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Infectious Diseases Society of America

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May 8, 2020

Vice President Mike Pence  
The White House  
1600 Pennsylvania Ave. NW  
Washington, DC 20500

Alex Azar, MD  
Secretary, U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Vice President Pence and Secretary Azar:

The Infectious Diseases Society of America (IDSAs) appreciates the development of the April 27 joint White House-U.S. Department of Health & Human Services Blueprint for Testing Plans and Rapid Response Programs (blueprint). This high-level proposal recommends evidence-based and public health-oriented steps to building testing capacity and ultimately reopening the country.

IDSAs represents over 12,000 infectious diseases physicians, scientists, and other healthcare and public health professionals who are on the frontlines of the COVID-19 response. We support the blueprint's proposed outline of roles, responsibilities, core principles and elements. However, many recommendations lack essential detail and fail to address external issues currently facing healthcare providers, public health professionals, laboratories, and state government. Additional guidance on fortifying state and local public health infrastructure to support the required additional efforts is particularly needed. Issues of testing capacity, data analysis, standardization, and insufficient personal protective equipment (PPE) must also be addressed.

**IDSAs strongly recommends a 14-day consecutive downward trend in a state or locality's diagnosed cases – or in the percentage of cases tested, in areas testing asymptomatic or minimally sick individuals – in order to move to the next "step" in reopening. There must be sufficient testing to show this, as well as contact tracing advances and capabilities.** We also recommend the inclusion of considerations and recommendations for instances when progress isn't linear. To facilitate state development & implementation of the testing plans and rapid response programs called for in the blueprint and [April 16 President's Guidelines](#), our society has developed the below list of considerations as well as outstanding questions to further inform critical testing programs and proposals. We hope our recommendations are helpful as you consider next steps.

### **Key considerations**

As you continue to further develop and refine a national strategy for testing, we urge you to address the key issues detailed below.

- The blueprint’s core principles should include a stronger federal role, rather than leaving implementation completely in the hands of the states. Specifically, we urge the Administration to work with Congress to secure additional federal funding for adequate testing capacity and the expansion of the public health workforce as necessary to implement many of the blueprint’s recommendations. Currently there is no good estimate for how or when states will have access to widespread contact tracing, adequate rapid testing, sentinel surveillance, PPE, etc., and the blueprint’s execution should be contingent on establishing this framework before states can responsibly lift distancing restrictions. While diagnostic tests in particular have become increasingly available, the distribution of testing is markedly uneven and must be addressed.

In addition to expanding the number of testing platforms, the federal government should offer evidence-based recommendations for the appropriate number of tests by type based on prevalence. For instance, nucleic acid amplification tests (e.g., PCR) are currently most appropriate for diagnostics. The lower the rate of infection the greater the number of false positives, and the higher the rate of infection the greater the number of false negatives. A two-test strategy helps ameliorate this to some degree.

- State, local, and tribal governments are being tasked to identify and overcome barriers to efficient testing. However, these issues are pervasive, severe, and stem from forces outside state and local governmental control. We appreciate that state, local and tribal governments may be well-situated to identify these barriers, especially those that may differ regionally. But additional resources and increased federal support are required to overcome many of them. In particular, a federal strategy to ensure the manufacture and appropriate distribution of PPE and testing supplies is critical and most efficient in achieving the goals outlined.
- The blueprint promises that expanded authorizations for innovative testing technologies “will increase testing simplicity and speed without compromising quality or reliability.” This has shown to be definitively false regarding the nearly 100 unregulated commercial antibody tests FDA began more strictly regulating in a May 5, 2020 Emergency Use Authorization (EUA) policy update. Without an FDA review process to certify validity and safety, the commercial antibody testing landscape quickly became known as a “Wild West” in need of quality enforcement. Further, the analytical validity requirements for an EUA do not necessarily confer clinical validity or utility (i.e., quality and reliability are variable and not guaranteed when test validation and review processes are expedited).

Many hospital laboratories are spending undue time and finite resources validating unproven diagnostic and antibody tests. IDSA would therefore emphasize the critical need for accuracy of both RT-PCR and serology testing and recommend expanding funding to the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) to support hospital and public health laboratories in this process. In light of the need for additional appropriations, we urge you to work with Congress to secure those funds in the next coronavirus package.

Finally, while the roadmap's "Path Forward" nicely outlines many of the current concerns and outstanding questions for SARS-CoV-2 antibody testing, IDSA recommends the inclusion of a definitive statement noting that antibody tests should only be used when adequately validated, and that we do not yet know whether the presence of antibodies (or which antibodies) confers immunity in any form. The sentence about false positives – "which can lead people to incorrectly believe they had the virus and may be immune from further infection" – appears to conflate the presence of antibodies with immunity and should be amended to reflect current research in future guidance.

- Supply chain and workforce capacity considerations are critical to achieving adequate testing capacity and the ability to successfully reopen. While increasing testing should indeed be the nation's overall goal, we should also be sure that we can provide clinical guidance and public health guidance to follow up on patient test results. Public health officials have reported that this is lacking in many counties. We would appreciate more concrete language from the federal government regarding the use of validated tests and testing algorithms, and the deployment and updating of timely state screening and testing. Additional helpful guidance might include examples from other countries' successful efforts and preliminary study outcomes.
- The testing blueprint suggests that sample collection may be enhanced by focusing on tests utilizing samples from the front of the nose or mouth. However, IDSA recommends enhancing sample collection based on the best available science rather than the most easily collected samples. While samples can be collected from non-nasopharyngeal sources, they may not yield the most accurate results. Sample type is also impacted by where patients are in the progression of disease when tested.
- Utilization of timely clinical monitoring systems can be a helpful tool to track potential surges and outbreaks. However, widespread testing – which remains unavailable – is required for success. Future plans should consider listing suggestions for sentinel monitoring of high-risk populations (e.g. incarcerated, homeless, senior living facilities, etc.) and how real-time data can be used to improve monitoring where it's needed most. Sentinel monitoring would also be helpful at food processing plants, since many are being forced to stay open despite having major outbreaks. Sentinel monitoring systems should further aim to identify asymptomatic cases, as the "critical locations" identified in the blueprint may not identify population-based outbreaks until those most vulnerable are affected. While these sites are important, additional sentinel surveillance should include strategies to monitor low-risk populations with higher contact rates such as schools or industrial workspaces.
- Rapid response programs require a rapid scale-up of a workforce capable of undertaking contact tracing efforts. Manpower and technical expertise will be in short supply during the expansion, and IDSA recommends additional planning and resources for the sustained recruitment, education, and training of the public health workforce.

### **Outstanding Questions**

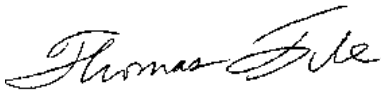
In addition to the various policy considerations, we request that you also address these additional questions from our experts to help improve the blueprint and federal policies regarding testing.

- What does the ideal testing and outbreak response infrastructure(s) look like in the views of the Task Force and the Centers for Disease Control and Prevention (CDC)?

- How will federal technical assistance (e.g., additional CDC staff/funding, state funding) be administered? If states do not have adequate money or staff for contact tracing, data entry, etc., how will those efforts be implemented?
- Will the federal government plan to share best practices in a bidirectional or top-down manner? Is there a rapid, straightforward way for various diverse stakeholders to communicate feedback and needs? How will suggestions be evaluated?
- The blueprint notes that states will be required to develop clinical monitoring systems in coordination with the CDC. Will this be federally funded, and if so, how much funding will states receive? How will allocation to states be determined?
- How and when did the administration complete its inventory of testing platforms in each U.S. ZIP code? Can this information be made publicly available? Did this assessment include laboratory developed tests? This data, if accurate, would be incredibly helpful to guiding various high-priority diagnostic policy initiatives (e.g., landscape analyses, reimbursement, R&D).
- What “barriers to maximizing the use of existing platforms” were identified, and how has this inventory effort helped states systematically overcome them?
- Which federal entities will be responsible for implementing each part of the blueprint details?

Successfully combating this pandemic will require strong national leadership, and we appreciate the role the administration is playing to advance the development of a comprehensive testing infrastructure. Beyond the immediate challenges, a successful reopening strategy will entail medium- and long-term planning for national testing capacity (drug and medical device stockpiles, public health workforce and infrastructure, health system preparedness, etc.). IDSA stands ready to facilitate expert collaboration, and we look forward to working with you to drive evidence-based public health solutions in the fight against COVID-19.

Sincerely,



Thomas M. File, Jr., MD, MSc, FIDSA  
President, IDSA