October 22, 2020

Alex M. Azar
Secretary
U.S. Department of Health and Human Services

ADM Brett P. Giroir, M.D.,
Assistant Secretary for Health
U.S. Department of Health and Human Services

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention

Stephen M. Hahn M.D.
Commissioner of Food and Drugs
Food and Drug Administration

Moncef Mohamed Slaoui
Chief Advisor
Operation Warp Speed

Dear Secretary Azar, ADM Giroir, Director Redfield, Commissioner Hahn, and Chief Advisor Slaoui:

As the nation plans for the upcoming allocation, distribution, and administration of a new COVID-19 pandemic vaccine, we write to emphasize that the success of that plan will be judged by how well it ensures equitable access for all. While continued efforts on testing and contact tracing are essential, we believe that deployment of a safe and effective COVID-19 vaccine is key to fully re-opening the American economy and to ensuring safe workplaces, schools, and communities. We expect this vaccination program will be the greatest public health effort of our generation and we greatly appreciate your leadership now to prepare the nation for this response.

The Adult Vaccine Access Coalition (AVAC) works to address rural, socio-economic, and racial disparities, and to increase immunization access among at-risk populations, persons with chronic illness, and maternal populations. It is with this in mind that members of AVAC join with stakeholder partners and allies to share several principles and policy recommendations to facilitate the equitable allocation, distribution, access, and utilization of a COVID-19 vaccine.

We strongly encourage transparency at every point of the planning, approval, allocation, and distribution process, as we believe it is the key to ensuring vaccine confidence and utilization, especially for high risk groups. AVAC appreciates that federal, state, and local governments have been laying the groundwork for months to distribute and administer a safe and effective COVID-19 vaccine. These plans rely on the strength of existing public health preparedness and response efforts and the immunization program infrastructure in the United States. Therefore, investments in communication efforts and immunization infrastructure must be increased.

To ensure equitable allocation, distribution, access, and utilization of forthcoming COVID-19 vaccines, we recommend the following actions be taken:

1. **Provide full transparency at every stage of the process to foster public confidence and maximize vaccine acceptance and use, especially among communities that have been the hardest hit by, and are most susceptible to severe illness as a result of, COVID-19.**
2. **Ensure information, resources, and vaccines reach and are utilized by at-risk and underrepresented populations.**
3. **Support essential immunization infrastructure and the community-based immunization providers.**

Providing full transparency in order to foster public confidence and maximize vaccine use, especially among communities that have been the hardest hit by, and are most susceptible to, COVID-19.
Much work is being done now to develop and get COVID-19 vaccine candidates to market. We share the sense of urgency the pandemic presents and believe an Emergency Use Authorization (EUA) sought by innovators can be in the public's interest. However, introduction of new COVID-19 vaccines under an EUA or full licensure must be supported by evidence. Expert scientists from the FDA should take a prominent role in communicating that the FDA gold standards for safety and effectiveness have been met. Clear and consistent communication of evidence-based information on COVID-19 vaccine authorizations and approvals will be vital to public acceptance and willingness to receive a vaccine, particularly during the early phases of a pandemic vaccination effort.

We specifically appreciate FDA's October issuance of *Guidance for Industry on Emergency Use Authorization for Vaccine to Prevent COVID-19.* The guidance, recognizing the potential for rapid and widespread administration of a vaccine authorized under an EUA to millions of individuals, calls for two months of monitoring safety data before submission for approval to the FDA.[1] Importantly, the guidance also reaffirms the commitment from FDA Commissioner Hahn at the September 23 Senate Health,

[1] Emergency Use Authorization for Vaccines to Prevent COVID-19, Guidance for Industry, October 2020 (p. 10)

Education, Labor and Pensions (HELP) Committee hearing to hold not only a general meeting of the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC), but to also convene additional VRBPAC open session meetings to review safety and effectiveness data for each vaccine candidate seeking an EUA.[2] We believe the transparency that will be facilitated by VRBPAC open sessions is extremely beneficial for building confidence in vaccines authorized under an EUA.

Once a vaccine is authorized or approved by FDA, it will be essential for the Advisory Committee on Immunization Practices (ACIP) to quickly meet and make strong and clear recommendations for the providers who will administer COVID-19 vaccines. These recommendations should include recommendation on a vaccine dosing schedule, including which populations should receive the vaccine first, and during what phase of the vaccine distribution process other populations should begin to receive the vaccine. Conflicting messages and intentional misinformation efforts around the COVID-19 vaccine can be combated by elevating the longstanding role of the ACIP as the vaccine policy recommending body for the US and by clearly communicating its transparent and rigorous thorough vetting process with the public.

We appreciate that guidance and numerous planning documents are underway to inform prioritization of populations to receive a vaccine in the short and long term, especially the National Academies of Science and Engineering Medicine's, "A Framework for Equitable Allocation of Vaccine for the Novel Coronavirus." The ACIP should take these recommendations into account, while continuing to review the research data, and make recommendations on who should receive specific COVID-19 vaccines. We support the work ACIP has done to date, including putting forth three criteria for the prioritization process: that it be ethically principled; evidence based; and transparent. We recommend further consideration on how the ethics and equity framework can be better incorporated into the ACIP evidence-to-recommendation process, along with clear definitions of who is included, so these recommendations can be implemented consistently and without controversy.

Additionally, all COVID-19 vaccines, regardless of whether authorized through an EUA or licensed through a BLA, should be continuously monitored for safety and efficacy through existing vaccine safety and reporting systems, including the Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink (VSD), Clinical Immunization Safety Assessment Project (CISA), and the Post-Licensure Rapid Immunization Safety Monitoring. Robust monitoring of COVID-19 vaccines post approval and communication of potential adverse events will be imperative to sustaining confidence and public trust during all phases of the pandemic vaccination effort.

Ensuring vaccines reach vulnerable and underrepresented populations.

We know that health inequity limits access to health care resources needed in many communities, including in Black, Hispanic or Latinx, American Indian, Alaska Native, Asian American and Native Hawaiian and Pacific Islander populations. This has long held true for vaccination rates, especially for those living in rural areas, below the poverty line, and in communities of color. These are the same

[2] same as last footnote, page 11.

populations that have experienced greater loss during the COVID-19 pandemic, including greater risk of COVID-19 infection and death. While vaccination planning to date addresses allocation, distribution, and administration, broad public confidence in a safe and effective vaccine is also a critical factor to combatting harmful health disparities. The Federal Government, working with immunization partners and trusted community leaders and organizations, must be proactive, clear, consistent, and highly visible in their communications to keep the public informed of vaccine development, safety processes, and approval and recommendation criteria.

Special consideration must be given to the protection of people who are most vulnerable from COVID-19. It is vital that those most at risk for complications and death are able and willing to receive the vaccine no matter their insurance status, immigration status, language ability, cultural awareness, chronic health conditions, ability to access care during regular business hours, transportation issues, and more.

Accordingly, we hope you will consider the following recommendations:

- Information about the new vaccine, the principles and process for allocation, phases of distribution, and priority populations must reach public health officials so they can plan accordingly to respond to the specific needs of their community. Guidance must be clear, understandable, and open for review, while also providing consistency between federal strategies and mass vaccination campaigns.
- A strategy to simultaneously educate and inform healthcare professionals (HCPs) to ensure they have confidence in receiving the vaccine and are able to make a strong recommendation to patients. In addition to the ability to leverage direct lines of communication to their patients, HCPs are trusted sources of information on how beneficiaries can safely receive preventative care during the COVID-19 pandemic. Training plans should be made available to all types of immunization providers throughout the country. Vaccine outreach and communication to HCPs should also encourage providers to raise awareness among patients regarding the need to receive all ACIP-recommended vaccinations and the alternative vaccination locations that may be available to them. Our country and public health infrastructure cannot afford to follow a pandemic with an increase in cases or large outbreaks of other vaccine preventable diseases.
- Trusted community leaders and partners should also receive proactive, clear, and consistent updates with regard to planning, allocation, and distribution efforts. Their support is critical for ensuring that information reaches the communities that have been hardest hit by COVID-19, including essential workers who are disproportionally from communities of color[3], and keeping the public informed of vaccine development, safety processes, and approval and recommendation criteria.
- The communications plan should be localized and flexible in its ability to reach different racial and ethnic communities and communities who have limited English proficiency, in order to build trust and acceptance. Vaccination campaigns must be able to extend to areas where people are least likely to be reached by traditional health care infrastructure and where there are known pockets of vaccine hesitancy. Community level grants should be made available to help support this work. Targeted resources will enable local leaders to test and tailor proactive messages,

[3] https://www.bls.gov/opub/reports/race-and-ethnicity/2018/home.htmexternal icon

while countering anti-vaccination sentiments. We know that the best messengers to communities experiencing health disparities are the organizations and partners they already trust.

Supporting essential immunization infrastructure and modernizing immunization information systems (IIS) to ensure equitable distribution of a vaccine to all Americans.

Adequate resources for distribution, tracking, and monitoring will be needed to successfully implement plans to vaccinate all Americans, especially those communities at greatest risk of COVID-19 complications and death. Infrastructure investments must go towards strengthening, enhancing, and expanding the ability of public health officials, primary care physicians, nurses, pharmacists, and other health care providers practicing at the top of their license in the community to meet demand for a future COVID-19 vaccine and also reach populations who are currently under-vaccinated. This important work will require the full strength of partnerships within the immunization neighborhood working together. We believe at least $8.4 billion in funding should be directed to support this effort.

- Funding for immunization infrastructure should include specific resources for recruiting and training the necessary additional workforce for state, local, Tribal, and territorial health departments; primary care settings; and pharmacies—with special focus on reaching communities of color and other vulnerable populations.
- Additional resources will be necessary to set-up federally supported supplemental vaccination sites in high risk communities and promote new strategies for mass vaccination, such as drive-thru clinics and clinics in nontraditional locations that are easy to access and are safe for vaccinators and the public.
- Immunization Information Systems (IIS), which can provide timely and accurate vaccination data, should be used to support any mass immunization efforts around COVID-19. IIS must be enhanced to meet new and changing data standards and access to IIS must be expanded to more providers and settings across the health care system. The interim playbook[4] recommends that, within 24 hours of administering a dose of COVID-19 vaccine and adjuvant (if applicable), the information should be recorded in the vaccine recipient's record and should be reported to the relevant state, local, or territorial public health authority. However, some IIS face challenges and policy barriers that limit their ability to maximize their use. To be optimally effective, IIS should encompass all vaccinations received during each person's lifetime, contain a person's consolidated immunization history, and fully meet the standards recommended by the CDC and American Immunization Registry Association (AIRA) to support clinicians in efforts such as administering a second dose of the appropriate vaccine product to a patient who has received an initial dose. There must also be coordination, interoperability, and bidirectional communication between the IIS and any new technologies such as the Vaccine Administration Management System (VAMS).
- There must be adequate Medicaid and Medicare reimbursement to cover the cost of vaccine administration counseling, and eventually the cost of the vaccine. Inadequate reimbursement discourages authorized healthcare providers, such as physicians, nurses, pharmacists and others, from proactively offering immunizations, and results in missed immunization

[4] https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf pg. 19

opportunities and declines in immunization rates. Adequate reimbursement will be essential for any vaccine approved under the regular approval process, or authorized under Emergency Use Authorization (EUA).

- Providers should be appropriately compensated for ancillary supplies. Public health officials, primary care physicians, nurses, pharmacists, and other health care providers in the community will need to manage the volume of procurement, storage, and distribution of ancillary supplies that will be required for a successful pandemic vaccination effort, such as personal protective equipment (PPE), syringes, and alcohol wipes.
- Providers should be compensated for virtual or in-person conversations about the importance and safety of vaccines. These will help build confidence in not only a future COVID-19 vaccine but all recommended vaccines. During the initial role out, grants should be made available to urban and rural providers, including FQHCs and rural community health centers, that may need additional financial assistance in order to successfully run COVID-19 vaccine clinics.
- Financial barriers to all ACIP recommended vaccines must be eliminated for individuals covered by Medicaid and Medicare to improve the underlying health of the communities most at risk for COVID-19.

Now is the time to redouble our efforts to eliminate the underlying vaccination disparities that have been prevalent in our health care system for too long. Again, thank you for the opportunity to share our perspective on principles, priorities, and recommendations to ensure equitable allocation, distribution, and access to the COVID-19 vaccine. Our organizations are available to answer your questions at your earliest convenience. Please reach out to AVAC Managers Abby Bownas, (abownas@nvgllc.com) or Lisa Foster (lfoster@nvgllc.com).

Sincerely,

Aging Life Care Association
Alliance for Aging Research
American Academy of Family Physicians
American Geriatrics Society
American Heart Association
American Immunization Registry Association
American Lung Association
American Public Health Association
American Society on Aging
American Society of Consultant Pharmacists
American Society for Microbiology
Asian & Pacific Islander American Health Forum
Association of Asian Pacific Community Health Organizations (AAPCHO)
Association of Black Cardiologists
Association of Immunization Managers (AIM)
Association of Maternal & Child Health Programs
Association for Professionals in Infection Control and Epidemiology
Association of State and Territorial Health Officials

Arthritis Foundation
BIO
California Primary Care Association
Caregiver Action Network
Dynavax
Emily Stillman Foundation
Families Fighting Flu
GSK
HealthyWomen
Heart Valve Voice US
Hep B United
Hepatitis B Foundation
Immunization Action Coalition
Immunize Nevada
Indivisible Northern Nevada
Infectious Diseases Society of America
Johnson & Johnson
Justice in Aging
March of Dimes
Medicago
National Adult Day Services Association (NADSA)
National Association of County and City Health Officials
National Association of Nutrition and Aging Services Programs
National Association of Pediatric Nurse Practitioners
NASTAD
National Black Nurses Association
National Consumers league
National Council on Aging
National Indian Council on Aging
National Minority Quality Forum
National Urban League
National Viral Hepatitis Roundtable
Nevada Academy of Family Physicians
Nevada Public Health Association
National Foundation for Infectious Diseases
OCHIN
Planned Parenthood Federation of America
Sanofi
Seqirus
Service Employees International Union
STChealth LLC
The AIDS Institute
The Gerontological Society of America
The Kimberly Coffey Foundation
The Mended Hearts

The National Black Nurses Association
The National Consumer Voice for Quality Long-Term Care
The Preventive Cardiovascular Nurses Association
Trust For America's Health
U.S. Pharmacopeia
Vaccinate Your Family
Vivent Health
WomenHeart: The National Coalition for Women with Heart Disease