STATEMENT

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Illinois Senate Health Committee
COVID-19 Vaccinations
February 11, 2021

America's biopharmaceutical companies continue to work tirelessly to develop ways to diagnose, prevent and treat those with coronavirus, building on their decades of experience with viruses such as SARS, influenza and HIV. Manufacturers are completing some development steps simultaneously, such as preparing for Phase 2 clinical trials during Phase 1 and preparing for manufacturing — making at risk investments — during Phase 3. Many companies began manufacturing vaccines and treatments before they were authorized or approved to ensure sufficient capacity to meet demand once authorized or approved. As a result, in less than a year's time since the virus was sequenced, as of January 21, 2021, the U.S. Food and Drug Administration (FDA) has approved one COVID-19 treatment and issued Emergency Use Authorizations (EUA) for two vaccines[1] [2]and multiple treatments.[3] Additional candidates for COVID-19 vaccines and treatments are currently being studied and advancing toward regulatory review.

Ensuring Vaccine Safety

The biopharmaceutical industry is committed to ensuring the highest of standards of research, clinical testing and manufacturing are upheld throughout the vaccine research and development process and post-approval. Extensive safety and effectiveness data have been collected from rigorous, large clinical trials — including the expectation that diverse populations are included[4] — and reviewed by FDA for the vaccines granted EUAs, and significant clinical development programs are underway for other vaccine candidates as well. In September, several major vaccine manufacturers publicly pledged to make the safety and well-being of vaccinated individuals the top priority in development of the first COVID-19 vaccines. The industry believes in a transparent review process of vaccine candidates by the FDA, including by the Agency's Advisory Committees.

Complementary to the robust R&D process, government regulators have constant access to the largest, most robust and sophisticated electronic safety monitoring system for vaccines and take the following critical steps to ensure ongoing vaccine safety and efficacy. Prior to granting approval and licensure, the FDA closely reviews data captured during each step of the

[1] https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19
[2] https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid
[3] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19
[4] https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMAPrinciples-of-Clinical-Trials-FINAL.pdf

development process, as well as information on how the vaccine is manufactured, to evaluate the safety profile and help ensure consistent purity and potency. The Centers for Disease Control and Prevention's (CDC) long-standing vaccine safety program closely monitors the safety of distributed vaccines. Data show that the U.S. vaccine supply is the safest in history, due in part to this program. One important element of the program, the Immunization Safety Office (ISO), monitors possible vaccine side effects and works with public health stakeholder to assess possible connects to vaccines. It is important to note, the current COVID-19 vaccines are held to the same regulatory standards for receiving EUAs and approvals as other medicines, and FDA has reviewed extensive clinical trial data for the vaccines granted EUAs.

Promoting Innovative and Diverse Clinical Trials

Clinical trials have long been a time-consuming part of the biomedical R&D process, due to the increasing complexity of clinical procedures and protocol designs as well as the high standards required to demonstrate the safety and efficacy of a potential treatment. Traditionally, participants in clinical trials are managed on-site at hospitals or clinics, which can create challenges to recruitment due to the need to travel to attend trial site visits for medical procedures and other activities related to their trial participation. But with COVID-19 prompting further utilization of and innovations in telehealth, some sponsors have adopted digital technologies to facilitate decentralized clinical trials, meaning patients are able to volunteer to participate remotely and are monitored using technology such as computers and cell phones. These tools can remove some of the practical barriers that can slow down recruitment and allow trials to recruit more rapidly. Clinical investigators are also able to use these digital tools to help reach a more diverse group of patients, helping clinical trials to be more reflective of the population that will eventually take their medicine if the trials are successful.

Providing Efficacious Vaccines to Save Lives

In the United States, 16 diseases are now preventable as a result of childhood vaccines.[5] Every day our scientists and researchers work in labs across the country developing new treatments and cures to help end debilitating diseases and alleviate human suffering. Our work against the pandemic continues as we conduct more research and develop additional medicines and boosters to fight new COVID variants that are appearing.

PhRMA appreciates the Committee's leadership and wants to thank members for their commitment to combat the pandemic and improve access to vaccines and treatments for all Illinoisans.

[5] https://www.cdc.gov/vaccines/vac-gen/10-shouldknow.htm