May 5, 2023

Senate Health, Education, Labor and Pensions Committee Hearing on PAHPA Reauthorization

On Thursday (May 4), the Senate Health, Education, Labor and Pensions (HELP) Committee held a hearing entitled, "Preparing for the Next Public Health Emergency: Reauthorizing the Pandemic and All-Hazards Preparedness Act" (PAHPA). During the hearing, committee members heard testimony from two panels. First, a panel of federal government leaders representing the Department of Health and Human Services' (HHS) Administration for Strategic Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA), and second a panel of academic and expert witnesses.

The hearing largely focused on ways to update PAHPA to better prepare for future pandemics with the bulk of lawmakers' questions directed at the federal government leaders. HELP Committee Chair Bernie Sanders (I-VT) and Ranking Member Bill Cassidy (R-LA) were the only two members to ask questions during the second panel and those questions focused on high prescription drug prices and the impact of potential cost containment measures.

- *For more information*: https://www.help.senate.gov/hearings/preparing-for-the-next-public-health-emergency-reauthorizing-the-pandemic-and-all-hazards-preparedness-act

Opening statements

HELP Committee Chair Bernie Sanders (I-VT): In his opening statement, Sanders said the committee's "job today is to take a hard look at where we are today in terms of preparing for another pandemic and the need to reauthorize the Pandemic and All-Hazards Preparedness Act, or PAHPA, later this year." Sanders said that the United States was "very very unprepared for what hit us" and noted that scientists believe "a pandemic as deadly as COVID-19 could occur in 10 years." Sanders said, "Our job is to make sure we are prepared if it does occur – that is what this hearing is about; that is what this legislation is about." As part of those efforts, Sanders said the committee will need to identify ways to bolster the health care and public health workforce, improve data accessibility, shore up vaccine and treatment supply chains, improve public communications, and protect the most vulnerable in our society. Prior to the second panel, Sanders spoke about the high price of prescription drugs and questioned whether the current prescription drug model is working for patients. Full statement.

HELP Committee Ranking Member Bill Cassidy (R-LA): In his opening statement, Cassidy said, "We need to keep in mind the wide array of threats that this bill seeks to address. Not just diseases, but also natural disasters, attacks, and accidents that could put our country at risk." He added, "While members of this committee don't always agree, we have always set politics aside and come together on reauthorizing PAHPA." Noting the lessons learned from the COVID-19 response, Cassidy said, "We need to update the playbook and ensure our framework is flexible to address threats beyond just a pandemic." Full statement

Panel I: Witness Testimony

Dawn O'Connell, Assistant Secretary for Preparedness and Response, Administration for Strategic Preparedness and Response: Ms. O'Connell said ASPR wants to ensure it has the "authority" needed to execute its work with the "excellence, efficiency, and expertise that American people deserve." She said it would be

"management malpractice" for ASPR to look and act the same as it did prior to the pandemic and noted the agency has taken steps to transform the organization and incorporate lessons learned, including becoming a standalone organization and completing a structural reorganization that changes reporting structures for the strategic national stockpile. O'Connell said she is requesting new authorities in PAHPA to solve three key problems: procurement of tools and supplies to respond to emergencies, increase domestic manufacturing, and accelerate hiring to respond to emergencies. Full Testimony

Rochelle Walensky, Director, Centers for Disease Control and Prevention: Dr. Walensky said public health agencies have a responsibility to remain "response ready" even as the COVID-19 public health emergency comes to an end. She said CDC is conducting an "all agency" review and is committed to addressing the lessons learned from COVID-19, increasing accountability, and improving how we deliver information to Americans." She said policy changes and funding are essential moving forward as the end of the PHE means the "CDC will no longer be able to collect data and share information," such as data on race and ethnicity that helps depict health disparities. She asked the committee to grant CDC new authorities on hiring, recruiting, and student loan reimbursement, as well as authorities to maintain vaccine infrastructure put in place during the pandemic. She also asked the committee to include data modernization policies in PAHPA to ensure CDC and the public maintain access to timely data. Full Testimony

Robert Califf, Commissioner, Food and Drug Administration: In his opening statement, Dr. Califf said the COVID-19 pandemic provided lessons learned on how FDA authorities under PAHPA can be modernized. For example, he said greater transparency in the supply chains and ensuring operational readiness and surge capacity and improving laboratory testing regulation are priorities that would improve public health preparedness. He also stressed the need for greater transparency into supply chains of our medical products but said the CARES Act requirement for manufacturers to notify FDA of surges in demand to prevent shortages ends with PHE. Dr. Califf said these measures would not only help "FDA serve the public in times of crisis but also enable us to prevent catastrophic outcomes and conduct our everyday work more efficiently and effectively." Full Testimony

Panel II: Witness Testimony

Reshma Ramachandran, Assistant Professor of Medicine, Yale School of Medicine: "With this year's reauthorization of PAHPA comes an opportunity to reflect on this [pandemic] period and utilize the lessons learned from disbursing this significant public investment. To inform this impending legislation, Congress can answer the following fundamental question: how can we ensure that the American public has equitable access to medical countermeasures developed in response to public health emergencies in the future?" She raised concerns about the impact cost-sharing and high vaccine prices will have on the nation's most vulnerable patients and government spending. She called on Congress to give federal agencies authority to negotiate better prices in contracting, mandate better data on safety and quality, and ensure equitable access to medical countermeasures. Full Testimony

Robert Weissman, President, Public Citizen: Mr. Weissman said Operation Warp Speed was both a "great success and a great failure." He criticized the Biomedical Advanced Research and Development Authority (BARDA)for imposing few restrictions on vaccine drugmakers. He said, "The reauthorization of PAHPA must be the moment to make our pandemic and emergency preparedness more robust. First, a reauthorized PAHPA should require BARDA and other agencies to build transparency, affordability, production and licensing terms into R&D and acquisition contracts. Second, it should require BARDA and other agencies to adopt prize funds and other creative measures to more efficiently fund biomedical R&D and advance public health objectives." Full Testimony

Martin Makary, Professor, Johns Hopkins University: In his statement, Makary criticized federal health agencies' response to the COVID-19 pandemic, noting that Johns Hopkins' COVID tracker, which was used worldwide, was

created by a single Johns Hopkins student. He also criticized BARDA's inability to quickly conduct research to provide answers early on in the COVID-19 pandemic on topics like, how does COVID spread? And when is a person most contagious? "We could have answered this with definitive basic clinical research early. They didn't," Makary said, which left doctors operating on opinion instead of clinical evidence. Full Testimony

Q&A

Committee Chair Sanders (I-VT) asked whether the US is moving fast enough to prepare for future pandemics. Ms. O'Connell said, "We are losing time to prepare for the next pandemic," and that more work is needed across all of the viral families that could generate the next public health emergency. Dr. Walensky said the CDC needs new authorities to recruit and retain a public health workforce, such as tax-exempt loan repayment, direct hire authorities, and danger pay. Dr. Califf spoke about the workforce shortage and the need for government funding to stimulate the industry to produce the products we will need for future pandemics.

During the second panel, Chair Sanders asked about the morality of having a vaccine that costs a few dollars to produce but is unavailable to vulnerable populations in the US and abroad. Dr. Ramachandran said, "No one should be poor because they are sick and no one should be sick because they are poor." Mr. Weissman said drug manufacturers should be required to, at a minimum, share the technology so it can be made by other manufacturers for low-income countries. Mr. Makary said cost should never be a barrier to care, but he said the best way to lower drug prices is to cut the waste in the drug system, like pharmaceutical benefit managers.

Ranking Member Cassidy (R-LA) asked about the impact of drug price controls on smaller biomanufacturing companies working on medical countermeasures. Ms. O'Connell said there is a risk if HRSA had to add limits in its contracting that they could limit the number of companies who would be willing to do this work. He also asked about the impact of an "X" price to incentivize innovative drugs instead of patents. Dr. Califf said while he agrees that prices of innovative drugs are too high, he would not do away with patents, you need a balance.

During the second panel, Sen. Cassidy asked about ways to improve information sharing and data and the value of drugmakers maintaining intellectual property rights and patents.

Sen. Roger Marshall (R-KS) asked about the impact of lockdowns on mental health in the US, as well as the value in understanding COVID-19 origins. Dr. Walensky said the US saw increases in mental health challenges before the pandemic and the collective loss associated with the pandemic – housing, food security, and lives – all impacted mental health. Ms. O'Connell said it would be useful to know the source of COVID-19, but noted that ASPR does not conduct that work and is tasked with responding. Sen. Marshall also asked Dr. Califf why only a few drug manufacturers succeeded in making vaccines. Dr. Califf spoke favorably of the government's decision to invest in nine or 10 vaccines, noting that it contributed to the US creating two or three successful vaccines. "You have to account for the high failure rate in drug and vaccine development," he said.

Sen. Patty Murray (D-WA) spoke about the Public Health Infrastructures Saves Lives Act to help support public health agencies. She asked what Congress can do to strategically help those who are most at risk in a public health emergency. Ms. O'Connell said the FY 2024 budget proposal includes an authority request to start a human services response fund to quickly move money into communities to ensure boots are on the ground when needed.

Sen. Murray asked how ASPR is implementing a Prevent Pandemics Act provision directing ASPR to assist local health departments access the Strategic National Stockpile. Ms. O'Connell said ASPR just released its 60-day guidance detailing how states and localities can access the Strategic National Stockpile.

When asked how the CDC is working to improve data collection, Dr. Walensky said CDC is actively working on data modernization and interoperability with states and localities. But she said, CDC received the data voluntarily and is asking for authority to mandate the data.

Sen. Ted Budd (R-NC) asked how ASPR is acting on Government Accountability Office (GAO) recommendations on Strategic National Stockpile. Ms. O'Connell said ASPR is working closely with GAO on the issue. When asked about ways to increase interagency coordination between ASPR's BARDA and the Advanced Research Projects Agency for Health (ARPA-H), Ms. O'Connell said she sees a very clear lane for BARDA to reduce overlap with work at ARPA-H. Sen. Budd also asked how Congress can reduce barriers to patient participation in clinical trials. Dr. Califf said that decentralized clinical trials will play a key role, but their success is contingent on patients having access to the internet and digital technologies in their homes.

Sen. Bob Casey (D-PA) asked about PPE shortages early in the pandemic and supply chains. Dr. Walensky said CDC is working with academic partners to improve innovation in PPE, while Ms. O'Connell said ASPR has invested $16 billion dollars in PPE domestic manufacturing, but warned that without additional funding they will be unable to maintain that ability. When asked how many medical device shortages the FDA has been able to prevent using emergency authorities, Dr. Califf said about 350, and noted that authority will go away at the end of the PHE, and said FDA needs notification authority when there is both a manufacturing disruption and a demand increase.

Sen. Mitt Romney (R-UT) asked how Congress can help improve public perception of the federal health agencies. Dr. Califf and Dr. Walensky asked Congress to "say a few nice things about federal employees." When asked about data improvements, Dr. Walensky said after the PHE it took CDC six months to negotiate data use agreements and that the agency needs line of sight into threats before they become emergencies.

Sen. Tammy Baldwin (D-WI) spoke about House Republicans' passage of the debt limit bill, which would enact cuts to the public health response. She asked about the importance of sustained funding for genomic sequencing efforts included in the Tracking Pathogens Act. Dr. Walensky said those continued efforts are very important both at the federal and state level. Sen. Baldwin spoke about the Disease X Act to support vaccine and medical countermeasure development and asked how Congress can support BARDA's research into medical countermeasures. Ms. O'Connell said to fulfill funding requests in the FY 2024 budget.

Sen. Mike Braun (R-IN) spoke about the bipartisan Promising Pathways Act and asked about FDA's involvement of patients in advisory committees for rare disease treatments and innovations. He also asked about COVID-19 vaccine mandates for small businesses.

Sen. Tim Kaine (D-VA) spoke about the need for a functioning public health data system and the Improving DATA in Public Health Act. Dr. Walensky said the CDC cannot act swiftly and robustly without the data and under the current system it takes months after a public health emergency is declared to get access to needed data. Sen. Kaine also asked what FDA is doing to prepare for and address drug shortages. Dr. Califf said the FDA has asked for authority to maintain access to the data needed to pre-empt and respond to shortages.

Sen. Ed Markey (D-MA) asked about the impact of the public health emergency ending on those who are still dying from COVID-19. Dr. Walensky said while CDC is not slowing down in its response to COVID and is looking at the impact on vulnerable communities, it will lose authorities and access to certain data that have helped drive its response. Sen. Markey also asked how the US needs to improve response to natural disasters and emergencies.

Sen. John Hickenlooper (D-CO) asked about FDA's requests to emerging pathogen preparedness and spoke about the platforms needed to prepare for the next pandemic. He also spoke about the potential for regulatory barriers to hinder response efforts.

If you have questions, please contact Heather Meade or Heather Bell.

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