



*The National Voice for Direct-Care RNs*

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December 9, 2020

The Honorable Stephen M. Hahn, Commissioner  
U.S. Department of Health and Human Services  
Food and Drug Administration  
Dockets Management Staff (HFA-305)  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**RE: Docket No. FDA-2020-N-1898, Vaccines and Related Biological Products;  
Notice of Meeting; Establishment of a Public Docket; Request for Comments**

Dear Commissioner Hahn:

On behalf of more than 170,000 registered nurses who work in every state in the nation, National Nurses United (NNU) submits these comments in response to the “Vaccines and Related Biological Products; Notice of Meeting; Establishment of a Public Docket, Request for Comments,” 85 Fed. Reg. 76082 (Nov. 27, 2020) (Docket No. FDA-2020-N-1898), regarding the forthcoming public advisory committee meeting on December 9, 2020, of the Vaccines and Related Biological Products Advisory Committee (Committee).

NNU is encouraged by news of progress in the development of Covid-19 vaccines. Nurses understand the importance of developing vaccines to prevent Covid-19 infections which have claimed the lives of nearly 300,000 people in the United States, including over 265 registered nurses. As the virus rages on in nearly every corner of the United States, a Covid-19 vaccine offers a glimmer of hope for nurses and other healthcare workers who have faced unprecedented risks during the pandemic. NNU calls on the U.S. Food and Drug Administration (FDA) and the federal government to ensure that all Covid-19 vaccine candidates undergo full scientific evaluation and that only candidates that meet all criteria for public safety are granted an emergency use authorization.

Even once a Covid-19 vaccine is authorized, public health measures must remain in place. Adopting an integrated, layered approach to Covid-19 prevention, including physical distancing measures, wearing face coverings, testing and contact tracing, in addition to a vaccine, remains the only way to limit the spread of the virus and protect the public. A vaccine alone is not a panacea. NNU strongly encourages the FDA to state that a Covid-19 vaccine does not replace the need for public health measures in any and all emergency use authorizations granted to Covid-19 vaccine candidates.

A Covid-19 vaccine should never replace infection control measures, safe workplaces, rigorous testing and contact tracing for patients, nurses, and other health care workers. A Covid-19 vaccine cannot ever replace optimal personal protective equipment (PPE), including a powered air-purifying respirator, coveralls that are impervious to viral penetration, head and shoe coverings, and medical-grade gloves, for nurses and other health care workers caring for

suspected and confirmed Covid-19 patients. NU strongly encourages the FDA to be explicit in any and all emergency use authorizations granted to Covid-19 candidates that optimal PPE and other workplace protections must be provided to all nurses and health care workers caring for suspected and confirmed Covid-19 patients regardless of vaccination status.

Finally, the effectiveness of a Covid-19 vaccine that has been evaluated with public safety as the top priority is dependent on its widespread use. The only way to ensure that a vaccine is fully accessible and available to all is to provide the vaccine free for all with no cost-sharing. Cost-sharing of any kind will limit uptake. Linking access to the vaccine to health insurance or immigration status will also limit vaccine uptake.

Attached herein for the Committee and FDA's consideration are comments submitted to the National Academies of Sciences, Engineering and Medicine (NASEM) by Zenei Cortez, President, on behalf of NU on September 4, 2020. The comments that NU provided to NASEM discuss the need to fully evaluate all Covid-19 vaccine candidates with public safety as the top priority, the importance of not replacing public health measures and PPE and other workplace protections for health care workers, and the need to make any authorized vaccine candidate available free to all with no cost-sharing.

We respect the work of the Vaccines and Related Biological Products Advisory Committee and appreciate the public broadcast of the Committee's meeting to discuss emergency use authorizations for Covid-19 vaccine candidates. We look forward to the FDA being transparent, in a timely fashion, with the public about the clinical effectiveness and safety data being evaluated. We sincerely hope that the FDA will incorporate our recommendations into any emergency use authorization granted for a Covid-19 vaccine candidate.

Nurses, as the most trusted profession, understand the importance of trust. Whether it is listening to our patients or helping to guide them in decisions about their care, we know that trust is fundamental to achieving the best outcomes. It is no different when it comes to public health advocacy; trust in the scientific process is central to moving forward and successful implementation of any Covid-19 treatment or vaccine.

Sincerely,

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Zenei Cortez, RN  
President, National Nurses United



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### ***Via Online Submission***

September 4, 2020

Committee on Equitable Allocation of Vaccine for the Novel Coronavirus  
National Academies of Sciences, Engineering, and Medicine  
500 Fifth St., N.W.  
Washington, D.C. 20001

**RE: Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine (2020)**

*To Whom it May Concern:*

National Nurses United (NNU), representing more than 150,000 members, is the largest union of registered nurses in the United States. As such, we are concerned that the process for creating and reviewing the *Discussion Draft of the Preliminary Framework for Equitable Allocation COVID-19 Vaccine (Preliminary Framework)* by the Committee on Equitable Allocation of Vaccine for the Novel Coronavirus (Committee) of the National Academies of Sciences, Engineering, and Medicine (NASEM) is being rushed. As COVID-19 vaccines will be administered to hundreds of millions of people residing in the United States, drafting the allocation framework should not be hastily undertaken. Moreover, there should be sufficient time for members of the public to review the document thoroughly, including time to evaluate the sources cited. The four days allotted to submit comments is wholly inadequate. We recommend that the Committee provide an opportunity for public comment before finalizing the next draft of the framework.

### *Vaccine Safety*

First and foremost, we must ensure that any vaccine meets the highest test of public safety as its top priority. Nurses and other health experts have expressed concerns that validated scientific and regulatory processes may be subverted by political and industry pressures (<https://www.nationalnursesunited.org/press/nurses-raise-caution-flag-covid-19-vaccine-push>). The rushed nature of this preliminary framework, when considered alongside decisions and statements from the highest levels of our federal government throughout this infectious disease crisis, provide ample evidence for concern.

The *Preliminary Framework* acknowledges that vaccine safety and hesitancy will be addressed in the final guidance. The Committee should clearly state in this framework that the first step in equitable allocation begins with scientific integrity and transparency. Like many safety measures, protection of health and safety begin well before the actual intervention. Any vaccine deployed must meet rigorous safety standards prior to its

deployment. It must be made clear in the final framework that any allocation of a vaccine is predicated upon a rigorous and transparent evaluation processes conducted by the US. Food and Drug Administration (FDA) and panels of expert scientists. This is necessary not only to protect public safety but also public trust which is vital for the success of any immunization program.

### *Occupational Health & Safety*

The FDA conveys in its guidance, "[Development and Licensure of Vaccines to Prevent COVID-19](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-help-facilitate-timely-development-safe-effective-covid)," that it "would expect that a COVID-19 vaccine would prevent disease or decrease its severity in at least 50% of people who are vaccinated." (<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-help-facilitate-timely-development-safe-effective-covid>). Given the level of efficacy required by the FDA, NNU is pleased that the *Preliminary Framework* acknowledges the need for additional occupational health and safety measures to protect health care workers:

Vaccination is not a substitute for non-medical or (non-therapeutic) preventive policies and equipment. All exposed workers should be, for example, provided an adequate supply of appropriate PPE. It is vitally important that the prospect of vaccination not supplant efforts to assure adequate supply of protective equipment or continuing the use mitigation strategies after vaccination.

As those administering the vaccine also should be provided PPE, we urge the Committee to call on the federal government to invoke the Defense Production Act of 1950 (DPA), as discussed below, to ensure sufficient PPE is available to all health care workers who need it.

### *Fair and Equitable Allocation of Vaccine*

As the *Preliminary Framework* acknowledges, people of color, particularly Black, Indigenous, and Latinx Americans have been disproportionately impacted by the pandemic with more severe illness and higher infection and death rates (37:776-77 and 76:1785-77:1787). Structural inequities, discrimination, and racism that existed long before this virus have all played a role. The *Preliminary Framework* proposes to use the Centers for Disease Control and Prevention's Social Vulnerability Index rather than addressing race or ethnicity directly (77:1791-93). Fair and equitable allocation of the COVID-19 vaccine demands that the Social Vulnerability Index be validated to ensure that it accurately captures the racial and ethnic disparities of the current pandemic.

An effective public health response to the COVID-19 pandemic includes widespread vaccination using a vaccine that has been fully evaluated with public safety as the top priority. The only way to ensure that a vaccine is fully accessible and available to all is to provide the vaccine free for all with no cost-sharing. Cost-sharing of any kind will limit

uptake, whether the cost-sharing is for the vaccine itself or for the office visit where the vaccine is administered. Similarly, linking access to the vaccine to health insurance or immigration status will also limit vaccine uptake.

The federal government must ensure that the vaccine is provided to all without cost. State and local public health departments have been underfunded for decades. Moreover, state and local tax revenue has fallen dramatically because of the economic effects of the pandemic and the failure to provide sufficient federal relief. This has left state and local governments struggling to manage the manifold economic, health, education, and social service needs of their populations. Finally, as noted in the *Preliminary Framework*, taxpayers have funded several of the vaccines currently being developed (77:1809).

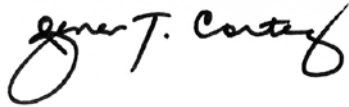
The *Preliminary Framework* “is intended to assist and guide policy makers in planning for vaccine allocation under conditions of scarcity that will necessitate vaccinating persons in phases over time” (33:663-65). Thus, the *Preliminary Framework* should urge the federal government to address the “conditions of scarcity” directly. To limit vaccine shortages due to inadequate production capacity and to facilitate distributing and administering the vaccine, the federal government must fully invoke the DPA immediately. Specifically, we urge the Committee to call on the president to immediately take the following actions:

- Invoke Title III of the Defense Production Act immediately by directing increased production of equipment and supplies from existing manufacturers, directing other industrial manufacturing facilities to transition to production of the equipment and supplies needed in the COVID-19 response, and immediately generate manufacturing purchase orders to ensure expedient production of essential equipment and supplies which meets industry standards and
- Direct the U.S. Department of Health and Human Services to gather information on supplies and implement restrictions on hoarding; and
- Ensure the immediate and continued release and distribution of COVID-19 vaccines (when available), personal protective equipment, testing equipment, ventilators, and (ECMO) machines in the strategic national stockpile.

Nurses understand the importance of developing vaccines to prevent COVID-19 infections which have claimed the lives of over 180,000 people in the United States including over 200 registered nurses. Despite the short time frame for review, the Preliminary Framework does address some important considerations for equitable allocation of COVID-19 vaccines. It is our hope that the committee will incorporate our recommendations in the final document and continue to include frontline nurses in these important policy decisions. We respect the work of the Committee but are concerned with the rushed nature of such an important project. The unprecedented level of cooperation amongst the international scientific and medical communities, which has increased our knowledge about SARS-COV-2 and COVID-19 infections, provides a source of hope. However, there is still much to learn. This body has an opportunity and obligation to set forth recommendations which will reflect necessary steps

for assuring that all stakeholders are able to proceed with confidence as we continue to work towards long-term solutions to address this global crisis.

Thank you,

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Zenei Cortez, RN  
President, National Nurses United