



April 7, 2020

Stephen Hahn, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Rockville, MD 20852
Email: CommissionerFDA@fda.hhs.gov

Dear Commissioner Hahn:

On behalf of the Asthma and Allergy Foundation of America (AAFA), I am writing to express our serious concern regarding asthma drug shortages in the context of the COVID-19 pandemic. AAFA is the leading patient organization advocating for people with asthma and allergies, and the oldest asthma and allergy patient group in the world.

As detailed in the New York Times on April 2, demand has increased sharply for a number of drugs used to treat COVID-19, including albuterol, a drug used to treat respiratory issues.¹ Hospitals have been ordering albuterol inhalers to treat breathing problems in COVID-19 patients because administering albuterol by nebulizers, which are commonly used in hospitals, can disseminate the virus to others.

However, many adults and children with asthma rely on albuterol inhalers as a rescue medication to treat asthma attacks, as do patients with chronic obstructive pulmonary disease. We are concerned that the increased demand for albuterol from hospitals, combined with recommendations that patients seek extended supplies of their prescription medications, are making it harder for people with asthma to access albuterol. Without albuterol, people are more likely to experience asthma attacks that they cannot control, potentially increasing hospitalizations.

We are already hearing from our patient community about challenges in filling their prescriptions, including for albuterol and other inhalers. We are currently surveying our community regarding the impact of COVID on their and their families' health. Based on interim results of 1,748 respondents, 45 percent reported that COVID had some impact on their ability to purchase or access prescription medications for asthma or allergy, with 10 percent reporting a "major" impact. Of those reporting an impact, 34 percent reported an impact on accessing asthma controller inhalers, and 53 percent reported challenges accessing asthma-quick relief inhalers, such as albuterol.

Though we cannot attribute all of these challenges directly to shortages, some survey respondents and others who have reached out to us directly have noted specific difficulty with delays or shortages of albuterol inhalers at the pharmacy. These challenges are compounded by those affecting many chronic disease patients in the current epidemic, including fear of exposure to COVID when visiting a pharmacy.

While AAFA is deeply concerned about the impact of COVID-19 on all Americans and people around the globe, our patient community with asthma experiences specific vulnerabilities. One in thirteen individuals

¹ Knavul Sheikh, "Essential Drug Supplies for Virus Patients Are Running Low." New York Times, April 2, 2020. Available at <https://www.nytimes.com/2020/04/02/health/coronavirus-drug-shortages.html>



in the U.S. – nearly 25 million people – are living with asthma.² The CDC has determined that people with moderate or severe asthma may be at higher risk of serious illness due to COVID-19.³ Preliminary analysis of U.S. COVID-19 cases with data available on underlying conditions indeed reflects that people with chronic lung disease, including asthma, are among those at higher risk of severe disease.⁴ Over 4 million Americans living with asthma are also 65 years old or older,⁵ likely rendering them particularly vulnerable to COVID-19 complications and death. It is important that people with asthma have access to their regular medications to keep their symptoms well controlled and optimize their baseline health.⁶

AAFA would like to work with FDA to mitigate the impact of any localized or general shortage on asthma patients. In addition to shortages caused by increased demand, we share the growing concern that the pandemic will affect global supply chains. We of course support the use of albuterol and other important medications to treat patients with COVID, but we believe that specific attention to the availability of the drug for existing uses is crucial. Our hope is that state, federal, and private sector efforts to protect access to asthma drugs can be developed before any official shortage is recorded.

I look forward to collaborating on an appropriate response.

Sincerely,

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America

² CDC, “Most Recent National Asthma Data” (Updated March 24, 2020). Available at https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm

³ CDC, “People with Moderate to Severe Asthma” (April 2, 2020). Available at https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/asthma.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fspecific-groups%2F asthma.html

⁴ Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus Disease 2019 — United States, February 12–March 28, 2020. MMWR Morb Mortal Wkly Rep 2020;69:382–386. DOI: <http://dx.doi.org/10.15585/mmwr.mm6913e2>

⁵ CDC, “Most Recent National Asthma Data” (Updated March 24, 2020). Available at https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm

⁶ American Academy of Allergy, Asthma and Immunology, “COVID-19 and Asthma: What Patients Need to Know” (March 23, 2020). Available at <https://www.aaaai.org/conditions-and-treatments/library/asthma-library/covid-asthma>.