



A Passionate Voice for Compassionate Care

September 22, 2020

The Honorable Stephen M. Hahn, M.D.
Commissioner U.S. Food and Drug Administration
10903 New Hampshire Avenue Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

On behalf of the Catholic Health Association of the United States (CHA), the national leadership organization of more than 2,200 Catholic health care systems, hospitals, long-term care facilities, sponsors, and related organizations, I write to you regarding the importance of ensuring safe, effective and ethically distributed COVID-19 vaccines.

We believe that all people, barring exceptional circumstances, have a responsibility to be vaccinated when needed to protect vulnerable people and broader public health. This responsibility is rooted not only in protecting one's own health but more fundamentally in our obligation to protect through solidarity those who are most at risk or unable to be vaccinated.

However, in order for individuals to exercise this responsibility it is first incumbent on public health authorities, vaccine manufacturers and policy makers to ensure that vaccines and treatments are safe, effective and available to all. We are particularly concerned about the disproportionate impact COVID-19 has had on vulnerable populations, such as the elderly, low-income communities, persons with pre-existing health conditions, and racial and ethnic minorities, and the implications for vaccine allocation and distribution. To this end, CHA has developed a set of principles that we believe provide a useful foundation for guiding efforts to effectively and justly develop and allocate a COVID-19 vaccine. These principles include the following:

1. Vaccines should be demonstrably safe and ethically tested

The traditional medical admonition of *Primum non nocere*, or "Do no harm," should lead us. Broad public support requires vaccines that are safe and for which the burden of testing is borne by all, and not just the poor. We therefore urge you to consider in your deliberations whether testing included sufficient representation by age, race, sex and underlying health condition so that we can ensure vaccines are effective and safe for use by all people.

2. Vaccines should be demonstrated to be scientifically effective

Maintaining public support and trust in vaccines' effectiveness is critical for responding to COVID-19 and other public health crises. While we all want a COVID-19 vaccine to be available in the fastest way possible, a vaccine that is ineffective or unsafe will have long-

term consequences for public support and trust in vaccines as a whole. It is critically important that decision makers follow the scientific evidence rather than rushing to adopt a COVID-19 vaccine for political or economic expediency. We urge you to continue to follow the scientific evidence and ensure any vaccine approved has proven to be demonstrably safe and effective. We also urge you to develop a phase VI study of any vaccine approved and licensed for distribution to ensure the vaccine's ongoing safety and efficacy. This commitment to safety and efficacy is critical for public health and addressing vaccine hesitancy and misinformation.

3. Vaccines development must respect human dignity

Vaccines that are developed should respect the human dignity of all persons and protect the sanctity of human life at all ages. Deliberately destroying innocent human life in order to safeguard other lives is ethically wrong.

4. Vaccines should be equitably distributed with priority to those at most risk

Vaccine distribution should first consider populations identified as most at risk for suffering negative health outcomes from COVID-19. While at-risk populations may vary from place to place, COVID-19 has had a disproportionate impact on vulnerable populations such as the elderly, low-income communities, persons with pre-existing health conditions, and racial and ethnic minorities. In addition, The Common Good requires the maintenance of health and essential services for the well-being of the community.

To this end, for the COVID-19 vaccine distribution we support prioritizing front line health and essential service workers, seniors, populations at higher risk and those with underlying health conditions which place them at greatest risk. Such a prioritization not only will provide an effective initial public health response but will also save lives by ensuring those who have the greatest likelihood of a negative health outcome receive the vaccine first. Further as vaccines become available, we urge you and other public health authorities to ensure that vaccines are available to all, regardless of ability to pay, health insurance coverage or immigration status

5. Efforts to develop and distribute an effective vaccine should emphasize Solidarity:

The global pandemic requires working together, domestically and internationally, to achieve a common purpose. Through strengthening and supporting existing frameworks for collective purchasing and distribution, we can help to ensure that all people have access to the vaccine while minimizing competition which drives up prices for the limited supplies. We therefore urge you to adopt a national purchasing and distribution plan that minimizes the competition between states and amongst health care providers for the vaccine and streamlines distribution to local providers. While states play a critical role in supporting distribution efforts, federal oversight of purchasing is vital for ensuring that states are not competing for the same limited vaccines.

6. Consistent with the principle of Subsidiarity, the distribution of effective vaccines should involve local communities

Local civil society, health care providers, religious and community leaders are critical partners in building trust and point of contact distribution of vaccines. Community surveys continue to show that vaccine hesitancy is at an all-time high. It is therefore critical that the FDA work to promote greater transparency of the COVID-19 vaccine approval process so that physicians and the broader community have the information they need to combat misinformation or concerns. As the FDA creates allocation strategies and public awareness campaigns for COVID-19 vaccines, we urge you to consider the important role that community groups, religious leaders and local health providers can play in combating misinformation, promoting greater health literacy and ensuring that vulnerable or marginalized communities' concerns are addressed. We urge the FDA to work closely with these partners to develop education and training materials which promotes public awareness, improves transparency and builds broader public support for the COVID-19 vaccine.

As the entire human community awaits in hope for vaccines to address COVID-19, CHA thanks you for the important work you are doing to ensure the production of safe and effective vaccines in as timely a manner as possible. We appreciate the opportunity to offer you our comments and welcome further discussion on how best to improve COVID-19 vaccine approval and distribution. If you have any questions about these comments, please do not hesitate to contact me or Kathy Curran, CHA senior director, public policy, at 202-721-6300.

Sincerely,

A handwritten signature in cursive script that reads "Sr. Mary Haddad". The signature is written in black ink and is positioned above the typed name and title.

Sr. Mary Haddad, RSM
President and CEO