

The Honorable Bernie Sanders  
Chairman  
Committee on Health, Education, Labor, and  
Pensions  
United States Senate  
Washington, DC 20510

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

March 29, 2023

Dear Chair, Ranking Member, and Members:

The Robert J. Margolis, MD, Center for Health Policy at Duke University (“Duke-Margolis” or “the Center”) appreciates this opportunity to provide comments and recommendations ahead of anticipated reauthorization of the *Pandemic and All-Hazards Preparedness Act (PAHPA)*. This important legislative vehicle is a vital next step in renewing our shared national commitments to not only disaster preparedness and response, but also to a host of challenge areas in antimicrobial stewardship, supply chain and manufacturing capabilities, national security, and the future of public health and health care coordination. The Center applauds this committee and their counterparts in the United States House of Representatives for advancing it.

The recommendations provided herein are based on longstanding research, analysis, and engagement efforts at the Center that span a number of our portfolios. Comments related to bacterial threats and antimicrobial resistance stem from collaborations and reports in our [Drug-Resistant Infections and Antimicrobial Resistance](#) portfolio. Recommendations on supply chain readiness and manufacturing capacity are the basis of our newly-launched [Drug Supply Chain Resilience and Advanced Manufacturing Consortium](#). Many of these comments are also rooted in the last three years of significant [COVID-19 response policy work](#) undertaken by the Center and its policy team – work that is actively being fed forward into a new strategic portfolio centered on [21<sup>st</sup> Century Public and Population Health](#) reforms.

Our team is also submitting a joint comment letter with the Healthcare Leadership Council (HLC) representing our two organizations’ ongoing work in the disaster response and preparedness space. This work has been inclusive of [a cornerstone report](#) issued in February 2021 outlining a broad set of recommendations for improving data and evidence generation, strengthening innovation and supply chain readiness, and advancing resilient care delivery approaches – all to support sustained and equitable response to current and future health-related disasters. Duke-Margolis and HLC are actively refining an updated set of recommendations in this space to be published this spring.

Across these portfolios and policy efforts, Duke-Margolis synthesizes insights generated from robust stakeholder engagement and convening with evidence from multidisciplinary research and analysis to put forward actionable, bipartisan policy recommendations. Our team stands ready to work with you and your staff on these issues or any other issues of strategic importance to HELP and the nation in the coming weeks and months.

Sincerely,

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## Program Effectiveness

What specific changes could Congress make to improve the efficiency and effectiveness of current HHS programs and activities? Specifically:

### Public Health Emergency Coordination and Policy

1. The responsibilities and authorities of the Secretary of Health and Human Services (HHS) prior to or during a public health emergency (PHE)

*Congress should direct HHS to create a new “Drug Supply Chain Lead” who is responsible for creating and coordinating solutions that work towards a goal of 1) building resilient supply chains for essential medicines and 2) ending essential medicine shortages. Authorities that should be considered for this position include:*

- 1) *Coordinating relevant efforts ongoing within ASPR, FDA, CMS, VA, DOD, and other agencies.*
  - 2) *Developing standards and best practices to promote sustainable private sector contracts (e.g. between manufacturers and GPOs/PBMs) while accounting for proprietary and commercial concerns. Example standards topic areas include manufacturer supply chain data reporting to a trusted third party that would translate ratings to GPOs/PBMs, GPO/PBM supply chain risk evaluations and stress tests, etc.*
  - 3) *Empowering organizations such as NGOs or public-private partnerships to assess private sector achievement of sustainable private sector contracting standards.*
  - 4) *Administration of an “Essential Medicine and Domestic Manufacturing Supply Chain Relief Fund” aimed at avoiding essential medicine discontinuations [such as this one](#).*
2. The authorities, duties, and functions of the Assistant Secretary for Preparedness and Response (ASPR)
    - 1) *ASPR’s mission should be expanded to include securing supply of a broader set of essential medicines, not just medical countermeasures.*
      - a. *The FDA Essential Medicines List is a good starting point, but also too focused on pandemic and terrorism threats.*
      - b. *Recommend using the [Vizient Essential Medicines List instead](#). This list is patient impact based rather than threat based.*
    - 2) *ASPR’s scope, and specifically the Industrial Base Management and Supply Chain (IBMSC) office, should be expanded to cover potential supply chain threats such as geopolitical, manufacturing quality, manufacturer financial issues, demand surges, etc. Systemic drug supply chain issues are pervasive and ongoing even outside of emergency situations, and hinder emergency response capabilities.*
      - a. *Currently too focused on pandemic and terrorism disasters.*

- b. *Some risks are so ingrained in medical supply chains that lack of availability occurs from events that would not typically register as “disasters”.*
- 3) *ASPR should play a critical role in the work of the “Drug Supply Chain Lead” mentioned above, using federal grants and contracts to support more secure supply chains and coordinating with other agencies to utilize additional policy options at the government’s disposal.*
3. The National Health Security Strategy (NHSS)

*The NHSS implementation plan for Strategic Goal #3: “Ensure a resilient and sustainable public health industrial base and supply chain” should include a study that identifies the top key starting materials (KSMs) and active pharmaceutical ingredients (APIs) for essential drugs, with options for onshoring or nearshoring (assuring robust access to) production for these KSMs and APIs. The [Duke-Margolis Drug Supply Chain Resilience Consortium](#) has convened experts with the capability to perform this analysis.*

4. The National Advisory Committees on Children and Disasters, Seniors and Disasters and Individuals with Disabilities and Disasters

#### Medical Countermeasures Development and Deployment

1. The Strategic National Stockpile (SNS)

*FDA and DOD should be directed to create a report on the Shelf Life Extension Program (SLEP) that 1) reports on findings from the program and 2) assess what it would cost to provide long-term stability data on every drug that is included in the SNS. Stability testing should be designed to support labeling the drugs with the longest feasible expiration dating.*

2. The Biomedical Advanced Research and Development Authority (BARDA)
3. Project BioShield

*Antibiotic manufacturing, particularly API and intermediate manufacturing, is highly concentrated in Asia, representing a risk to the domestic supply of antibiotics during global health threats or geopolitical conflicts. Congress can direct BARDA to leverage Project BioShield to advance domestic antibiotic manufacturing capacity and additional sources of reliable manufacturing. Doing so can mitigate the risk that that natural disasters or foreign adversaries unexpectedly restrict access to critical antibiotic medicines.*

4. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and related strategy, implementation plan, and budget plan

*Currently, the ASPR secures supplies of medical countermeasures with biothreat indications according to the Public Health Emergency Medical Countermeasures Enterprise's (PHEMCE) procurement strategy. However, policymakers ought to expand PHEMCE's procurement strategy to include high-impact novel antibiotics effective against drug-resistant infections and bacterial infections with the potential to surge during viral pandemics.*

5. Emergency Use Authorizations and related authorities
6. The Public Readiness and Emergency Preparedness (PREP) Act
7. The Material Threat Medical Countermeasures Priority Review Voucher Program

#### Support for Jurisdictional Preparedness and Response Capacity

1. The Public Health Emergency Preparedness (PHEP) Cooperative Agreements
2. The Hospital Preparedness Program (HPP) Cooperative Agreements
3. The National Disaster Medical System (NDMS)
4. The Medical Reserve Corps (MRC)
5. The Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP)
6. Epidemic Intelligence Service (EIS) Loan Repayment Program
7. The Epidemiology and Laboratory Capacity Cooperative Agreement Program and related activities, including mosquito abatement
8. Biosurveillance and Public Health Situational Awareness

*The 2019 reauthorization of PAHPA required HHS to develop a real-time electronic nationwide public health situational awareness and biosurveillance network. Biosurveillance is needed for early detection of emergent pathogens to facilitate effective development, manufacturing, and deployment of vaccines, tests, treatments, and other products. As documented in a recent Government Accountability Office report, HHS has failed to follow through with many of the*

*2019 PAHPA requirements. The lack of an active biosurveillance network hindered the Covid-19 pandemic response.*

*Despite the lack of a nationwide strategy for biosurveillance, the US has enhanced environmental and clinical biosurveillance, as a result of the numerous molecular, antigen, and other diagnostics that received emergency use authorization during the Covid-19 pandemic.*

*With improving availability of timely and reliable diagnostic tests for emerging threats of all types, and the availability of interoperable electronic record systems, biosurveillance capacity increasingly depends on academic centers, commercial labs, and other health care facilities for both timely detection and intervention (“test to treat”). By leveraging health care data systems, limited funding for automated, standardized, timely information on pathogens can quickly provide needed surveillance information. Limited but important additional funding could support innovative and low-cost detection mechanisms through sampling of wastewater and air in communities and high-risk settings. Support for efficient, effective, and non-burdensome surveillance mechanisms using new diagnostics and detection technologies was an important takeaway from a recent Duke-Margolis multi-stakeholder workshop for a project on policy solutions to facilitate effective transmission reduction of infectious diseases. Duke-Margolis would be glad to provide additional information on innovative environmental and clinical surveillance mechanisms that can detect an emergent pathogen to inform public health responses using limited additional resources.*

9. Vaccine tracking and distribution
10. Policies for the inclusion of at-risk individuals in public health emergency preparedness and response activities

#### Gaps in Current Activities & Capabilities

1. What gaps do you see in the PAHPA framework, or how it has been implemented to date? (These gaps could be related to any of the programs noted above, or other aspects of the public health and medical preparedness and response ecosystem that are otherwise currently unaddressed.)

*The PAHPA framework would benefit from a program for timely evaluation and use of repurposed drugs. In the context of an emerging infectious disease threat, drug repurposing (using an already approved drug for a new indication) is the best option for rapidly identifying and developing potential therapies to treat or reduce severity of the disease. Use of already approved drugs will be the first line of defense in the healthcare setting when a new threat emerges, and it is critical to develop evidence that can answer questions about the safety and efficacy of these products against the pathogen/disease. Drug repurposing was used for COVID-*

19 and informed the use of drugs such as dexamethasone and baricitinib. However, these efforts took time to implement and would have benefited from greater cross-government and private sector coordination.

While ASPR has taken steps to identify priority agents likely to have effect against major known types of emerging pathogens, there is currently no program or office within government that has responsibility for a) establishing and implementing an advance research agenda to identify available drug options for repurposing against potential threats; b) building cross-sector partnerships (e.g., academic researchers, industry, etc.) to establish a network that is willing and capable to participate in drug repurposing efforts; c) implementing drug repurposing evaluations rapidly in frontline settings in a public health emergency (potentially building on existing frontline clinical research platforms); and d) assuring adequate funding for an effective drug repurposing strategy. Establishing a program or formally assigning responsibility for such an effort to an existing program could address the challenges faced with recent repurposing efforts and should be considered in the PAHPA reauthorization. Duke-Margolis convened a meeting with cross-sector stakeholders on this topic and can provide additional detail on implementing such a program.

The current PAHPA framework is also missing a national strategy to use existing and emerging diagnostic and therapeutic technologies to contain or stop transmission of infectious diseases. Disease transmission places a heavy burden on the health care system, as well as workplaces, schools, businesses, and individuals. While the PAHPA framework includes important elements on vaccine and drug development, public health preparedness, medical surge capacity, and national leadership, these programs have not yet been updated to reflect emerging opportunities to use innovative products to contain the spread of disease.

Current vaccines, tests, and treatments have largely been developed, paid for, and implemented with a focus on benefit to individuals, particularly those at-risk for severe disease. But rapid diagnostic tests including over-the-counter tests, more effective therapies, and vaccines in development (e.g., intranasal vaccines) could also significantly enhance transmission prevention not just severe illness. There is an opportunity to leverage experiences with using current medical products and technologies—in combination with next-generation products that target transmission—to better align public health priorities, clinical care resources, and OTC tests to increase containment. Duke-Margolis is actively working on a project to identify regulatory, reimbursement, and implementation policies that can form a national strategy to reduce transmission of infectious diseases. A recent multi-stakeholder workshop covered gaps in existing regulatory and reimbursement frameworks, while considering use cases for medical and non-medical products that have an individual and public health benefit. Planned future activities include follow-on working meetings, a report detailing a national strategy to reduce transmission, and a public meeting to present the national strategy.

2. Additionally, aside from currently authorized programs and activities, what gaps exist in HHS' capabilities, and what types of activities or authorities are necessary for HHS to fulfill the intent of PAHPA and related laws?

*See comments above on new authorities needed for HHS and ASPR.*

*As efforts to better leverage and integrate new and existing surveillance capabilities among government agencies and private health care organizations are underway, PAHPA should support the further development of surveillance strategies that use increased availability of electronic interoperable clinical data related to viral and bacterial threats, including antibiotic resistance. Ongoing efforts and future policy proposals must recognize that effective surveillance relies on a well-trained workforce, a surveillance infrastructure that relies on increasingly sophisticated laboratory and genomic testing in routine health care use, and environmental surveillance like wastewater testing.*

### Partnerships

What specific steps could Congress take to improve partnerships with states and localities, community-based organizations, and private sector and non-government stakeholders, such as hospitals and health care providers, on preparedness and response activities? For example:

1. How can these entities be better supported in appropriately engaging with the federal government to understand available resources, capabilities, and expectations prior to, during, and following a public health emergency?

*Clinicians and public health agencies can combat the spread of infectious diseases more rapidly when health systems and the American public have access to rapid and reliable viral and bacterial diagnostics. HHS, the FDA, and the CDC should support a public-private partnership between health care organizations, novel antibiotic developers, point-of-care and OTC diagnostic developers, and public health in order to streamline bacterial diagnostic and antibiotic susceptibility test (AST) development and use.*

2. How can foundational programs, such as the Public Health Emergency Preparedness cooperative agreements and the Hospital Preparedness Program, be improved to ensure state, local, and health system readiness to mount effective responses?