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February 4, 2022

The Honorable Patty Murray,
Chair
Senate Committee on Health, Education,
Labor and Pensions (HELP)
U.S. Senate
428 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Richard Burr,
Ranking Member
Senate Committee on Health, Education,
Labor and Pensions (HELP)
U.S. Senate
833 Hart Senate Office Building
Washington, D.C. 20510

Dear Chair Murray and Ranking Member Burr,

The Pew Charitable Trusts is pleased to respond to the committee's request for feedback on your efforts to strengthen the nation's public health preparedness and pandemic response system. Pew is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of health care.

We appreciate the committee's efforts to identify new ideas and policies that expand the capacity of our public health system to fully respond to future pandemics and ensure the health and well-being of all Americans. To support your review of these important issues, our recommendations, included below, address a number of the challenges central to public health preparedness that may be relevant to your legislation.

Thank you for your leadership to improve our public health infrastructure and medical preparedness and response programs. We appreciate the opportunity to inform this important process. Please contact Kyle Kinner (kkinner@pewtrusts.org) in our Government Relations practice for additional information or questions.

Sincerely,

Kathy Talkington,
Director, Health Programs
The Pew Charitable Trusts

RECOMMENDATIONS RELATED TO ANTIBIOTIC RESISTANCE

Among the many sobering reminders of the COVID-19 pandemic has been the critical importance of public health preparedness. While we were not aware of COVID-19 prior to its emergence, experts have been warning for decades about the threat of antibiotic resistance. Recent data estimate that in 2019 alone, antibiotic resistant infections caused 1.27 million deaths worldwide.[i] Antibiotics are critical to the success of modern medicine, save countless lives, and are essential for public health. Yet, their value to healthcare has been taken for granted; all the while, their effectiveness gradually diminishes.

As the efficacy of our current arsenal of antibiotics fades, a strong pipeline of new antibiotics is critical to preparedness efforts. But the antibiotics market is broken and showing signs of collapse. Because antibiotics are typically used for a short duration and must be used judiciously to preserve their effectiveness, it is extremely difficult for innovators to earn a return on investment in new antibiotic research and development. As a result, most large pharmaceutical companies are no longer engaged in antibiotic R&D, and the small companies responsible for the vast majority of current antibiotic innovation are struggling to remain in business, even after they get a new antibiotic on the market.

At the same time, recent research from Pew reports overprescribing of antibiotics in hospital settings during the first six months of the pandemic, as physicians used all available tools to treat COVID-19 patients.[ii] The resulting uptick in antibiotic use risks accelerating the emergence of resistance and further amplifies the desperate need for new and effective drugs and increased surveillance and stewardship.

The committee's discussion draft directly addresses antibiotic resistance in **Title V, Enhancing Development and Combatting Shortages of Medical Products, Section 501, Advancing Qualified Infectious Disease Product Innovation**, and broadly provides the basis for Congress to address these urgent issues throughout the rest of the draft. We offer recommendations below, as solutions to strengthen the antibiotic market, appropriately monitor and manage the antibiotics in our arsenal, and ensure we are prepared for the public health crisis that we know is coming: antibiotic resistance.

Recommendation: Congress takes swift action to provide targeted economic incentives for drug makers to develop novel antibiotics to reinvigorate the currently stagnant pipeline.

While existing pre-market government funding is essential to support and de-risk the initial research and development of new antibiotics, these investments alone are insufficient to address the broken antibiotics market. The antibiotic market is categorically different from other therapeutic areas because older drugs are used preferentially for stewardship reasons and because bundled inpatient payments create perverse incentives that disfavor new drugs, leading to a low potential sales volume for new antibiotics coming to market; and pricing and reimbursement for antibiotics, even new and innovative ones, are considerably lower than other therapies. These unique market dynamics have resulted in a market crisis, as more and more pharmaceutical and biotech companies are backing away from developing new antibiotics. Most large

pharmaceutical companies, unable to recoup their investments after launching new products, have left the antibiotic field. The remaining small companies struggle to attract investments needed for the significant costs associated with commercializing products upon U.S. Food and Drug Administration (FDA) approval—including companies that have received federal funding. In fact, two such companies whose federal support catalyzed successful product development and FDA approval ultimately filed for bankruptcy in 2019, with several others signaling similar fates in the coming years.

To fix the market failure, **we need a package of economic incentives to stabilize the market and address the challenges that make antibiotic development economically infeasible** for both small and large companies, while ensuring patient access and preserving the effectiveness of existing drugs. Such a package of incentives should address the most urgent public health needs, ensure the appropriate use of antibiotics, and provide predictability to antibiotic developers. **Pew supports the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act, a bipartisan, bicameral bill reintroduced in the 117th Congress by Senators Bennet and Young and Representatives Doyle and Ferguson**. The PASTEUR Act would help stabilize the antibiotic market by creating a subscription program for critically needed antibiotics that treat the most threatening infections. Successful developers of qualifying antibiotics would receive a subscription contract, thereby providing revenues delinked from the antibiotic sales volume. This approach would deliver improved predictability for return-on-investments for antibiotic innovators, spurring additional investments in antibiotics discovery and development. The PASTEUR Act would also strengthen stewardship of these critical drugs by encouraging and financially supporting establishment of hospital stewardship programs, especially for resource-limited facilities such as rural and critical access hospitals. Recipients of subscription contracts would also be held accountable for guaranteed supply of the antibiotic.

Recommendation: To strengthen and complement the antibiotic drug development incentives discussed above, Congress should encourage widespread antibiotic use reporting to track and minimize inappropriate use to help slow development of resistance.

An established and effective platform to collect antimicrobial resistance (AR) and antibiotic use (AU) data is the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN), the nation's most widely used healthcare-associated infection surveillance network. Timely NHSN reporting of resistance data to NHSN's Antimicrobial Use and Resistance (AUR) Module can aid local practitioners in clinical decision making and prioritizing prevention activities and inform facility efforts to prevent transmission and limit propagation of emerging or established resistant pathogens. It also enables public health officials to conduct regional and national assessments of resistance and quickly identify new types of resistance or trends.

By reporting AU data to NHSN, hospitals can compare their antibiotic use over time and against that of other hospitals, detect areas where interventions may be needed to reduce inappropriate prescribing, and measure how well such interventions are working. Enactment of comprehensive antibiotic development incentives should be accompanied by expanded NHSN AU reporting to enhance public health agencies' ability to identify inappropriate national, state, and local

prescribing patterns, selectively track emerging resistance signals directly related to novel antibiotics, and develop regional strategies to improve prescribing and combat resistance.

Despite the national importance of collecting AR and AU data, participation in the NHSN AUR module is currently voluntary. As of January 2020, only about 10% of eligible hospitals were reporting AR data to NHSN and 23% of eligible hospitals were reporting AU data. These participation rates have a long way to go to meet the goals set forth in the 2020 National Action Plan.[iii] The plan identified the following benchmarks as significant outcomes to strengthen national surveillance efforts to combat resistance: 75% of acute care hospitals, 100% of Department of Defense hospitals, 100% of applicable Veterans Affairs (VA) hospitals that have transitioned to the VA's updated electronic health record, and 25% of critical access hospitals should be reporting to the NHSN AR Option; 100% of acute care and 50% of critical access hospitals should be reporting to the NHSN AU Option.

Moving forward, **Congress should consider strategies to encourage stewardship and widespread AUR reporting**. Specifically, in advancing legislation to create incentives for antibiotic drug development, Congress should include robust support for NHSN AUR reporting through existing agency programs; direct agencies to make grant funding available to hospitals and other inpatient facilities to provide financial support and technical assistance to strengthen antibiotic stewardship programming and help facilities report AUR data through NHSN participation, and improve disease and resistance surveillance at the national, State, and local level; and provide sufficient appropriations to address resource gaps and spur reporting.

Recommendation: Antibiotics are prioritized in the U.S. Strategic National Stockpile (SNS), as part of a package of economic incentives for antibiotics developers.

As noted in our above recommendation for Congress to provide targeted economic incentives to stabilize the collapsing antibiotics market, procurement contracts for the SNS would help provide market stability and should be a part of a package of economic incentives. The US Government, particularly BARDA, currently invests in the research and development of novel antibiotics. However, even with this upfront funding support, companies are struggling to sustain operations after FDA approval due to limited commercial viability. The absence of private market incentives risks the availability of these life-saving drugs. Therefore, in addition to enacting the PASTEUR Act, additional 'pull' incentives would help reinvigorate antibiotics innovation.

As the nation builds back the depleted supply of SNS medical countermeasures, essential therapies that would aid in a robust response to future public health events should be prioritized for inclusion, including antibiotics. The Public Health Emergency Medical Countermeasures Enterprise's (PHEMCE) procurement strategy, coordinated through ASPR's leadership, primarily focuses on procurement of medical countermeasures with biothreat indications. However, PHEMCE's scope should expand to also prioritize procurement of antibiotics that treat rising multi-drug resistant bacterial infections, as well as concurrent bacterial infections that often emerge with viral pandemics such as COVID-19. PHEMCE's procurement strategy should align with threat priorities identified by CDC to ensure there are stockpiled antibiotics that can

treat the resistant bacteria identified by the agency as urgent, serious, or concerning threats.[iv] To enhance incentives for antibiotic drug developers and strengthen U.S. biopreparedness, **Congress and HHS should consider expanding the scope for SNS procurement to include a broader array of antibiotics**, including those without a biothreat indication, to better equip the country for current and future pandemics.

RECOMMENDATIONS RELATED TO SUBSTANCE USE DISORDER

Over the past year, the American people have courageously battled the COVID-19 pandemic. However, we must not forget that before COVID-19, our nation was already in the midst of an opioid epidemic that continues to kill thousands of Americans each month.

The end of 2021 marked a sobering milestone. Amid the ongoing COVID-19 pandemic, provisional data from CDC shows an estimated 101,263 overdose deaths 12-month period ending in June 2021; three-quarters of these deaths involved opioids.[v] The American Medical Association has found more than 40 states have seen an increase in overdose deaths since the onset of COVID.[vi] This increasing death toll is not isolated to a specific region but is impacting American communities from coast to coast.

This devastating loss of life is even more tragic because it is preventable. Opioid use disorder (OUD) is a chronic brain disease that can be successfully treated. A conclusive body of research demonstrates that medication for opioid use disorder (MOUD) is the most effective way to treat the disease and substantially reduces mortality from overdoses.

Yet individuals with OUD struggle to get effective care: in 2020, approximately 4 million people aged 12 or older received any substance use treatment in the past year. [vii] This corresponds to about 1 in 10 Americans with a substance use disorder aged 12 or older. This includes treatment received at any location, such as a hospital (inpatient), rehabilitation facility (inpatient or outpatient), mental health center, emergency room, private doctor's office, self-help group, or prison/jail. As the coronavirus pandemic presents an added strain on the U.S. health care system, it is creating even greater hardships for those seeking OUD treatment.

Pew appreciates the committee's interest and leadership on these issues and offers several recommendations below, relevant to **Title I, Strengthening Federal and State Preparedness, Subtitle B, Local and State Readiness, Section 112, supporting access to mental health and substance use disorder services during public health emergencies**, as options for strengthening U.S. efforts to assist individuals with OUD find and successfully obtain treatment.

Congress should incorporate lessons learned from the coronavirus pandemic and its impacts on at-risk populations affected by opioid use disorder as it formulates policy changes related to public health preparedness.

Recommendation: Make permanent the COVID-19 regulatory flexibilities regarding telehealth treatment initiation and take-home doses of methadone so treatment systems are prepared for potential disruptions to care during crises.

Methadone and buprenorphine—FDA-approved medications to treat OUD—are the most effective treatments for OUD and reduce the risk of mortality by up to 50% for patients in treatment. However, the way these medications are regulated makes them more difficult to access than a typical prescription drug: buprenorphine can only be prescribed by providers with an X-waiver from the Drug Enforcement Administration (DEA), and methadone can only be dispensed by licensed opioid treatment programs. Because of these limits on prescribing and

dispensing, people on medications for OUD may be more likely than others to experience interruptions in access to treatment during public health disasters, which can increase the likelihood of withdrawal and returns to drug use.[viii] In fact, the Substance Abuse and Mental Health Services Administration (SAMHSA) recommends that opioid treatment programs prepare for a surge in patients needing access to medication treatment in times of disaster.[ix]

COVID-19 exposed and highlighted existing gaps in our nation's OUD treatment system as Federal laws and regulations continue to exacerbate a critical nationwide shortage in treatment providers. To help providers respond to the demand for treatment during the COVID-19 pandemic, SAMHSA and the DEA jointly issued guidance to ease access to medications for OUD, including: **1) removing the requirement for an in-person visit prior to prescribing buprenorphine to allow medication initiation via telehealth, including audio-only connections, and 2) extending take-home doses of methadone to allow up to a 28-day supply for stable patients, and up to 14-day supply for less stable patients**. Both changes have effectively kept people in treatment and engaged people who might have otherwise not received treatment, which **illustrates the importance of continuing these policies as a matter of standard practice so that treatment systems are well positioned to meet the needs of patients.**

For example, audio-only telehealth for buprenorphine initiation has been able to reach people who are less likely to have access to audiovisual technology (i.e. individuals living in areas with inadequate broadband or experiencing homelessness) using innovative methods, like 24/7 telephone hotlines that can initiate buprenorphine as soon as a patient is interested in treatment and provide linkages to ongoing community care.[x,xi] Telephonic visits may also afford privacy to people who would otherwise feel stigmatized by seeking OUD treatment in-person due to concern about discrimination from neighbors or employers.[xii] Emerging evidence on telehealth buprenorphine initiation has found similar rates of treatment retention compared to in-office treatment, and there is no evidence that in-person visits are more effective than telemedicine visits in curtailing diversion.[xiii,xiv]

Additionally, more flexibility for take-home dosing, or otherwise permitting individuals to consume their medication at home, removed a critical barrier to treatment for patients of opioid treatment programs who have historically had to navigate a punitive system of care involving strict requirements such as required daily attendance to receive their medications.[xv] These burdens disproportionately impact Black and Hispanic/Latino people with OUD whose communities are more likely to have capacity to provide methadone rather than buprenorphine. **Therefore, allowing patients to take methadone like any other prescription drug demonstrates a step toward reducing the stigma of the medication and making it more accessible to patients.** For example, in North Carolina, three opioid treatment programs reported that they were able to substantially increase the percentage of patients receiving take-home methadone doses (from 68% to 90% of patients) while diversion of the medication remained uncommon.[xvi] Furthermore, allowing patients to have a take-home supply early in treatment has been shown to increase retention.[xvii] While most states have implemented a policy allowing methadone take-homes for patients who had not previously met state and federal criteria, about a third only plan to maintain the policy for the duration of the emergency declaration.[xviii] In fact, 10 states have permanent restrictions on take-home dosing that go beyond federal requirements.

Setting a more accessible treatment standard at the federal level will demonstrate the importance of adopting similar policies at the state and provider level.

As Congress considers legislation to ensure continued access to medications for OUD in times of emergency, it should ensure that these flexibilities are included. Alternatively, a recent report by authors at George Washington University's Center for Regulatory Studies found that the relevant federal agencies possess substantial regulatory authority already: SAMHSA and the DEA jointly have authority to continue allowing audio-only buprenorphine prescribing and extended methadone take-home doses post-pandemic. Further, SAMHSA acted commendably in November by extending the take-home flexibilities for a year after the Covid PHE expires, while committing to working toward a permanent solution. **The Senate HELP Committee, in partnership with the Judiciary Committee, could use its oversight role to ensure SAMHSA and the DEA make these flexibilities permanent.**[xix]

Recommendation: Learn from state and federal agency, and provider efforts to increase access to substance use disorder treatment during public health crises through a GAO report.

Requiring GAO to conduct a report on SAMHSA's work during the COVID-19 pandemic is a positive addition to this bill. It should include lessons learned from various coordinating agency and state efforts to quickly make changes in the substance use disorder treatment infrastructure during the pandemic. Federal policy changes may not translate to the state and provider level, especially when it's unclear how long those temporary changes will be in effect. For example, while most states have implemented a policy allowing methadone take-homes for patients who had not previously met state and federal criteria, about a third only plan to maintain the policy for the duration of the emergency declaration.[xx]

The report should include an analysis of the impact on state agencies and providers of adopting flexibilities (as noted above) on a temporary basis, and recommendations for preparing future public health crises.

Recommendation: Remove barriers to prescribing buprenorphine to increase the number of providers available to treat people with OUD to ensure continuation of services in times of emergency.

Only about 6% of American doctors have chosen to obtain an X-waiver to prescribe buprenorphine for OUD. As of 2018, 40% of U.S. counties did not have a single X-waivered provider, and more than half of the 1,100 counties with the greatest need for treatment had insufficient provider capacity to prescribe patients buprenorphine.[xxi] This gap in buprenorphine treatment disproportionately affects rural areas, which accounted for 72% of the high-need, low-capacity counties identified by the HHS Office of the Inspector General. Therefore, **increasing the number of providers able to prescribe buprenorphine helps to address disparities in treatment access and provides a safety net for patients** who may become disconnected from their providers in times of emergency.

Recently, the Department of Health and Human Services (HHS) issued guidance intended to increase access to buprenorphine by making it easier for providers to become X-waivered to prescribe the medication. In the past, providers were required to prove to SAMHSA and the DEA that they had completed training—8 hours for physicians and 24 hours for nurse practitioners and physician assistants—and could provide counseling and ancillary services in order to apply for an X-waiver to prescribe buprenorphine. Now, the new practice guidelines removed these requirements for providers who only treat up to 30 patients. However, the application process to become a buprenorphine prescriber is still in place and removing this final barrier to expanding access to treatment requires legislative action. **Congress should pass the Mainstreaming Addiction Treatment Act (H.R. 1384 / S. 445) to remove the X-waiver requirement**, thereby increasing capacity to prescribe buprenorphine and eliminating the outdated provider opt-in system for treating OUD that has hindered its integration into medical care.

RECOMMENDATIONS RELATED TO PUBLIC HEALTH DATA

As we enter the second year of a health crises that has exposed deep gaps in our public health infrastructure, it will be imperative to for Congress to work together to address these deficiencies in long-term, sustainable ways that ensure the country and its health systems can respond to future public health threats and leverage existing capabilities to address on-going systemic health issues, such as vaping-related illnesses and chronic diseases. The committee's discussion draft addresses these issues comprehensively in **Title II, Improving Public Health Preparedness and Response Capacity, Subtitle B, Improving Public Health Data and our recommendations on this topic are exclusively directed at Subtitle B**.

Throughout the public health emergency, health agencies have struggled to adequately capture and report essential data elements needed to both respond to the pandemic and track the spread of other diseases, especially in vulnerable and underserved populations. Epidemiologists, for example, have indicated that patients' contact information is missing in more than half of COVID-19 lab results, while demographic information, such as race and ethnicity, is absent in 85% of the reports.[xxii] Manual reporting—or the non-electronic transmission of information through modalities such as fax—also results in wide-spread under-reporting, leaving officials at the state and federal level to make key decisions without complete information such as the location of a disease hot-spot. The Centers for Disease Control and Prevention (CDC) estimates that, in some circumstances, as few as 1 in 10 reportable cases are sent to public health agencies after the medical encounter.[xxiii] Additionally, from early COVID vaccine reporting, data on race and ethnicity is present in only 51.9% of cases.[xxiv]

The foundation of a strong federal public health preparedness and response system is adequate data, without which public health agencies may be unable to perform vital outreach activities, such as contact tracing and disease mapping, in order to keep communities healthy and safe. To achieve this, Pew recommends the following:

- Public health data exchange capabilities should be a requirement for EHRs, and the Office of the National Coordinator for Health Information Technology (ONC) should further require the use of standards to ensure that complete, quality data is consistently sent to public health agencies.
- Health care providers should be incentivized to adopt data exchange capabilities through payment programs, such as those developed by the Centers for Medicare & Medicaid Services (CMS).

Recommendation: ONC should require public health data exchange capabilities as a component of EHR certification

Despite the $30 billion investment in EHRs over the past decade, challenges remain widespread, particularly when it comes to the reliance on sharing information manually or difficulties with data exchange among different systems—all of which can result in incomplete data. As a foundational step to improving public health data exchange and infrastructure at large, policy levers within ONC should be utilized to ensure all EHRs have the functionality in place for electronic reporting to public health agencies.

Currently, federal regulations from ONC include optional components for EHRs used in doctors' offices and hospitals to send data to public health agencies for four use cases—lab reporting, case reporting, syndromic surveillance, and vaccination data. Given the importance of all four of these use cases to response efforts for current and future health emergencies, these optional capabilities should be required as part of base certification for EHRs so that all systems are able to communicate with state and local public health agencies. **As pertains to Section 213, Supporting Public Health Data Availability and Access**, ONC should update EHR certification provisions in two ways:

(1) Functionality for electronic lab reporting, case reporting, syndromic surveillance, and immunization registries should be mandatory—not optional—as part of the base definition for EHR certification. This change would ensure that all EHRs obtaining federal certification have these capabilities.
(2) ONC should require adherence to the specific consensus-based standards and implementation guides developed and/or supported by the agency's Public Health Data Systems Task Force. Adherence to standards would make it easier for public health agencies to prepare their own systems to accommodate a highly standardized report that contains all the necessary data.[xxv] Following these standards would also help ensure that EHRs can use automated triggers to send reports.[xxvi]

Requiring electronic reporting for public health data as part of EHR certification—as well as ensuring the requirements include adherence to standards—will ensure that public health agencies get the data they need, in a standard way, from health care providers and facilities in real time.

Recommendation: CMS should expand electronic reporting, work with ONC to encourage provider adoption

To date, health care providers have not prioritized electronic public health reporting on their own, resulting in significant data gaps. For example, in 2018, immunization registries captured only 56% of the adult population.[xxvii] Furthermore, research shows that 29% of emergency departments across the country do not send syndromic surveillance data to the CDC, making it challenging to create the national surveillance picture needed to identify widespread threats.[xxviii] Addressing this requires an all-hands federal approach, including through the use of programs like the Promoting Interoperability program and conditions of participation in Medicare. CMS, in a rule that was finalized in November 2021, rightly recognized the benefits of this approach by requiring providers to share data electronically with public health agencies on cases of disease and immunizations.[xxix] ONC, as the agency that oversees health IT, should follow the CMS' lead and enact its own regulations requiring these systems to be able to send all public health data to agencies electronically.

This is a step in the right direction; however, sending syndromic surveillance data–which aggregates data from individual patient interactions to paint communitywide pictures of potential health threats and track the emergence or spread of illnesses–remains optional for providers that don't practice in an emergency department. **As pertains to Section 211, Modernizing Biosurveillance Capabilities and Infectious Disease Data Collection**, in the next annual policy update, CMS should consider requiring urgent care providers to send syndromic surveillance data.

At the same time, ONC must ensure that any CMS requirement is mirrored across both agencies. ONC can accomplish this by updating EHR certification requirements to ensure CMS' action is supported by ONC certified technology that has the functionality to send electronic reports. Taking this dual approach will not only address provider barriers for reporting health data, but also address functionality gaps currently faced by EHRs.

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