Additional Questions for the Record House E&C Hearing on PAHPA Reauthorization May 11, 2023

The Honorable Cathy McMorris Rodgers

1) HHS's leadership and coordination of public health emergencies has been placed on GAO's high-risk list. What are CDC's specific priorities and planned actionable items to address the concerns raised by GAO to ensure our nation is more prepared for future public health emergencies than we were for the COVID-19 pandemic and prior threats?

CDC is implementing several initiatives and improvements to ensure the agency is operating efficiently to meet our core mission—to equitably protect the health, safety, and security of Americans. Our major agency-wide "CDC Moving Forward" initiative represents our effort to transform how the agency operates by refining and modernizing its structures, systems, and processes to address longstanding priorities and strengthen our ability to protect the nation's health. CDC staff and leadership have been working hard to identify and implement key actions, which will accelerate CDC's modernization effort. Currently, there are more than 160 individual actions CDC is tracking. At least 50 percent of those actions are anticipated to be completed by the end of the summer in 2023, with 80 percent targeted to be complete by January 2024.

CDC is taking steps to elevate readiness and response efforts through a number of efforts including prioritizing preparedness responsibilities across the agency instead of centralizing preparedness responsibilities in one center. CDC's new Office of Readiness and Response (ORR) will serve as a central hub to coordinate preparedness, readiness and response leadership, strategic direction, emergency operations, jurisdictional support, and laboratory support. ORR will continue to partner with CDC programs and state, tribal, local, and territorial health departments (STLTs) to support their preparedness activities and will also lead CDC's effort to be response ready.

ORR is also implementing an important new staffing initiative, CDCReady, which will propel ORR to fully integrate preparedness and readiness efforts across the agency. While not every response is as large as the COVID-19 response, each agency-wide response typically requires hundreds to thousands of responders with a range of skillsets throughout different response phases, both in the Emergency Operations Center or in Centers, Institutes, and Offices (CIOs) leading smaller responses, as well as in the field. CDCReady centralizes the identification, preparation, and coordination of staff across the agency for emergency response assignments. This ensures CDC can rapidly establish and sustainably maintain response activities when emergencies occur and connect staff across the agency to emergency response opportunities. CDCReady enrolls employees into groups that are categorized by discipline-specific pools of responders who meet certain qualification criteria—meaning they have certain skills, experience, or training—and who have been preidentified to take on emergency response assignments when needed. To further support CDCReady, the agency has incorporated response expectations into the performance plans for agency executives, managers, and supervisors.

To provide more timely and accurate data to the American public, CDC is working to share scientific findings and data faster by releasing information more quickly with the American public

and partners about CDC's current level of understanding of the science and data. To elevate CDC's readiness and response science, by October 1, 2023, ORR will stand up a new division, the Division of Readiness and Response Science (DRRS). DRRS's charge will be to develop and implement the science of readiness and response, build scientific expertise to address health disparities and community mitigation, evaluate the state of STLT readiness and response, and inform a broader framework for evaluating CDC's and partners' readiness status. Standing up DRRS will be an important step in solidifying ORR as the agency leader in readiness and response—not only guiding how the agency prepares and maintains readiness for responses, but also evaluating that readiness state and strengthening how we support populations at greatest risk of disease, disability, and death during public health emergencies.

Effectively responding to future health threats to protect Americans is a goal we all share. The underpinning of an effective response is timely and actionable data. For CDC to retain a competitive advantage with the rest of the world, we need sustained investments in improving the nation's public health data infrastructure, including legislation to support the collection and sharing of public health data.

Public health entities must be able to rapidly share data within and among jurisdictions, and with CDC, to enable local leaders to make the best decisions for their communities and save lives in dynamic situations. The ultimate goal of CDC's Data Modernization Initiative (DMI) is to get better, faster, actionable insights for decision-making at all levels of public health. The Response Ready Enterprise Data Integration platform (RREDI), which is the next generation of HHS Protect, is a secure decision-making and operations platform developed for the whole-of-government response to the COVID-19 pandemic and is now expanding to support emerging outbreaks such as mpox and future public health responses. RREDI creates a common operating picture by using and integrating data from more than 300 sources across federal, state, and local governments and the healthcare industry, and is accessible to 4,500+ unique users across 30+ federal agencies, 56 states and territories, and the private sector.

CDC has proposed multiple amendments to the Pandemic and All-Hazards Preparedness Act (PAHPA) as Congress discusses the legislation's impending reauthorization. Having additional authorities in place is critical before the next public health challenge to support our mission as a response agency so we can focus on the task at hand—protecting American lives.

Among other asks, we have requested:

Public health data reporting authority

- HHS is seeking authority to more effectively collect and coordinate public health data necessary to serve its mission and address current blind spots. HHS has requested the authority to require the reporting of minimum necessary data to serve a range of public health and other mission-critical use cases.
- OCDC largely relies on voluntary data reporting from state and local health departments, healthcare providers, laboratories, and other facilities. Data are reported to CDC in inconsistent ways and often under the parameters of individual data use agreements (DUA) negotiated with each data provider for each unique public health issue. This results in hundreds of separate DUAs, which can each take weeks or months to establish or modify while an emerging threat expands, actively hindering our ability to "see" the data that would optimize the public health response. As demonstrated during the COVID-19 and mpox public health

responses, these circumstances create major gaps in our public health surveillance systems and hinder efforts to stand up the robust, informed response that policy makers and the American public expect. To address these gaps, HHS requests authority to modernize the public health data policy framework in a more meaningful way by giving CDC the authority to set data reporting requirements about which data elements should be reported to public health authorities, including CDC, and to require the reporting of critical public health surveillance data (public health, healthcare capacity, and patient safety data) to public health authorities and systems, including CDC, by healthcare providers, laboratories, state and local health departments, and other entities as necessary.

OCDC recently released an ambitious public health data strategy to close public health data gaps at the local, state, and federal levels aimed at improving accountability and meaningfully changing how data is shared. But we also need help from Congress to obtain legislative changes to support consistent and real-time public health data for CDC, states, localities, and providers. When data flows to CDC, states, and localities seamlessly, we are better able to use our expertise to track and predict where a virus moves next. CDC needs the legal authority to secure access to public health data in a timely and coordinated way that gives CDC, its state and local partners, healthcare providers, decision makers, and the public a clearer picture of the nation's health – even before a public health emergency (PHE) occurs.

• Workforce flexibilities to enable surge capacity and employee retention, including:

- O Direct hire authority, allowing HHS, including the flexibility to direct hire for positions that directly support and aid preparedness, response, and recovery activities. Having this ability would support a nimble response that can quickly surge to address an emerging threat. While the PREVENT Pandemics Act included an important recognition of the importance of having this authority at the beginning of a PHE, there are two elements of the authority that are insufficient: The number of direct hire positions is insufficient to meet the demand of a response to the magnitude of the COVID-19 response, and the authority is limited to the beginning of the response.
- Overtime and danger pay flexibilities, allowing HHS to issue pay cap waivers for senior response leadership and subject matter experts to accrue overtime during a public health response sustained periods of time during a response, and danger pay for certain roles. This will help CDC to retain staff throughout lengthy responses and those working under dangerous conditions during public health outbreaks, such as individuals responding to Ebola.
- O Development of a Public Health Ready Response cadre: CDC seeks authority to use appropriated funds for supporting a cadre of response-ready staff who can deploy for any PHE or an event with significant potential to become a PHE. CDC proposes authority for the CDC director to dedicate up to 1 percent of each account for the purpose of funding these long-term, response-ready detailees/deployments.
- o Student loan repayment tax waivers, i.e., a Tax Code provision to exclude student loan repayments made for CDC fellows (authorized under section 317F of the

Public Health Service Act (42 U.S.C. 247b-7)) from gross income. HRSA's National Health Service Corps (NHSC) has a provision in the Internal Revenue Code that excludes the HRSA NHSC educational loan repayments as income; however, this waiver does not extend to CDC, (26 USC § 108(f)(4)). The proposed exception provides a powerful incentive for new graduates to enter the public health workforce with CDC and will relieve CDC of the tax burden on program funds that provide student loan repayment as a recruitment or retention incentive, enabling CDC to use more of its program funds to provide this benefit to more individuals.

- O Non-competitive fellowship conversion, which would allow for the conversion of CDC fellows in fellowship and training program appointments to term or permanent positions in the competitive service within 120 days of program completion without having to use a competitive selection process. CDC's public health training fellowships are among the best in the world, like our Epidemic Intelligence Service. We spend years training these future leaders, but then lose many of them because we are unable to convert them to permanent positions. This proposal would allow the agency to retain skilled fellows.
- Reemployed annuitant maximum hours/dual-compensation waivers to allow for hiring of reemployed annuitants to fill full-time roles without hour limitations during a declared Public Health Emergency response.

• Establishment of an adult immunization program [Vaccines for Adults (VFA)]

- CDC seeks authority to establish an adult immunization program to support uninsured adults' access to Advisory Committee on Immunization Practices (ACIP)-recommended routine and outbreak vaccines, at no cost.
- No formal adult immunization program exists at a national scale to effectively execute vaccine distribution and administration.
- We must leverage what we built for COVID-19 to create a sustainable adult vaccine infrastructure to be better prepared for the next pandemic and to improve vaccine access and equity across our population.
- o CDC is requesting legislative authority and capped mandatory funding to establish the Vaccines for Adults program.
- Establishing a robust infrastructure for adult vaccination will support response readiness by reducing vaccination coverage disparities, improving outbreak control of vaccine-preventable diseases, and enhancing and maintaining the infrastructure needed for responding to future pandemics
- 2) The CDC's Data Modernization Initiative (DMI) was launched in 2020, with the goal of modernizing and improving our public health data and surveillance infrastructure across the country. Over the course of the pandemic, Congress has appropriated at least \$1 billion for this program. However, recent reports, including from the Government Accountability Office (GAO), have indicated that a lack of actionable plans has hindered the initiative's progress.
 - a. How much of the \$1 billion has been spent by CDC? How much has been

allocated? How much remains unallocated and unobligated?

All FY 23 annual funds appropriated for CDC's DMI have been allocated, and by the end of fiscal year 2023, all annual funding will be obligated. To date, CDC has distributed more than \$1 billion in annual and supplemental funds directly to state and local health departments through the Public Health Infrastructure Grant and Epidemiology and Laboratory Capacity Cooperative Agreement and has provided additional funding to public health implementation partners for technical assistance for jurisdictions

Data modernization is a multi-billion dollar, all-of-public health effort, requiring the close collaboration of CDC, state and local health departments, healthcare providers and vendors, and other public health partners. Many state and local health departments continue to rely on manual, duplicative processes like paper- and fax-based reporting and internal data systems that cannot talk to one another. As such, most, if not all, state and local health departments are depending on CDC's modernization support. CDC expects to develop key data and technology solutions and further modernize some of its core data systems by the end of FY 2026, replacing outdated platforms to benefit all health departments and CDC programs and improve the connectivity of systems across public health. These large initial investments are critical for making the transition to flexible, scalable cloud-based tools that can meet the needs of public health practitioners in supporting communities. As with all technology, CDC's public health infrastructure and data systems need sustained resourcing for long-term continuous modernization to stay up-to-date and response-ready.

b. Please outline any actions CDC has taken to encourage states and localities to engage with stakeholders and experts in the field to ensure we aren't relying on a single centralized data source.

CDC and public health departments at the state and local level rely on a variety of data sources and systems to collect data to inform public health practice and emergency response operations. Some of the core, disease-agnostic data sources that CDC relies on are case surveillance, laboratory information, immunization reporting, vital records, and healthcare capacity and utilization information. Each of these types of information has its own data sources and pipelines in the public health and healthcare space. These data sources provide critical information needed to answer questions about the burden, impacts and characteristics of disease. One of the primary goals of CDC's DMI is to improve the harmonization and efficiency of these data sources, and to make them more easily utilized for public health action. Examples of CDC supporting the enhancement of these core data sources include the ongoing electronic case reporting (eCR) and electronic laboratory reporting (ELR) work.

To improve the timeliness, completeness, and accuracy of the reporting of case information from healthcare entities to public health departments, CDC has provided significant investment, technical assistance, and support for the implementation of eCR. eCR allows for the automated reporting of case information, reducing the manual reporting burden on providers to meet their reporting requirements and providing a secure method to transmit critical patient and clinical information to health departments. Working with the Association of Public Health Laboratories (APHL) and the Council of State and Territorial Epidemiologists (CSTE), CDC has supported implementation of eCR from more than 26,000 healthcare facilities to 68 health departments

across the nation.

To facilitate ELR from traditional and non-traditional testing sites, CDC and the U.S. Digital Service (USDS) built a free-to-use tool—SimpleReport—that makes it easy for COVID-19 testing sites to record results for rapid point-of-care tests and quickly report required data to public health departments. Since November 2020, SimpleReport has enabled over 12,000 facilities in 37 states and territories to report over 7,800,000 results of tests conducted using over 30 different types of COVID-19 testing devices to state and local health departments. This includes, among others, 4,122 schools, 2,010 long-term care facilities, 1,171 hospitals, 817 primary care providers, 443 labs, 368 urgent care centers, 298 pharmacies, 211 correctional facilities, and 143 employers. CDC and USDS are currently working to help health departments expand the use of SimpleReport to additional conditions.

c. What partnerships has CDC entered into under this initiative?

CDC and the Office of the National Coordinator for Health Information Technology (ONC) co-lead the Data Modernization Initiative Consortium, which exists to share individual and organization perspectives on priorities and strategies for modernizing public health data and surveillance in the United States; identify challenges that delay data modernization efforts and discuss possible solutions; gather with subject matter experts from a variety of backgrounds to obtain input to strategize and suggest new approaches to public health data surveillance based on their real-world experience; and stay updated about ongoing and future data modernization priorities. The Consortium includes public health associations, state, tribal, local, and territorial health department representatives, industry, academia, and community-based organizations.

Additionally, CDC has organized a series of events in collaboration with the CDC Foundation and ONC to bring together public and private sector partners to consider catalytic opportunities to unlock and modernize essential public health information that can be used for better, faster decision-making. In February 2023, the CDC/ONC Industry Day event was hosted in Washington DC, with robust engagement from both the private and public sectors.

CDC is also working closely with state, local, and tribal jurisdictions to improve data connections and ensure that there is never a reliance on one singular data flow. Outbreaks of rare, high-consequence pathogens may result in a rapid need for case data at the national level; yet clear mechanisms for rapid electronic notification from state, territorial, and local public health authorities have historically been a challenge. CDC partnered with the CSTE to complete a landscape analysis disseminated to 61 reporting jurisdictions in July 2022 to better understand current practice and challenges for data management and notification of low-incidence, high-consequence pathogens, particularly during outbreaks and events. Additionally, CDC is expanding Data Collation and Integration for Public Health Event Response (DCIPHER) as a response common operating platform, already in use for several low-incidence, high consequence pathogens for surveillance and outbreak response. Continued expansion of that platform has allowed for direct data pipelines to local jurisdictions to ensure efficient data flows and improve timely reporting.

d. What publicly available resources exist for stakeholders and constituents to track the current use of funding and access real-time updates on how the modernization efforts are proceeding?

CDC's Public Health Data Strategy is available online, outlining the data, technology, policy, and administrative actions essential to exchanging critical core data efficiently and securely across healthcare and public health entities. The strategy is designed to describe a path to address gaps in public health data, helping the nation become response-ready, promote health equity, and improve health outcomes for all.

Additional information about CDC's DMI is also available at CDC's DMI website² and includes of what "better data" really looks like and the on-the-ground steps taken to ensure its availability for public health decision-making.³

In close collaboration with the APHL and CSTE, CDC is rapidly onboarding healthcare facilities to eCR. As of April 2023, more than 25,000 facilities in all 50 states are actively sending electronic initial case reports to public health departments using eCR. The number of facilities in production for eCR, demonstrating continuous progress, is accessible on CDC's website.⁴

- 3) Throughout the course of the Covid-19 pandemic, wastewater-based epidemiology (WBE) has been used effectively by state and local governments, federal agencies, universities, and private businesses to monitor the spread of the virus and its variants, inform public health responses, and help predict the level of new cases in a community several days in advance. One noted benefit of WBE is that it produces aggregated and anonymized data from community wastewater samples, avoiding difficult personal data and privacy issues. It is also cost-effective because one sample could be representative of an entire community. In late 2021, CDC established the National Wastewater Surveillance System, or NWSS. Under the Consolidated Appropriations Act, 2023, Congress authorized the CDC Director to continue leveraging public-private partnerships for activities that would include wastewater-based epidemiology.
 - a. Please explain all current CDC efforts to utilize wastewater epidemiology across the agency.
 - b. Please explain any efforts to engage with private sector partners to utilize wastewater epidemiology across the agency.

CDC's National Wastewater Surveillance system (NWSS) is the first nationally coordinated wastewater surveillance system. Through NWSS, CDC works with health departments to track levels of SARS-CoV-2 to monitor and understand disease transmission. Since the inception of NWSS, CDC has expanded the surveillance system to include over 1,400 sampling sites (wastewater treatment plants) with data that represent over 144 million Americans. In August 2022, CDC expanded wastewater surveillance to track mpox at multiple NWSS wastewater sampling sites throughout the country. CDC continues to coordinate wastewater surveillance through partnership with wastewater utilities, public health laboratories, and health departments to ensure that communities receive timely, quality data. These data are being used to better inform public health action, including resource allocation, provider alerts, and implementation of mitigation strategies.

¹ https://www.cdc.gov/ophdst/public-health-data-strategy/index.html

² (https://www.cdc.gov/surveillance/data-modernization/index.html),

³ https://www.cdc.gov/surveillance/data-modernization/snapshot/2022-snapshot/2022-snapshot-visual-booklet-P.pdf

⁴ <u>Healthcare Facilities in Production for eCR | CDC</u>

Building upon the work of NWSS, CDC established the Healthcare-Wastewater Antimicrobial Network to build capacity for the detection of antimicrobial resistance (AR) threats in healthcare facilities through collaborations with academic, healthcare, and public health partners. These efforts guide efficient screening strategies for informing early prevention measures in healthcare facilities (e.g., nursing homes, long-term acute care hospitals), and have the potential to detect any emerging AR threat before their transmission and spread. To represent geographic diversity in the United States, CDC has partnered with collaborators from the Western (University of Utah), Central (Rush University Medical Center in Chicago, Illinois), and Eastern (Atlanta metro area) regions to pilot wastewater methodologies in high risk, high acuity healthcare settings with long-term residents (i.e., long-term acute care hospitals and skilled nursing facilities with ventilator capabilities).

Following the identification of the single case of polio and environmental detections of poliovirus in New York State last year, CDC worked with select jurisdictions across the country to strategically expand wastewater testing for poliovirus in certain counties with potentially low polio vaccination coverage. It is important to note that wastewater testing for poliovirus is different from testing for other pathogens such as COVID-19. Poliovirus wastewater testing is not routinely or broadly recommended, and there are strict laboratory safety requirements. However, the strategic use of wastewater testing can help determine if poliovirus is present and can be used to target vaccination efforts to rapidly improve local polio vaccination coverage if needed.

Beyond SARS-CoV-2, AR in health care, polio, and mpox, CDC is exploring potential uses of wastewater surveillance for non-infectious disease targets, taking into consideration any potential ethical and legal implications.

Through the NWSS Internal Advisory Council, the NWSS program leverages subject matter expertise across the agency. This group strives to ensure coordination and collaboration within the agency, including intra-agency data access and logistical coordination of communications materials and partnerships.

NWSS relies on partnerships with both public health and non-governmental partners to achieve program goals. CDC has contracted with a commercial laboratory partner that provides wastewater testing for over 380 sites for SARS-CoV-2 and mpox. Leveraging this partnership, CDC was able to quickly begin mpox testing and provide regular SARS-CoV-2 coverage.

Additional work between NWSS and the private sector includes:

- o Developing and validating a multi-pathogen assay panel for powerful, state-of-the-art digital PCR platforms to expand wastewater surveillance to include respiratory viruses, foodborne infections, emerging pathogens, and AR genes.
- o Engaging with molecular diagnostic companies to inform NWSS platform updates to allow submission of data generated from new testing technologies, such as rapid test cartridge systems, which are key for testing in remote locations.
- o Awarding Small Business Innovation Research contracts to spur ingenuity and advancements in the field of wastewater surveillance, such as a preservative for wastewater stabilization to protects samples during shipping and storage.
- o Supporting research contracts with academic partners to address critical data and methods needs. Projects include determining whether SARS-CoV-2 viruses in wastewater are infectious, analyzing the fecal shedding patterns of SARS-CoV-2 infections, and

- developing methods for detection, quantification, and characterization of viruses, bacteria, and fungi in wastewater.
- o Data and knowledge sharing partnership with WastewaterSCAN. Through this partnership, CDC shares successes and challenges, and facilitates data sharing from WastewaterSCAN testing sites through CDC's DCIPHER system. WastewaterSCAN began sharing data through DCIPHER in early 2023.

The Honorable Robert E. Latta

- 1) During the Monkeypox outbreak last summer, after noting the public health laboratories would not have the capacity to provide the magnitude of testing needed, the CDC engaged with five commercial laboratories (Aegis, Labcorp, Quest, Mayo Clinic, and Sonic Healthcare) to more than double the nation's capacity to do testing for patients who needed it. I commend that public-private engagement, which boosted testing capacity by 50,000 per week.
 - Can you speak to that experience, and what steps is CDC taking to work with ASPR, as appropriate, to ensure that we don't waste time with legal work and contracting when an emergency is happening, but to put such agreements in place before an emergency, so our commercial clinical laboratory partners with nationwide reach are ready to roll when we need them?

CDC understands the importance of engaging with commercial laboratories and expanding access to testing to meet critical demand.

CDC and the Food and Drug Administration (FDA) began working with five U.S. commercial laboratory companies on testing strategy within days of detecting the first U.S. case. CDC began shipping tests to commercial labs in June 2022 and all five labs were ready fully to run tests by July 18, 2022.

As of May 11, 2023, the International Reagent Resource (IRR), established by CDC to support laboratories worldwide, shipped 3,092 extraction and enzyme kits to 96 Laboratory Response Network (LRN) laboratories across the country, including Department of Defense LRN laboratories.

CDC continues to work to ensure there is sufficient testing in the future and continues to explore all available avenues to make testing more accessible. We continue to provide technical consultation, reagents for testing, and develop enhanced guidance for LRN laboratories. CDC will also continue to provide test kits to commercial laboratories to ensure access to tests remains widely available.

The Honorable Earl L. "Buddy" Carter

1) During public health emergencies, high rates of hospitalization can lead to increases in hospital acquired infections (HAIs) despite health care professionals following infection prevention guidelines to the best of their ability (which is harder to do in emergency conditions). HAIs increasing during an emergency can be due to several reasons, such as patients who are already sick being more susceptible to HAIs, the use of ventilators increasing the risk of HAIs, crowded conditions, and overwhelmed hospital staff. Many HAIs are increasingly resistant to available antibiotics. What more should the federal government do to prevent HAIs, address antibiotic resistance and ensure novel antibiotics are developed to support emergency responses?

To prevent healthcare-associated infections (HAIs), address antimicrobial resistance (AR), and ensure novel antibiotics are developed to support emergency responses, the federal government must:

- Increase investment in prevention of HAIs and AR.
- Provide sustainable resources for the National Healthcare Safety Network (NHSN).
- Expand health department capacity to prevent, detect, respond to, and contain HAIs and AR.
- Accelerate innovation for infection prevention.

Increase investment in prevention of healthcare-associated infections and antimicrobial resistance

CDC provides national leadership in HAI and antimicrobial resistance (AR) prevention and provides the scientific foundation for preserving quality care, improving patient safety, and advancing U.S. healthcare practices. Reducing HAIs and antimicrobial-resistant infections across all healthcare settings supports HHS's mission to prevent infections, improve patient safety, combat AR and its complications, as well as reduce excess U.S. healthcare costs. 1,2,3

CDC has demonstrated that our AR prevention efforts work – from 2013 to 2019, there was an 18% reduction in deaths from antimicrobial resistance in the United States. demonstrated that our AR prevention efforts work – from 2013 to 2019, there was an 18% reduction in deaths from antimicrobial resistance in the United States. demonstrated that our AR prevention efforts work – from 2013 to 2019, there was an 18 percent reduction in deaths from AR in the United States.

However, infection prevention and control practices and resiliency building in these programs must be enhanced and expanded to withstand future public health emergencies. Without additional sustained resources, progress made through current annual appropriations and COVID-19 supplemental funding will likely be lost. CDC's fiscal year (FY) 2024 President's Budget proposes an increase for the National Healthcare Safety Network (NHSN) and the AR Initiative funding lines to continue our efforts to transform how data are collected, as well as enhance support for state, local, and territorial outbreak and emerging infectious disease preparedness and prevention capabilities. These key investments strengthen the nation's core public health capacity to combat HAIs and AR and prepare for future public health threats.

Provide sustainable resources for the National Healthcare Safety Network

CDC's NHSN is the nation's most comprehensive and widely used system to identify emerging and enduring threats across healthcare, such as COVID-19, HAIs, and antimicrobial-resistant infections. More than 38,400 U.S. healthcare facilities—including nearly every hospital, ambulatory surgery center, dialysis facility, and CMS-certified nursing home—use NHSN and NHSN analytics to track, report, and take action related to a range of urgent health threats. CDC intends to continue analytic work to identify hotspots of infections within healthcare and disproportionately affected populations, respond to future emergencies, and aid other U.S. government agencies, state and local health departments, and individual healthcare facilities. Sustainable funding for NHSN is necessary to maintain U.S. preparedness and resilience to prevent, detect, and respond to infectious disease threats in healthcare.

Expand health department capacity to prevent, detect, respond to, and contain HAIs and AR CDC's Healthcare-associated Infections and Antimicrobial Resistance (HAI/AR) Program provides funding, technical expertise, and resources to support HAI/AR prevention and control across a network of 50 state health departments, six local health departments, and eight territories. Activities focus on a wide range of patient safety improvement areas, like HAI/AR response and prevention;

antibiotic stewardship; the Antimicrobial Resistance Laboratory Network (AR Lab Network); infection prevention and control education and training through CDC's Project Firstline; and NHSN surveillance and using data for action. These programs also lead healthcare-related outbreak investigations within their jurisdictions with technical and diagnostic assistance from CDC staff. For example, the recent response to a multistate outbreak of extensively drug-resistant Pseudomonas aeruginosa linked to artificial tears was identified directly through infection control American Rescue Plan Act (ARP) supplemental funding to provide additional CDC investment in HAI/AR programs in every state infection control program. Sustainable funding for HAI/AR programs is necessary to maintain U.S. preparedness and resilience to prevent, detect, and respond to infectious disease threats in healthcare.

Accelerate innovation for infection prevention

CDC's AR Solutions Initiative invests in academic, healthcare, and other partners to help develop innovative solutions to our most pressing AR challenges. CDC drives innovation through a range of patient safety investments that identify ways to provide better care more efficiently. CDC also supports industry and academic colleagues with access to an ever-growing number of pathogen samples available to inform research and development of new antibiotics, antifungals, and diagnostic tools through the CDC and FDA Isolate Bank, accelerating innovation and pathways to develop critical preventative agents like therapeutics, vaccines, and decolonization products. While the availability of existing antimicrobials and the development of new treatment options is a priority, we are also focused on preventing infections from happening in the first place. These innovative efforts include CDC and FDA working to identify ways to support pathogen reduction and decolonization products and building a vaccine data platform to inform and accelerate the development of new vaccines and assessment of vaccine impact, stopping infections before they start. CDC also works to maintain the effectiveness of existing antibiotics and antifungals by strengthening antibiotic and antifungal stewardship—the effort to measure and improve how these drugs are prescribed by clinicians and used by patients to ensure antibiotics are effective when needed.

2) With the upcoming expiration of several authorities and grant programs provided in the Pandemic and All-Hazards Preparedness Act (PAHPA), what adjustments should we consider in order to better encourage and support domestic pharmaceutical and medical product manufacturing within the U.S. to ensure a reliable and sustainable supply chain?

CDC defers questions related to supply chain concerns and pharmaceutical and medical product manufacturing to the Administration for Strategic Preparedness and Response (ASPR) and FDA.

3) The COVID-19 pandemic underscored vulnerabilities in our domestic public health supply chains, particularly for essential medical supplies and pharmaceuticals. What can we learn from the challenges faced during the pandemic and how might Buy American policies be used or modified to better support U.S.-based manufacturers and consequently improve our resilience to future health security threats? What incentives do you recommend is needed to strengthen and support domestic manufacturing of pharmaceuticals and essential medical supplies?

CDC defers questions related to supply chain concerns and pharmaceutical and medical product

manufacturing to ASPR and FDA.

The Honorable Gus Bilirakis

- 1) The Office of the Director of National Intelligence (ODNI) has identified the absence of field biosafety standards as a significant concern, particularly considering the increase in field sampling and advanced research, as mentioned in its recent Annual Threat Assessment. For instance, improper bat field research, including biomedical sampling, could lead to viral spillover. Field biosafety is typically overseen at the institutional level, and there are no federal biosafety standards across various departments and agencies, resulting in fragmented oversight and a lack of unified federal field biosafety standardization.
 - Is the CDC considering the inclusion of a field biosafety chapter in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual? If not, where is the appropriate place for field biosafety standards to be developed and published?

CDC partners with the U.S. National Institutes of Health to publish the Biosafety in Microbiological and Biomedical Laboratories (BMBL), an advisory document developed as a tool to enhance safe work practices in traditional biomedical and clinical laboratories (i.e., a room or building equipped for scientific experiments, research, or teaching). The BMBL does not provides details on how to work in non-traditional environments (i.e., field research), even though some lessons in the BMBL could be applied to non-traditional research settings. The core function of the BMBL is to be a tool used for protocol-driven risk assessment in biomedical and clinical laboratories and is part of a collection of documents that provide guidance on the subject. No single document can identify all the risks or possible mitigations needed to conduct biomedical research safely. Several documents can be used to supplement the BMBL related to field research. For example, the World Health Organization's monograph on Outbreak Preparedness and Resilience can be used as a guide to help deployers involved in outbreak response safely work in mobile laboratories or other temporary facilities.⁵

- 2) The Centers for Disease Control and Prevention (CDC) is supposed to be the nation's preeminent public health agency tasked with addressing communicable diseases, but the last several years the CDC has engaged in a vast amount of mission creep to include preventable, chronic conditions:
 - As we navigate CDC reform how do we ensure the CDC holds true to its intended mission?

CDC's work in the prevention of non-communicable diseases truly is foundational work at CDC to protect and enhance the health of all Americans. The agency has been working in this space for nearly 70 years. Today, as the nation's health protection agency, CDC is responsible for responding to emerging health threats, such as disease outbreaks, and for supporting ongoing disease prevention and health promotion efforts through partnerships with state and local public health agencies. Both infectious and non-infectious work at CDC is crucial and interdependent which allows the agency to leverage all aspects of the expertise that resides at CDC to tackle the health

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⁵ See World Health Organization. Laboratory Biosafety Manual, 4th Edition. Available at: <u>9789240011373-eng.pdf</u> (who.int)

challenges of our time.

Chronic disease (including cancer, heart disease, diabetes, and stroke) and overdose remain in the top 10 causes of death while responses to the increasing number of natural disasters will continue to have a critical role in maintaining the health and wellbeing of the American people.

This work requires not only the experts at CDC, but also one of CDC's greatest assets—the unique and trusted relationships that have been built between the agency and STLTs, which enables CDC to carry out its disease prevention mission.

We are stronger when we work together and leverage all aspects of the expertise that resides at CDC.

There are several examples of the interdependent nature of infectious and non-communicable disease prevention:

- **Birth Defects** During the Zika outbreak in 2015, CDC employed a cross-agency response that utilized both infectious disease specialists and National Center on Birth Defects and Developmental Disabilities (NCBDDD) experts to reduce the risk and impact of Zika virus in pregnant women, infants, and children.
- Chronic Conditions People with chronic diseases are often the most at risk for more severe health outcomes during public health emergencies, making it critical that infectious and non-infectious emergency public health efforts are tightly aligned.
- NIOSH National Institute for Occupational Safety and Health (NIOSH) research cuts across CDC to protect worker health and safety from occupational illnesses, including mental wellness, exposure-related cancers, and infectious diseases such as bloodborne infections.
- **Injury** The same approaches that CDC uses to detect and respond to infectious disease and the agency's existing partner networks, which include state epidemiologists, state laboratories, and state health departments, are needed to respond to the over 100,000 deaths annually from drug overdoses.
 - How will you work with your fellow agencies and the private sector to ensure suitable response from the appropriate agencies to address public health concerns?
 - Moving forward how will the CDC engage with private sector partners to maximize public health response during emergencies?

A key priority for CDC's Moving Forward initiative is to promote partnerships. To better coordinate these critical relationships, a new external affairs leadership position has been created within the agency. Our new Office of Public Health Data, Surveillance, and Technology and our Center for Forecasting and Outbreak Analytics are also hosting an industry day in May 2023 where private sector companies will hear about opportunities to collaborate and partner with CDC.

CDC is strongest when we seek out ingenuity of the private sector. We recognize that it is critical to maintain and build upon these partnerships so that they may be appropriately leveraged to most effectively respond to public health emergencies.

- 3) Currently CDC only recommends MPOX vaccines in an outbreak situation. However, vaccines are most effective when incorporated into routine preventive measures for those considered to be at risk for MPOX, rather than waiting for an emergency.
 - When will CDC revisit this recommendation to establish a more forward-looking policy for at-risk groups?

CDC anticipates the Advisory Committee on Immunization Practices (ACIP) to likely schedule a vote on routine use in late 2023. Information can be found at <u>Advisory Committee on Immunization Practices (ACIP) | CDC</u>

The Honorable Debbie Dingell

Telehealth has become a critical tool for so many Americans. It enables patients to access healthcare in the comfort and safety of their own homes, but it especially benefits seniors, individuals living with disabilities, and those living in rural or underserved communities who do not have to deal with the physician and financial challenges of traveling to their appointments.

That's why I was glad that legislation I introduced alongside Representative Cheaney was included as part of the fiscal year 2023 omnibus to extend Medicare telehealth flexibilities through 2024.

As we look forward, I believe more can be done to embrace telehealth services beyond 2024.

1) Dr. Walensky, what are the benefits of telehealth, especially during public health emergencies?

In-person office visits may be necessary in some cases, but there are many benefits to using telehealth, especially during a public health emergency (PHE). Limiting physical contact during a PHE can reduce exposure to pathogens. Access to telehealth in general allows people get healthcare wherever they are located. Virtual visits help cut down on travel time from work, and the need for childcare. Telehealth can also increase access to specialists who are located far away, and virtual healthcare tools can shorten the wait time for appointments.

Telehealth existed as a mode of service delivery long before the COVID-19 PHE. In the case of the COVID-19 PHE, there was an urgent need to expand the use of technology to help keep individuals at risk for worse outcomes from COVID-19 and people with mild symptoms in their homes while still making sure they had access to needed care.

Telehealth utilization has changed since the steep increase during the COVID-19 pandemic. However, it remains an important mode of service delivery that helps get healthcare to people – especially in underserved areas. (add concluding sentence about why it is necessary when planning for future PHEs/why funding for it is critical etc.).