COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

December 6, 2022

Moira Szilagyi, MD, PhD
President
American Academy of Pediatrics
345 Park Boulevard
Itasca, IL 60143

Re: Addressing the Environmental Impact of Pressurized Metered Dose Inhalers

Dear Dr. Szilagyi,

The impact of the climate crisis on health is well documented, and the health care industry – the sector that seeks to address the health needs of individuals and populations – is responsible for an estimated 8.5 percent of greenhouse gas emissions in the United States (U.S.).[1, 2, 3] As the Committee on Ways and Means continues to explore issues related to the intersection of our health system and the climate crisis, it has become increasingly clear that many more straightforward undertakings remain unaddressed. For example, studies show that pressurized metered dose inhalers (pMDIs), commonly used for treatment of asthma and chronic obstructive pulmonary disease (COPD), release hydrofluorocarbon (HFC, a harmful greenhouse gas) propellants, which contribute to climate change – a factor that exacerbates the very diseases inhalers are meant to treat.[4, 5, 6] This cycle is particularly troublesome given that safer alternatives exist. Thus, I seek to better understand the work that the American Academy of Pediatrics (AAP) is undertaking to limit the harmful environmental impact of pMDIs while ensuring those who need inhalers have safe and effective treatments.

HFC pMDIs have an enormous negative environmental impact.[7] In 2019, medical providers dispensed an estimated 55,344,000 pMDIs in the U.S., which contain HFC propellants – powerful greenhouse gases.[8, 9] In the U.S. alone, HFC propellants in pMDIs were projected to

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[4] *Id.*
[5] *Market Characterization of the U.S. Metered Dose Inhaler Industry*, ICF (Sept. 2021), https://www.epa.gov/sites/default/files/2021-03/documents/epa-hq-oar-2021-0044-0002_attachment_1-mdis.pdf.
[6] *Global Strategy for Asthma Management and Prevention (2022 update),* GLOBAL INITIATIVE FOR ASTHMA (2022), https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf.
[7] Mathew J. Eckelman et al., *supra* note 3.
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contribute *2.5 million metric tons of carbon dioxide equivalent (CO_{2e})* in 2020, which is equal to the yearly carbon emissions of 543,478 passenger vehicles.[10, 11] According to a 2022 report, inhalers alone represent three percent of *total* National Health Service emissions in England.[12] Despite the overwhelming negative environmental impact, HFC pMDIs still have a *75 percent share* in the U.S. inhaler market.[13]

HFC pMDIs exacerbate the cause of the illness they are intended to treat, disproportionately affecting communities of color. Providers commonly prescribe pMDIs to patients who experience asthma and chronic obstructive pulmonary disease (COPD).[14, 15] Many patients experiencing acute asthma or COPD exacerbations receive short-acting β_2-agonists (SABA), such as albuterol and ipratropium bromide, via pMDIs, which provide immediate relief but simultaneously release harmful HFC greenhouse gas.[16, 17] The release of these greenhouse gases worsen air pollution, which can contribute to or exacerbate chronic conditions.[18] According to the Centers for Disease Control and Prevention (CDC), in 2018, an estimated 25 million and 16.4 million Americans were diagnosed with asthma and COPD, respectively.[19, 20] The prevalence of asthma is greater among Black Americans, Puerto Ricans, and families whose income is 250 percent or below the federal poverty line.[21] Literature suggests there is an association between outdoor air pollution and asthma exacerbation – particularly problematic for communities of color that have experienced historical redlining, which has been associated with

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[12] *Delivering a 'Net Zero' National Health Service*, NHS ENGLAND at 32 (July 2022), https://www.england.nhs.uk/greenernhs/wp-content/uploads/sites/51/2022/07/B1728-delivering-a-net-zero-nhs-july-2022.pdf; Joachim Starup-Hansen et al*., Climate change in healthcare: Exploring the potential role of inhaler prescribing*, 8:6 PHARMACOL RES PERSPECT. at 1 (2020), https://doi.org/10.1002/prp2.675.

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[16] *Short-Acting Beta-Agonists (SABAs),* AM. ACADEMY OF ALLERGY ASTHMA & IMMUNOLOGY (April 2020), https://www.aaaai.org/tools-for-the-public/drug-guide/short-acting-beta-agonists-(sabas).

[17] *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2022 report), supra* note 15.

[18] Center for Science Education, *Air Quality and Climate Change*, UCAR, https://scied.ucar.edu/learning-zone/air-quality/air-quality-and-climate-change (last visited Oct. 12, 2022).

[19] *2018 Archived National Asthma Data,* CTRS. FOR DISEASE CONTROL AND PREVENTION (Mar. 30, 2021), https://www.cdc.gov/asthma/archivedata/2018/2018_archived_national_data.html.

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All parts of the health sector must work together to address this problem. In addition to provider prescribing patterns, payors will have a role to play in these efforts, given that environmentally friendly alternatives to pMDIs are usually more expensive and, as a result, out-of-reach financially for some patients. For example, in the Medicare program, the average cost per claim filled for Albuterol Sulfate, a SABA pMDI, is $50.92, while Symbicort, an ICS+LABA DPI costs $495.02 per claim filled. [34] Inhalers are among the top-spending drugs in Medicare Part D: Symbicort was 11th on the highest expenditures list for Medicare Part D in

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2020.[35] Overall, Medicare spent nearly $40 billion on 40 brand-name and two generic inhalers between 2012 and 2018.[36] The Government Accountability Office (GAO) found that respiratory agents – a category that includes inhalers – account for nearly one-third of Medicare Part D expenditures and rebates.[37] With the historic passage of *the Inflation Reduction Act*, Congress established new tools to address high-cost drugs and associated out-of-pocket costs for drugs like high-cost inhalers.

While there is a large differential in cost that could affect the utilization of these inhalers, the *environmental cost* differential of the various inhalers is also substantial. For example, Symbicort DPIs generate anywhere from 3.4 to 12.5 times less CO_{2e} emissions than Albuterol Sulfate pMDIs, depending on the dosage and frequency of the DPI.[38] We do not want a cycle where treatments exacerbate the ongoing climate crisis, making more people ill and requiring more of these same treatments. The indirect costs employers and taxpayers incur for inhalers and the direct costs consumers pay at the pharmacy counter must be balanced with the environmental costs that exacerbate the very condition inhalers are used to treat.

Given the prevalence of asthma and COPD in the U.S., AAP has a critical role to play in switching patients to environmentally safer inhalers *when medically feasible*. The Committee would like to work with you to ensure that these issues are fully examined and, where appropriate, addressed expeditiously. Thus, I ask that you respond to the following questions, in writing, by Tuesday, December 20, 2022.

a. Does your organization have an active initiative to educate providers on the environmental impact of pMDIs and safe and effective alternatives when prescribing inhalers? If so, please describe this initiative.
b. Does your organization have goals with respect to reducing the usage of pMDIs over time? If so, please describe the goals and any progress you have made toward achieving them.
c. What obstacles have your organization identified that prevent clinicians and patients from choosing less environmentally harmful inhalers? What has your organization done to mitigate these difficulties?
d. Has your organization identified any federal policy interventions that would better support efforts to reduce the climate impact of pMDIs?
e. pMDIs are one of many environmentally harmful medical treatments. Has your organization identified other medical practices and treatments common among your practitioners that have deleterious effects on the environment? Please describe any efforts to reduce the climate impact of these additional medical practices and treatments.

[35] *Id.*
[36] William B. Feldman et al., *Trends in Medicare Part D Inhaler Spending: 2012-2018,* 18:3 ANNALS OF THE AM. THORACIC SOCIETY at 548–550 (2021), https://doi.org/10.1513/AnnalsATS.202008-1082RL.
[37] *Medicare Part D: use of pharmacy benefit managers and efforts to manage drug expenditures and utilization*, U.S. GOV. ACCOUNTABILITY OFFICE (July 2019), https://www.gao.gov/assets/gao-19-498.pdf.
[38] *The environmental impact of inhalers,* supra note 26.

i. Does your organization consider environmental harm (e.g., carbon footprint) when developing evidence-based practice guidelines? If so, please describe how such harm is considered.
ii. Beyond pMDIs, what steps has AAP taken to educate clinicians, residents, and students on making environmentally conscious decisions while practicing evidence-based medicine?

Thank you for your attention to this critical matter. If you have any question about this request, please contact Amy Hall of the Committee on Ways and Means Democratic Staff at Amy.Hall@mail.house.gov or (202) 225-3625.

Sincerely,

Richard E. Neal
Chairman
Committee on Ways and Means

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
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December 6, 2022

Jack Resneck, MD
President
American Medical Association
330 N Wabash Ave., Suite 39300
Chicago, IL 60611

Re: Addressing the Environmental Impact of Pressurized Metered Dose Inhalers

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[38] *The environmental impact of inhalers,* supra note 26.

i. Does your organization consider environmental harm (e.g., carbon footprint) when developing evidence-based practice guidelines? If so, please describe how such harm is considered.
ii. Beyond pMDIs, what steps has the AMA taken to educate clinicians, residents, and students on making environmentally conscious decisions while practicing evidence-based medicine?

Thank you for your attention to this critical matter. If you have any question about this request, please contact Amy Hall of the Committee on Ways and Means Democratic Staff at Amy.Hall@mail.house.gov or (202) 225-3625.

Sincerely,

Richard E. Neal
Chairman
Committee on Ways and Means

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

December 6, 2022

Tochi Iroki-Malize, MD, MPH, MBA
President
American Academy of Family Physicians
1140 Tomahawk Creek Parkway
Leawood, KS 6621

Re: Addressing the Environmental Impact of Pressurized Metered Dose Inhalers

Dear Dr. Iroki-Malize,

The impact of the climate crisis on health is well documented, and the health care industry – the sector that seeks to address the health needs of individuals and populations – is responsible for an estimated 8.5 percent of greenhouse gas emissions in the United States (U.S.).[1, 2, 3] As the Committee on Ways and Means continues to explore issues related to the intersection of our health system and the climate crisis, it has become increasingly clear that many more straightforward undertakings remain unaddressed. For example, studies show that pressurized metered dose inhalers (pMDIs), commonly used for treatment of asthma and chronic obstructive pulmonary disease (COPD), release hydrofluorocarbon (HFC, a harmful greenhouse gas) propellants, which contribute to climate change – a factor that exacerbates the very diseases inhalers are meant to treat.[4, 5, 6] This cycle is particularly troublesome given that safer alternatives exist. Thus, I seek to better understand the work that the American Academy of Family Physicians (AAFP) is undertaking to limit the harmful environmental impact of pMDIs while ensuring those who need inhalers have safe and effective treatments.

HFC pMDIs have an enormous negative environmental impact.[7] In 2019, medical providers dispensed an estimated 55,344,000 pMDIs in the U.S., which contain HFC propellants

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[1] A. Crimmins et al., *The Impacts of Climate Change on Human Health in the United States: A Scientific Assessment*, U.S. GLOBAL CHANGE RESEARCH PROGRAM (2016), https://health2016.globalchange.gov/high/ClimateHealth2016_FullReport.pdf.
[2] Matthew J. Eckelman & Jodi Sherman, *Environmental Impacts of the U.S. Health Care System and Effects on Public Health*, 11:6 PLOS ONE (2016), https://doi.org/10.1371/journal.pone.0157014.
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[4] *Id.*
[5] *Market Characterization of the U.S. Metered Dose Inhaler Industry*, ICF (Sept. 2021), https://www.epa.gov/sites/default/files/2021-03/documents/epa-hq-oar-2021-0044-0002_attachment_1-mdis.pdf.
[6] *Global Strategy for Asthma Management and Prevention (2022 update),* GLOBAL INITIATIVE FOR ASTHMA (2022), https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf.
[7] Mathew J. Eckelman et al., *supra* note 3.

– powerful greenhouse gases. [8, 9] In the U.S. alone, HFC propellants in pMDIs were projected to contribute *2.5 million metric tons of carbon dioxide equivalent (CO_{2e})* in 2020, which is equal to the yearly carbon emissions of 543,478 passenger vehicles.[10, 11] According to a 2022 report, inhalers alone represent three percent of *total* National Health Service emissions in England.[12] Despite the overwhelming negative environmental impact, HFC pMDIs still have a *75 percent share* in the U.S. inhaler market.[13]

HFC pMDIs exacerbate the cause of the illness they are intended to treat, disproportionately affecting communities of color. Providers commonly prescribe pMDIs to patients who experience asthma and chronic obstructive pulmonary disease (COPD).[14, 15] Many patients experiencing acute asthma or COPD exacerbations receive short-acting β_2-agonists (SABA), such as albuterol and ipratropium bromide, via pMDIs, which provide immediate relief but simultaneously release harmful HFC greenhouse gas.[16, 17] The release of these greenhouse gases worsen air pollution, which can contribute to or exacerbate chronic conditions.[18] According to the Centers for Disease Control and Prevention (CDC), in 2018, an estimated 25 million and 16.4 million Americans were diagnosed with asthma and COPD, respectively.[19, 20] The prevalence of asthma is greater among Black Americans, Puerto Ricans, and families whose income is 250 percent or below the federal poverty line.[21] Literature suggests there is an

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[8] *Market Characterization of the U.S. Metered Dose Inhaler Industry*, *supra* note 5.
[9] *Global Strategy for Asthma Management and Prevention (2022 update), supra* note 6.
[10] According to the Environmental Protection Agency (EPA), the unit *carbon dioxide equivalent* is used to measure greenhouse gas (GHG) emissions and account for the global warming potential (GWP) of different gases. In other words, *carbon dioxide equivalent* is equal to GHG emissions multiplied by the gas's GWP. *Overview of Greenhouse Gases,* U.S. ENVIRONMENTAL PROTECTION AGENCY (May 16, 2022), https://www.epa.gov/ghgemissions/overview-greenhouse-gases.
[11] The EPA estimates that a typical passenger vehicle emits about 4.6 metric tons of carbon dioxide per year (2,500,000 metric tons of CO_2 divided by 4.6 metric tons of CO_2 = 543,478.261 vehicles). *Market Characterization of the U.S. Metered Dose Inhaler Industry*, *supra* note 5, at 9; *Greenhouse Gas Emissions from a Typical Passenger Vehicle,* U.S. ENVIRONMENTAL PROTECTION AGENCY (June 30, 2022), https://www.epa.gov/greenvehicles/greenhouse-gas-emissions-typical-passenger-vehicle.
[12] *Delivering a 'Net Zero' National Health Service*, NHS ENGLAND at 32 (July 2022), https://www.england.nhs.uk/greenernhs/wp-content/uploads/sites/51/2022/07/B1728-delivering-a-net-zero-nhs-july-2022.pdf; Joachim Starup-Hansen et al*., Climate change in healthcare: Exploring the potential role of inhaler prescribing*, 8:6 PHARMACOL RES PERSPECT. at 1 (2020), https://doi.org/10.1002/prp2.675.
[13] *Id.*
[14] *Global Strategy for Asthma Management and Prevention (2022 update), supra* note 6.
[15] *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2022 report),* GLOBAL INITIATIVE FOR CHRONIC OBSTRUCTIVE LUNG DISEASE (2021), https://goldcopd.org/2022-gold-reports-2/.
[16] *Short-Acting Beta-Agonists (SABAs),* AM. ACADEMY OF ALLERGY ASTHMA & IMMUNOLOGY (April 2020), https://www.aaaai.org/tools-for-the-public/drug-guide/short-acting-beta-agonists-(sabas).
[17] *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2022 report), supra* note 15.
[18] Center for Science Education, *Air Quality and Climate Change*, UCAR, https://scied.ucar.edu/learning-zone/air-quality/air-quality-and-climate-change (last visited Oct. 12, 2022).
[19] *2018 Archived National Asthma Data,* CTRS. FOR DISEASE CONTROL AND PREVENTION (Mar. 30, 2021), https://www.cdc.gov/asthma/archivedata/2018/2018_archived_national_data.html.
[20] *COPD Prevalence,* AM. LUNG ASSOC., https://www.lung.org/research/trends-in-lung-disease/copd-trends-brief/copd-prevalence (last visited Jul. 14, 2021).
[21] *2018 National Health Interview Survey (NHIS) Data*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Dec. 17, 2019), https://www.cdc.gov/asthma/nhis/2018/table4-1.htm.

association between outdoor air pollution and asthma exacerbation – particularly problematic for communities of color that have experienced historical redlining, which has been associated with disproportionate exposure to higher amounts of air pollution. [22, 23] Air pollution also exacerbates COPD, increases associated health care costs, and, ultimately, increases mortality rates.[24]

Environmentally safer alternatives to pMDIs already exist through dry powder inhalers (DPIs) and soft mist inhalers (SMIs) for most patients over the age of five.[25] These formulations can be seen in medications, such as Symbicort (and the approved generic Breyna) and Spiriva Respimat, respectively, both of which are recommended for the treatment of asthma and COPD in adult patients. [26, 27] Across different asthma medications, these alternative delivery systems emit up to *25 times less* CO_{2e} than pMDIs.[28] Though these safer alternatives exist, 88 percent of U.S. inhaler prescriptions in 2020 were for pMDIs.[29] Estimates in England have projected that for every 10 percent of pMDIs that are switched to DPIs, there may be a decrease of 58,000 metric tons of CO_{2e} in England's carbon emissions every year, which is equal to removing 12,600 passenger vehicles from the roads.[30, 31] Prescribing patterns in Sweden show that in many instances, DPIs can replace pMDIs, with DPIs representing nearly 90 percent of inhaler prescriptions in that country.[32] With Sweden as a model, England's National Health Service has current long-term plans to reduce its total emissions by transitioning to DPIs as clinically indicated.[33]

All parts of the health sector must work together to address this problem. In addition to provider prescribing patterns, payors will have a role to play in these efforts, given that environmentally friendly alternatives to pMDIs are usually more expensive and, as a result, out-of-reach financially for some patients. For example, in the Medicare program, the average cost per claim filled for Albuterol Sulfate, a SABA pMDI, is $50.92, while Symbicort, an

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[23] Haley M. Lane et al., *Historical Redlining Associated with Present-Day Air Pollution Disparities in the U.S. Cities*, 9:4 ENVIRON. SCI. TECHNOL. LETT. at 345-350 (2022), https://doi.org/10.1021/acs.estlett.1c01012.
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[26] Breyna is not yet readily available due to legal actions relating to patents. *See* Nick Paul Taylor, *AstraZeneca sues Mylan after securing fresh delivery patent on Symbicort,* FIERCE PHARMA (May 3, 2022), https://www.fiercepharma.com/pharma/astrazeneca-sues-mylan-after-securing-fresh-delivery-patent-symbicort.
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[29] *Market Characterization of the U.S. Metered Dose Inhaler Industry*, *supra* note 5, at 5.
[30] Alexander J K Wilkinson et al., *Costs of switching to low global warming potential inhalers. An economic and carbon footprint analysis of NHS prescription data in England*, 9:10 BMJ OPEN at 5 (2019), http://dx.doi.org/10.1136/bmjopen-2018-028763.
[31] *Greenhouse Gas Emissions from a Typical Passenger Vehicle,* supra note 11.
[32] Christer Janson et al., *Carbon footprint impact of the choice of inhalers for asthma and COPD*, 75 THORAX at 82 (2020), http://dx.doi.org/10.1136/thoraxjnl-2019-213744.
[33] *Delivering a 'Net Zero' National Health Service, supra* note 14, at 33—4.

ICS+LABA DPI costs $495.02 per claim filled. [34] Inhalers are among the top-spending drugs in Medicare Part D: Symbicort was 11th on the highest expenditures list for Medicare Part D in 2020.[35] Overall, Medicare spent nearly $40 billion on 40 brand-name and two generic inhalers between 2012 and 2018.[36] The Government Accountability Office (GAO) found that respiratory agents – a category that includes inhalers – account for nearly one-third of Medicare Part D expenditures and rebates.[37] With the historic passage of *the Inflation Reduction Act*, Congress established new tools to address high-cost drugs and associated out-of-pocket costs for drugs like high-cost inhalers.

While there is a large differential in cost that could affect the utilization of these inhalers, the *environmental cost* differential of the various inhalers is also substantial. For example, Symbicort DPIs generate anywhere from 3.4 to 12.5 times less CO_{2e} emissions than Albuterol Sulfate pMDIs, depending on the dosage and frequency of the DPI.[38] We do not want a cycle where treatments exacerbate the ongoing climate crisis, making more people ill and requiring more of these same treatments. The indirect costs employers and taxpayers incur for inhalers and the direct costs consumers pay at the pharmacy counter must be balanced with the environmental costs that exacerbate the very condition inhalers are used to treat.

Given the prevalence of asthma and COPD in the U.S., AAFP has a critical role to play in switching patients to environmentally safer inhalers *when medically feasible*. The Committee would like to work with you to ensure that these issues are fully examined and, where appropriate, addressed expeditiously. Thus, I ask that you respond to the following questions, in writing, by Tuesday, December 20, 2022.

a. Does your organization have an active initiative to educate providers on the environmental impact of pMDIs and safe and effective alternatives when prescribing inhalers? If so, please describe this initiative.
b. Does your organization have goals with respect to reducing the usage of pMDIs over time? If so, please describe the goals and any progress you have made toward achieving them.
c. What obstacles have your organization identified that prevent clinicians and patients from choosing less environmentally harmful inhalers? What has your organization done to mitigate these difficulties?
d. Has your organization identified any federal policy interventions that would better support efforts to reduce the climate impact of pMDIs?
e. pMDIs are one of many environmentally harmful medical treatments. Has your organization identified other medical practices and treatments common among your practitioners that have deleterious effects on the environment? Please describe any

[34] *Medicare Part D Spending by Drug,* CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 27, 2022), https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug.
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efforts to reduce the climate impact of these additional medical practices and treatments.

i. Does your organization consider environmental harm (e.g., carbon footprint) when developing evidence-based practice guidelines? If so, please describe how such harm is considered.
ii. Beyond pMDIs, what steps has AAFP taken to educate clinicians, residents, and students on making environmentally conscious decisions while practicing evidence-based medicine?

Thank you for your attention to this critical matter. If you have any question about this request, please contact Amy Hall of the Committee on Ways and Means Democratic Staff at Amy.Hall@mail.house.gov or (202) 225-3625.

Sincerely,

Richard E. Neal
Chairman
Committee on Ways and Means

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

December 6, 2022

David A. Khan, MD
President
American Academy of Allergy, Asthma, and Immunology
555 East Wells Street Suite 1100
Milwaukee, WI 53202

Re: Addressing the Environmental Impact of Pressurized Metered Dose Inhalers

Dear Dr. Khan,

The impact of the climate crisis on health is well documented, and the health care industry – the sector that seeks to address the health needs of individuals and populations – is responsible for an estimated 8.5 percent of greenhouse gas emissions in the United States (U.S.).[1, 2, 3] As the Committee on Ways and Means continues to explore issues related to the intersection of our health system and the climate crisis, it has become increasingly clear that many more straightforward undertakings remain unaddressed. For example, studies show that pressurized metered dose inhalers (pMDIs), commonly used for treatment of asthma and chronic obstructive pulmonary disease (COPD), release hydrofluorocarbon (HFC, a harmful greenhouse gas) propellants, which contribute to climate change – a factor that exacerbates the very diseases inhalers are meant to treat.[4, 5, 6] This cycle is particularly troublesome given that safer alternatives exist. Thus, I seek to better understand the work that the American Academy of Allergy, Asthma, and Immunology (AAAAI) is undertaking to limit the harmful environmental impact of pMDIs while ensuring those who need inhalers have safe and effective treatments.

HFC pMDIs have an enormous negative environmental impact.[7] In 2019, medical providers dispensed an estimated 55,344,000 pMDIs in the U.S., which contain HFC propellants – powerful greenhouse gases.[8, 9] In the U.S. alone, HFC propellants in pMDIs were projected to

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contribute *2.5 million metric tons of carbon dioxide equivalent (CO_{2e})* in 2020, which is equal to the yearly carbon emissions of 543,478 passenger vehicles.[10, 11] According to a 2022 report, inhalers alone represent three percent of *total* National Health Service emissions in England.[12] Despite the overwhelming negative environmental impact, HFC pMDIs still have a *75 percent share* in the U.S. inhaler market.[13]

HFC pMDIs exacerbate the cause of the illness they are intended to treat, disproportionately affecting communities of color. Providers commonly prescribe pMDIs to patients who experience asthma and chronic obstructive pulmonary disease (COPD).[14, 15] Many patients experiencing acute asthma or COPD exacerbations receive short-acting β_2-agonists (SABA), such as albuterol and ipratropium bromide, via pMDIs, which provide immediate relief but simultaneously release harmful HFC greenhouse gas.[16, 17] The release of these greenhouse gases worsen air pollution, which can contribute to or exacerbate chronic conditions.[18] According to the Centers for Disease Control and Prevention (CDC), in 2018, an estimated 25 million and 16.4 million Americans were diagnosed with asthma and COPD, respectively.[19, 20] The prevalence of asthma is greater among Black Americans, Puerto Ricans, and families whose income is 250 percent or below the federal poverty line.[21] Literature suggests there is an association between outdoor air pollution and asthma exacerbation – particularly problematic for communities of color that have experienced historical redlining, which has been associated with

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While there is a large differential in cost that could affect the utilization of these inhalers, the *environmental cost* differential of the various inhalers is also substantial. For example, Symbicort DPIs generate anywhere from 3.4 to 12.5 times less CO_{2e} emissions than Albuterol Sulfate pMDIs, depending on the dosage and frequency of the DPI.[38] We do not want a cycle where treatments exacerbate the ongoing climate crisis, making more people ill and requiring more of these same treatments. The indirect costs employers and taxpayers incur for inhalers and the direct costs consumers pay at the pharmacy counter must be balanced with the environmental costs that exacerbate the very condition inhalers are used to treat.

Given the prevalence of asthma and COPD in the U.S., AAAAI has a critical role to play in switching patients to environmentally safer inhalers *when medically feasible*. The Committee would like to work with you to ensure that these issues are fully examined and, where appropriate, addressed expeditiously. Thus, I ask that you respond to the following questions, in writing, by Tuesday, December 20, 2022.

a. Does your organization have an active initiative to educate providers on the environmental impact of pMDIs and safe and effective alternatives when prescribing inhalers? If so, please describe this initiative.
b. Does your organization have goals with respect to reducing the usage of pMDIs over time? If so, please describe the goals and any progress you have made toward achieving them.
c. What obstacles have your organization identified that prevent clinicians and patients from choosing less environmentally harmful inhalers? What has your organization done to mitigate these difficulties?
d. Has your organization identified any federal policy interventions that would better support efforts to reduce the climate impact of pMDIs?
e. pMDIs are one of many environmentally harmful medical treatments. Has your organization identified other medical practices and treatments common among your practitioners that have deleterious effects on the environment? Please describe any efforts to reduce the climate impact of these additional medical practices and treatments.

[35] *Id.*
[36] William B. Feldman et al., *Trends in Medicare Part D Inhaler Spending: 2012-2018,* 18:3 ANNALS OF THE AM. THORACIC SOCIETY at 548–550 (2021), https://doi.org/10.1513/AnnalsATS.202008-1082RL.
[37] *Medicare Part D: use of pharmacy benefit managers and efforts to manage drug expenditures and utilization*, U.S. GOV. ACCOUNTABILITY OFFICE (July 2019), https://www.gao.gov/assets/gao-19-498.pdf.
[38] *The environmental impact of inhalers,* supra note 26.

i. Does your organization consider environmental harm (e.g., carbon footprint) when developing evidence-based practice guidelines? If so, please describe how such harm is considered.
ii. Beyond pMDIs, what steps has AAAI taken to educate clinicians, residents, and students on making environmentally conscious decisions while practicing evidence-based medicine?

Thank you for your attention to this critical matter. If you have any question about this request, please contact Amy Hall of the Committee on Ways and Means Democratic Staff at Amy.Hall@mail.house.gov or (202) 225-3625.

Sincerely,

Richard E. Neal
Chairman
Committee on Ways and Means

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

December 6, 2022

Louis-Philippe Boulet, MD
Chair
Global Initiative for Asthma
P.O. Box 558
Fontana, WI 53125

Re: Addressing the Environmental Impact of Pressurized Metered Dose Inhalers

Dear Dr. Boulet,

The impact of the climate crisis on health is well documented, and the health care industry – the sector that seeks to address the health needs of individuals and populations – is responsible for an estimated 8.5 percent of greenhouse gas emissions in the United States (U.S.).[1, 2, 3] As the Committee on Ways and Means continues to explore issues related to the intersection of our health system and the climate crisis, it has become increasingly clear that many more straightforward undertakings remain unaddressed. For example, studies show that pressurized metered dose inhalers (pMDIs), commonly used for treatment of asthma and chronic obstructive pulmonary disease (COPD), release hydrofluorocarbon (HFC, a harmful greenhouse gas) propellants, which contribute to climate change – a factor that exacerbates the very diseases inhalers are meant to treat.[4, 5, 6] This cycle is particularly troublesome given that safer alternatives exist. Thus, I seek to better understand the work that the Global Initiative for Asthma (GINA) is undertaking to limit the harmful environmental impact of pMDIs while ensuring those who need inhalers have safe and effective treatments.

HFC pMDIs have an enormous negative environmental impact.[7] In 2019, medical providers dispensed an estimated 55,344,000 pMDIs in the U.S., which contain HFC propellants – powerful greenhouse gases.[8, 9] In the U.S. alone, HFC propellants in pMDIs were projected to

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[1] A. Crimmins et al., *The Impacts of Climate Change on Human Health in the United States: A Scientific Assessment*, U.S. GLOBAL CHANGE RESEARCH PROGRAM (2016), https://health2016.globalchange.gov/high/ClimateHealth2016_FullReport.pdf.
[2] Matthew J. Eckelman & Jodi Sherman, *Environmental Impacts of the U.S. Health Care System and Effects on Public Health*, 11:6 PLOS ONE (2016), https://doi.org/10.1371/journal.pone.0157014.
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[4] *Id.*
[5] *Market Characterization of the U.S. Metered Dose Inhaler Industry*, ICF (Sept. 2021), https://www.epa.gov/sites/default/files/2021-03/documents/epa-hq-oar-2021-0044-0002_attachment_1-mdis.pdf.
[6] *Global Strategy for Asthma Management and Prevention (2022 update),* GLOBAL INITIATIVE FOR ASTHMA (2022), https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf.
[7] Mathew J. Eckelman et al., *supra* note 3.
[8] *Market Characterization of the U.S. Metered Dose Inhaler Industry*, *supra* note 5.
[9] *Global Strategy for Asthma Management and Prevention (2022 update), supra* note 6.

contribute *2.5 million metric tons of carbon dioxide equivalent (CO_{2e})* in 2020, which is equal to the yearly carbon emissions of 543,478 passenger vehicles.[10, 11] According to a 2022 report, inhalers alone represent three percent of *total* National Health Service emissions in England.[12] Despite the overwhelming negative environmental impact, HFC pMDIs still have a *75 percent share* in the U.S. inhaler market.[13]

HFC pMDIs exacerbate the cause of the illness they are intended to treat, disproportionately affecting communities of color. Providers commonly prescribe pMDIs to patients who experience asthma and chronic obstructive pulmonary disease (COPD).[14, 15] Many patients experiencing acute asthma or COPD exacerbations receive short-acting β_2-agonists (SABA), such as albuterol and ipratropium bromide, via pMDIs, which provide immediate relief but simultaneously release harmful HFC greenhouse gas.[16, 17] The release of these greenhouse gases worsen air pollution, which can contribute to or exacerbate chronic conditions.[18] According to the Centers for Disease Control and Prevention (CDC), in 2018, an estimated 25 million and 16.4 million Americans were diagnosed with asthma and COPD, respectively.[19, 20] The prevalence of asthma is greater among Black Americans, Puerto Ricans, and families whose income is 250 percent or below the federal poverty line.[21] Literature suggests there is an association between outdoor air pollution and asthma exacerbation – particularly problematic for communities of color that have experienced historical redlining, which has been associated with

[10] According to the Environmental Protection Agency (EPA), the unit *carbon dioxide equivalent* is used to measure greenhouse gas (GHG) emissions and account for the global warming potential (GWP) of different gases. In other words, *carbon dioxide equivalent* is equal to GHG emissions multiplied by the gas's GWP. *Overview of Greenhouse Gases,* U.S. ENVIRONMENTAL PROTECTION AGENCY (May 16, 2022), https://www.epa.gov/ghgemissions/overview-greenhouse-gases.

[11] The EPA estimates that a typical passenger vehicle emits about 4.6 metric tons of carbon dioxide per year (2,500,000 metric tons of CO_2 divided by 4.6 metric tons of CO_2 = 543,478.261 vehicles). *Market Characterization of the U.S. Metered Dose Inhaler Industry*, *supra* note 5, at 9; *Greenhouse Gas Emissions from a Typical Passenger Vehicle,* U.S. ENVIRONMENTAL PROTECTION AGENCY (June 30, 2022), https://www.epa.gov/greenvehicles/greenhouse-gas-emissions-typical-passenger-vehicle.

[12] *Delivering a 'Net Zero' National Health Service*, NHS ENGLAND at 32 (July 2022), https://www.england.nhs.uk/greenernhs/wp-content/uploads/sites/51/2022/07/B1728-delivering-a-net-zero-nhs-july-2022.pdf; Joachim Starup-Hansen et al*., Climate change in healthcare: Exploring the potential role of inhaler prescribing*, 8:6 PHARMACOL RES PERSPECT. at 1 (2020), https://doi.org/10.1002/prp2.675.

[13] *Id.*

[14] *Global Strategy for Asthma Management and Prevention (2022 update), supra* note 6.

[15] *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2022 report),* GLOBAL INITIATIVE FOR CHRONIC OBSTRUCTIVE LUNG DISEASE (2021), https://goldcopd.org/2022-gold-reports-2/.

[16] *Short-Acting Beta-Agonists (SABAs),* AM. ACADEMY OF ALLERGY ASTHMA & IMMUNOLOGY (April 2020), https://www.aaaai.org/tools-for-the-public/drug-guide/short-acting-beta-agonists-(sabas).

[17] *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2022 report), supra* note 15.

[18] Center for Science Education, *Air Quality and Climate Change*, UCAR, https://scied.ucar.edu/learning-zone/air-quality/air-quality-and-climate-change (last visited Oct. 12, 2022).

[19] *2018 Archived National Asthma Data,* CTRS. FOR DISEASE CONTROL AND PREVENTION (Mar. 30, 2021), https://www.cdc.gov/asthma/archivedata/2018/2018_archived_national_data.html.

[20] *COPD Prevalence,* AM. LUNG ASSOC., https://www.lung.org/research/trends-in-lung-disease/copd-trends-brief/copd-prevalence (last visited Jul. 14, 2021).

[21] *2018 National Health Interview Survey (NHIS) Data*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Dec. 17, 2019), https://www.cdc.gov/asthma/nhis/2018/table4-1.htm.

disproportionate exposure to higher amounts of air pollution. [22, 23] Air pollution also exacerbates COPD, increases associated health care costs, and, ultimately, increases mortality rates.[24]

Environmentally safer alternatives to pMDIs already exist through dry powder inhalers (DPIs) and soft mist inhalers (SMIs) for most patients over the age of five.[25] These formulations can be seen in medications, such as Symbicort (and the approved generic Breyna) and Spiriva Respimat, respectively, both of which are recommended for the treatment of asthma and COPD in adult patients. [26, 27] Across different asthma medications, these alternative delivery systems emit up to *25 times less* CO_{2e} than pMDIs.[28] Though these safer alternatives exist, 88 percent of U.S. inhaler prescriptions in 2020 were for pMDIs.[29] Estimates in England have projected that for every 10 percent of pMDIs that are switched to DPIs, there may be a decrease of 58,000 metric tons of CO_{2e} in England's carbon emissions every year, which is equal to removing 12,600 passenger vehicles from the roads.[30, 31] Prescribing patterns in Sweden show that in many instances, DPIs can replace pMDIs, with DPIs representing nearly 90 percent of inhaler prescriptions in that country.[32] With Sweden as a model, England's National Health Service has current long-term plans to reduce its total emissions by transitioning to DPIs as clinically indicated.[33]

All parts of the health sector must work together to address this problem. In addition to provider prescribing patterns, payors will have a role to play in these efforts, given that environmentally friendly alternatives to pMDIs are usually more expensive and, as a result, out-of-reach financially for some patients. For example, in the Medicare program, the average cost per claim filled for Albuterol Sulfate, a SABA pMDI, is $50.92, while Symbicort, an ICS+LABA DPI costs $495.02 per claim filled. [34] Inhalers are among the top-spending drugs in Medicare Part D: Symbicort was 11th on the highest expenditures list for Medicare Part D in

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[23] Haley M. Lane et al., *Historical Redlining Associated with Present-Day Air Pollution Disparities in the U.S. Cities*, 9:4 ENVIRON. SCI. TECHNOL. LETT. at 345-350 (2022), https://doi.org/10.1021/acs.estlett.1c01012.
[24] Nadia N. Hansel et al., *The Effects of Air Pollution and Temperature on COPD*, 13:3 J. OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE at 372-379 (2016), https://doi.org/10.3109/15412555.2015.1089846.
[25] *The environmental impact of inhalers,* NORTH & EAST DEVON FORMULARY AND REFERRAL (July 3, 2022), https://northeast.devonformularyguidance.nhs.uk/formulary/chapters/3.-respiratory/the-environmental-impact-of-inhalers.
[26] Breyna is not yet readily available due to legal actions relating to patents. *See* Nick Paul Taylor, *AstraZeneca sues Mylan after securing fresh delivery patent on Symbicort,* FIERCE PHARMA (May 3, 2022), https://www.fiercepharma.com/pharma/astrazeneca-sues-mylan-after-securing-fresh-delivery-patent-symbicort.
[27] *Global Strategy for Asthma Management and Prevention (2022 update), supra* note 6.
[28] *The environmental impact of inhalers,* supra note 26.
[29] *Market Characterization of the U.S. Metered Dose Inhaler Industry*, *supra* note 5, at 5.
[30] Alexander J K Wilkinson et al., *Costs of switching to low global warming potential inhalers. An economic and carbon footprint analysis of NHS prescription data in England*, 9:10 BMJ OPEN at 5 (2019), http://dx.doi.org/10.1136/bmjopen-2018-028763.
[31] *Greenhouse Gas Emissions from a Typical Passenger Vehicle,* supra note 11.
[32] Christer Janson et al., *Carbon footprint impact of the choice of inhalers for asthma and COPD*, 75 THORAX at 82 (2020), http://dx.doi.org/10.1136/thoraxjnl-2019-213744.
[33] *Delivering a 'Net Zero' National Health Service, supra* note 14, at 33—4.
[34] *Medicare Part D Spending by Drug,* CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 27, 2022), https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug.

2020.[35] Overall, Medicare spent nearly $40 billion on 40 brand-name and two generic inhalers between 2012 and 2018.[36] The Government Accountability Office (GAO) found that respiratory agents – a category that includes inhalers – account for nearly one-third of Medicare Part D expenditures and rebates.[37] With the historic passage of *the Inflation Reduction Act*, Congress established new tools to address high-cost drugs and associated out-of-pocket costs for drugs like high-cost inhalers.

While there is a large differential in cost that could affect the utilization of these inhalers, the *environmental cost* differential of the various inhalers is also substantial. For example, Symbicort DPIs generate anywhere from 3.4 to 12.5 times less CO_{2e} emissions than Albuterol Sulfate pMDIs, depending on the dosage and frequency of the DPI.[38] We do not want a cycle where treatments exacerbate the ongoing climate crisis, making more people ill and requiring more of these same treatments. The indirect costs employers and taxpayers incur for inhalers and the direct costs consumers pay at the pharmacy counter must be balanced with the environmental costs that exacerbate the very condition inhalers are used to treat.

Given the prevalence of asthma and COPD in the U.S., GINA has a critical role to play in switching patients to environmentally safer inhalers *when medically feasible*. The Committee would like to work with you to ensure that these issues are fully examined and, where appropriate, addressed expeditiously. Thus, I ask that you respond to the following questions, in writing, by Tuesday, December 20, 2022.

a. Does your organization have an active initiative to educate practitioners on the environmental impact of pMDIs and safe and effective alternatives? If so, please describe that initiative and any metrics (as well as progress on such metrics) associated with it.
b. Does your organization have goals with respect to reducing the use of pMDIs over time? If so, please describe the goals and any progress you have made toward achieving them.
c. Has your organization incorporated considerations of environmental harm (e.g., carbon footprint) when developing evidence-based practice guidelines? If so, please describe how such harm is considered.
    i. What obstacles has your organization identified that prevent the recommendation of environmentally preferred inhalers?
    ii. If your guidelines recommend environmentally preferred inhalers, what obstacles have your organization identified that prevent clinicians and patients from choosing these options?
    iii. What has your organization done to mitigate these difficulties?
d. pMDIs are one of many environmentally harmful medical treatments. Has your organization identified other medical practices and treatments common among

[35] *Id.*
[36] William B. Feldman et al., *Trends in Medicare Part D Inhaler Spending: 2012-2018,* 18:3 ANNALS OF THE AM. THORACIC SOCIETY at 548–550 (2021), https://doi.org/10.1513/AnnalsATS.202008-1082RL.
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practitioners that have deleterious effects on the environment? Please describe any efforts to reduce the climate impact of these additional medical practices and treatments.

Thank you for your attention to this critical matter. If you have any question about this request, please contact Amy Hall of the Committee on Ways and Means Democratic Staff at Amy.Hall@mail.house.gov or (202) 225-3625.

Sincerely,

Richard E. Neal
Chairman
Committee on Ways and Means

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

December 6, 2022

Alvar G. Agusti, MD
Chair
Global Initiative for Chronic Obstructive Lung Disease

Re: Addressing the Environmental Impact of Pressurized Metered Dose Inhalers

Dear Dr. Agusti,

The impact of the climate crisis on health is well documented, and the health care industry – the sector that seeks to address the health needs of individuals and populations – is responsible for an estimated 8.5 percent of greenhouse gas emissions in the United States (U.S.).[1, 2, 3] As the Committee on Ways and Means continues to explore issues related to the intersection of our health system and the climate crisis, it has become increasingly clear that many more straightforward undertakings remain unaddressed. For example, studies show that pressurized metered dose inhalers (pMDIs), commonly used for treatment of asthma and chronic obstructive pulmonary disease (COPD), release hydrofluorocarbon (HFC, a harmful greenhouse gas) propellants, which contribute to climate change – a factor that exacerbates the very diseases inhalers are meant to treat.[4, 5, 6] This cycle is particularly troublesome given that safer alternatives exist. Thus, I seek to better understand the work that the Global Initiative for Chronic Obstructive Lung Disease (GOLD) is undertaking to limit the harmful environmental impact of pMDIs while ensuring those who need inhalers have safe and effective treatments.

HFC pMDIs have an enormous negative environmental impact.[7] In 2019, medical providers dispensed an estimated 55,344,000 pMDIs in the U.S., which contain HFC propellants – powerful greenhouse gases.[8, 9] In the U.S. alone, HFC propellants in pMDIs were projected to contribute *2.5 million metric tons of carbon dioxide equivalent (CO_{2e})* in 2020, which is equal to

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[4] *Id.*
[5] *Market Characterization of the U.S. Metered Dose Inhaler Industry*, ICF (Sept. 2021), https://www.epa.gov/sites/default/files/2021-03/documents/epa-hq-oar-2021-0044-0002_attachment_1-mdis.pdf.
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the yearly carbon emissions of 543,478 passenger vehicles.[10, 11] According to a 2022 report, inhalers alone represent three percent of *total* National Health Service emissions in England.[12] Despite the overwhelming negative environmental impact, HFC pMDIs still have a *75 percent share* in the U.S. inhaler market.[13]

HFC pMDIs exacerbate the cause of the illness they are intended to treat, disproportionately affecting communities of color. Providers commonly prescribe pMDIs to patients who experience asthma and chronic obstructive pulmonary disease (COPD).[14, 15] Many patients experiencing acute asthma or COPD exacerbations receive short-acting β_2-agonists (SABA), such as albuterol and ipratropium bromide, via pMDIs, which provide immediate relief but simultaneously release harmful HFC greenhouse gas.[16, 17] The release of these greenhouse gases worsen air pollution, which can contribute to or exacerbate chronic conditions.[18] According to the Centers for Disease Control and Prevention (CDC), in 2018, an estimated 25 million and 16.4 million Americans were diagnosed with asthma and COPD, respectively.[19, 20] The prevalence of asthma is greater among Black Americans, Puerto Ricans, and families whose income is 250 percent or below the federal poverty line.[21] Literature suggests there is an association between outdoor air pollution and asthma exacerbation – particularly problematic for communities of color that have experienced historical redlining, which has been associated with

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[16] *Short-Acting Beta-Agonists (SABAs),* AM. ACADEMY OF ALLERGY ASTHMA & IMMUNOLOGY (April 2020), https://www.aaaai.org/tools-for-the-public/drug-guide/short-acting-beta-agonists-(sabas).

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[32] Christer Janson et al., *Carbon footprint impact of the choice of inhalers for asthma and COPD*, 75 THORAX at 82 (2020), http://dx.doi.org/10.1136/thoraxjnl-2019-213744.
[33] *Delivering a 'Net Zero' National Health Service, supra* note 14, at 33—4.
[34] *Medicare Part D Spending by Drug,* CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 27, 2022), https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug.

2020.[35] Overall, Medicare spent nearly $40 billion on 40 brand-name and two generic inhalers between 2012 and 2018.[36] The Government Accountability Office (GAO) found that respiratory agents – a category that includes inhalers – account for nearly one-third of Medicare Part D expenditures and rebates.[37] With the historic passage of *the Inflation Reduction Act*, Congress established new tools to address high-cost drugs and associated out-of-pocket costs for drugs like high-cost inhalers.

While there is a large differential in cost that could affect the utilization of these inhalers, the *environmental cost* differential of the various inhalers is also substantial. For example, Symbicort DPIs generate anywhere from 3.4 to 12.5 times less CO_{2e} emissions than Albuterol Sulfate pMDIs, depending on the dosage and frequency of the DPI.[38] We do not want a cycle where treatments exacerbate the ongoing climate crisis, making more people ill and requiring more of these same treatments. The indirect costs employers and taxpayers incur for inhalers and the direct costs consumers pay at the pharmacy counter must be balanced with the environmental costs that exacerbate the very condition inhalers are used to treat.

Given the prevalence of asthma and COPD in the U.S., GOLD has a critical role to play in switching patients to environmentally safer inhalers *when medically feasible*. The Committee would like to work with you to ensure that these issues are fully examined and, where appropriate, addressed expeditiously. Thus, I ask that you respond to the following questions, in writing, by Tuesday, December 20, 2022.

a. Does your organization have an active initiative to educate practitioners on the environmental impact of pMDIs and safe and effective alternatives? If so, please describe that initiative and any metrics (as well as progress on such metrics) associated with it.
b. Does your organization have goals with respect to reducing the use of pMDIs over time? If so, please describe the goals and any progress you have made toward achieving them.
c. Has your organization incorporated considerations of environmental harm (e.g., carbon footprint) when developing evidence-based practice guidelines? If so, please describe how such harm is considered.
    i. What obstacles has your organization identified that prevent the recommendation of environmentally preferred inhalers?
    ii. If your guidelines recommend environmentally preferred inhalers, what obstacles have your organization identified that prevent clinicians and patients from choosing these options?
    iii. What has your organization done to mitigate these difficulties?
d. pMDIs are one of many environmentally harmful medical treatments. Has your organization identified other medical practices and treatments common among

[35] *Id.*
[36] William B. Feldman et al., *Trends in Medicare Part D Inhaler Spending: 2012-2018,* 18:3 ANNALS OF THE AM. THORACIC SOCIETY at 548–550 (2021), https://doi.org/10.1513/AnnalsATS.202008-1082RL.
[37] *Medicare Part D: use of pharmacy benefit managers and efforts to manage drug expenditures and utilization*, U.S. GOV. ACCOUNTABILITY OFFICE (July 2019), https://www.gao.gov/assets/gao-19-498.pdf.
[38] *The environmental impact of inhalers,* supra note 26.

practitioners that have deleterious effects on the environment? Please describe any efforts to reduce the climate impact of these additional medical practices and treatments.

Thank you for your attention to this critical matter. If you have any question about this request, please contact Amy Hall of the Committee on Ways and Means Democratic Staff at Amy.Hall@mail.house.gov or (202) 225-3625.

Sincerely,

Richard E. Neal
Chairman
Committee on Ways and Means

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

December 6, 2022

Matt Eyles
President and CEO
America's Health Insurance Plans
601 Pennsylvania Avenue, NW
South building, Suite 500
Washington, DC 20004

Re: Addressing the Environmental Impact of Pressurized Metered Dose Inhalers

Dear Mr. Eyles,

The impact of the climate crisis on health is well documented, and the health care industry – the sector that seeks to address the health needs of individuals and populations – is responsible for an estimated 8.5 percent of greenhouse gas emissions in the United States (U.S.).[1, 2, 3] As the Committee on Ways and Means continues to explore issues related to the intersection of our health system and the climate crisis, it has become increasingly clear that many more straightforward undertakings remain unaddressed. For example, studies show that pressurized metered dose inhalers (pMDIs), commonly used for treatment of asthma and chronic obstructive pulmonary disease (COPD), release hydrofluorocarbon (HFC, a harmful greenhouse gas) propellants, which contribute to climate change – a factor that exacerbates the very diseases inhalers are meant to treat.[4, 5, 6] This cycle is particularly troublesome given that safer alternatives exist. Thus, I seek to better understand the work America's Health Insurance Plans (AHIP) is undertaking to limit the harmful environmental impact of pMDIs while ensuring those who need inhalers have safe and effective treatments.

HFC pMDIs have an enormous negative environmental impact.[7] In 2019, medical providers dispensed an estimated 55,344,000 pMDIs in the U.S., which contain HFC propellants

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[1] A. Crimmins et al., *The Impacts of Climate Change on Human Health in the United States: A Scientific Assessment*, U.S. GLOBAL CHANGE RESEARCH PROGRAM (2016), https://health2016.globalchange.gov/high/ClimateHealth2016_FullReport.pdf.
[2] Matthew J. Eckelman & Jodi Sherman, *Environmental Impacts of the U.S. Health Care System and Effects on Public Health*, 11:6 PLOS ONE (2016), https://doi.org/10.1371/journal.pone.0157014.
[3] Mathew J. Eckelman et al., *Health Care Pollution and Public Health Damage in The United States: An Update*, 39:12 HEALTH AFFAIRS (2020), https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01247.
[4] *Id.*
[5] *Market Characterization of the U.S. Metered Dose Inhaler Industry*, ICF (Sept. 2021), https://www.epa.gov/sites/default/files/2021-03/documents/epa-hq-oar-2021-0044-0002_attachment_1-mdis.pdf.
[6] *Global Strategy for Asthma Management and Prevention (2022 update),* GLOBAL INITIATIVE FOR ASTHMA (2022), https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf.
[7] Mathew J. Eckelman et al., *supra* note 3.

– powerful greenhouse gases. [8, 9] In the U.S. alone, HFC propellants in pMDIs were projected to contribute *2.5 million metric tons of carbon dioxide equivalent (CO_{2e})* in 2020, which is equal to the yearly carbon emissions of 543,478 passenger vehicles.[10, 11] According to a 2022 report, inhalers alone represent three percent of *total* National Health Service emissions in England.[12] Despite the overwhelming negative environmental impact, HFC pMDIs still have a *75 percent share* in the U.S. inhaler market.[13]

HFC pMDIs exacerbate the cause of the illness they are intended to treat, disproportionately affecting communities of color. Providers commonly prescribe pMDIs to patients who experience asthma and chronic obstructive pulmonary disease (COPD).[14, 15] Many patients experiencing acute asthma or COPD exacerbations receive short-acting β_2-agonists (SABA), such as albuterol and ipratropium bromide, via pMDIs, which provide immediate relief but simultaneously release harmful HFC greenhouse gas.[16, 17] The release of these greenhouse gases worsen air pollution, which can contribute to or exacerbate chronic conditions.[18] According to the Centers for Disease Control and Prevention (CDC), in 2018, an estimated 25 million and 16.4 million Americans were diagnosed with asthma and COPD, respectively.[19, 20] The prevalence of asthma is greater among Black Americans, Puerto Ricans, and families whose income is 250 percent or below the federal poverty line.[21] Literature suggests there is an

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[8] *Market Characterization of the U.S. Metered Dose Inhaler Industry*, *supra* note 5.
[9] *Global Strategy for Asthma Management and Prevention (2022 update), supra* note 6.
[10] According to the Environmental Protection Agency (EPA), the unit *carbon dioxide equivalent* is used to measure greenhouse gas (GHG) emissions and account for the global warming potential (GWP) of different gases. In other words, *carbon dioxide equivalent* is equal to GHG emissions multiplied by the gas's GWP. *Overview of Greenhouse Gases,* U.S. ENVIRONMENTAL PROTECTION AGENCY (May 16, 2022), https://www.epa.gov/ghgemissions/overview-greenhouse-gases.
[11] The EPA estimates that a typical passenger vehicle emits about 4.6 metric tons of carbon dioxide per year (2,500,000 metric tons of CO_2 divided by 4.6 metric tons of CO_2 = 543,478.261 vehicles). *Market Characterization of the U.S. Metered Dose Inhaler Industry*, *supra* note 5, at 9; *Greenhouse Gas Emissions from a Typical Passenger Vehicle,* U.S. ENVIRONMENTAL PROTECTION AGENCY (June 30, 2022), https://www.epa.gov/greenvehicles/greenhouse-gas-emissions-typical-passenger-vehicle.
[12] *Delivering a 'Net Zero' National Health Service*, NHS ENGLAND at 32 (July 2022), https://www.england.nhs.uk/greenernhs/wp-content/uploads/sites/51/2022/07/B1728-delivering-a-net-zero-nhs-july-2022.pdf; Joachim Starup-Hansen et al*., Climate change in healthcare: Exploring the potential role of inhaler prescribing*, 8:6 PHARMACOL RES PERSPECT. at 1 (2020), https://doi.org/10.1002/prp2.675.
[13] *Id.*
[14] *Global Strategy for Asthma Management and Prevention (2022 update), supra* note 6.
[15] *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2022 report),* GLOBAL INITIATIVE FOR CHRONIC OBSTRUCTIVE LUNG DISEASE (2021), https://goldcopd.org/2022-gold-reports-2/.
[16] *Short-Acting Beta-Agonists (SABAs),* AM. ACADEMY OF ALLERGY ASTHMA & IMMUNOLOGY (April 2020), https://www.aaaai.org/tools-for-the-public/drug-guide/short-acting-beta-agonists-(sabas).
[17] *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2022 report), supra* note 15.
[18] Center for Science Education, *Air Quality and Climate Change*, UCAR, https://scied.ucar.edu/learning-zone/air-quality/air-quality-and-climate-change (last visited Oct. 12, 2022).
[19] *2018 Archived National Asthma Data,* CTRS. FOR DISEASE CONTROL AND PREVENTION (Mar. 30, 2021), https://www.cdc.gov/asthma/archivedata/2018/2018_archived_national_data.html.
[20] *COPD Prevalence,* AM. LUNG ASSOC., https://www.lung.org/research/trends-in-lung-disease/copd-trends-brief/copd-prevalence (last visited Jul. 14, 2021).
[21] *2018 National Health Interview Survey (NHIS) Data*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Dec. 17, 2019), https://www.cdc.gov/asthma/nhis/2018/table4-1.htm.

association between outdoor air pollution and asthma exacerbation – particularly problematic for communities of color that have experienced historical redlining, which has been associated with disproportionate exposure to higher amounts of air pollution. [22, 23] Air pollution also exacerbates COPD, increases associated health care costs, and, ultimately, increases mortality rates.[24]

Environmentally safer alternatives to pMDIs already exist through dry powder inhalers (DPIs) and soft mist inhalers (SMIs) for most patients over the age of five.[25] These formulations can be seen in medications, such as Symbicort (and the approved generic Breyna) and Spiriva Respimat, respectively, both of which are recommended for the treatment of asthma and COPD in adult patients. [26, 27] Across different asthma medications, these alternative delivery systems emit up to *25 times less* CO_{2e} than pMDIs.[28] Though these safer alternatives exist, 88 percent of U.S. inhaler prescriptions in 2020 were for pMDIs.[29] Estimates in England have projected that for every 10 percent of pMDIs that are switched to DPIs, there may be a decrease of 58,000 metric tons of CO_{2e} in England's carbon emissions every year, which is equal to removing 12,600 passenger vehicles from the roads.[30, 31] Prescribing patterns in Sweden show that in many instances, DPIs can replace pMDIs, with DPIs representing nearly 90 percent of inhaler prescriptions in that country.[32] With Sweden as a model, England's National Health Service has current long-term plans to reduce its total emissions by transitioning to DPIs as clinically indicated.[33]

All parts of the health sector must work together to address this problem. In addition to provider prescribing patterns, payors will have a role to play in these efforts, given that environmentally friendly alternatives to pMDIs are usually more expensive and, as a result, out-of-reach financially for some patients. For example, in the Medicare program, the average cost per claim filled for Albuterol Sulfate, a SABA pMDI, is $50.92, while Symbicort, an

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[22] Pablo Orellano et al., *Effect of outdoor air pollution on asthma exacerbations in children and adults: Systematic review and multilevel meta-analysis*, PLOS ONE at 1-15 (2017), https://doi.org/10.1371/journal.pone.0174050.
[23] Haley M. Lane et al., *Historical Redlining Associated with Present-Day Air Pollution Disparities in the U.S. Cities*, 9:4 ENVIRON. SCI. TECHNOL. LETT. at 345-350 (2022), https://doi.org/10.1021/acs.estlett.1c01012.
[24] Nadia N. Hansel et al., *The Effects of Air Pollution and Temperature on COPD*, 13:3 J. OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE at 372-379 (2016), https://doi.org/10.3109/15412555.2015.1089846.
[25] *The environmental impact of inhalers,* NORTH & EAST DEVON FORMULARY AND REFERRAL (July 3, 2022), https://northeast.devonformularyguidance.nhs.uk/formulary/chapters/3.-respiratory/the-environmental-impact-of-inhalers.
[26] Breyna is not yet readily available due to legal actions relating to patents. *See* Nick Paul Taylor, *AstraZeneca sues Mylan after securing fresh delivery patent on Symbicort,* FIERCE PHARMA (May 3, 2022), https://www.fiercepharma.com/pharma/astrazeneca-sues-mylan-after-securing-fresh-delivery-patent-symbicort.
[27] *Global Strategy for Asthma Management and Prevention (2022 update), supra* note 6.
[28] *The environmental impact of inhalers,* supra note 26.
[29] *Market Characterization of the U.S. Metered Dose Inhaler Industry*, *supra* note 5, at 5.
[30] Alexander J K Wilkinson et al., *Costs of switching to low global warming potential inhalers. An economic and carbon footprint analysis of NHS prescription data in England*, 9:10 BMJ OPEN at 5 (2019), http://dx.doi.org/10.1136/bmjopen-2018-028763.
[31] *Greenhouse Gas Emissions from a Typical Passenger Vehicle,* supra note 11.
[32] Christer Janson et al., *Carbon footprint impact of the choice of inhalers for asthma and COPD*, 75 THORAX at 82 (2020), http://dx.doi.org/10.1136/thoraxjnl-2019-213744.
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ICS+LABA DPI costs $495.02 per claim filled. [34] Inhalers are among the top-spending drugs in Medicare Part D: Symbicort was 11th on the highest expenditures list for Medicare Part D in 2020.[35] Overall, Medicare spent nearly $40 billion on 40 brand-name and two generic inhalers between 2012 and 2018.[36] The Government Accountability Office (GAO) found that respiratory agents – a category that includes inhalers – account for nearly one-third of Medicare Part D expenditures and rebates.[37] With the historic passage of *the Inflation Reduction Act*, Congress established new tools to address high-cost drugs and associated out-of-pocket costs for drugs like high-cost inhalers.

While there is a large differential in cost that could affect the utilization of these inhalers, the *environmental cost* differential of the various inhalers is also substantial. For example, Symbicort DPIs generate anywhere from 3.4 to 12.5 times less CO_{2e} emissions than Albuterol Sulfate pMDIs, depending on the dosage and frequency of the DPI.[38] We do not want a cycle where treatments exacerbate the ongoing climate crisis, making more people ill and requiring more of these same treatments. The indirect costs employers and taxpayers incur for inhalers and the direct costs consumers pay at the pharmacy counter must be balanced with the environmental costs that exacerbate the very condition inhalers are used to treat.

Given the prevalence of asthma and COPD in the U.S., AHIP has a critical role to play in switching patients to environmentally safer inhalers *when medically feasible*. The Committee would like to work with you to ensure that these issues are fully examined and, where appropriate, addressed expeditiously. Thus, I ask that you respond to the following questions, in writing, by Tuesday, December 20, 2022.

a. Please provide the Committee with an overview of AHIP's efforts to reduce the environmental impact of pMDIs.
    i. What, if any, do the roles of inhaler price and rebates affect your member's consideration of inhalers when establishing formularies?
    ii. How does your consideration of formulary placement and out-of-pocket costs affect patient uptake of pMDIs compared to other safe and effective alternatives?
b. When developing drug formularies, to what extent do your members contemplate environmental factors?
    i. If these considerations are not being made, please explain why.
c. Have your member organizations completed any cost analyses on the impact of additional health care costs including hospital and physician visits related to increased asthma and/or COPD rates in their patient populations compared to switching more patients to environmentally preferred inhalers? Please describe any findings.

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[34] *Medicare Part D Spending by Drug,* CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 27, 2022), https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug.
[35] *Id.*
[36] William B. Feldman et al., *Trends in Medicare Part D Inhaler Spending: 2012-2018,* 18:3 ANNALS OF THE AM. THORACIC SOCIETY at 548–550 (2021), https://doi.org/10.1513/AnnalsATS.202008-1082RL.
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[38] *The environmental impact of inhalers,* supra note 26.

d. Please describe any barriers your members have encountered in placing environmentally preferred inhalers as preferred options for patients on formularies.

Thank you for your attention to this critical matter. If you have any question about this request, please contact Amy Hall of the Committee on Ways and Means Democratic Staff at Amy.Hall@mail.house.gov or (202) 225-3625.

Sincerely,

Richard E. Neal
Chairman
Committee on Ways and Means

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

December 6, 2022

JC Scott
President & CEO
Pharmaceutical Care Management Association
325 7th Street, NW
Washington, DC 20004

Re: Addressing the Environmental Impact of Pressurized Metered Dose Inhalers

Dear Mr. Scott,

The impact of the climate crisis on health is well documented, and the health care industry – the sector that seeks to address the health needs of individuals and populations – is responsible for an estimated 8.5 percent of greenhouse gas emissions in the United States (U.S.).[1, 2, 3] As the Committee on Ways and Means continues to explore issues related to the intersection of our health system and the climate crisis, it has become increasingly clear that many more straightforward undertakings remain unaddressed. For example, studies show that pressurized metered dose inhalers (pMDIs), commonly used for treatment of asthma and chronic obstructive pulmonary disease (COPD), release hydrofluorocarbon (HFC, a harmful greenhouse gas) propellants, which contribute to climate change – a factor that exacerbates the very diseases inhalers are meant to treat.[4, 5, 6] This cycle is particularly troublesome given that safer alternatives exist. Thus, I seek to better understand the work that the Pharmaceutical Care Management Association (PCMA) is undertaking to limit the harmful environmental impact of pMDIs while ensuring those who need inhalers have safe and effective treatments.

HFC pMDIs have an enormous negative environmental impact.[7] In 2019, medical providers dispensed an estimated 55,344,000 pMDIs in the U.S., which contain HFC propellants – powerful greenhouse gases.[8, 9] In the U.S. alone, HFC propellants in pMDIs were projected to

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[4] *Id.*
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[6] *Global Strategy for Asthma Management and Prevention (2022 update),* GLOBAL INITIATIVE FOR ASTHMA (2022), https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf.
[7] Mathew J. Eckelman et al., *supra* note 3.
[8] *Market Characterization of the U.S. Metered Dose Inhaler Industry*, *supra* note 5.
[9] *Global Strategy for Asthma Management and Prevention (2022 update), supra* note 6.

contribute *2.5 million metric tons of carbon dioxide equivalent (CO_{2e})* in 2020, which is equal to the yearly carbon emissions of 543,478 passenger vehicles.[10, 11] According to a 2022 report, inhalers alone represent three percent of *total* National Health Service emissions in England.[12] Despite the overwhelming negative environmental impact, HFC pMDIs still have a *75 percent share* in the U.S. inhaler market.[13]

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[13] *Id.*

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[15] *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2022 report),* GLOBAL INITIATIVE FOR CHRONIC OBSTRUCTIVE LUNG DISEASE (2021), https://goldcopd.org/2022-gold-reports-2/.

[16] *Short-Acting Beta-Agonists (SABAs),* AM. ACADEMY OF ALLERGY ASTHMA & IMMUNOLOGY (April 2020), https://www.aaaai.org/tools-for-the-public/drug-guide/short-acting-beta-agonists-(sabas).

[17] *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2022 report), supra* note 15.

[18] Center for Science Education, *Air Quality and Climate Change*, UCAR, https://scied.ucar.edu/learning-zone/air-quality/air-quality-and-climate-change (last visited Oct. 12, 2022).

[19] *2018 Archived National Asthma Data,* CTRS. FOR DISEASE CONTROL AND PREVENTION (Mar. 30, 2021), https://www.cdc.gov/asthma/archivedata/2018/2018_archived_national_data.html.

[20] *COPD Prevalence,* AM. LUNG ASSOC., https://www.lung.org/research/trends-in-lung-disease/copd-trends-brief/copd-prevalence (last visited Jul. 14, 2021).

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[28] *The environmental impact of inhalers,* supra note 26.
[29] *Market Characterization of the U.S. Metered Dose Inhaler Industry*, *supra* note 5, at 5.
[30] Alexander J K Wilkinson et al., *Costs of switching to low global warming potential inhalers. An economic and carbon footprint analysis of NHS prescription data in England*, 9:10 BMJ OPEN at 5 (2019), http://dx.doi.org/10.1136/bmjopen-2018-028763.
[31] *Greenhouse Gas Emissions from a Typical Passenger Vehicle,* supra note 11.
[32] Christer Janson et al., *Carbon footprint impact of the choice of inhalers for asthma and COPD*, 75 THORAX at 82 (2020), http://dx.doi.org/10.1136/thoraxjnl-2019-213744.
[33] *Delivering a 'Net Zero' National Health Service, supra* note 14, at 33—4.
[34] *Medicare Part D Spending by Drug,* CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 27, 2022), https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug.

2020.[35] Overall, Medicare spent nearly $40 billion on 40 brand-name and two generic inhalers between 2012 and 2018.[36] The Government Accountability Office (GAO) found that respiratory agents – a category that includes inhalers – account for nearly one-third of Medicare Part D expenditures and rebates.[37] With the historic passage of *the Inflation Reduction Act*, Congress established new tools to address high-cost drugs and associated out-of-pocket costs for drugs like high-cost inhalers.

While there is a large differential in cost that could affect the utilization of these inhalers, the *environmental cost* differential of the various inhalers is also substantial. For example, Symbicort DPIs generate anywhere from 3.4 to 12.5 times less CO_{2e} emissions than Albuterol Sulfate pMDIs, depending on the dosage and frequency of the DPI.[38] We do not want a cycle where treatments exacerbate the ongoing climate crisis, making more people ill and requiring more of these same treatments. The indirect costs employers and taxpayers incur for inhalers and the direct costs consumers pay at the pharmacy counter must be balanced with the environmental costs that exacerbate the very condition inhalers are used to treat.

Given the prevalence of asthma and COPD in the U.S., PCMA has a critical role to play in switching patients to environmentally safer inhalers *when medically feasible*. The Committee would like to work with you to ensure that these issues are fully examined and, where appropriate, addressed expeditiously. Thus, I ask that you respond to the following questions, in writing, by Tuesday, December 20, 2022.

a. Please provide the Committee with an overview of PCMA's efforts to reduce the environmental impact of pMDIs.
    i. What, if any, do the roles of inhaler price and rebates affect your member's consideration of inhalers when establishing formularies?
    ii. How does your consideration of formulary placement and out-of-pocket costs affect patient uptake of pMDIs compared to other safe and effective alternatives?
b. When developing drug formularies, to what extent do your members contemplate environmental factors?
    i. If these considerations are not being made, please explain why.
c. Have your member organizations completed any cost analyses on the impact of additional health care costs including hospital and physician visits related to increased asthma and/or COPD rates in their patient populations compared to switching more patients to environmentally preferred inhalers? Please describe any findings.
d. Please describe any barriers your members have encountered in placing environmentally preferred inhalers as preferred options for patients on formularies.

[35] *Id.*
[36] William B. Feldman et al., *Trends in Medicare Part D Inhaler Spending: 2012-2018,* 18:3 ANNALS OF THE AM. THORACIC SOCIETY at 548–550 (2021), https://doi.org/10.1513/AnnalsATS.202008-1082RL.
[37] *Medicare Part D: use of pharmacy benefit managers and efforts to manage drug expenditures and utilization*, U.S. GOV. ACCOUNTABILITY OFFICE (July 2019), https://www.gao.gov/assets/gao-19-498.pdf.
[38] *The environmental impact of inhalers,* supra note 26.

Thank you for your attention to this critical matter. If you have any question about this request, please contact Amy Hall of the Committee on Ways and Means Democratic Staff at Amy.Hall@mail.house.gov or (202) 225-3625.

Sincerely,

Richard E. Neal
Chairman
Committee on Ways and Means