

The Honorable Xavier Becerra  
Secretary of the Department of Health and Human Services  
The U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

**RE: Support for an FDA Emerging Pathogens Preparedness Program**

Dear Secretary Becerra,

We thank you for your leadership and contribution towards the United States' pandemic preparedness strategy. In light of the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA), we write to express our strong support for the FDA's proposal to create an Emerging Pathogens Preparedness Program within the FDA's Center for Biologics Evaluation and Research (CBER).

The FDA's [Summary of FY 2024 Legislative Proposals](#) puts forward a plan for an Emerging Pathogens Preparedness Program that would “defend against emerging pathogens so the agency is better positioned to respond to identified threats of concern and focus experienced resources to work quickly on medical countermeasure development.”

The increased regulatory capacity CBER provided to review COVID-19 vaccines was crucial to the success of Operation Warp Speed. According to Paul Mango's Warp Speed memoir, CBER director Peter Marks “restructured his team and its internal processes to work around the clock to accelerate the evaluations.” A permanent office within CBER to handle preparedness and response would enhance this capacity for future pandemics. The reauthorization of PAHPA offers the perfect opportunity to do so, by embedding the regulatory successes of Operation Warp Speed in a more sustainable way.

An IMF paper recently estimated that each day of the COVID-19 pandemic in 2020 and 2021 cost the U.S. economy \$26 billion.<sup>1</sup> The massive value of preventing or shortening pandemics makes it critical to prepare for “Disease X” – a future catastrophic biological risk that could in theory be far worse than COVID. This has led to proposals by the G7<sup>2</sup> and the Coalition for Epidemic

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<sup>1</sup>Baker, J., Chaudhuri, A., & Kremer, M. (2021). *Accelerating Vaccinations*. Finance & Development, 58(1).

<sup>2</sup>United Kingdom Cabinet Office. (2021). *100 Days Mission to Respond to Future Pandemic Threats*.

Preparedness Innovations<sup>3</sup> for a “100 Day Mission” to roll out vaccines and other countermeasures within a hundred days of the start of the next pandemic. To do this will require conducting early clinical trials on prototype vaccines against pathogen families with pandemic potential before an emergency occurs. These trials will need close supervision by the FDA and proactive guidance of how their data would be used in the event of a pandemic. Providing dedicated regulatory capacity at the FDA for this purpose is crucial to achieving these important goals.

Finally, a dedicated CBER office could be used to facilitate future programs in the model of Operation Warp Speed. By ensuring rapid regulatory decision-making for target product categories whose social value greatly exceeds their market value, the proposed office could build a “warm base” of regulatory capacity that could be drawn on in the event of an emergency. We have been excited to see the announcement of President Biden’s “Project NextGen.” Creating an office like the one described can ensure that the next generation of coronavirus vaccines receive the same regulatory capacity and accelerated development that was so crucial to vaccines approved during Operation Warp Speed.

The anticipated annual cost of an office to support the FDA’s proposed program is about \$10-15 million, but its value in supporting preparation and response for the next pandemic is immense. Merely providing 1% of Project Next Gen’s \$5 billion would ensure strong coronavirus vaccine review capacity for the next several years. Therefore the signatories below express our strong support for the program’s creation and funding.

Sincerely,

1Day Sooner

American Society for Microbiology

BIO

Coalition to Stop Flu

Critical Path Institute

Federation of American Scientists

Global Health Technologies Coalition

Infectious Diseases Society of America

Institute for Progress

International Vaccine Institute

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<sup>3</sup> Coalition for Epidemic Preparedness Innovations. (2022). *CEPI 100 Days Report: Building a More Prepared World to Stop Pandemics*.

Medical Countermeasures Coalition  
National Foundation for Infectious Diseases  
Research!America  
Technologies for Pandemic Defense

CC: Major General (ret) Paul Friedrichs  
Inaugural Director of the Office of Pandemic Preparedness and Response Policy (OPPR) and  
Principal Advisor on Pandemic Preparedness and Response.

CC: Ms. Dawn O'Connell  
Assistant Secretary for Preparedness and Response (ASPR).