



June 23, 2022

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

RE: Pharmacists prescribing for COVID-19 oral antivirals

Dear Dr. Califf,

Our paths last crossed when I was Deputy Director of CDER's Office of Compliance during your first tenure at FDA. I have since retired from FDA and am now Interim CEO of the American Pharmacists Association (APhA), representing our nation's pharmacists in all practice settings in the U.S. We welcome and support your second tenure at FDA and appreciate your efforts to protect public health.

I write to impress upon you and FDA staff the significant role that pharmacists can play addressing health equity and providing access to important COVID-19 therapeutics if FDA breaks down the barrier preventing pharmacist prescribing of these important drugs, particularly Paxlovid.

APhA and other pharmacy organizations have met with CDER staff over the past 6 months, providing supportive information demonstrating the expertise, knowledge, and capability of pharmacists to prescribe these drugs, as authorized under the [Ninth Amendment to Declaration under the Public Readiness and Emergency Preparedness Act](#). Pharmacists are ready to help.

Last month, we shared with FDA an [analysis](#) that APhA conducted demonstrating that underserved and vulnerable communities do not have equitable access to treatment in the current federal Test to Treat program. Our analysis was recently confirmed by the Centers for Disease Control and Prevention (CDC) in an [MMWR](#) that was published this week regarding dispensing rates in socially vulnerable parts of the country. We just updated our analysis to fill in the gap between CDC's analysis and today to see if the situation is improving regarding access. It has not improved.

According to our updated analysis, as of June 22, 2022, there are over 28,000 community pharmacies located in federally recognized underserved communities, yet only 838 Test to Treat sites have been established in those communities. Tapping the pharmacies in these areas could

increase access to treatments by about 3,200%. The data shows that the *least* vulnerable areas nationwide have access to 75% of Test to Treat locations, limiting the *most* vulnerable communities to only 25% (666) of these locations. However, these areas—which fall in the top 30% of the social vulnerability index—have an estimated 24,000 community pharmacies, most of which are not Test to Treat points of care for oral COVID-19 antiviral medications.

At Test to Treat locations, patients who test positive for COVID-19 and have a high risk for progression to severe COVID-19 disease can receive a prescription for an oral COVID-19 medicine and choose to conveniently fill that prescription at the same site of care. Throughout the COVID-19 pandemic, pharmacists have expanded access to testing and vaccination services but currently cannot prescribe these medicines because of limits by FDA in the Emergency Use Authorizations (EUAs), despite being specifically authorized by the Secretary of Health and Human Services (HHS) to prescribe oral COVID-19 therapeutics.

By allowing pharmacists to order oral COVID-19 treatments, access to prescriptions for these products could expand far beyond the current 2,654 Test to Treat sites currently available nationwide, significantly increase one-stop points of care at community pharmacies and increase equitable access to those who need it most.

As you consider changes to the EUA, please ensure that additional barriers or conditions of use are not imposed preventing access to these lifesaving medications to those who can benefit the most. A key way to address these proven health inequities and access is by utilizing our nation's community pharmacies across the country.

I welcome the opportunity to discuss with you and others at FDA our analysis and the role that pharmacists can play if barriers to prescribing are removed. I can be reached at ibernstein@aphanet.org or 202-429-7533.

Sincerely,

A handwritten signature in black ink that reads "Ilisa B Bernstein". The signature is fluid and cursive, with the first name "Ilisa" and last name "Bernstein" clearly legible.

Ilisa Bernstein, PharmD, JD, FAPhA
Interim CEO and Executive Vice President
American Pharmacists Association

cc: Dr. Janet Woodcock; Dr. Patrizia Cavazzoni; Dr. John Farley; Dr. Debra Birnkrant