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TO: Senator Patty Murray (D-WA), Senator Richard Burr (R-NC)
FROM: Institute for Progress
DATE: February 4, 2022
RE: PREVENT Pandemics Act discussion draft feedback

Thank you for undergoing the mountain of work required to craft such critical legislation. It is a testament to your leadership and dedication to preventing, preparing for, and responding to pandemics that you are doing this in a bipartisan fashion and with input from stakeholders. It's important to get it right and we are thoroughly grateful for the opportunity to provide our expertise.

We are very excited to see the introduction of the PREVENT Pandemics Act. The Institute for Progress is a non-partisan research and advocacy organization dedicated to accelerating scientific, technological, and industrial progress while safeguarding humanity's future and this is much needed legislation towards these goals.

The PREVENT Pandemics Act goes a long way towards preparing the United States to respond to existing viruses and emerging threats. Overall, the draft introduces many important policies for responding to future pandemics. However, there is more that can be done in preparing for, and, most importantly, preventing them. Increased focus on both development and implementation of countermeasures and early detection methods is needed. Further, the inclusion of measures to increase laboratory biosafety and biosecurity would help this bill achieve more of its ends.

Our recommendations are as follows:

Title II, Subtitle B - Ensure the establishment of a sustainable, nationwide, pathogen-agnostic genomic surveillance system

We were excited to see the inclusion of genomic sequencing in Sec. 212, however there needs to be a larger focus on developing and implementing this important technology. It is vital to learn about an outbreak as soon as possible in order to respond quickly. Early detection and action can keep an outbreak from becoming a pandemic.

- **Widen the scope of partners the CDC can work with**. The CDC and academic labs alone will not be able to establish a sustainable, nationwide, pathogen-agnostic genomic surveillance system. This will require partnerships with non-profit, private, and international entities, healthcare clinics, and clinically focused agencies like the Centers for Medicare & Medicaid Services and the Department of Veterans Affairs.

- **Ensure early detection via pathogen-agnostic testing.** Metagenomic sequencing will allow the CDC to detect any rapidly increasing novel pathogen rather than being limited to known threats. It is vital that the CDC focus on metagenomic technologies in order to detect the next pandemic.

- **Invest in expanding technology**. Further investment in the development of sequencing technology is critical for success. A core U.S. policy goal should be to improve the capabilities and decrease the cost of a sustainable surveillance system.

- **Increase funding to do it right.** The White House's Pandemic Preparedness plan estimates that a surveillance system would require $5.4 billion over the next decade. An appropriately funded surveillance system can detect and stop an outbreak. Every day counts in preventing an outbreak from becoming a

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pandemic and the more comprehensive the system, the smaller the outbreak will be at detection, and the smaller the cost of responding.

Title III - Research is insufficient: BARDA should drive development.

We support the increase in research funding and the focus on pathogens of pandemic potential, but this effort should be broader than preclinical research on medical countermeasures. BARDA has shown itself to be uniquely qualified for turning biological research into practiced countermeasures and this expertise is not fully utilized in the discussion draft.

- **Don't stop research at the preclinical stage**. Countermeasure research, development, and implementation should be pursued as far as is possible. This is especially important for platform technologies that may be crucial components of warm base manufacturing capacity.

- **Include nonpharmaceutical interventions**. Nonpharmaceutical interventions, such as personal protective equipment, disinfection, sterilization, and filtration, are effective against a broad range of potential pathogens and can be developed and implemented well before an outbreak. Nonpharmaceutical interventions should be further studied, optimized, and installed[1] – they merit a larger focus in this legislative effort.

- **BARDA should play a larger role**, either by:
    - increasing the commitment to the development of products, in partnership with BARDA, in existing sections, or;
    - including the **Disease X Act** introduced by Senator Baldwin in 2021

- **Increase the funding amount and duration.** The necessary research and development, as outlined in the White House's Pandemic Preparedness Plan, would require $45 billion in funding over 10 years. Sustained, substantial funding is necessary in order to obtain the high quality partnerships needed for success.This is the opportuntity to invest in a down payment towards this vision and establish a strong foundation.

Title V - FDA should be instructed to use EUA liberally and for public health[2]

We applaud the latitude granted to the secretary in 503(2)(D) to determine how to best expedite EUA, which will give the FDA the freedom to respond as the situation dictates. Similarly, we support the inclusion of expedited approval for platform technologies. However, given current FDA reluctance to utilize their already existing tools, we believe further Congressional guidance is necessary.

- **Include public health use and benefit** as a component of the FDA approval rubric and strongly weight this category, especially during a public health emergency.

- **Guide the FDA to use and revoke EUA** to get products to market quickly, even with limited evidence or marginal efficacy, and remove the products once there are better, more plentiful alternatives.

[1] Just as many buildings are required to have sprinkler systems to prevent a fire, they should be required to have air filtration or sterilization systems to prevent disease transmission.
[2] For more on this point, see Nikki Teran, "Taking emergency use authorization seriously," *Institute for Progress*, Jan. 27, 2022. https://progress.institute/taking-emergency-use-authorization-seriously/

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- **Implement emergency regulatory reciprocity** to allow for products approved by a foreign regulatory body with standards comparable to the FDA's to be sold in the United States before EUA. This could provide an alternative solution for reacting quickly to a pandemic threat while maintaining a high standard for EUA.

Reform biosafety and biosecurity

Safe, efficient labs will be critical to quickly responding to a pandemic threat. The United States needs to understand what laboratory resources exist and ensure they are capable of carrying out the research needed to understand a pathogen and prepare countermeasures.

- **Establish an independent commission** to oversee, regulate, and provide evidence-based tools and standards for laboratories to safely conduct research with pathogens.

- **Allow for regulatory authority** over all pathogen research. Currently, compliance with biosafety standards are voluntary for privately funded research and work with risky pathogens can occur with no oversight.

- **Increase oversight and transparency of risky research**. Independent security experts should be involved in decisions around high-risk research to ensure that the scientific findings of an experiment warrant the risk of conducting it. Safer alternatives should be implemented wherever possible.[3]

- **Transfer the Select Agent Program** to the independent biosafety commission and reform regulations to conform with a risk-based, rather than list-based approach. The list-based approach does not provide the flexibility needed to regulate novel pathogens which, by their nature, are unlikely to be on the previously constructed and relatively short list. Current protocols are also so strict that they may impede research and response in a pandemic. The commission, with its focus on ensuring safe handling of pathogens, would be better suited for balancing these tradeoffs.

Thank you for considering our recommendations. We are happy to answer any questions about these or other components of the draft. We share a united goal: ensuring that the United States can prevent, prepare for, and respond to all pandemic threats and are looking forward to working together in the future.

[3] Experiments on a single part of a pandemic pathogen may produce the same knowledge as an experiment with the entire, infectious pathogen, and should be favored.