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October 20, 2020

The Honorable Michael Pence
Vice President of the United States
The White House
Washington, DC 20500

Dear Vice President Pence:

I am writing to ask for your help to address regulatory roadblocks that are preventing Americans from accessing a form of vitamin D known as 25-hydroxyvitamin D3. As you may know, there is a rapidly increasing body of evidence indicating low vitamin D status is associated with increased COVID-19 cases, disease severity, and mortality. This is not surprising as vitamin D has long been associated with immunity, particularly for viral and respiratory infections. Dr. Anthony Fauci, the nation's leading infectious disease expert, recently noted that he takes vitamin D supplements to maintain a healthy immune system.

I understand 25-hydroxyvitaminD3 is 3x more powerful than the vitamin D currently found on store shelves. Notably, 25-hydroxyvitamin D3 is a naturally occurring source of vitamin D found in food, is the predominant form of vitamin D found in the bloodstream, and is the form measured by doctors to determine a person's vitamin D status.

Vitamin D levels in the body are provided by synthesis in the skin in response to sunlight and by the diet. Unfortunately, these routes are generally inadequate—few foods are rich in vitamin D, and synthesis in the skin is limited substantially in the elderly, those with darker skin, and for everyone during the winter months. Studies show 95 percent of American adults consume inadequate amounts of vitamin D through their diets, and more than half are insufficient in vitamin D. In some communities, like the African American community, insufficiency is in excess of 80 percent, which reflects a public health crisis. Indeed, the U.S. Food and Drug Administration (FDA) considers vitamin D a nutrient of public health concern.

The challenge is that it can take months to reach recommended vitamin D levels with currently available vitamin D supplements. As we deal with the COVID-19 pandemic, more time inside during the winter months, and the upcoming flu season, it is critical that Americans are able to quickly achieve an optimal vitamin D status to provide maximum immunity protection. This is particularly true for populations, including the elderly and people with darker skin, who tend to

have lower vitamin D status and who are particularly vulnerable to COVID-19. Provision of 25-hydroxyvitamin D3 via supplementation could dramatically improve this situation and play a leading role in the "tool kit" we as a country must deploy at scale to protect our fellow citizens against COVID-19 and respiratory infections. It is also safe, inexpensive and effective.

Unfortunately, the FDA blocked the 25-hydroxyvitamin D3 form of vitamin D from coming on the market as a new dietary ingredient. It is important to stress that this denial was not because of any concerns regarding safety or efficacy. Rather, as required under FDA rules, the denial was due to the fact that a foreign pharmaceutical company previously filed to approve a new drug that also had 25-hydroxyvitamin D3 as an active ingredient at a far higher dosage to treat those with compromised kidney function.

As we continue to address the COVID-19 pandemic and prepare for the upcoming flu season, we should take every step to help Americans stay healthy. I am writing to ask you to work with the FDA to take immediate action, through an interim final rule or other authority, to allow this vitamin D supplement to immediately be marketed and help Americans quickly boost their immunity. This would not require new legislation or regulation – the FDA has confirmed that it has the authority to issue an exception and allow a dietary ingredient to enter the market as a supplement alongside a pharmaceutical drug with the same or similar active ingredient.

Thank you for your consideration. I look forward to your response and working with you to remove any bureaucratic roadblocks that limit access to critical products like this important form of vitamin D supplement.

Sincerely,

cc: Dr. Stephen Hahn, Commissioner, U.S. Food and Drug Administration
Alex Azar, Secretary, U.S. Department of Health and Human Services