Pandemic and All Hazards Preparedness Act
Request for Information
NILA Response

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Medical Reserve Corps

Future pandemic response should coordinate among all actors in the laboratory industry. To avoid concentration and inefficient allocation of test volume in the future, NILA recommends the establishment of a "Clinical Laboratory Ready Reserve" to guard against atrophy following the COVID-19 pandemic and to ensure that there is national capacity and capability to ramp up a widespread and coordinated laboratory testing response within ten days of a new infectious disease outbreak or bioterror attack. This would be accomplished through a federally supported network of clinical laboratories, of all sizes and from all regions of the nation, that would participate on a voluntary basis. This new entity could be an extension of the Medical Reserve Corps, led by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR).

Participating laboratories would be encouraged to maintain in reserve (i) testing equipment, (ii) personnel, and (iii) expertise and know-how. Seminars, exercises and "tabletop" drills or contests would be held at least annually, whereupon sequences of novel pathogens or other analytes would be distributed along with positive specimens (controls), and laboratories and diagnostic kit manufacturers would practice and even compete to develop and validate assays in as short a time as possible. In addition to modest yearly stipends, cash prizes could be awarded to those laboratories that demonstrate the ability to deploy accurate testing in the shortest time.

Matching funds would be needed to encourage laboratories to maintain in good working condition "dual use" but excess equipment (e.g., PCR thermocyclers, extractors, liquid handling robots, etc.) that could be repurposed should mass screening be needed. Grants would also be provided to help laboratories maintain a cadre of skilled part-time laboratory technicians ready to be deployed in an emergency. These arrangements would be modeled much like a volunteer fire department. Diagnostic kit and instrument manufacturers would also be recruited and incentivized to participate as part of the Reserves.

Strategic National Stockpile

Community and regional laboratories play a critical role in pandemic response and, like other health care providers, need uninterrupted access to the supplies necessary to carry out testing and transport of specimens. Throughout the COVID-19 public health emergency, community laboratories filled a wide gap in testing when national laboratories were overwhelmed. Despite providing essential testing capacity, many community and regional laboratories struggled to access needed testing supplies—including swabs, reagents, PPE, and test kits—to adequately serve their communities. Additionally, state

governments often failed to distribute supplies equally among laboratories and made inconsistent and non-transparent decisions regarding the allocation of resources. Prioritization of supplies for the largest, national laboratories at the expense of community and regional laboratories left many community and regional independent laboratories to fend for themselves or go underutilized, limiting testing capacity and hampering pandemic response.

Many community and regional independent laboratories were also forced to place large supply orders with upfront payment and no guarantee that ordered stock would be utilized. In the future, a more transparent supply distribution process that accounts for the entire laboratory industry and considers where additional laboratory capacity could absorb more testing if supplies were available would help NILA laboratories to better respond to the needs of their communities. Future distribution plans should also ensure that needed supplies consider and reach all laboratories that are responding to the public health emergency. Distribution and stockpiling plans should also recognize the diversity of public health threats that could impact the nation and recognize the upfront capital investments that may be needed by community and regional laboratories to adequately respond.

One reason for stockpiling medical countermeasures is that the commercial supply chain is not optimized to dispense a product in the right time or amount during a response. We learned from COVID-19 that this is true of our diagnostic testing supply chain. And, while the Strategic National Stockpile (SNS) was designed for a mass response, it failed to acknowledge that the laboratory is a key health care provider in the event of a pandemic. Currently, though statute does not preclude it, the SNS has no requirement or funding to store diagnostic testing supplies.

The SNS must store key laboratory supplies and be widely advertised to stakeholders so that laboratories and officials understand the routes required to access the SNS when disaster occurs. Necessary supplies that should be made available to laboratories through the SNS include surgical gloves, protective gowns, plastics including pipette tips, and viral transport media.

Upon adding diagnostic testing supplies to the SNS, NILA recommends a transparent and open process for maintaining and disseminating the contents of the SNS. Further, to ensure the supplies are available and in working order in the event of an emergency, the SNS must be funded for routine inventory and replacement of laboratory supplies. First, there should be periodic review of the contents of the SNS to ensure that supplies are not depleted and that they are unexpired and in working order for deployment when necessary. Second, NILA supports the dissemination of guidance regarding the process by which the Secretary will deploy the contents of the SNS. The full scope of laboratory infrastructure, including community and regional laboratories, must be considered in such guidance to ensure the greatest capacity possible in responding to a pandemic.

Last, during the COVID-19 pandemic the National Institutes of Health (NIH) funded a number of laboratories to bring instruments in-house to facilitate rapid testing in the future. There should be ongoing funding provided to those laboratories that received NIH funding to maintain such equipment for use should another pandemic occur. This could be carried out via a partnership program between the SNS and the clinical laboratories, ensuring that regional and community independent laboratories are included.

Other Areas
In recent years we have been focused on combating infectious disease, but a future public health emergency could involve threats that are not linked to pathogenic organisms. We must be prepared to respond to toxic spills, radiation, natural disaster, biological warfare, and the proliferation of drugs like opioids and fentanyl.

Laboratory Data Reporting
New and burdensome data reporting requirements during the COVID-19 emergency response imposed significant costs on laboratories. Unlike other areas of health technology, there has been little incentivization or investment in the laboratory information technology sector. As a result, many laboratories lacked the required technology and manpower early in the pandemic to respond to new public health data reporting mandates, further slowing the pandemic response, and imposing additional costs on laboratories already under tremendous financial constraints. Both public health information systems and independent clinical laboratory infrastructure need financial investments to allow all laboratories to receive and communicate patient data to public health authorities more effectively. While public health departments need investments to build an infrastructure that will allow for more streamlined reporting and consistency across state reporting requirements, this is not enough without additional investments in the private clinical laboratory infrastructure. As we have seen with COVID-19, it is not just public health laboratories reporting results to public health departments—independent laboratories, including NILA members, are now responsible for a much higher volume of public health reporting than before.

NILA supports independent laboratories' role in this regard but believes strongly that federal investments should be made in independent laboratories, as well as public health departments, to ensure interoperability. Incentive payments to independent laboratories for public health data reporting could also support the adoption of technology that would streamline reporting and improve the consistency and accuracy of the data collected. Each state's Department of Health requires a unique and individual interface and/or electronic reporting format. Therefore, many independent laboratories must duplicate resources in staffing and interface support costs in establishing reporting across many different states. Importantly, inconsistent reporting requirements across all fifty states and the federal government, as well as requirements to report data that laboratories do not always have, hinder laboratories' ability to report data. Uniform data standards would improve the ability to report. A centralized data repository to which laboratories could provide data which is then subsequently sent to the interested state and federal parties would create efficiencies. Important public health data, including demographic and race and ethnicity data, may be better collected from the ordering clinician who has access to the patient's records, which laboratories often do not.

Novel Pathogen Testing
We learned from the COVID-19 pandemic that state public health laboratories do not have the capacity to respond to a pandemic of that magnitude. Future planning must include the entire laboratory community— especially community and regional independent laboratories—to ensure we use the full capacity our nation's laboratory infrastructure. The reliance on public health laboratories and the CDC assay at the beginning of the COVID-19 pandemic greatly hampered the pandemic response. The initial problems with CDC's first COVID-19 diagnostic tests created difficulties for laboratories that impeded the initial response to the pandemic. It delayed access to the data laboratories needed to develop their own tests. It also prolonged the period when public health laboratories were the primary laboratories performing COVID-19 diagnostic tests, limiting access to testing services for many patients. More planning to secure early access by public and private entities to specimen samples is needed to identify

when and how private entities can supplement public health testing and test development capacity and provide additional expertise. Failure to do so early in the COVID-19 pandemic led to undetected and uncontrolled spread of the virus.

Laboratory Developed Tests

Many NILA members use laboratory-developed tests (LDTs) to provide expansive diagnostic test menus for providers and patients—particularly of tests for which test kits are not available on the commercial market. LDTs serve an irreplaceable role in patient care and preparedness. Manufactured and commercialized in vitro diagnostic (IVD) test kits cover only a small fraction of clinically-ordered tests. Additionally, test kits can quickly become outdated. Unlike IVDs, LDTs can be developed rapidly in response to emerging public health threats, including pandemics. For example, LDTs continue to detect the rash of synthetic fentanyls and other drugs fueling the ongoing opioid epidemic. Without LDTs, public health officials and physicians will not have access to tests that can identify new and dangerous substances, identify emerging infectious agents, and provide other clinically important information, thus leaving the public at risk and slowing opportunities to save lives.

NILA has concerns about the Verifying Leading-edge IVCT Development (VALID) Act as introduced in the 117th Congress. The VALID Act creates a costly new oversight and registration requirement for LDTs that will burden smaller community and regional clinical laboratories, limit patient access to critical diagnostic testing, and hinder preparedness. As drafted, the VALID Act would be a major obstacle to community and regional clinical laboratories that have already suffered damage from reimbursement cuts under the Protecting Access to Medicare Act, made significant investments to respond to the COVID-19 pandemic, and are now facing dramatic increases in costs for reagents, equipment, supplies and laboratory personnel due to a very high inflation rate and a persistently low unemployment rate.

Our nation's community and regional independent laboratories are a critical component in the overall clinical laboratory infrastructure that is necessary for responding to pandemics and other emerging threats to health. Legislation as far-reaching as the VALID Act should be considered under the regular committee process, with opportunity for hearings and amendments. Should the committee consider including the VALID Act in the PAHPA reauthorization, we urge you to ensure the legislation is reviewed thoroughly during the committee process and that comments from all stakeholders are taken into consideration.