

March 11, 2022

The Honorable Dawn O’Connell  
Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Assistant Secretary O’Connell,

The Pew Charitable Trusts (Pew) is pleased to respond to the request for public comments to help inform the 2023-2026 National Health Security Strategy (NHSS). Pew is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of health care.

We commend the Department of Health and Human Services and the Assistant Secretary for Preparedness and Response (ASPR) for your efforts to strengthen the country’s capabilities to respond to health disasters and emergencies – including future pandemics – in the next NHSS. To support your development of the NHSS, our recommendations, included below, address several challenges central to public health preparedness.

Thank you for your leadership in addressing the health security threats and public health challenges facing our nation as you update the Strategy. We appreciate the opportunity to inform this important process. Please contact Kyle Kinner ([kkinner@pewtrusts.org](mailto:kkinner@pewtrusts.org)) in our Government Relations practice for additional information or questions.

Sincerely,



Kathy Talkington,  
Director, Public Health Programs  
The Pew Charitable Trusts

## **RECOMMENDATIONS RELATED TO ANTIBIOTIC RESISTANCE**

The Centers for Disease Control and Prevention estimate that at least 2.8 million individuals in the U.S. suffer from antibiotic-resistant infections each year, and at least 35,000 die.<sup>i</sup> Just six of the most common resistant pathogens lead to national health care costs exceeding \$4.6 billion each year, according to a January 2021 CDC report.<sup>ii</sup>

The need for new antibiotics has never been more urgent – not only to sustain the practice of modern medicine, so much of which relies on the availability of effective antibiotics, but also to ensure we are [better] prepared for the next pandemic.

Among its many lessons, the COVID-19 pandemic has underscored the 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. Antibiotics save countless lives, and yet, their value to health care has been taken for granted; all the while, their effectiveness gradually diminishes, while bacteria continue to develop resistance and become more dangerous to patients.

At the same time, the ongoing pandemic is probably exacerbating the public health threat of resistance. Pew research has shown there was likely 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.<sup>iii</sup> And, according to the Centers for Disease Control and Prevention some drug-resistant health care-associated infections rose during the pandemic.<sup>iv</sup> 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.

**Recommendation:** DHS/ASPR works with Congress to take swift action to provide targeted economic incentives for drug makers to develop novel antibiotics to reinvigorate the currently stagnant pipeline.

Despite the importance of novel antibiotics in securing modern medicine and protecting patients during pandemics, the pipeline of these types of drugs is woefully insufficient to meet patient needs. And while existing pre-market government funding is essential to support the initial research and development of new antibiotics, these investments alone cannot adequately address the broken antibiotics market.

The antibiotic market is categorically different from other therapeutic areas because older drugs are used preferentially to avoid contributing to resistance, and because antibiotics are designed to only be used when needed at the minimal dose necessary to cure a patient. This leads to a low potential sales volume for new antibiotics coming to market; as a result, these drugs are a losing business venture for most companies. These unique market dynamics have resulted in an industry crisis, as more and more pharmaceutical and biotech companies are backing away from developing new antibiotics.

To fix the market failure and stimulate the antibiotics pipeline, Pew recommends DHHS/ASPR works with Congress to support 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. To achieve this, 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 appropriate use of these critical drugs—preserving their long-term effectiveness—by encouraging and financially supporting establishment of hospital stewardship programs, especially for resource-limited facilities such as rural and critical access hospitals.

**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.

A key component of improving antibiotic use—and combatting the rise of dangerous infections—is requiring antibiotic use and resistance reporting by hospitals, which is proven to improve patient outcomes, lower health care costs, and reduce inappropriate antibiotic use.<sup>v</sup> Widespread reporting of antibiotic use and antibiotic resistance data is essential to identify and track emerging threats and evaluate the impact of interventions to address antibiotic resistance.

Despite the fundamental importance of reporting to effective antibiotic stewardship, participation in the U.S. Centers for Disease Control and Prevention’s National Healthcare Safety Network Antimicrobial Use and Resistance (AUR) Module, which collects such data, 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.<sup>vi</sup> 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.

Pew recommends that DHHS/ASPR works with the CDC and the Centers for Medicare and Medicaid Services to increase reporting into the AU and AR Options through existing regulatory requirements for acute care hospitals and establish funding programs to provide financial support and technical assistance to help facilities report data to NHSN. Additionally, Pew

recommends: DHHS/ASPR works with Congress to include robust support for NHSN AUR reporting through existing agency programs in any legislation that creates economic incentives for antibiotic development; helps facilitate financial support and technical assistance to hospitals and other inpatient facilities to strengthen antibiotic stewardship programming and help facilities report AUR data through NHSN participation; and improves disease and resistance surveillance at the national, state, and local level.

## **RECOMMENDATIONS RELATED TO PUBLIC HEALTH DATA**

Making available timely, granular, and actionable data, while ensuring data security and integrity is paramount to our nation's ability to prepare for, respond to, and recover from national health security threats. The COVID-19 pandemic has elevated longstanding challenges surrounding data acquisition, access, and analysis for rapid disease detection and an equitable response. Early in the pandemic, the federal government, via DHHS, requested that hospitals report data daily and directly to the federal government, unless a written release was in place with their state.<sup>vii</sup> At the same time, hospitals received numerous similar requests from other entities, leading to duplicate data sharing and burdensome reporting. In addition, in early 2020, only a few public health agencies and healthcare facilities had implemented electronic case reporting, the ability to automatically transmit case reports in real-time from electronic health records (EHRs) to public health agencies.<sup>viii,ix</sup> While available data have highlighted the disproportionate impact of COVID-19 on certain racial and ethnic groups,<sup>x</sup> lack of complete race and ethnicity data for people vaccinated against COVID-19<sup>xi</sup> has posed challenges for achieving equitable vaccination uptake.

Throughout the pandemic response, state and local public health agencies leveraged a myriad of existing and new data systems and digital technologies to obtain, manage, and analyze information.<sup>xii,xiii</sup> Expanding interoperability across these systems has the potential to facilitate more effective and efficient public health responses. While local health departments have reported overall improved interoperability of information systems compared to 2018, only a small percentage reported that all their systems are interoperable.<sup>xiii</sup> The federal government, in the National COVID-19 Preparedness Plan, has committed efforts enabling greater linkages between case surveillance and hospital data to vaccination data through strengthened data infrastructure and interoperability.<sup>xiv</sup>

Given the progress our nation can continue to make in preparing for swifter responses to national health security threats through enhanced and protected data systems that seamlessly exchange information, Pew makes the following recommendations:

**Recommendation:** Broaden and deepen efforts, through a whole-of-government approach, to improve protected public health data exchange capabilities of EHRs.

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. Furthermore, manual reporting via phone, fax, or mail result in time delays that hinder a

rapid public health response. Currently, federal regulations from The Office of the National Coordinator for Health Information Technology (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, Pew has called for (1) these optional capabilities to be required as part of base certification for EHRs so that all systems are able to communicate with state and local public health agencies; and (2) adherence to the specific consensus-based standards developed or supported by the Public Health Data Task Force of the Health Information Technology and Advisory Committee. 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.<sup>xv</sup> Following these standards would also help ensure that EHRs can use automated triggers to send reports.<sup>xvi</sup> As base certification for EHRs currently do not require capabilities for public health reporting of these four use cases, the NHSS should build on its current objective of preparing, mobilizing, and coordinating a whole-of-government approach and elevate coordination efforts across ONC, the Centers for Medicare & Medicaid Services (CMS), ASPR, CDC, and other federal agencies to address the current gaps and complement efforts to improve EHR public health data exchange capabilities.

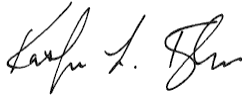
**Recommendation:** Ensure that hospitals, healthcare facilities, and healthcare systems expand secure electronic reporting to public health agencies.

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.<sup>xvii</sup> 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.<sup>xviii</sup>

Addressing this requires an all-hands federal approach, including through 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.<sup>xix</sup> This is a step in the right direction; however, it should be expanded to require syndromic surveillance and laboratory data. 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 do not practice in an emergency department.

The NHSS should redouble efforts to require, incentivize, or otherwise promote secure electronic reporting from hospitals, healthcare facilities, and healthcare systems to public health agencies. Wherever possible, the expectation of electronic public health reporting should be incorporated in every aspect of the NHSS' strategic approach and objectives.

Addressing these and other opportunities to improve electronic public health data exchange will pave the way for collective progress toward more robust preparedness for, nimble response to, and swifter recovery from health security threats to our nation.



Kathy Talkington  
Health Policy Group, Director  
Pew Charitable Trusts

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<sup>i</sup> U.S. Centers for Disease Control and Prevention, “About Antibiotic Resistance” (2022), <https://www.cdc.gov/drugresistance/about.html>.

<sup>ii</sup> U.S. Centers for Disease Control and Prevention, “CDC Partners Estimate Healthcare Cost of Antibiotic-Resistant Infections” (2021), <https://www.cdc.gov/drugresistance/solutions-initiative/stories/partnership-estimates-healthcare-cost.html>.

<sup>iii</sup> The Pew Charitable Trusts, “Could Efforts to Fight the Coronavirus Lead to Overuse of Antibiotics?” (2021), [https://www.pewtrusts.org/-/media/assets/2021/03/could\\_efforts\\_to\\_fight\\_coronavirus\\_lead\\_to\\_overuse\\_of\\_antibiotics\\_final.pdf](https://www.pewtrusts.org/-/media/assets/2021/03/could_efforts_to_fight_coronavirus_lead_to_overuse_of_antibiotics_final.pdf).

<sup>iv</sup> U.S. Centers for Disease Control and Prevention, “COVID-19 Impact on HAIs in 2020” (2021), <https://www.cdc.gov/hai/data/portal/covid-impact-hai.html>.

<sup>v</sup> Barlam, T.F., et. al., “Implementing an Antibiotic Stewardship Program: Guidelines by the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America,” *Clinical Infectious Diseases*, 15 May 2016, <https://doi.org/10.1093/cid/ciw118>.

<sup>vi</sup> U.S. Centers for Disease Control and Prevention, “U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria (National Action Plan)” (2020), <https://www.cdc.gov/drugresistance/us-activities/national-action-plan.html>.

<sup>vii</sup> Federal Emergency Management Agency, “Coronavirus (COVID-19) Pandemic: HHS Letter to Hospital Administrators” (2020), <https://www.fema.gov/press-release/20210318/coronavirus-covid-19-pandemic-hhs-letter-hospital-administrators>.

<sup>viii</sup> Association of Public Health Laboratories, “History of eCR” accessed March 4, 2022, <https://ecr.aimsplatform.org/general/history>.

<sup>ix</sup> U.S. Centers for Disease Control and Prevention, “Electronic Case Reporting (eCR) Fact Sheet” accessed March 4, 2022, <https://www.cdc.gov/ecr/docs/eCR-Fact-Sheet-508.pdf>.

<sup>x</sup> Stokes, E.K., et. al., “Coronavirus Disease 2019 Case Surveillance — United States, January 22–May 30, 2020” *Morbidity and Mortality Weekly Report*, 19 June 2020, <http://dx.doi.org/10.15585/mmwr.mm6924e2>.

<sup>xi</sup> Painter, E.M., et al., “Demographic Characteristics of Persons Vaccinated During the First Month of the COVID-19 Vaccination Program – United States, December 14, 2020–January 14, 2021” *Morbidity and Mortality Weekly Report*, 5 February 2021, <https://www.cdc.gov/mmwr/volumes/70/wr/mm7005e1.htm>.

<sup>xii</sup> Association of State and Territorial Health Officials, “COVID-19 Technology & Digital Tools ASTHO Data Product” last modified February 2022, <https://datastudio.google.com/u/0/reporting/24bf5e55-9eb8-4063-a254-b855c6858a1b/page/vOgIC>.

<sup>xiii</sup> Bosco, L. J., et. al., “Heterogeneity and Interoperability in Local Public Health Information Systems” *Journal of Public Health Management & Practice*, (2021), [https://journals.lww.com/jphmp/Fulltext/2021/09000/Heterogeneity\\_and\\_Interoperability\\_in\\_Local\\_Public.15.aspx](https://journals.lww.com/jphmp/Fulltext/2021/09000/Heterogeneity_and_Interoperability_in_Local_Public.15.aspx).

<sup>xiv</sup> White House, “National COVID-19 Preparedness Plan” (2022), <https://www.whitehouse.gov/covidplan/>.

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<sup>xv</sup> HL7 International, “HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2 - US Realm - the Electronic Initial Case Report (eICR)” last modified June 16, 2016, [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=436](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=436).

<sup>xvi</sup> Association of Public Health Laboratories, “eCR Now FHIR App,” accessed March 4, 2022, <https://ecr.aimsplatform.org/ecr-now-fhir-app>.

<sup>xvii</sup> U.S. Centers for Disease Control and Prevention, “2018 IISAR Data Participation Rates,” accessed March 4, 2022, <https://www.cdc.gov/vaccines/programs/iis/annual-report-iisar/2018-data.html>.

<sup>xviii</sup> Centers for Disease Control and Prevention, “What is Syndromic Surveillance” accessed March 4, 2022, <https://www.cdc.gov/nssp/overview.html>.

<sup>xix</sup> Pew Charitable Trusts, “New Federal Policies Seek More Data for Public Health, Emphasize Health IT Safety” last modified November 15, 2021, <https://www.pewtrusts.org/en/research-and-analysis/articles/2021/11/15/new-federal-policies-seek-more-data-for-public-health-emphasize-health-it-safety>.