June 7, 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,

On April 13, the Office of Management and Budget (OMB) sent a memo to the heads of each federal government agency urging them to "substantially increase meaningful in-person work at Federal offices, particularly at headquarters and equivalents." In addition, the White House announced on May 2 that the vaccine mandate for federal workers would end on May 11, the same day the public health emergency for COVID-19 ends.

Throughout the COVID-19 pandemic, it has become clear that many workers can perform their jobs remotely and in person. However, more workers will be required to return to in-person work. In that case, a wide variety of treatment and protection options must be available to workers. Especially for those workers who are immunocompromised and cannot take a vaccine, as well as those who choose not to take one. And while antivirals have been effective for many Americans who contracted COVID-19, immunocompromised patients, including many seniors, cannot take them because of severe drug-drug interactions with medicines they are already taking.

Keeping federal workers safe from COVID-19 is not only a workplace safety issue but a health equity issue. People of color make up 40 percent of the federal workforce. A Kaiser Family Foundation study showed that Hispanic and Black Americans are 1.5 times more likely to get a COVID-19 infection than White Americans. And according to the Centers for Disease Control and Prevention (CDC), the age-adjusted mortality rate for Hispanics and Blacks is 70 to 80 percent higher than among Whites.

It is also worth noting that many seniors, another group vulnerable to COVID-19, are in the federal workforce. As of December, there were nearly 300,000 federal workers over 60. That is nearly twice as many as the number of federal workers under 30.

We are entering a new phase of the pandemic, where Americans continue to return to normalcy while also accepting that COVID-19 is something we will have to live with for the foreseeable future. We are asking that FDA do everything in its power to ensure that everyone can live in a world with COVID-19. A big first step would be to expand its approach beyond one overly reliant on vaccines and antivirals.

Expediting the approval of new treatments, such as monoclonal antibodies, will make it possible for everyone returning to the office to do so as safely as possible. Antibody treatments have a successful track record in protecting the immunocompromised from COVID-19. Unfortunately, due to the evolving nature of the virus, all five monoclonal antibody treatments granted Emergency Use Authorization (EUA) are no longer effective against current strains of the virus.

This highlights the need for FDA to streamline the approval process to reflect the proven science behind these technologies. The COVID-19 vaccines today demonstrated that the agency could move quickly and efficiently without compromising safety when there is an urgent public health demand. A similar strategy should be put in place to allow the development of monoclonal antibody treatments to keep up with the virus.

We thank you for considering the critical public health issue, and we would be happy to discuss our concerns with you further if you feel that would be helpful.

Sincerely,

Randy Erwin
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National Federation of Federal Employees

Clayola Brown
National President
A. Philip Randolph Institute

Richard Fiesta
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