



THE AMERICAN ASSOCIATION OF
IMMUNOLOGISTS

June 26, 2020

The Honorable Lamar Alexander
Chair, Senate Health, Education, Labor and Pensions Committee
428 Dirksen Senate Office Building
Washington, DC 20510-6300

Dear Mr. Chairman:

The American Association of Immunologists (AAI), the nation's largest professional association of research scientists and physicians who study the immune system, greatly appreciates having this opportunity to submit comments regarding your document, "Preparing for the Next Pandemic: A White Paper." Many AAI members, including immunologists around the world, are working tirelessly to understand of the role of the immune system in COVID-19, the disease caused by the virus SARS-CoV-2, and to develop urgently needed treatments and vaccines.

Although these comments are more general in nature, we stand ready to provide any technical assistance that we can and invite you and your staff to contact us at any time (email Lauren G. Gross, J.D., AAI Director of Public Policy and Government Affairs, at lgross@aai.org).

AAI appreciates your effort to look ahead to the "next" pandemic, even as the COVID-19 pandemic continues to afflict the world. As you do, we urge you to prioritize those items which will have the most immediate impact, as U.S. COVID-19 cases continue to increase rapidly amid a national weariness of behaviors necessary to contain its spread. Strong national, state, and local leadership, together with recommended public health practices modeled by all, is essential to reducing transmission, illness, and death from COVID-19.

As important as it is to start preparing for the next pandemic now, there is still much we do not know about what has worked well – or not – during our current response. As such, we strongly urge you to direct the National Academies of Sciences, Engineering, and Medicine (NASEM), or a non-partisan federal commission, to conduct a comprehensive review of the pandemic response as soon as feasible.

With that said, there are already some important "lessons learned" that will help us both combat the current pandemic and prepare for future ones. These include:

1. Ensuring Scientific Independence

It is critically important for scientists and public health leaders to be able to speak freely to policy-makers, legislators, and the public. They should not simply recommend the appropriate public health measures and research directions, they should also play a leading role in their determination. One thing we have learned from the COVID-19 pandemic thus far is that economic recovery depends not simply on controlling the virus, but also on restoring public confidence in the safety of everyday activities. Clear, frank, transparent information, provided regularly by trusted, apolitical health leaders, will help the public take the precautions necessary to protect themselves as they transition back to school, work, and other pre-pandemic activities, and thus will help control the spread of COVID-19. AAI recommends, therefore, that Congress take immediate action to ensure this free flow of information, and direct NASEM to expeditiously recommend ways to ensure the development and presentation of unfiltered, professional scientific opinions and judgments regarding pandemics/epidemics/outbreaks of infectious diseases, to policymakers, legislators, and the public. NASEM should include recommendations to strengthen the Centers for Disease Control and Prevention's (CDC) ability to develop and disseminate this critical information.

2. Reliance on Accurate, Data-driven Scientific Information

Accurate data, shared quickly, widely, and clearly, is key to a rapid response to a pandemic. This includes, but is not limited to, data necessary for operational planning [e.g., patient numbers, personal protective equipment (PPE), etc.], clinical care (testing, symptoms, type of care, guidelines, drugs, etc.); and policy decisions.

Ensuring the availability and credibility of data-driven science will require active efforts to combat disinformation, whatever its source. One possible approach would be to ask NASEM or another relevant, independent scientific body to develop a network of trained research scientists who could quickly read, interpret, and summarize emerging scientific data for policymakers and the public during a public health crisis.

3. Increased International Cooperation and Collaboration

The U.S. must not only work to enhance international cooperation and collaboration, it must also lead these efforts. AAI urges the U.S. to rejoin and work with the World Health Organization (WHO) to facilitate international communication, collaboration, and planning, during the present and future pandemics. Further, Congress should explore the U.S. decision to reject usage of the WHO SARS-CoV-2 test, and to decide whether, for example, the U.S. should create a special independent research team to validate tests developed in response to a novel pathogen.

The U.S. should also immediately join The Coalition for Epidemic Preparedness Innovations (CEPI), a multinational public-private collaboration that is working to develop a vaccine for (among other diseases) COVID-19. In addition to providing funding to many of the biopharmaceutical companies

that are working on COVID-19 vaccines, CEPI is coordinating with global health authorities (including WHO) and private partners to develop plans for the allocation, distribution, and oversight of the billions of vaccine doses that will be needed globally. While theirs is an essential role in the current pandemic, what they learn from the current crisis will no doubt be essential to any future one. In addition, Congress should seek ways to ensure deeper ties and more integration between the CDC and comparable entities in other countries.

4. Heightened Attention to Vulnerable Populations and Communities of Color

The COVID-19 pandemic has highlighted the devastatingly disproportionate impact that infectious disease can have on vulnerable populations and communities of color, in particular Black and Latinx populations. Whether they are

- essential workers whose jobs preclude sheltering at home,
- living in crowded conditions or in poverty,
- living in rural or other areas lacking an adequate health care infrastructure,
- needing to utilize public transportation,
- living with underlying health conditions or co-morbidities, or
- lacking health insurance,

these individuals are at a heightened risk of illness and death from COVID-19, and most likely, from a future pandemic. Every new measure put in place should consider carefully how vulnerable populations can best be helped. This will be particularly important component of any vaccine education and distribution program that is developed (see #5, below).

Addressing this issue begins with data collection to ensure that we understand the true scope of the problem. During the current pandemic, the federal government was slow to track information about race and ethnicity for those who have contracted, or been tested for, COVID-19. The federal government must modernize its data collection methods so that it is better able to collect this crucial information now and during future pandemics.

5. Vaccine and Pandemic Preparedness Education

It is critically important that Congress authorize and fund strong, lay-oriented education programs addressing these urgent issues: vaccination use, hesitancy, and safety; viral/pathogen spread; disease surveillance; slowing spread/social distancing/wearing of masks; and contact tracing. Without public understanding and support, even the best public health communication and surveillance, and the most effective treatments and vaccines, will fail to vanquish a pandemic. Because particular attention must be paid to underserved or underrepresented communities, as well as those with specific vulnerabilities, Congress should authorize funding for educational programs that are led by local members of these communities.

Last year, this Committee approved bipartisan legislation called the Vaccine Awareness Campaign to Champion Immunization Nationally and Enhance Safety (VACCINES) Act. The bill requires CDC to

develop a national surveillance system to monitor vaccination rates and to conduct a national campaign to increase awareness about the safety, efficacy, and importance of vaccines. This legislation was important last year and is even more important now, as misinformation about COVID-19 and possible treatments and vaccines is already ubiquitous. The effectiveness of any potential COVID-19 vaccine depends heavily on the national vaccine rate. In addition, there is already clear data showing that childhood vaccination rates have gone down during the current pandemic, in part because people are reluctant to visit hospitals and other settings where patients with COVID-19 could be present. It is vital to communicate to parents, many of whom are not necessarily “vaccine hesitant,” the importance of adhering to recommended vaccine schedules, even during a pandemic.

The COVID-19 pandemic has also clearly illustrated the lack of basic understanding of infectious disease among some health care professionals, particularly those with unrelated specialty areas who were called upon to treat COVID-19 patients during surge periods. In addition to ensuring that all physicians have a basic understanding of infectious disease and immunology (ensuring a solid foundation to expedite pathogen-specific training in the case of a pandemic), there should be an increased emphasis on developing best practices and on holding training programs for health care professionals at all career stages, to ensure appropriate continuity of care throughout the country.

6. Testing

Mass testing is crucial to containing this pandemic and preventing another one. Much time was lost in the early days of the COVID-19 pandemic as missteps followed by failures led to a delay in detection and uncontrolled spread of the disease. Some of the questions that remain and must be addressed now and for the future are:

- How can we reliability accelerate testing to meet the public health demand?
- How should tests be administered? (Drive-through, take home mail-in kits, etc.)
- Who will administer them?
- How will those administering the tests obtain the supplies they need? (In this pandemic, there have been shortages of everything from swabs to viral media and qPCR reagents, machines, and trained personnel.)
- Who will coordinate and track the testing?
- Who should determine how much testing should be done and for how long?
- Who will fund the testing (Federal or state governments?)

7. Animal Research and Surveillance

Understanding infection and reciprocal transmission dynamics between animals and people is critical in the prevention of pandemics and in the response to an emerging health threat. Thus, we need to have well established mechanisms that support clear communication, collaboration, and coordination among the human, animal, and environmental health sectors.

In addition to the general themes above, AAI has comments at this time about the following specific recommendations and questions contained in your White Paper.

1. Tests, Treatments, and Vaccines – Accelerate Research and Development

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.

AAI strongly supports Recommendation 1.2. To date, Congress and the Administration have provided robust funding to address the COVID-19 pandemic, while the National Institutes of Health (NIH) and other federal research agencies have provided important flexibility regarding grant deadlines and access to funding. It is particularly important during a pandemic, when the urgency of scientific research collides with public health restrictions affecting the scientific workforce, that grant funds be allowed to roll over from one fiscal year to the next. Similarly, NIH should be granted carryover authority, permitting the agency to use unspent appropriations from one fiscal year during the next fiscal year.

To ensure that the scientific community can respond quickly to another pandemic, it is crucial that Congress provide continuous, robust funding for research not only on infectious diseases, viruses, and pathogenic bacteria, but also on the immune responses to them. Such research will help determine appropriate prevention strategies and treatments. If not for our country's significant investment in research, particularly into other coronaviruses like Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS), we would not have been as well positioned to make rapid progress toward combatting COVID-19. National Institute of Allergy and Infectious Diseases (NIAID) Director Anthony S. Fauci, M.D., has pointed out that this research enabled scientists to begin phase one clinical trials of a vaccine candidate within a record three months of the virus' gene sequencing. Dr. Fauci has also indicated that one or more vaccines may be developed and approved by late 2020 or early 2021; if so, this would mark an astonishing new record in vaccine development (the current record is approximately four years).

Questions:

3. What could the federal government have done to be better positioned with diagnostics, vaccines, and treatments for COVID-19?; and 7. How can Congress and HHS make sure CDC and FDA are working more closely with the private sector on diagnostic tests to detect emerging diseases?

The federal government should provide more guidance to scientists new to the drug/device/diagnostic process. While the FDA has limited resources and staff, it should support educational programs to help those developing novel tests, treatments, and vaccines understand the process – and in particular to understand the key questions, which differ drastically from those for scientific exploration. Many applications to FDA contain excellent experiments that either do not, or insufficiently, address questions around safety and efficacy for the target population. Although there are many programs for accelerating drug/device/diagnostic approval, a lack of understanding of the process wastes precious time.

The federal government should also support efforts to explore the repurposing of existing vaccines and drugs to combat emerging pathogens in cases where treatment is urgently needed. The COVID-19 pandemic has already shown that available FDA-approved treatments may be effective, alone or in combination, against SARS-CoV-2. Together with a database summarizing cross-protective effects of these therapies, a strong repurposing effort would not only expedite the process for new pathogens, but also be more cost-effective and help to alleviate any concerns over safety and toxicity for human use.

4. How can the federal, state, and private sector work together to more effectively distribute and administer treatments and vaccines?

As stated above, it is critically important, particularly in advance of the release of a vaccine, for there to be extensive public education about the benefits of vaccination, the importance of herd immunity, and the location(s) where a vaccine can be obtained. Particular attention should be paid to educating health care providers, parents, school and institutional (including nursing home) administrators, and community groups that serve underserved or underrepresented populations. Clear information should also be provided about the risks, if any, of a particular treatment or vaccine, so that physicians can best serve their individual patients as we strive for broad public protection.

9. What the lessons learned from the current fast tracking of tests, treatments, and vaccines to make them available even more rapidly?

AAI members and immunologists around the world are working urgently to develop safe, effective treatments and vaccines, and see great value in continuing to “fast track” their development. Inherent in the approval process are bureaucratic burdens and inefficiencies not related to safety and efficacy. Removing these roadblocks is of great importance. However, AAI agrees with Dr. Fauci and FDA Commissioner Stephen Hahn, M.D., who cautioned at a recent congressional hearing that “fast tracking” should not compromise safety or efficacy.

In addition, communication of this accelerated process should be thorough and clear, in order to avoid public fear of, misuse of, or resistance to the use of newly approved treatments and vaccines.

2. Disease Surveillance – Expand Ability to Detect, Identify, Model, and Track Emerging Infectious Diseases

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 disease and death, to help inform state and local response and address any potential disproportionate impact on minority populations.

AAI supports Recommendation 2.1 but believes that the communication “between health professionals, states, the CDC, and the public...” must be not only timely, but also candid. During this pandemic, there have been numerous reports of public health officials being muzzled. Any such limitations on public health officials communicating the truth about the pandemic to legislators and the general public

must be stopped immediately.

As we have also learned from data collected to date, COVID-19 appears to be disproportionately impacting vulnerable populations and communities of color, in particular Black and Latinx populations. In addition to providing clear information to those at greatest risk, it is essential to collect information, including race and ethnicity, in order to effectively direct resources. This will require the development of a more connected public health and surveillance network in the U.S., with infrastructure support for public health offices in underserved and rural communities.

It is also important to be able to differentiate between mild and severe cases, and share this information rapidly, to facilitate better treatment plans for those who are more vulnerable to such infections.

RECOMMENDATION 2.2: CDC, states, and health professionals should work together to identify barriers to earlier identification of cases, including whether case definitions and testing recommendations were overly narrow for too long.

AAI supports Recommendation 2.2 but believes that an independent body, such as NASEM, should also conduct an evaluation. Any such evaluation should begin with the premise that there must be a clear strategy for defining and streamlining information, and for ensuring bi-directional communication. During the COVID-19 pandemic, an inadequate detection system, misinformation, and/or inconsistencies in identifying those most at risk contributed to delays in testing and diagnosis that proved deadly. In addition, our inability to simultaneously institute tracing methods to identify viral hotspots was a substantial contributor to the spread of the infection and enabled it to more rapidly disperse in the population.

Questions

1. What other barriers, in addition to limited testing capacity, and insufficient and outdated technology, make it difficult to detect and conduct public health surveillance of emerging infectious diseases?

The U.S.'s unwillingness to work with the WHO and our global allies on testing and surveillance has had catastrophic consequences. Congress should examine carefully why the U.S. rejected a SARS-CoV-2 test that was both accurate and already working in populations across the world. While it is important for the U.S. to have some level of independence from global stockpiles and resources, we must also have practices and policies in place to assess the situation in real-time and take action when our efforts are less efficient or are coming up short. The delay in diagnoses and the incorrect diagnoses due to our use of CDC's contaminated test could have been alleviated, in some part, if we had worked more closely with our global partners.

4. Has our focus in medical countermeasure development been too much on the known threats, such as anthrax and smallpox, to the detriment of emerging threats like coronaviruses, including COVID-19, SARS and Middle East Respiratory Syndrome?

Research on threats including SARS and MERS has been critical to jumpstarting research on SARS-CoV-2, the virus that causes COVID-19. Congress should direct NIH to examine its research portfolio and prioritize basic and translational research that is most likely to lay the best foundation for any biological or bioterror threat, whether natural or manmade. NIH is well positioned to work with other federal agencies to prioritize medical countermeasure development.

3. Stockpiles, Distribution, and Surges – Rebuild and Maintain Federal and State Stockpiles and Improve Medical Supply Surge Capacity and Distribution

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.

AAI supports Recommendation 3.4, but believes it is essential for the “private sector” to include all relevant stakeholders, including professional scientific and medical associations; medical and public health providers; hospitals and medical systems; academic institutions/local school systems; community organizations; patient advocacy organizations, and pharmaceutical and manufacturing companies.

With regard to the COVID-19 pandemic, the disastrous consequences surrounding the creation, distribution and use of tests must be understood and avoided, immediately and for the future. It is not too late, but soon will be, to avoid such a fate with regard to any treatments or vaccine. In particular, the development of a vaccine education plan to prepare the public is an urgent priority that cannot wait until a vaccine is developed.

RECOMMENDATION 3.5: Moving forward, state and health system stockpiles must be developed and maintained, with some federal support, to ensure the United States is ready for the next public health emergency. The federal Strategic National Stockpile must also be replenished and expanded to include certain supplies we now know are needed to respond to a pandemic and maintained with more oversight and accountability.

AAI supports a thorough evaluation of the role, responsibilities, and funding of the federal Strategic National Stockpile (SNS), in view of its utility and performance during the COVID-19 pandemic. We also urge that the SNS anticipate and provide for the needs of the scientific research workforce. Scientific researchers are as essential during a pandemic as they are in preventing a future one. Their work cannot stop, and any delay will lose lives to either the pandemic or an existing disease or condition that could have been treated or cured.

In addition, the SNS should be replenished based on an assessment of what is needed, including for prevention, testing, treatment, and research needs. While some items, like swabs, do not have expiration dates, they should be kept sterile. Reagents have expiration dates and need to be stored at colder temperatures. A barcode or other system should be implemented to create alerts when supplies are low.

4. Public Health Capabilities – Improve State and Local Capacity to Respond

RECOMMENDATION 4.1: Get Americans back to their routine health care safely, and develop better plans for the future so that doctors and hospitals can continue to provide health care services and outpatient treatment during a pandemic.

To assure Americans that they can safely return to routine care, health care providers must have access to all PPE needed to protect themselves and their patients and must communicate this to their patients (virtually and in person).

The COVID-19 pandemic has underscored the need to examine some of the structural aspects of our buildings, especially hospitals and other health care settings, to ensure that air flow prevents rather than exacerbates the spread of infectious agents.

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

AAI supports Recommendation 4.2 but notes that we must improve infrastructure not only for telehealth, but also for telework (including scientific research) and tele-education (including medical education).

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.

AAI supports Recommendation 4.3. Because state and local epidemiological studies can help ensure better and more accurate case statistics and contact tracing, policies are needed to regulate how contact tracing is carried out at the state and local level. It is also important for the general public to understand the importance of providing information to health professionals and to be told exactly how that information will be used and distributed. In addition, the public needs to understand the importance of “quarantining” after or during exposure.

Questions

4. How should the federal government ensure agencies like CDC maintain an appropriate mission focus on infectious diseases in the periods between emergencies to strengthen readiness to respond when a new threat arises?

Ongoing, regular, and robust federal funding to support basic, translational, clinical, and epidemiological research would best position CDC, NIH, and other health agencies to respond to a new threat. NIH (and in particular, NIAID) and CDC already have an appropriate mission focus on these areas. NIAID would greatly benefit from an ongoing stream of additional funds dedicated to better understanding the immune response to various pathogens and bacteria, potentially paving the way to faster, more efficient development of vaccines and therapeutics.

5. Who Is on the Flagpole? – Improve Coordination of Federal Agencies During a Public Health Emergency

RECOMMENDATION 5.1: Congress must clarify who is in charge and has the ability and authority to keep a continued focus on preparedness for pandemics and other major public health threats when other priorities may seem more pressing, and improve how federal agencies will coordinate during a pandemic. These roles and responsibilities must also be clearly communicated to states and local governments so they can include this information in their own preparedness planning.

The White Paper identifies myriad federal agencies that have been created in response to, or have responsibility for, pandemics and/or natural disasters. While allocation of duties and delegation of effort is necessary due to the range of response required for such events, the U.S. lacks a clear policy or line of authority. During the early days of the COVID-19 pandemic, President Donald Trump appointed a White House Coronavirus Task Force led by Vice President Mike Pence, which was to lead pandemic-related activities. Initially, that Task Force provided important information, regularly, to Members of Congress and the public (and presumably, to the President). Until today, however, the Task Force had been publicly silent and invisible for two months, making the country's pandemic response rudderless and woefully insufficient. Congress should act immediately to ensure that no such leadership vacuum can occur again and should recommend best practices to states to prevent such problems on the state or local level.

Thank you again for this opportunity to share our views of some of the critically important issues raised in your White Paper. We look forward to being of any assistance that we can on these and other issues in the days ahead.

Sincerely,



Ross M. Kedl, Ph.D.
Chair, AAI Committee on Public Affairs

cc. The Honorable Patty Murray
Ranking Member
Senate Health, Education, Labor and Pensions Committee