expense of public health, safety and trust. Science, not politics, should drive these decisions.

A vaccine against SARS-CoV-2 is a key step in moving through and beyond this pandemic, which has claimed over 1 million lives worldwide and sickened millions more. The FDA's EUA guidance will help ensure that the public can have confidence that a vaccine not only works, but also is safe. Without a strong, evidence-based approach we run the risk that vaccination efforts will be futile and the extraordinary research and development work to develop a successful vaccine at a record pace will be wasted.

It is vital at all times, but especially during a public health emergency, that our nation's response lead with science and with the best data available. Our continued response to and successful recovery from the COVID-19 crisis depends on adherence to sound scientific and public health guidance from the experts, and time-tested, data-driven regulatory processes that prioritize safety and efficacy for medical countermeasures.

ASM reiterates our commitment to science and stringent regulatory processes that safeguard public health and ensure the American people can be confident in a vaccine that will protect them from COVID-19.

###

The American Society for Microbiology is one of the largest professional societies dedicated to the life sciences and is composed of 30,000 scientists and health practitioners. ASM's mission is to promote and advance the microbial sciences.

ASM advances the microbial sciences through conferences, publications, certifications and educational opportunities. It enhances laboratory capacity around the globe through training and resources. It provides a network for scientists in academia, industry and clinical settings. Additionally, ASM promotes a deeper understanding of the microbial sciences to diverse audiences.