

July 6, 2021

Honorable Michael S. Regan  
Administrator  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
Dear Administrator Regan:  
RE: EPA-HQ-QAR-2021-0044

Administrator Regan:

On behalf of the American Thoracic Society, I appreciate the opportunity to comment on the proposed rule to reduce U.S. HFC emissions. The ATS is a medical professional organization of over 16,000 physicians, scientists, respiratory therapists, nurses, and allied health professionals dedicated to the prevention, detection, treatment and cure of respiratory disease, critical care illness and sleep disordered breathing. Our members pursue this mission through research, education, and advocacy. Our members are actively treating patients who used HFC metered dose inhalers to manage their respiratory disease. It is with our extensive clinical experience in prescribing MDIs and treating patients who rely on essential MDI medications that we offer the following comments.

### **ATS Agrees that HFC's Contribution to Climate Change Require a Response from the U.S. and EPA**

The ATS knows that climate change is real, poses an immediate and growing public health threat and requires immediate response by local, state, and federal agencies. The EPA has provided ample documentation of the reality of climate change and that HFCs are an important and controllable source of GHG emissions that are driving climate change. The ATS appreciates the action Congress and the Administration took by enacting the American Innovation and Manufacturing Act and looks forward to the EPA's implementation of supporting regulatory policy.

While not directly germane to the substance of this proposed rule, the ATS notes that the current estimated social cost of carbon under-estimate health-related costs of climate change. A more complete accounting of health-related costs would add further

justification for EPA rule-making to phase down HFC damage, making reductions in HFC emissions likely to be even more significant than the current estimates state.

### **ATS Agrees the CFC Phase Out has important lessons for the HFC Phase Down**

ATS agrees with the Agency that the ODS phase out and the CFC phase out, have important parallels for addressing MDI HFC use.

### **MDIs are an Essential Medical Treatment**

The ATS is pleased that Congress and the EPA understand and expressly recognize the essential role that MDIs play in the treatment of respiratory disease by establishing MDIs HFC use as one of six recognized applications in the American Innovation and Manufacturing statute. The Agency correctly notes that several alternative or not in-kind products have been developed by the pharmaceutical industry. These NIK products, while effective for many patients, are not appropriate for all respiratory patients. Dry powder inhalers pose unique challenges for pediatric patients. Research has documented that children under four years of age can't effectively coordinate lung inspiration to use DPIs. Many children with chronic respiratory conditions associated with prematurity or neuromuscular disorders have developmental delays, effectively expanding the age band for children unable to use DPIs. Further, patients of all ages with severe lung disease may lack the inspiratory flow capacity to trigger DPI devices, making DPI products ineffective in a wide range of respiratory patients.

The ATS expects the pharmaceutical industry will continue to explore alternatives to MDIs, however, until such time as more broadly accepted DPI or other NIK devices are developed that work in all patient populations, it is essential that MDIs remain on the U.S. and global market to treat patients with a wide range of respiratory conditions.

### **MDI use broader than asthma and COPD**

In the proposed rule, EPA states:

“MDIs provide reliable and effective therapy for asthma and chronic obstructive pulmonary disease (COPD).”

This is an accurate, but incomplete description of the medical conditions that may use MDIs. A more comprehensive list includes:

- Acute viral infections, including COVID
- Asthma
- Bronchiectasis

- COPD
- Idiopathic Pulmonary Fibrosis
- Non-specific shortness of breath
- Post-COVID infection
- Post-Infection Chronic Cough
- Sarcoidosis

While asthma and COPD are the most frequent conditions requiring MDI use, the other listed conditions also account for substantial MDI use. We share the information about the broad use of MDIs with the agency to provide context for our recommendation of an increase in the baseline estimate for future HFC allocations for the MDI application.

### **MDI definition of MDI**

The ATS agrees with EPA definition of MDI.

### **MDI Specific Allowance**

As called for in the underlying legislation and included in the proposed rule, the ATS agrees with the creation of an MDI specific application allowance for HFCs. Establishing the MDI specific allowance is needed to preserve long-term access to essential respiratory drugs.

### **MDI Specific Allowance Estimates**

In the proposed rule, EPA states,

“EPA estimates that in 2020, approximately 458 MT of HFC-134a and 78 MT of HFC-227ea propellant were contained in MDIs sold in the United States.”

The ATS is concerned that this initial estimate is low and does not accurately estimate the actual amount of HFC used for MDIs in the U.S. The ATS urges the EPA to work closely with source manufacturers of medical grade HFCs to establish a more accurate baseline for current HFC/MDI use in the U.S.

Based on our conversations with industry and suppliers of bulk HFCs, the ATS believes that a more accurate annual estimate of HFC use is likely 1000-1500 MT.

### **Growth Use Inflater**

The ATS notes EPA has proposed a variety of methods to estimate the growth rate of future use of HFCs in MDI and other sector allowances. While population growth and gross domestic product both are reasonable starting points, both have limitations. GDP

is subject to changes both up and down and these economic swings do not correlate to changes in MDI consumption. Population growth is more likely to capture some of the increased demand for MDIs driven by a growing population, but even population growth will likely miss events that may cause a sudden change in MDI demand, including respiratory events like COVID, air pollution/wildland fire triggered acute events or other inhalation disasters.

### **ATS Supports Trading HFC Allowances Within Sectors**

The ATS agrees with the EPA's proposal to allow trading of HFC allowances within sectors. We believe the EPA's trading allowance proposal will allow flexibility while preserving the overall intent to reduce total industrial HFC emissions.

### **Issues EPA Should Consider in Future Rule Making**

#### **Appropriate disposal of MDI products**

The ATS encourages EPA to consider addressing hospital and consumer disposal of used and expired MDI products. While the proposed rule clearly establishes processes and standards for industry disposal of HFC gases, it is silent on consumer disposal of MDI products. For future rule making, the agency may want to consider if HFC emissions from consumer disposal of MDIs warrants further rule-making.

#### **Encouraging the Adoption of Lower GWP HFC Substitutes**

The ATS notes that the majority of MDIs that contain HFC propellants use either HFC 134a or HFC 227ea. HFC 134a has a GWP of 1,430 while HFC 227ea has a GWP of 3220. The ATS is aware that industry is considering switching to HFCs with a lower GWP, namely HFC 152a which has a GWP of 124 or non HFC propellants like HFO 1234ze.

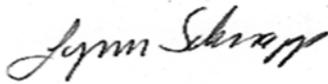
In future rule-makings, the EPA should consider what policies the agency can implement that would encourage and reward companies for switching to MDI propellants with lower GWP.

We further note that the FDA has an essential role to play in this area as well. During the ODS phase out of CFCs, FDA determined that MDIs that used a new propellant, even though they used the same drug, were considered a new drug, and had to undergo FDA new drug review. The decision to require new drug application added time to the phase out process, added costs to the pharmaceutical companies and ultimately led to higher drug prices for consumers. The ATS strongly urges the EPA

and the FDA, who has jurisdiction over this decision, to consider propellant switching as a reformulation of an existing drug. Reviewing MDIs that have switched to propellants with a lower GWP as reformulations will reduce time and cost for companies and consumers alike, while still preserving the FDA's oversight of the reformulated drug.

Again, the ATS appreciates the opportunity to submit these comments. If you have questions or need additional information, please contact Mr. Gary Ewart in the ATS Washington Office.

Sincerely,



Lynn M. Schnapp MD, ATSF  
President  
American Thoracic Society