

The Biopharmaceutical Industry's Commitment to Ending the Pandemic and Building a More Resilient Health Care System

The COVID-19 pandemic has reaffirmed the value of science and the importance of a robust innovation ecosystem that drives scientific advances to the benefit of patients and society. Since the pandemic began, we have seen incredible progress in the fight against COVID-19. America's unique research and development (R&D) ecosystem provided the opportunity for the industry to quickly build on knowledge gained from decades of infectious disease to develop safe and effective treatments and vaccines for COVID-19 with unprecedented speed and efficiency.

Resilient health care systems have the depth, flexibility, and foresight to respond to emerging health challenges and provide equitable health care. This pandemic reinforces the need for a long-term vision and strategy to ensure a robust response to future public health threats including pandemics and other public health emergencies. Essential for responding to public health threats are globally diverse and resilient supply chains for biopharmaceuticals and other medical equipment, a strong public health and emergency preparedness infrastructure, and public policies that enhance the health care system's ability to respond quickly, whether due to a pandemic, an antibiotic-resistant superbug or other natural and public health disasters.

The biopharmaceutical industry remains committed to ending the current pandemic.

Biopharmaceutical companies have been working around the clock since the pandemic began to research, develop and deliver safe and effective therapeutics and vaccines to combat COVID-19. Enabled by the policy and regulatory framework that exists in the U.S., the industry has led in unprecedented fashion, with a historically high level of collaborations among and between manufacturers, and others in the health care system, in the U.S. and around the globe, to address this global health crisis. As new variants arrive, biopharmaceutical companies have continued to seek new partnerships and licensing agreements, enabled by intellectual property (IP) protections, to boost manufacturing capacity in an effort to meet global vaccine needs with more than 10 billion vaccines to be delivered globally this year.

The industry will continue to drive coordination, collaboration and joint problem-solving across the R&D, manufacturing and distribution ecosystem to fight the pandemic. Today, there are multiple treatments and vaccines authorized and approved for use by the U.S. Food and Drug Administration and global regulatory agencies for use against COVID-19, and one medicine is approved for the treatment of COVID-19. But none of this would have been possible without our unique innovation ecosystem that has made the U.S. a global bioscience leader founded on science-based policies that encourage the public and private sectors to play complementary roles in drug discovery and development.

Over the course of the pandemic, biopharmaceutical manufacturers and suppliers have ramped up manufacturing to unprecedented levels. Relying on their carefully built global supply chains, our industry has taken steps to safely and efficiently increase manufacturing capacity – even before therapeutics and vaccines were approved or authorized – in an effort to meet anticipated global demands of COVID-19. Biopharmaceutical manufacturers continue to identify manufacturing partners around the globe with the appropriate scientific, regulatory, quality control, and manufacturing expertise and to identify potential facilities that can be adapted to meet global vaccine manufacturing needs.

The United States competes with other countries that recognize the significant economic contributions of this R&D-intensive industry and which have continued to expand the financial and other incentives during the pandemic to attract and grow a robust biopharmaceutical

R&D and manufacturing presence. To continue to enhance U.S. manufacturing as part of our preparedness arsenal, we need public policies, such as tax and other targeted incentives, investments in a 21st century workforce, and IP and other policies that encourage public-private collaboration to foster continued investments in innovation, advanced manufacturing technologies and platforms in the U.S. and to increase U.S. global competitiveness.

As we look to the future, the biopharmaceutical industry's work to combat this public health crisis is not finished. The industry continues to advance new vaccine and treatment candidates, conduct research to assess the potential need for boosters and new therapeutic approaches, while also conducting additional clinical trials to expand access to additional pediatric populations.

Preparation for the next public health emergency is needed.

The COVID-19 pandemic has demonstrated that we need to strengthen our public health infrastructure to ensure we are well positioned to address future public health emergencies and other crises. Numerous studies have highlighted the need to create a robust, long-term national preparedness strategy at the local, state and federal levels and strengthen policies that bolster the capabilities of the health care system to prevent and respond to outbreaks and pandemics.

In order to successfully achieve these goals, we must modernize our existing data and reporting infrastructure at the local, state and federal levels, not only to support the response to the current pandemic but to enhance our ability over the longer term to detect, identify, model, track and mitigate emerging infectious diseases and needs in a natural disaster or other public health emergency. We must also improve our existing infrastructure to allow for collection of more complete demographic information, including race and ethnicity, to help better understand and address ongoing inequities in access to care.

Preparing for the next public health crisis also means we need to develop a clear long-term vision for the Strategic National Stockpile (SNS), the country's national repository of antibiotics, vaccines, chemical antidotes, antitoxins and other critical medical supplies. A successful long-term vision for the SNS will require clarifying its role and priorities and how it relates with other federal, state or local government pandemic response efforts. A vision that articulates the roles of federal, state, and local level actors and considers alternative approaches to ensuring supply chain continuity is needed to ensure we are better positioned to respond to a host of public health threats. Such approaches should consider creating incentives for maintaining on-demand or surge manufacturing capacity, supporting maintenance of additional stockpiles of certain supplies by manufacturers, and funding to support expansions to build new manufacturing facilities in the U.S.

Building a more resilient health care system also requires a recognition of the importance of globally diverse supply chains and the need to deepen our relationships with trading partners to support a coordinated global response in times of public health crisis.

Finally, we cannot be prepared for the next public health emergency without addressing the growing threat of antimicrobial resistance (AMR). The progress we've made over the last decade in successfully treating infectious diseases and pathogens is threatened by AMR. Unfortunately, the problem of increasing AMR has been exacerbated during the pandemic as COVID-19 patients battling secondary bacterial and fungal infections must use large amounts of antimicrobial medicines, which in turn increases the risk that subsequent infections become resistant to our dwindling arsenal of antimicrobials, thereby potentially increasing resistance rates around the world.

Comprehensive policy solutions are needed to help ensure a sustainable pipeline for new treatments; including advancing reforms to reduce payment incentives that discourage the appropriate use of antimicrobial medicines and those that create incentives to promote the development of new antimicrobial treatments and rapid diagnostics.

America's biopharmaceutical industry is committed to building on the lessons learned from the COVID-19 pandemic and working across health care system and with policymakers to advance public policies to further enhance the resilience of our health care system, to support the ongoing response to the current crisis, and ensure a robust preparedness infrastructure moving forward.