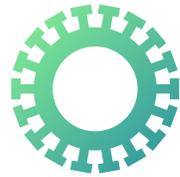




PARTNERSHIP TO FIGHT CHRONIC DISEASE



Partnership to Fight
Infectious Disease

June 26, 2020

The Honorable Lamar Alexander
U.S. Senate

The Honorable Patty Murray
U.S. Senate

Re: Response to “Preparing for the Next Pandemic”

Dear Chairman Alexander and Ranking Member Murray:

The Partnership to Fight Chronic Disease (PFCD) commends your leadership of the Senate Health, Education, Labor and Pensions Committee to address the challenges we face during the COVID-19 pandemic. We also applaud your efforts to examine what we’ve learned through past pandemics as well as the current one to help us better prepare for the next pandemic, as described in the “Preparing for the Next Pandemic” white paper and explored in your Committee hearing on June 23. We share your concerns and appreciate the opportunity to provide comments.

PFCD is an internationally recognized organization of patients, providers, community organizations, business and labor groups, and health policy experts committed to raising awareness of the number one cause of death, disability, and rising health care costs: chronic disease. As the current and past pandemics have made clear, the people most at risk for severe illness and death from infectious diseases are those living with underlying chronic conditions. Six in ten adults in the U.S. have at least one chronic conditions, and more than four in ten

adults have two or more.¹ Older Americans and communities of color are disproportionately affected by many chronic diseases, and, as a result, are being disproportionately impacted by severe cases of COVID-19.

Our comments are focused on four key areas we believe need significant attention to prepare for the next pandemic and will be a metric by which we judge pandemic preparedness measures moving forward. We provided some background on each area below and rely upon this information to address related questions you posed in the white paper.

- 1. Need to address the growing problem of anti-microbial resistance to ensure that we have available diagnostics and treatments to treat infections adequately before, during, and after a pandemic.**
- 2. Enhance our public health infrastructure through consistent state and federal funding to enable accurate, real time surveillance and consistency in reporting, early warnings of potential outbreaks and at risk communities to enable prevention, detailed data allowing early identification of high risk populations, and allocation of resources during an outbreak.**
- 3. Protect against discrimination so that all people to have equal access to testing, care, and assistance to avoid the significant ethnic and racial disparities currently making the impact of COVID-19 on communities of color dramatically worse. Policies should also address the potential for discrimination in decisions regarding coverage, available care and resources based on measures that devalue the lives of people living with disabilities, having underlying chronic conditions, or being of advanced age.**
- 4. Maintain and build upon gains in access to care realized in the proliferation of telehealth services during COVID-19.**

Addressing Antimicrobial Resistance

Though anticipating the exact pathogen that will spark a pandemic, there are lessons we've learned that can help us anticipate and prevent much of the toll from infectious disease outbreaks. In most past pandemics, severe illness and deaths were not caused by the virus itself, but resulted from subsequent bacterial infections leading to pneumonia or sepsis, hospitalizations, and deaths. Our ability to treat these underlying infections depends upon having a robust arsenal of antimicrobial treatments, but we're already behind in that regard. According to the CDC, more than 2.8 million drug-resistant infections occur in the U.S. each year and more than 35,000 people die as a result. Antimicrobial resistance (AMR) is a serious and growing problem. Being prepared for the next pandemic must address the growing problem of antimicrobial resistance and lack of effective treatments against this threat to make a significant difference in our level of readiness.

¹ C Buttorff, T Ruder, & M Bauman. Multiple Chronic Conditions in the United States. RAND Corporation. Available online at https://www.rand.org/content/dam/rand/pubs/tools/TL200/TL221/RAND_TL221.pdf.

PFCDD recently launched a strategic initiative, the Partnership to Fight Infectious Disease, to address AMR. According to a recent national poll of likely voters, there is considerable urgency around and support for policy changes to address AMR. When presented with some background on AMR, 85 percent of respondents expressed concern about the issue and 76 percent believe that the development of new antibiotics should be a top or high priority. Those voters seriously impacted by COVID-19 were the most likely to be very concerned about AMR and express that the development of new antibiotics should be a top or high priority. Levels of concern were also notably higher among older Americans and people of color.²

Addressing antimicrobial resistance through a comprehensive approach engaging the public and private sectors not only will help us prepare for the next pandemic, but has the added benefit of addressing a pressing need of today that threatens to undermine the significant advances we have made and are making against chronic diseases. Both new treatments and diagnostics are critically important to enable reliable point-of-care testing, tracking resistance growth, identification of emerging threats, and matching infections with effective treatments.

A comprehensive preparedness strategy must include policies to address the rising threat of AMR and engage governments, industry, academia, insurers, healthcare providers, and patients and caregivers in developing sustainable solutions.

Enhancing in the Public Health Infrastructure

As all the witnesses at the June 23 Committee hearing testified, the current pandemic has demonstrated that having a robust public health infrastructure and workforce is foundational to a rapid, effective response. Playing “catch up” during a crisis is expensive – both in terms of the human and economic toll – with preventable, less than optimal results. Enhancing and sustaining our collective capacity to respond to infectious disease outbreaks will enable us to save lives, limit the economic fallout from future outbreaks, and empower us to respond more swiftly and effectively to emerging threats. Boosts in funding during a time of crisis help to build the infrastructure needed during those times, but that capacity erodes without a sustained commitment and funding.

Federal efforts must include funding to enhance surveillance, data collection, and reporting with detail needed for near-real-time or real-time detection of disproportionate impact and populations at higher risk; laboratory capabilities to allow robust and timely assessments of infectious disease threats; and ensuring a robust, skilled public health workforce enabled with the latest technology to support prevention and enhance the public’s health, to detect and respond rapidly to emerging threats, and to act swiftly to a crisis.

² Likely Voters Overwhelmingly Concerned about Antimicrobial Resistance, June 24, 2020. Available online at <https://www.fightinfectiousdisease.org/post/likely-voters-overwhelmingly-concerned-about-antimicrobial-resistance>.

Enhancing the CDC's capacity and capabilities are central to these efforts. Accordingly, we support increasing funding for the CDC 22 percent by 2022³ and sustained levels of funding moving forward. Adequate and sustained funding will not only enhance CDC's efforts to protect our nation's health from both communicable and non-communicable diseases, but also will build capacity at the state and territorial level given the close collaborations between the CDC and state and territorial health departments.

CDC's mission on both communicable and non-communicable disease control and prevention should continue. As we are seeing in the current pandemic, communicable and non-communicable diseases are inextricably linked – those with underlying chronic conditions are at greatest risk for poor outcomes from COVID-19. Moreover, federal and state data on the prevalence of chronic conditions helps to inform chronic disease prevention efforts, but also can help to identify communities at risk for more severe COVID-19 cases given information on chronic disease prevalence and related risk factors within each community.

Increased and sustained investment in the CDC and our public health workforce, technology, programs, and collaboration among federal, state and territorial health counterparts will significantly enhance the nation's preparedness for future pandemics while continuing to improve the nation's health in the meantime.

Protecting Against Discrimination

COVID-19 and its disproportionate impact on communities of color is revealing in real time the significant ethnic and racial health disparities in the U.S. Hospitalizations⁴ and deaths from COVID-19 are much higher for American Indians, African Americans, and Latinx among every age group.⁵ Half of all cases reported to the CDC lack information on race or ethnicity, we cannot measure the full extent of the disproportionate impact.

As Congress considers preparedness for the next pandemic and response to the current one, health equity should be a cornerstone that guides policy response. The quality of our response depends upon improving the quality of our data to not only fully understand the extent of the damage, but to facilitate the distribution of resources to prevent and treat outbreaks to communities most in need.

³ Trust for America's Health. 22% by 2022: A Strong CDC Is Critical to a Strong America. Available online at https://www.tfah.org/wp-content/uploads/2019/01/22-x-22-Overview_rev-1-16-19-003.pdf.

⁴ CDC, Coronavirus Disease 2019: Data Visualization. Available online at <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/data-visualization.htm>.

⁵ T Ford, S Reber & R Reeves. Race Gaps in COVID-19 Deaths Are Even Bigger Than They Appear. The Brookings Institution. Available online at <https://www.brookings.edu/blog/up-front/2020/06/16/race-gaps-in-covid-19-deaths-are-even-bigger-than-they-appear/>.

The bipartisan Social Determinants Accelerator Act (HR 4004) represents a significant jumpstart to efforts aimed at addressing the social determinants of health associated with health disparities and disproportionate impact of both chronic and infectious diseases on communities of color. The Act would establish an interagency council on social determinants of health to advise and assist state and local governments to improve outcomes, collect evidence and develop strategies to improve health and social outcomes, and encourage greater collaboration among federal, state, and local governments and service providers to improve health and social outcomes for Medicaid beneficiaries. Likewise, H.R.6561 the Improving Social Determinants of Health Act of 2020 would create a Social Determinants of Health (SDOH) Program at the Centers for Disease Control and Prevention (CDC). Through grants, this program would improve the capacity of public health departments and community organizations to address social determinants of health and reduce health care costs by building multi-sector collaborations and addressing policies that currently inhibit good health.

More can and should be done to move us closer to achieving health equity in America. Pandemic preparedness efforts must recognize and act to address the disproportionate impact of this and future pandemics on communities of color and other underserved populations. Funding for clinical trials developed at Historically Black Colleges and Universities (HBCUs) should be increased. Promoting more research and development of therapies and treatment protocols at these institutions would help move towards an eradication of racial and ethnic health disparities.

Maintaining Gains in Access Through Telehealth

The COVID-19 pandemic has led to the rapid expansion of telehealth services that enables patients to maintain access to healthcare services while limiting both patient and provider exposure to COVID-19. Congress and the Administration worked swiftly to roll back decades worth of regulatory hurdles placed on providers who would have otherwise gravitated to some level of virtual and digital care years ago. CMS's leadership in adjusting payment policies to facilitate provider reimbursement for telehealth services enabled the growth and led other payors to adopt similar policies. Most of these reforms are temporary in nature, tied to the public health emergency. As such, Congress must act quickly to begin informing state and federal regulators about which of these policy changes and enforcement flexibilities will remain. A good start would be an extension of the current public health emergency until the end of the year to allow providers and health systems to prepare a surge in new COVID cases this fall. Building upon this success to address concerns about HIPPA compliance and patient privacy with an updated and comprehensive framework for privacy and security of patient data is critically important moving forward.

CMS will need to focus on payment mechanisms that make the most sense, in consultation with the provider community. Also, while we applaud making access to care more readily available to patients, we recognize the importance on establishing and maintaining a personal relationship between providers and patients as much as possible. Clearly, originating site and

geographic payment restrictions need to be re-evaluated. A continued move to value-based prospective payments in Medicare and Medicaid will aid in this effort too by removing the current practice of tying payment to a “visit” virtual or otherwise. Telehealth visits make sense in a lot of settings, but should be a tool to enhance the patient-provider relationships as much as possible. Trust built during patient-provider relationships can make a difference in patient confidence and adherence to recommended treatments so critical to preventive care, disease management, and health improvement.

COVID-19 and future pandemics also exact a devastating toll on people’s mental health and wellbeing. Facilitating access to mental and behavioral health services through telehealth and otherwise should be a priority in pandemic preparedness. As noted in at the recent HELP Committee hearing, mental health visit “no shows” are actually down with the addition of telehealth services. People face less stigma in seeking care from the privacy of their own homes.

Enabling greater access to broadband services is needed to facilitate better access in both rural and urban areas currently without dependable access. Improving access to broadband to underserved areas also has the added benefit of enabling more equal access to online education services needed during the current and future pandemics. Educational attainment is a key social determinant of health. More than a temporary expansion of the FCC’s Rural Health Care Program that subsidizes broadband services is needed, including making sure that incentives are available for underserved areas in both rural and urban areas. A particular focus on lower income communities, communities of color, and other underserved areas would help to promote health equity and address disproportionate impact.

Responses to Specific Questions Posed

Tests, Treatments, and Vaccines – Accelerate Research and Development

1. What incentives can the federal government offer to the private sector to encourage development of more medical countermeasures with no commercial market?

We support changes that activate and support education, encourage the research and development of new treatments and therapies for infectious diseases, motivate broad change in the way antibiotics are developed, distributed, and consumed, and reinforce awareness among all public and private stakeholders about the value of antibiotics, the impact to the practice of modern medicine and the threat to individual health.

The lack of market incentives present a huge challenge to the development of medical countermeasures to enable pandemic preparedness. We’re seeing this play out in real time with the growing crisis of antimicrobial resistance. As we’ve seen in past pandemics, the infections that lead to pneumonia, sepsis, and ultimately death are most often caused not by the pathogen sparking the pandemic, but accompanying bacterial infections. Market

conditions for agents and diagnostics to address AMR have led to a sparse pipeline and federal action is needed to incentivize greater investment.

Strong market incentives should appeal to both large and small innovators to include both “push” incentives that spur investment in R&D and “pull” incentives that address challenges in reimbursement and commercialization. For example, hospital-administered antimicrobials are subject to DRG bundled payments that can work to disincentivize the use of higher cost antimicrobials though they are the most appropriate treatment for the patient.

Any policies need to be sustainable and predictable given the significant time and investment needed to develop new therapies. In launching the Partnership to Fight Infectious Disease initiative, we’ve developed a core set of policy principles that should guide policymaking to address these issues (copy attached).

3. What could the federal government have done to be better positioned with diagnostics, vaccines, and treatments for COVID-19?

Learning from past pandemics, we can anticipate the need for treatments to address the resulting bacterial infections that often drive hospitalizations and deaths. Recognizing and adopting policies to address the growth in AMR and the need to develop new treatments and diagnostics are necessary elements of any comprehensive pandemic preparedness plan. We have developed a core set of policy principles that can help guide policy changes needed to address the current and growing threat of AMR to lessen the toll of future pandemics (See Appendix).

The collaboration between industry and government in the search for new diagnostics, treatments, and vaccines for COVID-19 has led to significantly shortening the timeline for availability of treatments and access to clinical trials. We should not miss the significant opportunity to discuss, evaluate, and document what has worked well from the perspectives of industry, the government, and healthcare providers, what has and hasn’t worked well and where improvements can be made. Congress can and should assist those efforts to foster greater public-private collaboration during future pandemics.

8. How can the United States better leverage public-private partnerships, industry, and academic institutions?

Public-private partnership is critically important in addressing emerging infectious disease threats. In recent public polling among 1,000 likely voters, on the issue of AMR, voters support an industry-led

A lack of accurate point-of-care diagnostics is helping to fuel the growth in AMR. Easy to use, accurate diagnostics can help a healthcare provider determine the most effective antimicrobial to prescribe to eliminate an infection. More accurate diagnostics and reporting can also help to identify potential outbreaks and growth of antimicrobial resistance in an area.

For the past 40 years, the Bayh-Dole Act has facilitated academic research and industry partnerships leading to significant healthcare and medical advances. Public and private R&D investments are complimentary, and the Bayh-Dole Act allows universities to advance knowledge in the life sciences and partner with industry to apply that knowledge in the research and development of new therapies, diagnostics, and medical devices. Building on the success of the Bayh-Dole Act and facilitating greater collaboration will help us be better prepared for future pandemics.

Disease Surveillance – Expand Ability to Detect, Identify, Model, and Track Emerging Infectious Diseases

1. What other barriers, in addition to limited testing capacity, and insufficient and outdated technology, make it difficult to detect and conduct public health surveillance of emerging infectious diseases?

We have to improve data collection to reduce health disparities. That includes requiring the collection of specific information on race and ethnicity, disability status, and primary language. Currently, half the data on COVID-19 the CDC receives does not indicate the race or ethnicity of the individual affected. That limits our ability to respond effectively. We also need to update our standards of data collection among the category of Asian/Pacific Islander. For example, the category “Asian” captured currently in federal Department of Education reporting includes more than 48 ethnicities with widely divergent educational experiences and access.⁶ There may be significant challenges with COVID-19 within different communities grouped under broad ethnicity categories that we are missing because of a lack of more specific data capture and reporting. Greater specificity could enable not only more rapid detection of outbreaks, but also tracing to the source of outbreaks and enabling more effective responses.

Public Health Capabilities – Improve State and Local Capacity to Respond

1. What specific changes to our public health infrastructure (hospitals, health departments, laboratories, etc.) are needed at the federal, state, and local levels?

The current pandemic has demonstrated that having a robust public health infrastructure and workforce is foundational to a rapid, effective response. That requires sustained funding, investments in workforce development and retention, and adoption of technology to enable greater tracking, analysis, and communication about existing and emerging threats.

As we’re witnessing, ramping up after a crisis strikes involves substantial expense, involves missteps and learning on the fly, and results in avoidable loss of life. We need to enhance and sustain our investments in the public health infrastructure at the state and federal level. We

⁶ Demographic Data & Policy Research on Asian Americans & Pacific Islanders, Data Disaggregation Fact Sheet, available online at http://aapidata.com/wp-content/uploads/2018/02/SEARAC_Fact_Sheets_DATA_AGG_FINAL-1.pdf.

should also examine the lessons learned from the collective experiences of other countries in their responses to COVID-19 and their results both in terms of policies and practices to avoid and those to emulate.

Often additional funding resources for public health efforts are tied to a specific challenge that may limit use of funding for broader initiatives or investments that aid in general preparedness. In developing policies to aid in preparing for future pandemics, we strongly encourage policymakers to work with public health experts to ensure that funding supports pandemic preparedness efforts without being so limited as to miss opportunities for investments in workforce development or technology that offer holistic benefits that enhance our public health systems overall.

We thank you, again, for your ongoing leadership these important issues and appreciate the opportunity to provide comments to help us prepare for future pandemics. We welcome the opportunity to provide additional information, if desired, and on stand ready to lend our support to elevating your efforts.

Best,

A handwritten signature in black ink, appearing to read "K. Thorpe". The signature is fluid and cursive, with the first letter of the first name being a large, stylized capital 'K'.

Kenneth E. Thorpe, PhD
Chairman