June 23, 2020

Dear General Perna and Dr. Slaoui:

As the nation's leaders of state and local immunization programs, we applaud the commitment demonstrated in the Administration's announcement of Operation Warp Speed (OWS) to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, diagnostics, and ancillary supplies. We want to offer our support, expertise, experience, and partnership, which we believe will be crucial to planning and executing a successful national COVID-19 vaccine program. We particularly wish to offer feedback on the importance of building on existing vaccine delivery infrastructure and the opportunity to clarify the expected role of the military.

Following are some key questions and initial recommendations. We hope these can guide initial dialogue and underscore the need for close cooperation with state, territorial, tribal and local public health agencies and immunization programs:

- **Build on existing plans and infrastructure.** Does OWS anticipate utilizing a new vaccine distribution system? Under the Centers for Disease Control and Prevention's (CDC) leadership, our nation has a decades-long track record of facilitating both public and private infrastructure to successfully deliver life-saving vaccines. Additionally, the CDC has required all states to both maintain and exercise pandemic influenza plans. Especially as time is of the essence, we strongly recommend building upon existing plans and assessing, enhancing, and utilizing the existing coordinated public and private vaccine delivery infrastructure.

  The Vaccines for Children (VFC) program, for example, was established in 1994 to provide vaccine to Medicaid-eligible and uninsured children. State immunization programs manage the program using Immunization Information Systems (IIS) to enroll public and private providers, receive and approve vaccine orders, document doses administered, assure proper vaccine storage and handling, and manage vaccine supply

and inventory. These systems provide official immunization records, allow for follow-up if needed, and help immunization programs identify populations at high risk for vaccine-preventable diseases and target interventions and resources efficiently.

Vaccine is distributed directly to providers through a centralized ordering system and a national distributor managed by CDC. The VFC program is highly efficient and effective, providing vaccine to more than 50% of the nation's children and enrolling more than 90% of the nation's pediatricians, with approximately 44,000 provider sites participating. These providers order approximately 82 million VFC vaccine doses to administer to an estimated 40 million children.

This system was expanded to enroll adult providers during the 2009 H1N1 pandemic vaccination campaign. CDC used a central vaccine distributor to ship the H1N1 vaccine from regional distribution centers that received the H1N1 vaccines from five vaccine manufacturers to individual providers or organizations identified by state and local jurisdictions. State and local health officials, in conjunction with professional associations such as the American Medical Association, identified providers who signed agreements to administer the H1N1 vaccine, including providers who had not previously participated in the Vaccines for Children program, such as obstetricians, gynecologists, and other physicians who treat and immunize adults. A 2011 report by the Government Accountability Office (GAO) found this practice was generally cited as effective by state officials.[1] We want to stress this system is proven effective and already in place. It is capable of expansion, as demonstrated during H1N1 pandemic when it was used to distribute approximately 138 million doses of influenza vaccine.

We strongly encourage you to build upon this existing system for COVID-19 vaccination and not reinvent vaccine distribution and information management systems.

- **Clarifying the Role of Department of Defense**. What is the expected role of the Department of Defense in both vaccine distribution and administration? As noted above, the Centers for Disease Control and Prevention already leads and maintains a highly effective system of vaccine ordering and distribution utilizing the McKesson pharmaceutical distribution network to ship vaccine while maintaining the required cold-chain to ensure vaccine effectiveness along with the Vaccine Tracking System (VTrcks) to process orders and communicate allocations. Again, with time of the essence we strongly recommend against designing new and untested systems of vaccine distribution.

  Additionally, the announcement of OWS implied a possible role for the military in vaccine administration. It will be important to consider together if uniformed military vaccinators will improve or undermine confidence in a COVID-19 vaccine, particularly in certain minority and underserved communities where trust in the medical and political systems are already strained. Public health agencies already have systems in place to provide people with routine vaccinations and will need to be aware if a new vaccine

[1] Government Accountability Office Report, INFLUENZA PANDEMIC Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning, June, 2011

distribution is envisioned. If new avenues of distribution are indeed under consideration, this needs to be communicated to state and local partners immediately so that plans can be adapted where possible.

- **Working Together to Increase Vaccine Confidence and Reach the Most Affected Populations**: How can we work together to deploy evidence-based messages to increase vaccine confidence and reach the most affected communities? State and local immunization program leaders are on the front lines confronting vaccine hesitancy and combatting misinformation. A May 27 poll released by the Pew Research Center found a full 27 percent of those polled said they "definitely or probably **would not** get a Covid vaccine if it were available today." We need to build upon CDC and other partners' expertise to employ evidence-informed strategies now to build vaccine confidence to assure the success of this effort. We strongly recommend that any future communications about OWS more prominently highlight the ways the government has maintained the United States' long-standing vaccine safety standards during this accelerated vaccine development process, and how vaccines against COVID-19 will be safe and effective with ongoing monitoring systems that occur after vaccines are deployed.

  An additional lesson learned from the 2009 H1N1 outbreak was that the inability to effectively reach minority and vulnerable populations resulted in decreased vaccination rates, delays in seeking vaccination, spread of misinformation, and ultimately disparate percentages of hospitalizations and deaths in minority patients with H1N1 compared to non-minorities. A review by the Association of State and Territorial Health Officials (ASTHO) recommended that "governments at all levels needed to develop and use more effective strategies to reach minority communities and special and vulnerable populations during the H1N1 outbreak."[2] Similarly an H1N1 policy workshop report provided by the National Association of County and City Health Officials (NACCHO) indicated the need for evidenced-based communication strategies and tools for vulnerable populations.[3] Given what we know about the disparate impact of COVID on minority communities, we need to redouble our commitment in this area and give it the highest urgency.

- **Managing Expectations**: How can we best protect and enhance our credibility? Our experience with the H1N1 pandemic of 2009 taught us that announcements about when vaccine might be available need to include careful phrasing to manage public expectations and take into account likely delays or changes in expected availabilities. The GAO report cited earlier found that "the credibility of all levels of government was diminished when the amount of vaccine available to the public in October 2009 did not meet expectations set by federal officials." The subsequent review by ASTHO echoed that loss of government credibility also was a concern at the state level. ASTHO concluded that "state health department officials felt that dealing with slow and variable vaccine delivery and shifting messages about vaccine availability overshadowed all of their other response activities."[4] This was further confirmed in a H1N1 Supplement Survey Report conducted by NACCHO indicating the loss of credibility at the local level

[2] ASTHO, Assessing Policy Barriers to Effective Public Health Response in the H1N1 Influenza Pandemic, page 28.
[3] NACCHO, NACCHO H1N1 Policy Workshop Report, page 6
[4] ASTHO, Assessing Policy Barriers to Effective Public Health Response in the H1N1 Influenza Pandemic, page 23.

with lasting impacts due to receiving less than anticipated H1N1 vaccine.[5]

We recommend working together to stress the importance of preparing the public to understand that the demand for initially available doses will likely far exceed supply. We expect the CDC's Advisory Committee on Immunization Practices (ACIP) will develop a careful set of recommendations on how to prioritize groups such as first responders and other critical workforce to receive vaccine first, and how to expand to other populations as additional vaccine becomes available. This process needs to be carefully and precisely communicated to the public to manage expectations and maintain credibility which is of even greater importance in light of increased vaccine hesitancy.

We strongly believe that a safe and effective vaccine will be the key to a full return to normalcy in our nation, and further that the enterprise to deliver and administer this vaccine to every American who wants it will be the greatest public health effort of our generation. We seek to enhance the close coordination and cooperation between federal, state, local, and tribal authorities that will be necessary to achieve success. We share your goals and stand ready to bring our expertise and commitment to this endeavor. Any questions or requested follow-up can be directed to Claire Hannan, Executive Director of the Association of Immunization Programs (AIM) at channan@immunizationmanagers.org or 301-424-6080.

Sincerely,

Association of Immunization Managers (AIM)
American Immunization Registry Association (AIRA)
Association of State and Territorial Health Officials (ASTHO)
National Association of County and City Health Officials (NACCHO)

cc:

Vice President Mike Pence
Dr. Deborah Birx
Secretary Alex Azar
Dr. Robert Redfield
Dr. Nancy Messonnier
Dr. Anthony Fauci

[5] NACCHO, H1N1 Sentinel Network Supplemental Survey Report, page 8