



March 9, 2023

Dockets Management Staff (HFA-305)  
Food and Drug Administration (FD)  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Submitted Electronically: <https://www.regulations.gov/commenton/FDA-2022-N-2782-0004>

RE: Docket No. FDA-2022-N-2782 for "Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments."

Dear Director Stein:

LeadingAge appreciates the opportunity to submit comments to the Antimicrobial Drugs Advisory Committee (committee) and the Food and Drug Administration (FDA) on the new drug application for Pfizer's Paxlovid. Based on a small number of member nursing home and assisted living providers' data and many anecdotal reports from aging services providers, LeadingAge supports approval of the application.

The mission of LeadingAge is to be the trusted voice for aging. We represent more than 5,000 mission driven aging services providers that touch millions of lives every day. Alongside our members and 38 state partners, we use applied research, advocacy, education, and community-building to make America a better place to grow old. Our membership encompasses the entire continuum of aging and disability services. We bring together the most inventive minds to lead and innovate solutions that support older adults wherever they call home.

As mission driven providers, our members prioritize the health, wellbeing, and wellness of all residents in their communities through multifaceted care and service delivery. The coronavirus that causes COVID-19 has killed more than 1.1 million Americans with more than 75%<sup>1</sup> of those deaths occurring in individuals over the age of 65- precisely the age demographic our membership is serving.

Members, their staff, medical directors, and consultants called early and often for vaccinations and therapeutics that would stymie the spread and lethality of COVID-19. With the evolution of the pandemic, those resources became available and have had profoundly positive affects saving thousands of lives. For prevention of severe disease, Paxlovid has proven an effective mitigator. One member reported that following the availability of Paxlovid, approximately 40% of individuals who tested positive for SARS-CoV-2 across two settings received Paxlovid as a therapeutic to shorten their illness and lessen severity. Another organization indicated more than 50% of their residents that tested positive for SARS-CoV-2 took Paxlovid. Both organizations noted no negative effects and reported that mild or

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<sup>1</sup> [https://www.cdc.gov/nchs/nvss/vsrr/covid\\_weekly/index.htm](https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm), accessed on March 7, 2023

asymptomatic cases accounted for large portions of positive cases that did not receive a therapeutic intervention like Paxlovid.

Similarly, members reported that availability of Paxlovid has proven a lifeline for so many high-risk residents. Even individuals on medications that were contraindicated with Paxlovid, clinical staff across our continuum reported that they did not hesitate to make short term amendments to daily regimens like statin or blood pressure medications because doing so would allow the safe administration of Paxlovid and optimize the individual's recovery.

LeadingAge urges the committee and FDA to consider the outsized opportunity for utilization by individuals receiving services or care from aging services provider. The risks of COVID-19 to older and clinically complex individuals continues to be a threat. More individuals are testing positive for SARS-COV-2 and outbreaks in local communities are flaring. Maintaining access to all viable and safe treatment options is our societal obligation.

The quick response and emergency authorization of Paxlovid and other therapeutics has prevented hospitalizations, averted unnecessary spending, and saved lives. We appreciate the opportunity to share our perspective and appreciate the work of the committee and the FDA in assuring access to safe and effective treatments remain available. Thank you for your ongoing concern and efforts to maintain health across the nation.

Sincerely,

A handwritten signature in black ink that reads "Katie Smith Sloan". The signature is written in a cursive, flowing style.

Katie Smith Sloan  
President and CEO, LeadingAge