

PREPARING FOR TOMORROW'S PUBLIC HEALTH EMERGENCY

For more than two decades, Emergent has been hard at work helping prepare our nation and other allied countries in the event of a public health crisis. Through these many years of collaboration with the United States government to address public health threats, we have learned a great deal – what works, what doesn't, and what needs to be part of a public health preparedness plan.

In response to BARDA's recent request for information, Emergent has outlined some fundamentals critical to the development of flexible and effective public health emergency preparedness plans.

Sustainability – A robust commitment from the US government (USG) underpins the success of all future preparedness efforts. The US needs a bipartisan, comprehensive, and sustained effort around pandemic preparedness, and a comprehensive, unified biodefense budget. Adequate USG funding for pandemic preparedness is critically important to; 1) train and maintain a workforce that can be part of emergency response, 2) research and develop new treatments and countermeasures, 3) maintain and exercise sufficient manufacturing capacity, and 4) ensure the integrity of the supply chain, including appropriately managing the Strategic National Stockpile (SNS).

Strategy –The USG must provide strategic direction, coordination, and robust funding for preparedness, enabling the private sector to innovate and produce the tools at the necessary scale to effectively respond to a public health emergency (PHE). Public-private partnerships, along with the prior existence of appropriate incentives, sufficient investment in innovation, de-risking private sector investment to provide certainty and predictability, and government flexibility with regard to removal of regulatory barriers during a crisis, can create the conditions for the private sector to quickly respond to protect the American public.

Structure - Clearly defined leadership roles for pandemic preparedness within the government are needed at all times. A strong Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) with a reaffirmed mandate would enable the agency to deliver on its mission to advance preparedness and effectively deliver medical countermeasures (MCMs) in a sustainable manner. The recent National Academies of Science PHEMCE Review recommends an advisory committee incorporating the PHEMCE's private sector and non-federal partners and stakeholders, to help build collaborative solutions, enhance transparency and two-way communication, and identify and close gaps.

Skilled Workforce - The most effective response element to the COVID-19 pandemic is our talented and committed workforce. Government and industry need to invest in jobs and training to prepare for the next pandemic. Sustainable preparedness requires investment in the people who will manufacture the therapeutics, vaccines or MCMs that lead us out of a future PHE. Industry needs a qualified manufacturing workforce now and “bench strength” to meet surge requirements during a future PHE.

Standardization – Government-industry partnerships with multi-year contracts that are transparent, consistent, and certain can enhance industry's ability to build expertise and maintain and retain a skilled workforce and surge-ready facilities. The USG should share both short and long-term priorities openly with industry partners, continue to provide funding to support innovation, and help to sustain that workforce development and innovation over time. It is critical that the government create the market conditions, including certainty around the terms of arrangements with industry, for private sector engagement.

Speed - Harmonizing regulatory approaches, data requirements and secure information-sharing platforms across geographies is critically important in enabling faster access to medicines. While the FDA's Emergency Use Authorization (EUA) process functioned largely as intended to ensure safe and effective medicines were available for mass distribution as quickly as possible, the EUA process proved to be more complex and challenging when providing EUA to several manufacturing facilities. Issues of this nature could be managed through an emergency response framework expediting decisions by regulators.

Stockpile – The SNS must be equipped to respond to a wide variety of natural, accidental, or deliberate threats, including those threats that have effective response capabilities, and continue to serve its unique role in protecting the public. Policy measures should strengthen the SNS while ensuring MCMs are ready to address all public health risks, including creative contracting approaches that maintain MCM supplies on a rolling basis and providing the SNS with flexibility in procuring and distributing products in a timely manner.