

December 14, 2020

The Honorable Nancy Pelosi
Speaker of the House of Representatives
U.S. House of Representatives
H-232, The Capitol
Washington, D.C. 20515

The Honorable Kevin McCarthy
Minority Leader of the House
U.S. House of Representatives
2468 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Mitch McConnell
Senate Majority Leader
United States Senate
317 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Charles Schumer
Senate Minority Leader
United States Senate
322 Hart Senate Office Building
Washington, D.C. 20510

Dear Speaker Pelosi, Leader McCarthy, Leader McConnell, and Leader Schumer:

As representative organizations of America's pharmaceutical supply and payment chain, including prescription and over-the-counter brand and generic manufacturers; pharmacies and pharmacists across all practice settings, including health systems and hospitals, community, specialty, and managed care; supermarkets; wholesalers; pharmaceutical quality standard developers; employers and other health plan sponsors; health insurance providers; and pharmacy benefit managers, the Pharmaceutical Supply and Payment Chain Coalition (the Coalition) came together in March 2020 on the singular principle that the private sector and state and federal governments must work together to facilitate Americans' reliable access to needed medications and preventatives, including vaccines, during the COVID-19 pandemic.

On October 22, 2020, the Coalition released *Guiding Principles for Safe and Efficacious COVID-19 Vaccine Development, Distribution, Allocation, and Mass Immunization*, which include that distribution must be guided by a well-coordinated national strategy aligned with existing state and local strategies for the distribution of routine vaccines (see Enclosure). The Coalition's members are committed to supporting a national strategy whether by amplifying public health messaging, directing patients to vaccination sites, or directly facilitating the development, distribution and administration of the vaccine(s).

We believe efficient, well-coordinated distribution, allocation, and mass vaccination activities against the novel coronavirus (SARS-CoV-2) will help ensure vaccination is an effective countermeasure to the current pandemic. Distribution and related activities guided by a well-coordinated and appropriately funded national strategy are essential to the effective allocation strategies of local communities and to achieving high COVID-19 vaccination rates.

To this end, the undersigned representative organizations of the Coalition urge you to support the Centers for Disease Control and Prevention (CDC) and National Governors Association request for supplemental appropriations to cover operations related to the cost of planning, preparing for, distributing, and facilitating administration of COVID-19 vaccines.

This needed funding will allow the CDC to provide mission-critical support to state and local governments, as well as private sector partners, as they collectively prepare to rapidly provide broad-based distribution and access to the vaccine(s) following authorization by the U.S. Food and Drug Administration (FDA) and recommendation by the CDC Advisory Committee on Immunization Practices. The successful development, authorization, and recommendation of the vaccine(s) will mark a groundbreaking step in our fight against the pandemic.

The massive demand for authorized vaccines as they come to market will require extensive coordination across the pharmaceutical supply and payment chain and with the public sector. Without additional funding, the Coalition is concerned efforts to ensure equitable distribution, prepare vaccination sites, leverage existing infrastructure, prepare for moving and storing vaccines, and provide critical guidance to healthcare providers may be delayed or weakened. This funding has been included in both the House's and Senate's respective COVID-19 relief packages—an acknowledgment of the critical need for these funds.

It is similarly critical that Congress advance federal funding for a robust, multiprong outreach and communication effort to build public trust in the COVID-19 vaccine(s), encourage Americans to be vaccinated, as well as a strategy to ensure equitable distribution and allocation across the country. We are encouraged by private-sector initiatives, including the Reagan-Udall Foundation for the FDA's COVID-19 Vaccine Confidence Project¹ and the COVID-19 Vaccine Education and Equity Project², and urge Congress to ensure vaccine education, awareness, and promotion efforts are included in supplemental federal funding to the CDC, states, and other jurisdictions as part of distribution efforts.

There are many components to the safe and efficacious COVID-19 vaccine development, distribution, allocation, and mass immunization that depend on the expertise of, and collaboration with, the private sector. From the advancement of vaccine candidates to the leveraging of logistics expertise for distribution, the grocers and neighborhood pharmacies serving as point-of-care sites across the country to the systems for monitoring adverse events and reminding of second doses, public-private collaboration continues to be critical to our nation's response to the pandemic.

This is a moment that requires urgent action in Congress. We ask that you provide the supplemental funding to help the CDC, states, and other jurisdictions meet the challenges and opportunities ahead. We appreciate your leadership and thank you for considering our request.

The strong and ongoing collaboration demonstrated by the pharmaceutical supply and payment chain has been essential for a host of issues important to Americans during the COVID-19 pandemic. The coalition looks forward to continuing to work with Congressional leaders in the best interest of the individuals and families that we collectively serve.

¹ Reagan-Udall Foundation for the FDA, "COVID-19 Vaccine Confidence Project."
<https://covid19.reaganudall.org/covid-19-vaccine-confidence-project>

² The COVID-19 Vaccine Education and Equity Project is led by the Alliance for Aging Research, Healthy Women, and the National Caucus and Center on Black Aging. Please see the following for more information:
<https://covidvaccineproject.org/about-the-project/>.

December 14, 2020
Page 3

Please feel free to contact Kristen Freitas, vice president of Federal Government Affairs for the Healthcare Distribution Alliance (kfreitas@hda.org), with any questions.

Sincerely,

Academy of Managed Care Pharmacy
America's Health Insurance Plans
American Pharmacists Association
American Society of Health-System Pharmacists
Association for Accessible Medicines
Biotechnology Innovation Organization
Blue Cross Blue Shield Association
U.S. Chamber of Commerce
Consumer Healthcare Products Association
FMI – the Food Industry Association
Healthcare Distribution Alliance
National Association of Chain Drug Stores
National Association of Specialty Pharmacy
National Community Pharmacists Association
National Grocers Association
Pharmaceutical Care Management Association
U.S. Pharmacopeia

Enclosure: *Guiding Principles for Safe and Efficacious COVID-19 Vaccine Development, Distribution, Allocation, and Mass Immunization (October 22, 2020)*

Guiding Principles for Safe and Efficacious COVID-19 Vaccine Development, Distribution, Allocation, and Mass Immunization

The efficient, well-coordinated distribution, allocation, and mass vaccination activities against the novel coronavirus (SARS-CoV-2) will help ensure vaccination is an effective countermeasure to the current pandemic. High COVID-19 vaccination rates with an effective vaccine are essential to mitigating the pandemic now and protecting against future outbreaks.

The Pharmaceutical Supply and Payment Chain Coalition offers the following guiding principles for the safe and efficacious development, distribution, and allocation of a vaccine(s) to achieve coordinated mass vaccination against COVID-19:

- **COVID-19 vaccine development, approval, and post-marketing surveillance must adhere to transparent and scientifically rigorous processes that engender public trust in the safety and efficacy of these products.** The U.S. Food & Drug Administration (FDA) is the global “gold standard” for the safety and efficacy of medical products. In addition to FDA, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) has unparalleled experience and expertise in defining use considerations and guidelines for vaccines so they are used safely and effectively by hundreds of millions of people. Widespread confidence in all licensed or authorized COVID-19 vaccines is critical for individuals to choose to be vaccinated and to overcome vaccine hesitancy. In furtherance of this trust, the FDA should continue to facilitate timely access to vaccine pharmacovigilance data and other relevant safety information as the vaccination process unfolds.
- **Equitable allocation of COVID-19 vaccine is paramount, and priority should be given to achieving the greatest public health impact.** Decision-making about who should be granted priority access to the initial supply of COVID-19 vaccine(s) must be transparent, comprehensive, inclusive, and adhere to the highest possible ethical standards. Timely national dialogue, through multiple forms of community engagement, will encourage public trust in fair vaccine allocation and distribution strategies.
- **Consistent public engagement and clear communication on initial and subsequent prioritization decisions by ACIP will be needed.** Public health officials recognize that initial supply and subsequent availability may be insufficient for the vaccination of all priority groups. Decision-making processes for subsequent prioritization by ACIP must adhere to the same high standards and transparent processes as initial decisions. Vaccine selection and immunization decisions should continue to be made based on updated evidence of vaccine effectiveness, including evidence demonstrating relative effectiveness for specific patient populations (e.g., pediatrics, pregnancy, older adults, patients with complex health conditions, and other sub-groups).
- **Distribution must be guided by a well-coordinated national strategy that is aligned with existing strategies for the distribution of routine vaccines.** Deliberate planning at all levels of government and in collaboration with state and local public health stakeholders, and the private sector, will be necessary for appropriately executing national guidelines to the unique and changing needs of local communities. Distribution should leverage existing mechanisms and infrastructure; this includes ensuring equitable access and availability across the country, particularly in rural and underserved areas.

Guiding Principles for Safe and Efficacious COVID-19 Vaccine Development, Distribution, Allocation, and Mass Immunization (Continued)

- **Vaccination program policies and deployment strategies must account for the readiness of local vaccination infrastructure and safety of the immunizer workforce.** Policies and deployment strategies must ensure vaccinations are conducted under safe conditions, with the immunizer workforce and other essential health care workers prepared and protected from associated risk. As front-line health care workers, the immunizer workforce – consisting of pharmacists, physicians, nurses, pharmacy technicians, and other health care professionals – requires priority access to the initial vaccine supply. Those responsible for local vaccine infrastructure will need to adhere to the FDA-approved labeling instructions for each respective vaccine for proper storage and handling of vaccines throughout the supply chain. Strategies must also account for specific instructions for storage, handling, and administration of vaccines, including proper handling of sharps.
- **Vaccination for the prevention and management of infectious disease, including COVID-19, is a core health service that should be prioritized and promoted.** Achieving high COVID-19 vaccination rates will require minimizing vaccine hesitancy and misinformation and ensuring vaccines are administered properly and in accordance with national clinical guidance. Health care professionals, including pharmacists, will be relied on to provide patient education about vaccine options and safety, and manage patients with complex health care conditions. National clinical guidance for immunization providers should be issued and should include considerations for differing clinical application of various COVID-19 vaccines and where booster doses are needed to maintain efficacy. There also needs to be clear communication regarding how long the vaccine is effective and when individuals may need booster doses. A coordinated vaccine registry approach and record-keeping guidance, particularly to track vaccines requiring booster doses, also may be needed.
- **Ensuring affordability and access, including by preventing and removing financial barriers, will be critical to a successful public health response to COVID-19.** Upon FDA licensure or authorization, and once recommendations are issued by ACIP, manufacturers, payors, physicians, pharmacists, and other critical stakeholders, such as community health centers, should promote broad access and affordability following national clinical guidance. ACIP should ensure that its recommendations are made immediately available so there is not a lag between the licensure or authorization decision and the ACIP recommendation. Reimbursement of immunization providers for reasonable administration fees is essential to maximizing access.