May 26, 2022

Dr. Ashish Jha
COVID-19 Response Coordinator
The White House Coronavirus Task Force

Dear Dr. Jha:

We appreciate the Administration's announcement that it will open new test-to-treat centers and deploy federal personnel to assist clinicians in areas with high COVID-19 caseloads. While these steps will incrementally expand access to oral antivirals in a small number of communities, the government could dramatically expand access in all communities by removing the federal barrier preventing pharmacists from initiating therapy with these time-sensitive medications.

To meaningfully expand test-to-treat access, the Food and Drug Administration (FDA) must modify its Emergency Use Authorization (EUA) to remove the limitation preventing pharmacists from prescribing oral antivirals.

At present, Americans who test positive at a pharmacy can access time-sensitive oral antivirals on the spot from only a limited number of pharmacies with in-house access to non-pharmacist prescribers. In practical terms, this means a patient may test positive for COVID-19 at a pharmacy, and the pharmacy may have the medication in stock, but until another clinician signs off on the prescription, the patient has to wait for treatment. Particularly in rural and underserved communities that have fewer pharmacies with in-house non-pharmacist clinicians, patients are less likely to benefit from your test-to-treat approach until the FDA removes its limitation on pharmacist initiation of therapy.

Many states license pharmacists to initiate therapy, either independently or in collaboration with a physician. In September, Secretary Becerra took an important step to expand patient access by authorizing pharmacists in all 50 states to order oral treatments for COVID-19. Unfortunately, the FDA undermined patient access by specifically excluding pharmacist prescribers from the EUAs for COVID oral antivirals. FDA's unorthodox action is in direct conflict with Secretary Becerra's authorization and inhibits the success of test-to-treat expansion.

FDA's EUA restriction is inconsistent with clinical practice, as well as the agency's history of provider-neutral approval decisions. The agency provided no clinical justification for this restriction.

Pharmacists are clinically trained medication experts and are the primary healthcare professionals responsible for ensuring safe medication use, including identifying and mitigating drug interactions associated with oral antiviral medications for COVID-19. Preventing state-licensed pharmacists from initiating therapy with these medications is an extreme and atypical action for the FDA.

Thank you again for recognizing the potential of pharmacists to improve patient access to COVID-19 treatments. We urge the Administration to direct the FDA to remove its EUA limitation preventing pharmacists from initiating therapy with oral antivirals, so that we can achieve the full potential of the test-to-treat initiative.

Sincerely,

Tom Kraus, J.D.
Vice President, Government Relations
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