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December 4, 2023

The Honorable Robert M. Califf, M.D., MACC  
Commissioner  
Food and Drug Administration (FDA)  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Califf,

As we are sure you are aware, the U.S. is currently experiencing another surge of COVID-19-related cases, hospitalizations, and deaths. While it is encouraging to see a new round of booster vaccines being made available to the public to protect them from the new variant spreading across the country, we believe more needs to be done.

COVID-19 vaccines continue to save lives, but the fact is, a vaccine-only strategy is not sufficient for protecting all Americans from COVID. There are an estimated seven million immunocompromised individuals in the U.S. They tend to get sicker and suffer from symptoms for much longer when they get COVID-19. Even for those immunocompromised patients who can receive the vaccine, many do not get the same benefit from vaccines as patients with healthy immune systems. In addition, antivirals, such as Paxlovid, are not always an option for immunocompromised patients because they can have severe interactions with other drug treatments they are already taking.

It is not just the immunocompromised who would benefit from having more COVID-19 treatment options. As former health officials, Irasema Garza and Guadalupe Pacheco pointed out in a recent op-ed, Latinos “are 19% of the population but account for more than 24% of Covid cases in the United States. When the CDC used weighted population distributions, Latinos comprised 33% of Covid deaths, highlighting the serious disproportionate impact of Covid on this community.”

They also correctly point out that vaccine uptake has become a polarizing issue in the U.S., with only a third of Americans fully vaccinated and 20 percent of Americans opting not to get the vaccine at all. Even for those who are vaccinated, with each new variant, it is unknown exactly how effective vaccines, boosters, and other treatments will be. This is why it is so critical for FDA to be nimble enough to ensure that we are keeping up with a constantly mutating virus.

We are writing to ask that your agency expedite the study and approval of COVID-19 treatments, beyond just vaccines. One good example of this approach is how the U.S. fights against the flu. The flu vaccine is a key part of that strategy, but it is not the only part. The strategy also includes prevention and, most importantly, a variety of drug treatments for those who get sick. In fact, there are currently four different FDA-approved treatments for the seasonal flu.

One treatment option that FDA should be embracing is monoclonal antibodies. They showed great promise early in the pandemic. Unfortunately, as you know, none of the five antibody treatments approved by FDA for emergency use for COVID are currently on the market because they are no longer effective against new COVID strains. This is similar to what continues to happen with vaccines. As the virus mutates, the companies that produce the vaccines “update” them to be effective against the current strain, and FDA expedites their approval. We urge you to take the same approach with monoclonal antibodies and other COVID treatments that were once effective, but now need to be updated to provide protection against new mutations.

Inequities in outcomes have persisted throughout the entire pandemic, with the immunocompromised, low-income Americans, Latinos, and other communities of color faring the worst. Putting your agency’s authority behind expanding treatment options beyond just vaccines would go a long way toward achieving equity in COVID outcomes.

We thank you for considering this critical public health issue, and any of our coalition members would be happy to discuss this with you.

Sincerely,

National Hispanic Medical Association

Latinx Medical and Health Society

National Association of Latino Healthcare Executives

National Hispanic Nurses Association

The Latino Coalition

Equality Science

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Latino Medical Students Association

Clinical and Translational Science Institute, University of Miami Miller School of Medicine

Alliance for Aging Research

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HealthyWomen

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National Hispanic Council on Aging

Why We Vaccinate