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June 26, 2020

The Honorable Lamar Alexander
Chairman
Senate Committee on Health, Education, Labor and Pensions (HELP)
U.S. Senate
Washington, D.C. 20510

Dear Chairman Alexander,

The Pew Charitable Trusts is pleased to respond to the committee's request for feedback on the *Preparing for the Next Pandemic* white paper. Pew is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of health care. Specifically, the responses to the white paper are on behalf of three Pew health projects—the Antibiotic Resistance Project (ARP), the Health Information Technology project (HIT), and the Health Care Products (HCP) project. Below please find brief descriptions of these initiatives:

1. ARP—Pew's Antibiotic Resistance project works to advance policies that spur the development of new antibiotics and ensure effective antibiotic stewardship in human health care settings and food animals. For more information on Pew's antibiotic resistance work, please visit: https://www.pewtrusts.org/en/projects/antibiotic-resistance-project.
2. HIT—Pew's Health Information Technology project focuses on advancing the interoperable exchange of health data and improving the safe use of electronic health records (EHRs). For more information on Pew's health IT work, please visit: https://www.pewtrusts.org/en/projects/health-information-technology
3. HCP—Pew's Health Care Products project works to advance policies that will effectively balance medical innovation with appropriate consumer protection, including in the area of diagnostic tests. For more information on Pew's health care products work, please visit: https://www.pewtrusts.org/en/projects/health-care-products

Thank you for the opportunity to respond to the committee's white paper. If you need additional information, please contact Sarah Despres at (202) 540-6601, sdespres@pewtrusts.org or Elise Ackley at (202) 540-6464, eackley@pewtrusts.org.

Sincerely,

Sarah Despres
Director, Government Relations
The Pew Charitable Trusts

Antibiotic Resistance

Antibiotics underpin all of modern medicine and are not only essential for public health, but also national security. Antibiotic-resistant bacteria can exacerbate casualties associated with both natural emergencies and bioterror or other attacks, compounding the impact of any widespread disease that causes weakened immune systems and therefore increased risk for secondary bacterial infections. Studies show that during previous viral outbreaks, such as the 1918 Spanish flu and the 2009 H1N1 influenza virus, secondary bacterial infections were a predominant cause of death.[1,2] Although scientists are still investigating the prevalence of bacterial infections in COVID-19 patients specifically, it is well-established medical knowledge that vulnerable patients who are on ventilators are at increased risk for infections, and recent studies in The Lancet reported evidence of secondary infections among coronavirus patients.[3,4] At the same time, initial trends suggest increased use of antibiotics in hospital settings, as physicians use all available tools to treat COVID-19 patients.[5] The resulting global 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.

WHITE PAPER RECOMMENDATION 1.2: **Congress and the administration should continue to support NIH research and its academic partnerships, which have provided key infrastructure to rapidly pivot to COVID-19 research and clinical trials.**

Congress and the administration should continue sustained funding to the National Institutes of Health (NIH), as well as to the Biomedical Advanced Research and Development Authority (BARDA) and the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), all of which are critical in supporting antibiotic discovery and development. NIH enables antibiotic research through grants and the Antibacterial Resistance Leadership Group (ARLG) clinical trial network. The agency has also recently established the Combating Antibiotic-Resistant Bacteria (CARB) Interdisciplinary Research Units and developed the Chemistry Center for Combating Antibiotic-Resistant Bacteria (CC4CARB). BARDA and CARB-X support antibiotic development by providing crucial non-dilutive funding, allowing companies to invest in developing new antibiotics without giving away any ownership of the business. CARB-X is one of the largest global public-private partnerships for accelerating early development of antibacterials, through provision of critical funding and access to product development services.

WHITE PAPER QUESTION 1.1: What incentives can the federal government offer to the private sector to encourage development of more medical countermeasures with no commercial market?

While existing pre-market government funding is essential to support and de-risk the initial research and development of new antibiotics, these investments are insufficient to address the uniquely broken antibiotics market. The antibiotic market is categorically different from other therapeutic areas because older drugs are used preferentially, 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 in a market crisis, as more and more pharmaceutical and biotech companies are backing away from developing new antibiotics. Most larger 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 year.

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. Any package of incentives should address the most urgent public health needs, ensure the appropriate use of antibiotics, provide predictability to antibiotic developers, and stabilize the market for companies already developing new antibiotics. Pew recommends a combination of reimbursement reform, such as through the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act; additional antibiotics-targeted funding for BARDA to specifically support commercialization; and a market entry reward program for companies that successfully develop innovative FDA-approved antibiotics. Ultimately, in order to ensure any new antibiotics are used judiciously—to slow the emergence of resistance—Congress should create a program that delinks reimbursement from an antibiotic's sales volume to avoid encouraging overuse and additional emerging resistance and to provide a reasonable return on investment. One such concept under consideration is for companies to enter into subscription agreements, which would be paid out for a specified period of time during patent exclusivity, rather than leaving companies to rely solely on product sales revenue. The Government Accountability Office, in a report issued in March 2020, recommended that Health and Human Services (HHS) develop a plan to incentivize development of new antibiotics through post-market financial incentives.[6]

Any economic incentives must also be paired with stewardship and surveillance requirements. 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. Widespread NHSN AU reporting also enables public health agencies to identify inappropriate national, state, and local

prescribing patterns, 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 percent of eligible hospitals were reporting AR data to NHSN and 23 percent of eligible hospitals were reporting AU data.[6] These participation rates fall far short of the goal set forth in the 2015 National Action Plan, which identified 95 percent participation in the AUR Module by 2020 as a significant outcome to strengthen national surveillance efforts to combat resistance.[7]

Moving forward, Congress should coordinate with CDC, CMS, and other agencies to promote and require widespread AUR reporting. Specifically, Congress can work with these agencies to ensure that NHSN AUR reporting is required through existing regulatory programs; grants are made available to regional stakeholders to provide financial support and technical assistance to help facilities report AUR data; and sufficient appropriations are made to address resource gaps and spur reporting.

Health Information Technology

The white paper highlights that major gaps remain in the ability of health care organizations to share data with public health authorities. For example, all too often health care organizations share data manually, such as through fax or mail, or only send minimal information—limiting the data to public health authorities and delaying actions that could address public health threats.[8]

To date, Congress has taken a number of steps to address public health data infrastructure gaps—including investing $550 million through coronavirus relief legislation. However, absent a coordinated, national effort to ensure effective data sharing, this and future investments may fall victim to the same lack of standardization and interoperability gaps that plagued the more than $30 billion federal investment in electronic health record (EHR) systems that began more than a decade ago via the Health Information Technology for Economic and Clinical Health Act (HITECH) Act.

Across all the health information technology recommendations, existing efforts should inform future public health data infrastructure upgrades. First, over the last decade, the Office of the National Coordinator for Health Information Technology (ONC) has created and published requirements for EHRs to improve data exchange. Instead of creating alternative requirements, or otherwise taking different approaches to data exchange, existing policies and approaches from ONC can serve as a guidepost for harmonizing standards and functionality across all health IT systems—including systems that obtain data from EHRs. For example, ONC's U.S. Core Data for Interoperability (USCDI) indicates the critical information needed for data exchange and should inform public health data modernization. Second, just like in clinical care, public health also relies on linking records with the right person. This process, known as patient matching, relies on demographic data—such as names and phone numbers—which also underlie effective public health activities, such as contact tracing and immunization registries. However, research has shown that more than half the time public health authorities may not receive phone numbers, inhibiting their ability to commence contact tracing.[9] Finally, Congress, in the 21st Century Cures

Act (Cures), recognized the importance of effective, standardized data exchange by requiring the use of application programming interfaces (APIs) to extract data from EHRs. APIs are tools that allow two systems or software applications to communicate with each other seamlessly. In implementing this provision from Cures, ONC established that starting in mid-2022, EHRs must have standardized APIs that will facilitate data exchange out of these systems. That same approach may offer opportunities to further public health data exchange, such as the submission of case reports to state and local health departments.

These principles underlie the following feedback on the relevant recommendations in the white paper that can support an improved, interoperable public health infrastructure.

WHITE PAPER RECOMMENDATION 2.1: Ensure timely communication between health professionals, states, the CDC, and the public, as appropriate, of case data and information regarding how emerging infectious diseases affect populations, including who is at higher risk for severe illness and death, to help inform state and local response and address any potential disproportionate impact on minority populations.

Timely communication requires electronic tools. Faxes, phone calls, and other manual processes add time, as well as increase the risk of error, in understanding and responding to public health crises. Instead, the submission of electronic case reports (eCR) from health care providers to public health authorities would: promote greater real-time submission of information; facilitate more accurate data by, for example, reducing the opportunity for typos associated with manual data entry; and enable more robust analytics.

For example, an application called eCR Now uses an API to pull information from EHRs to create an electronic case report and send the report to relevant public health authorities in real time.[10] eCR Now eliminates the need for providers to fax paper reports or make phone calls to the local health department in order to report cases. Because it pulls data using an API, it also eliminates the need for health care organizations to set up multiple point-to-point interface connections to share the same information. When data entered into a patient's record indicate that the individual has a certain reportable condition, the application automatically triggers the creation of a case report that includes relevant clinical information, such as medications, co-morbidities, and symptoms.

While eCR Now provides public health authorities with the needed data, uptake and use of this solution among health care provider organizations is low. Electronic case reporting is not required, and many providers and facilities resort to manual means, such as fax or phone calls, to report cases. Broad use of technology like eCR Now would more consistently provide public health authorities with the information they need to respond to public health crises. Establishing this type of functionality could be accomplished by building on the APIs originally required by Cures, which would ensure the receipt of contact information, key patient demographic data, and other clinical information needed by public health authorities. Access to this data in real-time will enable public health agencies to evaluate rates of illnesses across different communities, conduct more robust analytics on electronic data, and obtain other information to inform public health decisions. Future policies should scale these types of electronic reporting mechanisms that leverage existing infrastructure—such as APIs—to promote rapid public health responses.

WHITE PAPER RECOMMENDATION 2.3: The Departments of Health and Human Services, Homeland Security, and Transportation should coordinate to improve access to passenger contact information by appropriate public health officials to inform public health responses to infectious diseases, like measles and COVID-19, with necessary privacy protections in place. CDC should, in coordination with state health officials, review and improve the systems used to communicate such information to states.

Public health authorities need contact information in order to perform contact tracing and other disease mitigation efforts. Regardless of the source of contact information—airlines, health care facilities, or other organizations—state and local health officials require up-to-date identity information to begin contact tracing processes.

As mentioned, research has shown that more than half of lab results shared with state public health agencies are missing the patient's phone number, leaving public health officials to track down basic contact information in order start contact tracing efforts—all while the virus may be spreading.[11]

Some states have used work arounds to obtain this contact information for COVID cases. For example, some states use health information exchanges (HIEs) that may have patients' phone numbers to supplement the information provided by laboratories. States may also use manual processes—such as calling provider offices—to track down missing contact information. Given that state and local public health authorities are already under resourced, these steps can add significant burden.

To address this issue, ONC, as part of recent rulemaking, established the USCDI, which is a set of data elements that EHRs must share. The USCDI includes key demographic data that should serve as the roadmap for all systems to share complete demographic information when exchanging data. Federal, state, and local policies should build on the USCDI.

In fact, recent guidance from the Department of Health and Human Services (HHS) explains the data that should be shared with lab results and builds on the USCDI.[12] The guidance, for example, encourages—albeit does not require—the inclusion of crucial contact information, including telephone number. If the inclusion of this information were a requirement for the initial lab order, the data elements would have a greater likelihood of reaching public health officials from laboratories. HHS should continue to advance adoption of its guidance so that the sharing of this information can become a requirement.

WHITE PAPER RECOMMENDATION 2.4: Congress should pass the Public Health Data Systems Modernization Act, included in the Lower Health Care Costs Act, to modernize our nation's biosurveillance systems.

As stated in the white paper and underscored by recent legislation, an effective biosurveillance system requires real-time, standard data. Provisions in both the Lowering Health Care Costs (LHCC) Act and the Health and Economic Recovery Omnibus Emergency Solutions (HEROES)

Act would require the use of ONC standards as a condition of grants to state and local governments to modernize their public health data systems.

Reliance on ONC standards could both ensure harmonization across EHR and public health data systems and facilitate easier data receipt by public health authorities in a uniform manner. For example, meeting a shared set of standards could facilitate electronic reporting to state and local governments, obviating the need for faxes or other manual processes, and ensure that public health authorities receive the information they need to communicate regional trends to the CDC.

WHITE PAPER RECOMMENDATION 3.1: Utilize existing authorities to build public-private partnerships, such as vendor managed inventory contracts with manufacturers and distributors, to create excess medical supplies managed by private sector partners that could be needed for the next pandemic or public health emergency. Additionally, the Strategic National Stockpile could contract with manufacturers to maintain manufacturing capability for certain products, such as N95 masks or other personal protective equipment, to rapidly manufacture supplies needed for a future pandemic.

The supply chain shortages that hampered the response to the COVID pandemic highlight an ongoing challenge in health care: limited visibility into the supplies that hospitals have in their inventory. Congress in 2007 required the FDA to address this issue through the creation of a unique device identifier (UDI) system that would assign each product a code corresponding to its brand and model type. Despite FDA finalizing its UDI regulations in 2013, some hospitals have not integrated this device tracking system into their electronic databases, which both hampers patient safety efforts and can result in an inaccurate understanding of the supplies they have on hand.

For example, one hospital system estimated the inventory it had on-hand in its cardiac catheterization lab. Once implementing UDI, the hospital system found that it had more than double the supply it estimated.[13] For hospitals that have not tracked their inventory with UDI, they may not have accurate estimates of the personal protective equipment, ventilator supplies, or other devices essential to COVID response.

Congress, in working with the FDA and ONC, should ensure robust adoption of UDI by hospitals, including through the addition of device identifiers to medical insurance claims. The addition of device identifiers to claims would both ensure the capture of this information and provide valuable data to track the safety of device models, as recommended by both the FDA and the Inspector General of HHS.

WHITE PAPER RECOMMENDATION 3.4: The federal government, states, and the private sector must work more effectively together to distribute tests, treatments, and vaccines. Plans should be established in advance for how the federal government, states, and the private sector will coordinate to assess needs and distribute newly developed tests, treatments, or vaccines.

Many experts have cited the development and effective distribution of a vaccine as essential to keeping many aspects of the economy open and enabling a safe return to many communal

activities. Once a vaccine has been developed, the country will likely have an initially limited supply and the immunization may require multiple doses to take effect.

As a result, effective distribution of the vaccine will require tracking on who has obtained a dose of which type of vaccine, and how many remaining doses individuals need. This type of management requires advanced use of immunization information systems (IIS), which are databases already in use across the country to track measles, whooping cough, influenza, and other vaccinations.

The effective use of IIS requires clinicians and other health professionals to check the system for a patient's record to determine whether a dose is needed, and then input information on any doses given. Absent these steps, clinicians may not provide the right number of doses to secure immunity or provide too much of the vaccine when supply is low.

These steps rely on the ability for health care professionals to locate the right record. To do so, they use demographic data—such as name, date of birth, and address. As a result, the same challenges faced to match records across health care organizations also emerge in the use of IIS.

To address this challenge, many IIS adopt a forward-thinking approach to standardize addresses in the system.[14] Research has shown that standardizing address to the format used by the U.S. Postal Service (which indicates, for example, appropriate street suffixes) can improve the accuracy of matching records by approximately 3%, which could improve the number of matched records by tens of thousands of records per day.[15] Although many immunization registries have adopted this data-driven policy, other parts of the health care industry critical to vaccine distribution do not yet use this standard—including EHRs, pharmacy systems, and lab information systems. Without all systems using the same format, data exchanged between them will not reap the full benefits from the standardization for improved data quality and increased match rates—and will hamper the effective distribution of COVID vaccines once available.

Congress should work with ONC and USPS to take two steps to address patient matching challenges in preparation for vaccine distribution. First, ONC should ensure that all systems use the demographic data in the USCDI to identify patients in these systems. As previously mentioned, the USCDI indicates the key data that systems should use for matching, yet many do not. Second, USPS offers a free address standardization web tool, however the agency restricts its use to shipping. As a result, health organizations cannot use it for patient safety and pandemic response even though it's already made available for free to other services. IIS that use the USPS standard obtained grant funding to pay a commercial company to make this commonsense public health change, and such an approach is not feasible for the health care industry writ large. Congress should encourage USPS and ONC to enable the use of the already free tools by health care.

WHITE PAPER RECOMMENDATION 4.2: Ensure that the United States does not lose the gains made in telehealth.

The increased reliance of patients on telehealth services to receive care demonstrates a key gap in data exchange: for too long patients have served as the intermediary sharing information

across health care providers. Patients must often manually pick up their records and transfer them to another facility. In the age of COVID, patients can no longer pick up and drop off their records. Instead, patients and clinicians require electronic tools to access patients' records.

APIs and broader gains to support interoperability across health care providers can obviate the need for patients to manually pick and deliver their records. The recent rulemaking from ONC to implement Cures will require EHRs to have standard APIs that allow patients to download critical information on their care onto personal devices, such as smartphones. Such remote access will ensure that patients and clinicians can obtain data electronically without requiring the manual transfer of records.

Congress should continue to work with ONC and the Centers for Medicare & Medicaid Services to ensure the implementation of API regulations without further delay and build on the existing requirements so that patients and health care providers can obtain the information they need.

WHITE PAPER RECOMMENDATION 4.3: States need to maintain the capacity to trace contacts for emerging infectious diseases, and have programs in place to surge that capacity if necessary.

As mentioned, keeping the country open requires, among other responses, effective and timely contact tracing. However, some estimates indicate that the country as a whole only had several thousand contact tracers at the start of the pandemic—a tiny fraction of the 100,000 to 300,000 contact tracers that may be needed.[16] Given the gap between the current number of contact tracers and nationwide needs, improvements to the public health data infrastructure can help more efficiently use their time. Additionally, as cited above, public health authorities may not obtain phone numbers for infected individuals more than half the time, resulting in time wasted searching for contact information. Ensuring the exchange of the relevant data (demographic data in the USCDI) and the use of standards (e.g. the USPS address format) can ensure more efficient use of contact tracers' time.

Health Care Products

The pandemic has only underscored the need for timely and accurate *in vitro* testing, which drives treatment decisions by providers and patients and allows for the serosurveys, contact tracing, and other surveillance activities that are needed to support an effective public health response. In the event of an emergency, the widespread and timely access to these essential products translates to lives saved.

However, pandemics exert pressures on the global supply chains for these goods in the form of both supply shocks and demand spikes—sometimes leading to critical shortages. In responding to these situations, it is important for the federal government to maintain a focus on both rapid scale up and quality of testing. These are not only integral, but inseparable factors to be taken into consideration if the nation is to mount an effective response.

The white paper appropriately focuses on testing capacity and strategies to ensure greater access to testing. Any future policy proposals that follow from this process, however, should ensure the

quality of the tests on the market. The FDA's role in reviewing and authorizing all tests before they enter the market is an essential safeguard, and the agency is uniquely equipped to ensure that test developers in both the public and private sector are offering quality tests.

WHITE PAPER RECOMMENDATION 1.4: Engage and partner with the private sector early to develop diagnostic tests, ensure flexibility to develop and use laboratory-developed tests in a public health emergency, and ensure that the stockpile is better prepared to address diagnostic needs.

The FDA has demonstrated a great deal of flexibility when it comes to authorizing clinical tests for COVID-19, both lab-developed and commercially manufactured. Since the public health emergency was declared in early February, the agency has reviewed and authorized dozens of diagnostic and antibody tests, and, as noted in this white paper, allowed some state regulators to review and authorize lab-developed tests independently. The agency has also held regular briefings with test developers aimed at helping them prepare their Emergency Use Authorization (EUA) applications. Importantly, they have also moved quickly to update the labels of authorized tests and, where necessary, revoke authorizations in cases where tests have proven to be inaccurate and unreliable.[17] These actions highlight another important lesson of this pandemic: though scaling test capacity is an essential element of pandemic response, these efforts cannot come at the expense of quality. A bad test can, in many cases, be worse than having no test at all. The EUA mechanism is critical for ensuring that the information provided by testing is of sufficient quality to be actionable in the context of pandemic response. A compelling illustration of this point was the agency's temporary implementation of "Pathway D", which allowed serology test developers to come to market without an EUA, provided that they claimed to have validated their own tests. Within weeks, more than 70 companies had entered the market with serology tests of highly variable quality.[18] The agency had no way of knowing how many unreliable tests had been sold, or to whom, or what harms may have occurred because of a faulty test. Fortunately, it moved quickly to reverse course and require all test developers to obtain an EUA.

Though other regulatory agencies have an important role to play in ensuring the quality of laboratory operations and the adequate reporting of testing results. The FDA is the only federal agency with the expertise and infrastructure necessary to ensure the quality of the tests themselves, and is well situated to perform a coordinating role at the federal level when it comes to test development. As you consider future policy proposals, it is essential that the FDA retain primary authority over which tests can be marketed and used for patient care. Additionally, it is important during a public health emergency to maintain the FDA's flexibility in authorizing state-level regulators to conduct test reviews as necessary. However, this should only be allowed in cases where state regulators have the infrastructure and expertise to conduct those highly sophisticated reviews.

WHITE PAPER QUESTION 1.3 What could the federal government have done to be better positioned with diagnostics, vaccines, and treatments for COVID-19?

Under the current system, diagnostic tests are regulated by the FDA as medical devices, which means manufacturers must submit studies confirming a test's accuracy and usefulness in

diagnosing a particular condition before bringing it to market. However, the FDA has historically exempted from this requirement any *in-vitro* diagnostic (IVD) tests that are developed and used in the same lab. This policy of enforcement discretion—which was established in the 1970s—no longer serves public health and has led to a landscape where tests are regulated not according to their risk, but according to where they are run. It also means that many otherwise high-quality and advanced laboratories are not familiar with the FDA review process or requirements. This created a challenge once HHS Secretary Azar declared a public health emergency, as this meant that the FDA's policy of enforcement discretion for IVDs was no longer in effect, and all test developers were required to obtain an EUA In the early weeks, it was clear that some labs had difficulty in navigating that process, owing primarily to their lack of familiarity with the FDA and with the EUA process. Device manufacturers, by contrast, were in some cases able to obtain authorizations within a few days. This situation could be avoided in the future if there was a uniform regulatory pathway for diagnostics that was based on the risk that a particular test poses to patient or public health, rather than on the site where it was developed.

The Verifying Accurate, Leading-edge IVCT Development (VALID) Act, introduced earlier this year, seeks to accomplish this. Though this bill contains many provisions that require further discussion and evaluation, the basic framework would enable high-quality laboratories considerable flexibility in modifying or even developing new tests without prior FDA review. This would streamline the review of diagnostics and facilitate the implementation of a risk-based regulatory system that takes into account the need for innovation while still ensuring that tests meet baseline standards for validity. Such a system would also better position the nation's testing industry to navigate the EUA process in the case of a future emergency.

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