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June 24, 2024

The Honorable Dawn O'Connell  
Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services  
200 Independence Avenue S.W.  
Washington, D.C. 20201

Dear Assistant Secretary O'Connell,

As the Administration for Strategic Preparedness and Response (ASPR) prepares to invest in mRNA vaccines for pandemic influenza, potentially with manufacturers including Moderna and Pfizer, as part of commendable efforts to diversify domestic production options for pandemic flu vaccines, we urge you to account for global needs by conditioning public support on global access assurances.

We must lay the groundwork up-front to ensure that public funding adequately equips us to protect people in future pandemics. To that end, government funding agreements should include terms ensuring:

- Reasonable and affordable pricing, at home and for developing countries;
- Adequate supply, including through licensing and affirmative technology and knowledge sharing for geographically diversified manufacturing; and
- Contract transparency, contributing to public understanding and funding recipient accountability.

Public funding and federal science were essential to the creation of COVID-19 vaccines and accelerated their deployment. In the case of Moderna, the U.S. government provided key technology and billions in funding buoying the development and roll-out of the NIH-Moderna vaccine.

Unfortunately, the lack of safeguards in government funding agreements allowed drug and vaccine corporations to sell at exorbitant prices, control supply and largely ignore developing country needs, leaving most people worldwide without access to critical medical tools. Hundreds of thousands of people, perhaps more, needlessly lost their lives. Variants came to the United States and caused hundreds of thousands more deaths and untold economic damage. It is imperative that we learn from these mistakes before the next pandemic.

In December 2023, ASPR announced that it was making fair pricing a standard part of contract negotiations for the development or purchase of medical products. This welcome change will help ensure that Americans are not paying more than people in other wealthy countries for medicines their tax dollars support. We urge ASPR to publish its funding agreements, to confirm when fair pricing has been incorporated and support public understanding of our federal government's investments fighting pandemics. Contract transparency also supports awardee accountability to taxpayers.

But the U.S. government must not leave out the rest of the world. Federal contracts should include clauses for global access, especially when providing support for pandemic-related products.

Despite longstanding investment into preparedness and response for pandemic flu, an adequate global response to such a pandemic is far from assured.

An estimated best-case scenario for pandemic flu vaccine production is up to 8.31 billion doses annually – enough for half as many people, considering two doses would likely be needed – however, a more likely estimate puts this closer to 4.15 billion doses.<sup>1</sup> Even the best case scenario is a substantial shortfall from what may be needed for a global pandemic response.

The large majority of pandemic flu vaccine production capacity relies on embryonated eggs, the supply of which could be threatened in the event of an avian flu pandemic, underscoring the need for greater availability of diverse production methods worldwide. Further, 80% of pandemic flu vaccine production capacity is located in high-income countries.<sup>2</sup> This, combined with pre-existing supply agreements in many countries, warns of limited initial supplies for the vast majority of the global population in the event of a pandemic.

Notably, what production capacity for flu vaccines does exist in low- and middle-income countries is owed in part to a partnership where the U.S. Biomedical Advanced Research and Development Authority, alongside the World Health Organization, helped build facilities, provide technical assistance, and transfer technology for scalable manufacturing.<sup>3</sup> ASPR recognizes the necessity and value in funding pandemic-related R&D and increasing global manufacturing capacity. A key way that ASPR can join these two objectives is through public funding conditions.

The U.S. can advance its commitments to pandemic preparedness, access to medicines, and local production of flu vaccines by promoting affordability and scalable global supply in exchange for funding. In doing so, it can address the shortfall in needed vaccine supply for the globe and enhance American health security.

We would appreciate your response to this letter. Thank you for your time and work.

Sincerely,



Peter Maybarduk  
Access to Medicines Director

Cc:  
Stephanie Psaki, U.S. Coordinator for Global Health Security  
Loyce Pace, Assistant Secretary for Global Affairs

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<sup>1</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7814984/>

<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7814984/>

<sup>3</sup> <https://www.citizen.org/article/a-plan-for-the-peoples-vaccine/>