



Chiquita Brooks-LaSure, Team Lead  
U.S. Department of Health and Human Services Agency Review Team

Robert Gordon, Team Lead  
U.S. Department of Health and Human Services Agency Review Team

December 8, 2020

Dear Ms. Brooks-LaSure and Mr. Gordon:

Thank you for volunteering your expertise and time to lead the Biden-Harris Department of Health and Human Services (HHS) Review Team. Our nation urgently needs strong leadership as we grapple with the COVID-19 pandemic, and we are encouraged by the initial priorities and plans of the President-elect, Vice President-elect and transition team. On behalf of the Infectious Diseases Society of America (IDSA) and its HIV Medicine Association (HIVMA), we offer ourselves as resources to you. We have developed the attached recommendations for agencies and offices within HHS, highlighting key issues that we urge you to prioritize.

IDSA and HIVMA represent over 12,000 infectious diseases physicians, scientists, public health professionals and other clinicians on the front lines of the COVID-19 pandemic, caring for patients with COVID-19, developing infection prevention and patient management protocols, leading multidisciplinary hospital teams, directing state and local health departments and conducting research to deepen our understanding of COVID-19 to inform the development of new tools for prevention, diagnosis and treatment. While the pandemic is currently our top priority, we continue to confront an array of infectious diseases epidemics and threats, including HIV, influenza, viral hepatitis, infections associated with injection drug use, sexually transmitted infections, tuberculosis and infections caused by multidrug-resistant pathogens.

To successfully control the COVID-19 pandemic and reduce the burden of infectious diseases, we need evidence-based approaches, a commitment to health equity, a strong infectious diseases workforce, a sufficiently resourced public health infrastructure, a well-funded biomedical research enterprise and international collaboration. **We urge President-elect Biden to appoint department and agency leaders who reflect our shared commitment to promoting science, public health, health equity, diversity and inclusion.** Our attached recommendations identify short-term priorities to strengthen the prevention, detection and treatment of infectious diseases in the U.S. and around the world, including:

Department-level

- Rescind the Section 1557 regulations promulgated by the Trump Administration and re-establish broad protections including for gender identity.

### Centers for Disease Control and Prevention

- Provide additional funding to build vaccine confidence and to support the equitable distribution of COVID-19 vaccines, based upon recommendations from the CDC Advisory Committee on Immunization Practices;
- Increase funding for the Antibiotic Resistance Solutions Initiative, Advanced Molecular Detection program and National Healthcare Safety Network and establish a new grant program to support the antibiotic stewardship programs in health care facilities;
- Increase funding for global COVID-19 responses and global health security.

### Centers for Medicare and Medicaid Services

- Review, revise and revalue inpatient evaluation and management (E/M) services using an evidence-based approach to appropriately value ID physician care and help secure the future ID physician workforce;
- Maintain flexibilities in the payment and provision of telehealth services;
- Improve reimbursement for diagnostic tests;
- Rescind the “Opportunities to Promote Work and Community Engagement Among Medicaid Beneficiaries” and “Healthy Adult Opportunity” Medicaid guidance.

### Food and Drug Administration

- Ensure COVID-19 vaccine candidates are thoroughly reviewed in a transparent process and that vaccine sponsors present sufficient safety and effectiveness data, prior to authorization or licensure, and that they continue clinical trials following an Emergency Use Authorization (EUA);
- Communicate benchmarks for an EUA for COVID-19 therapeutics, to include a plan for continuing clinical trials, as the agency has done for COVID-19 vaccines;
- Advise Congress to revise and expand exemptions in the *Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2020* (S. 3404/H.R. 6102), adopting a facility-based approach for tests developed by clinical laboratories that ensures that all laboratory developed tests (LDTs) are appropriately subject to either Clinical Laboratory Improvement Amendments (CLIA) or FDA requirements.

### Healthcare Resources and Services Administration

- Designate infectious diseases specialists as eligible for the proposed U.S. Public Health Service Corps to respond to the pandemic;
- Provide loan repayment for ID and HIV providers working in underserved areas through the National Health Service Corps or other mechanisms;
- Issue strong national guidance for states to reduce barriers to HIV services by streamlining Ryan White HIV/AIDS Program certification and recertification processes.

### National Institutes of Health

- Increase funding and mentorship opportunities for early career physician-scientists, particularly for early stage investigators from underrepresented groups and those who are caregivers;
- Advance and expand the COVID-19 strategic plan to include research priorities identified by frontline clinicians and physician-scientists;
- Increase funding to support research on antimicrobial resistance, prioritizing the discovery and development of new antibiotics;
- Sustain funding for HIV research to end the HIV epidemic in the U.S. and around the world.

Office of the Assistant Secretary of Health

- Fully commit to and strengthen the Ending the HIV Epidemic initiative and reinvigorate the National HIV/AIDS Strategy (NHAS) as a road map for our country's HIV response;
- Fully commit to the Sexually Transmitted Infections National Strategic Plan and to the elimination of viral hepatitis in the U.S.

Office of the Assistant Secretary of Preparedness and Response

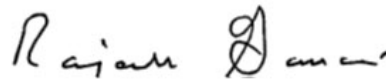
- Publicly disclose data used to determine allocations of COVID-19 therapeutics and provide more advance notice of allocation decisions to allow health care facilities to plan their distribution to patients;
- Better leverage the Strategic National Stockpile to address shortages of key medical supplies, personal protective equipment (PPE) and testing supplies;
- Develop new financial models to sustain antibiotic research and development, including enacting the bipartisan [\*Pioneering Antibiotic Subscriptions To End Upsurging Resistance \(PASTEUR\) Act\*](#) (S. 4760).

Thank you again for your leadership and hard work. If you have any questions or if there is anything we can do to support your efforts, please feel free to contact us through Amanda Jezek, IDSA Senior Vice President for Public Policy and Government Relations at [ajezek@idsociety.org](mailto:ajezek@idsociety.org) or Andrea Weddle, HIVMA Executive Director at [aweddle@hivma.org](mailto:aweddle@hivma.org).

Sincerely,



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Rajesh T. Gandhi, M.D., FIDSA  
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