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The Honorable Patty Murray
Chair, Committee on Health, Education, Labor, and Pensions United States Senate
Washington, DC 20510

The Honorable Richard Burr
Ranking Member, Committee on Health, Education, Labor, and Pensions United States Senate
Washington, DC 20510

Dear Chairwoman Murray and Ranking Member Burr:

We at Boston University's (BU) Center for Emerging Infectious Diseases Policy and Research (CEID) strongly support your efforts to improve the nation's public health and medical preparedness and response programs in the wake of the COVID-19 pandemic. We appreciate the opportunity to provide input on these critical topics. CEID's core mission is to improve resilience against the threat of emerging & epidemic infectious diseases worldwide through transdisciplinary research, global and local capacity strengthening, training, generating evidence for policy support, and community engagement. Alongside our sister institute, National Emerging Infectious Diseases Laboratories (NEIDL), BU's maximum containment research program, we work to improve global response to these threats.

CEID's faculty bring decades of experience responding on the frontline of emerging infectious outbreaks, running biocontainment patient care units, leading national special pathogens research networks, codirecting Geosentinel Surveillance Network, running national and international public health and pandemic preparedness programs, and providing input to our national's research, public health, research and biosecurity agencies.¹

In the aftermath of the 2013-2016 Ebola Virus Disease epidemic, the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response supported the creation of a nationwide regional treatment network for Ebola and other special pathogens, providing funding for readiness to a limited number of healthcare facilities as either frontline, assessment or specialized treatment centers.² Despite the success of this effort in improving infection control and treatment readiness for the care of a small number of patients with highly communicable infections at the involved facilities, we believe the COVID-19 pandemic has revealed gaps in our national response strategy.³

These are the strategies and recommendations that can address these gaps and further the goal of pandemic preparedness.

1) Create a “warm base” research and clinical trial infrastructure

We must invest in a unified national clinical trials infrastructure which can quickly be funded and employed during outbreaks to identify effective medical treatments and reduce patient harms as well as marginal costs of widely deploying unproven drugs. Below, we share strategies that can further the goal of preparedness in these areas.

During emerging infectious diseases outbreaks and the early days of a pandemic, response capabilities can be hampered by limited understanding of the pathogen and little objective data on clinical progression and optimal supportive care. Recent outbreaks, epidemics, and the COVID-19 pandemic have shown the importance of early identification of effective countermeasures to both improve patient outcomes and also to mitigate the impact of an outbreak or pandemic.⁵ These emergencies have underscored the importance of an integrated system that allows for rapid conduct of research across large and diverse populations.⁶ The RECOVERY Trial network in the United Kingdom, which benefits from common healthcare infrastructure of National Health Service (NHS), was able to rapidly deploy large trials which helped shape medical care of COVID-19 patients worldwide.⁷

In the absence of a nationalized healthcare system, the US has to invest in similar capability through other inter-connected systems. Clinical trials networks such as the National Institute of Health’s Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership and Adaptive COVID-19 Treatment Trials have demonstrated the value of such clinical trial infrastructure.^{8,9} However, much of the work must be conducted outside of the emergency setting.

We propose that the federal agencies:

- **Identify sustainable funding needed for the further development and maintenance of a “warm base” that establishes research infrastructure, which can then be activated quickly during emergencies.** Such leg work involves exploring common patient data elements that can be collected from sometimes disparate electronic health records, creation of umbrella human subjects protocols, staff training, creation of patient clinical sample biorepositories and strengthening the regulatory environment across institutions and with federal and state public health partners regarding sample and data sharing. These activities may appear too granular, but they are the hurdles which have time and again undermined our public health research response capability during pandemics.

A system such as this can expedite the evaluation of approved drugs that can be repurposed in the use of new infectious diseases and investigational drugs that need to be stewarded from preclinical studies through clinical trials emergently before use. Rapid deployment of trials and operational research ensures patient safety is prioritized and patient rights are protected during deployment of off-label and investigational use. Unified research methodology and preexisting research partnerships can ensure that patients are rapidly recruited, and drug and safety efficacy questions are quickly answered, thus saving lives, improving outcomes, protecting the healthcare system, and reducing the cost of medical countermeasure development.

2) Create and incentivize pandemic preparedness metrics for healthcare facilities

We need to be better prepared to not only provide technical depth of care for sporadic patients with high-consequence pathogens (e.g. Ebola Virus Disease, Lassa Fever) but also have the readiness to respond and support expansion of services to a large influx of patients due to epidemic prone novel respiratory viruses.⁴ Such readiness can be achieved by creating widely accepted metrics and related incentives for pandemic preparedness of healthcare facilities.

Unlike other nations, public health in the U.S. exists in the public sector whereas most of healthcare is in the private sector. Creating a unified plan for preparedness requires the creation of incentives and the identification of sustainable support that allows the private healthcare industry to invest in a continuous level of readiness through training of staff, updating of standard operating procedures and stockpiling of required supplies. Recently, the US Health and Human Services Office of Inspector General found that the authority of the Centers for Medicare and Medicaid Services (CMS) is not sufficient for it to fulfill its responsibility to ensure that accredited hospitals would maintain quality and safety during an emerging infectious disease emergency. Furthermore, the organization could not determine that all accredited hospitals updated their emergency preparedness plans during the COVID-19 pandemic.¹⁰

We believe the federal government should:

- Work with public health and healthcare institutions to **evaluate how US public and private accreditation and certification organizations such as Joint Commission and CMS can add metrics to evaluate pandemic readiness** for private and public health organizations.¹¹
- **Create incentives through CMS payments for private and public health organizations to refresh pandemic preparedness plans** and identify logistics, resources and healthcare staffing plans. Such plans would provide a roadmap for private insurers who are also looking to build resilience against patient surges during outbreaks.
- **Reduce the need to employ crisis standards of care by improving individual healthcare system resilience in emergencies.** This could be accomplished through the facilitation of improved regional partnerships, novel approaches to preparedness and response, and incentivizing public/private healthcare partnerships.

3) Promote public health and healthcare workforce readiness and resilience for emerging infectious threats

We believe the nation's public health work force will benefit immensely from programs aimed at sustained special pathogens occupational training, and those that provide mental health services for recovery during and after outbreaks.

Healthcare workers often bear a disproportionate burden of disease during outbreaks due to their occupational risk. Maintaining special pathogens infection control training and readiness can instill confidence and decrease exposures and illnesses among those at our nation's healthcare

frontlines.¹² Additionally, public health and healthcare worker response during outbreaks also carries social and mental health burden.¹³ We need to improve the mental support who provide to healthcare workers during and after this crisis and in place for future emergencies.

We recommend that federal agencies:

- **Identify sustainable federal funding support for healthcare facilities to incorporate pandemic preparedness and maintain readiness through annual refresher training, education, drills and exercises for hospitals.** There are over 6,000 hospitals in the United States with a highly variable state of readiness for infectious disease outbreaks. Dr. Syra Madad, a faculty member at CEID, led one of the nation's first comprehensive Region 2 Frontline Hospital Special Pathogens Training Program in 2018-2019 which revealed over half of participants never previously attended a hospital-sponsored special pathogen training before.¹⁴ Preparing for and maintaining readiness for an emergency that does not yet exist is difficult for healthcare leaders to invest in. By incorporating sustainable funding specifically for pandemic preparedness, healthcare delivery sites can continue to maintain a state of readiness.
- **Create and fund more programs for emotional and psychological support for frontline healthcare workers and public health workers during and after outbreaks.** Healthcare and public health workers work tirelessly during all phases of an outbreak – from preparedness, response to recovery and have reported higher rates of mental illness (e.g., anxiety, depression, PTSD, and suicidal ideation) compared to the general population. One recent study showed that up to 30% of COVID-19 frontline healthcare workers suffered from traumatic stress, depression, anxiety, alcohol use and insomnia.¹⁵ A 2021 survey of public health workers revealed 53% of the respondents had at least symptom of a mental health condition.¹⁶ Human resources are an important asset to tackling any new pathogen and providing support for recovery for health workers will ensure their ability to continue to provide general healthcare and return to support the response to a future crisis. After the September 11, 2001 terrorist attacks, the World Trade Center Health Program was created with funding from CDC, which in part covered mental health services for first responders involved in that crisis.¹⁷ Our nation's frontline health workers have suffered sustained trauma over the course of the COVID-19 pandemic. We need a similar program for their recovery.

4) Promote community centered pandemic planning

We need to improve equity in distribution of care during health emergencies through community involvement in pandemic planning. To achieve a better understanding of the fault lines that cause some populations to suffer disproportionate burden during health emergencies, we believe all pandemic planning must include at least community representation, and ideally community-centered governance.

From polio to Ebola Virus Disease, successful outbreak responses have integrated community input and sought stakeholder collaboration.^{18,19} However, community involvement is often not as integrated

in pandemic preparedness planning or outbreak response, particularly here in the United States.^{20,21} Outbreaks often affect already marginalized communities and worsen health inequities. Involving community organizations and patient representative groups in pandemic planning through their integration at the policy, as well as healthcare-network level, can provide various advantages.

The Biden Administration took an important role in furthering these efforts by integrating community health workers from heavily affected communities in COVID-19 response.²² We believe this investment should continue and a core reserve of community health workers should be maintained to forward public health activities in minoritized communities.

Federal and state governments can promote further community engagement by:

- **Seeking community organizations' input and partnership on pandemic preparedness programs conducted by state and local public health authorities.** Insights from community organizations (particularly those representing Black Indigenous and Other People of Color (BIPOC)) will lead to identification of "fault lines" that allow hazards to become disasters in underserved communities. Further, it can lead to effective and equitable response strategies *led* by stakeholders who are community leaders, members, and representatives. Additionally, such engagement will create greater accountability to ensure investment in preparedness measures and promotion of data transparency.
- **Requiring representation from patient and community organizations in key pandemic preparedness and research activities that are federally funded by private organizations.** Engagement of the community by private organizations and research institutions working on pandemic preparedness will promote trust before crises occur, leading to more meaningful partnerships during response. It will allow organizations working in the sector to identify and engage trusted communicators prior to emergencies and foster partnerships that lead to effective information dissemination during fast moving public health emergencies with evolving scientific knowledge, inoculating against disinformation and misinformation. Global experience also shows that community involvement in preparedness can incentivize early detection and reporting of clusters of cases with infections of interest. Lastly, requiring community representation in large research enterprises in the field of emerging infectious diseases response will improve the participation of community members in research and knowledge generation, and thereby increase trust in vaccines and treatments.
- **Creating consortia of legislative, community and public health organizations that meet regularly to provide input on recovery from the COVID-19 pandemic and discuss how lessons of this pandemic can be applied to create more resiliency for tomorrow.** Such coalitions will allow work to continue on the "long tail" of recovery, or management of the persistent of medical, social and economic challenges that exist after the current pandemic, ensuring community needs are met. It will also allow a real time feedback loop during future epidemics to better aid public health policy and provide a venue for input in "post hoc" analysis after future health emergencies.

Thank you again for your efforts to improve the resilience of our nation's healthcare system against threats of emerging and epidemic infections. We welcome the opportunity to expand on the

information we have provided above and serve as a resource to you as you continue these efforts. Please feel free to contact us with any questions.

Sincerely,

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References

1. Center for Emerging Infectious Diseases Policy and Research. Faculty Bios. 2021. www.bu.edu/ceid
2. Office of the Assistant Secretary for Preparedness and Response. Regional Treatment Network for Ebola and Other Special Pathogens. 2017. <https://www.phe.gov/Preparedness/planning/hpp/reports/Documents/RETN-Ebola-Report-508.pdf>
3. Flinn JB, Hynes NA, Sauer LM, Maragakis LL, Garibaldi BT. The role of dedicated biocontainment patient care units in preparing for COVID-19 and other infectious disease outbreaks. *Infect Control Hosp Epidemiol* 2021;42:208-11. <https://www.ncbi.nlm.nih.gov/pubmed/32883382>
4. Bhadelia N. Coronavirus: hospitals must learn from past pandemics. *Nature* 2020;578:193. <https://www.ncbi.nlm.nih.gov/pubmed/32047315>
5. Bhadelia N, Sauer L, Cieslak TJ, et al. Evaluating Promising Investigational Medical Countermeasures: Recommendations in the Absence of Guidelines. *Health Secur* 2019;17:46-53. <https://www.ncbi.nlm.nih.gov/pubmed/30724616>

6. Lurie N, Keusch GT, Dzau VJ. Urgent lessons from COVID 19: why the world needs a standing, coordinated system and sustainable financing for global research and development. *Lancet* 2021;397:1229-36.<https://www.ncbi.nlm.nih.gov/pubmed/33711296>
7. Mullard A. RECOVERY 1 year on: a rare success in the COVID-19 clinical trial landscape. *Nat Rev Drug Discov* 2021;20:336-7.<https://www.ncbi.nlm.nih.gov/pubmed/33864035>
8. National Institutes of Health. Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) 2021.<https://www.nih.gov/research-training/medical-research-initiatives/activ>
9. National Institutes of Health. Fourth iteration of COVID-19 treatment trial underway2021.<https://www.nih.gov/news-events/news-releases/fourth-iteration-covid-19-treatment-trial-underway>
10. US Health and Human Services Office of Inspector. CMS's Controls Related to Hospital Preparedness for an Emerging Infectious Disease Were Well-Designed and Implemented but Its Authority Is Not Sufficient for It To Ensure Preparedness at Accredited Hospitals2021.<https://oig.hhs.gov/oas/reports/region2/22101003.asp>
11. Berwick DM, Shine K. Enhancing Private Sector Health System Preparedness for 21st-Century Health Threats: Foundational Principles From a National Academies Initiative. *JAMA* 2020;323:1133-4.<https://www.ncbi.nlm.nih.gov/pubmed/32207806>
12. DiLorenzo MA, Baker CA, Herstein JJ, et al. Institutional policies and readiness in management of critical illness among patients with viral hemorrhagic fever. *Infect Control Hosp Epidemiol* 2021:1-6.<https://www.ncbi.nlm.nih.gov/pubmed/33583468>
13. Serrano-Ripoll MJ, Meneses-Echavez JF, Ricci-Cabello I, et al. Impact of viral epidemic outbreaks on mental health of healthcare workers: a rapid systematic review and meta-analysis. *J Affect Disord* 2020;277:347-57.<https://www.ncbi.nlm.nih.gov/pubmed/32861835>
14. Tolf E, Madad S. Interactive, Hands-On Training for Hospital Workers Increases Level of Special Pathogen Preparedness. *Sci* 2021;3:29.<https://www.mdpi.com/2413-4155/3/2/29>
15. Wright HM, Griffin BJ, Shoji K, et al. Pandemic-related mental health risk among front line personnel. *J Psychiatr Res* 2021;137:673-80.<https://www.ncbi.nlm.nih.gov/pubmed/33189356>
16. Bryant-Geneviev J, Rao CY, Lopes-Cardozo B, et al. Symptoms of Depression, Anxiety, Post-Traumatic Stress Disorder, and Suicidal Ideation Among State, Tribal, Local, and Territorial Public Health Workers During the COVID-19 Pandemic - United States, March-April 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:947-52.<https://www.ncbi.nlm.nih.gov/pubmed/34197362>
17. CDC. World Trade Center Health Program.<https://www.cdc.gov/wtc/conditions.html>
18. Anoko JN, Barry BR, Boiro H, et al. Community engagement for successful COVID-19 pandemic response: 10 lessons from Ebola outbreak responses in Africa. *BMJ Glob Health* 2020;4.<https://www.ncbi.nlm.nih.gov/pubmed/32816819>
19. Perry HB, Solomon R, Bisrat F, et al. Lessons Learned from the CORE Group Polio Project and Their Relevance for Other Global Health Priorities. *Am J Trop Med Hyg* 2019;101:107-12.<https://www.ncbi.nlm.nih.gov/pubmed/31760974>
20. Adalja AA, Sell TK, Bouri N, Franco C. Lessons learned during dengue outbreaks in the United States, 2001-2011. *Emerg Infect Dis* 2012;18:608-14.<https://www.ncbi.nlm.nih.gov/pubmed/22469195>
21. Alberti PM, Lantz PM, Wilkins CH. Equitable Pandemic Preparedness and Rapid Response: Lessons from COVID-19 for Pandemic Health Equity. *J Health Polit Policy Law* 2020;45:921-35.<https://www.ncbi.nlm.nih.gov/pubmed/32464654>
22. The White House. FACT SHEET: Biden Administration Announces Historic \$10 Billion Investment to Expand Access to COVID-19 Vaccines and Build Vaccine Confidence in Hardest-Hit and Highest-Risk Communities2021.<https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/25/fact-sheet-biden-administration-announces-historic-10-billion-investment-to-expand-access-to-covid-19-vaccines-and-build-vaccine-confidence-in-hardest-hit-and-highest-risk-communities/>