

United States Senate

May 1, 2024

Emma Walmsley, Chief Executive Officer
GlaxoSmithKline
2929 Walnut Street Ste. 1700
Philadelphia, PA 19104

Dear Ms. Walmsley,

At the end of 2023, GlaxoSmithKline (GSK) stopped producing its Flovent HFA inhaler – the most commonly prescribed inhaler for young children with asthma, and one of the only inhalers that infants can use. Meanwhile, pursuant to an agreement with GSK, Prasco Laboratories has continued to produce and market an authorized generic version of Flovent called fluticasone. While GSK has committed to capping the price of many of its brand-name inhaler products at \$35, the price of the authorized generic fluticasone is not capped at \$35 and is generally not covered by insurance. In this way, your company appears to be exploiting a licensing agreement with Prasco Laboratories in order to circumvent your public commitments and price-gouge families without access to affordable alternatives to Flovent. Further, your decision to discontinue the brand product and force patients to purchase full-price fluticasone appears to have been designed to evade payments that GSK owed Medicaid for raising prices faster than inflation. This has led to a crisis for children with asthma, leaving families across the country with no way to afford this life-saving medication. I strongly encourage you to bring the Flovent HFA inhaler back to market until there are accessible alternatives, and to compel Prasco Laboratories to lower the price of the generic fluticasone to \$35.

Over 4 million children have asthma, including over 26,000 in New Hampshire.¹ Childhood asthma is a major cause of emergency department visits, hospitalizations, missed school days, and missed workdays for parents. The overall burden of childhood asthma costs the US health care system \$6 billion per year.²

The active steroid ingredient in Flovent, fluticasone, significantly decreases emergency department visits, hospitalizations, and has been prescribed for decades to control the symptoms of asthma.³ Flovent has been the top-prescribed pediatric asthma product for years because it is one of the only corticosteroid inhalers that can be used by children as young as infancy. In

¹ Centers for Disease Control and Prevention, “2021 Child Asthma Data: Prevalence Tables”, July 14, 2023. <https://www.cdc.gov/asthma/brfss/2021/child/tableL1.html>

² Pharmacoeconomics, “The Economic Burden of Pediatric Asthma in the United States: Literature Review of Current Evidence”, February 2019. doi: 10.1007/s40273-018-0726-2.

³ Centers for Disease Control and Prevention, “Asthma-related Missed School Days among Children aged 5–17 Years”, October 5, 2015. https://www.cdc.gov/asthma/asthma_stats/missing_days.htm ; Journal of Allergy and Clinical Immunology, “Observational Study of the Association of Fluticasone propionate/Salmeterol via a Single Device and Inhaled Corticosteroid Use in Children on Asthma Related Emergency Department and Hospitalization Visits”, February 2008. <https://doi.org/10.1016/j.jaci.2007.12.027>

addition, Flovent is often the only appropriate asthma inhaler for elderly patients, people with developmental disabilities, and other adults who cannot use a different steroid.⁴

After stopping production of Flovent in 2023, GSK shifted all of its Flovent inhalers to an identical-but-repackaged product under the generic manufacturer Prasco Laboratories. GSK announced this shift immediately before the company was scheduled to begin paying Medicaid new rebates to account for years of price increases for Flovent.

In early 2024, a new Medicaid rule for prescription drugs newly required manufacturers to pay rebates based on the historical price of their product compared to inflation. Congress reestablished these rebates in the American Rescue Plan Act of 2021 to account for decades of drug price increases that outpaced inflation.

Despite having had Flovent on the market for decades, GSK has consistently raised the list price well above inflation. For example, GSK increased the price of its Flovent HFA inhaler by nearly 50 percent since 2014.⁵ However, instead of paying Medicaid the rebates it owed in 2024, GSK appears to have used a loophole to preserve its profits from years of exorbitant price increases. GSK replaced both of its brand Flovent inhalers with an identical line of products licensed to a different manufacturer – a company that is conveniently exempt from Medicaid rebates, since it has no existing price history. Through your arrangement with Prasco Laboratories, GSK appears to be circumventing Medicaid rebates to protect decades of profits gained by price-gouging patients and public programs.

Since GSK's switch in January 2024, parents of children with asthma have faced a worst-case scenario: they cannot afford the new authorized generic product, which is not covered by most insurers and pharmacy benefit managers. Countless children no longer have a single age-appropriate inhaler covered by their insurance plan.

Physicians have shared with us the barriers that parents are facing to get fluticasone for their children. One family, whose 4-year-old son with severe asthma had multiple hospitalizations as a younger child, was charged \$130 for a month supply of generic fluticasone. Another family, whose 4-year-old son with severe asthma was doing well on Flovent, was denied coverage of any age-appropriate product for their child, despite two direct appeals from his pediatrician to their insurance company.

Although the list price of the new generic fluticasone inhaler is lower than the previous list price of Flovent HFA, Prasco Laboratories is not offering negotiable pricing terms to insurers to get the product covered on insurance formularies. This means that families either must pay the full list price – anywhere from \$150 to \$250 per month – or go without their children's medication. While GSK is no longer listed on the package, the authorized generic is still a GSK product, and GSK has a clear role – and financial stake – in Prasco's marketing strategy.

I urge GSK to put Flovent HFA back on the market in the short term and to work with Prasco to ensure access to affordable fluticasone. GSK and Prasco should do this by lowering the list price

⁴ ERJ Open Research, "Spacer devices for inhaled therapy: why use them, and how?" April 2018. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6004521/>

⁵ GoodRx Research, "Cash Price Trend for fluticasone propionate", February 28, 2024. <https://www.goodrx.com/healthcare-access/research>

of the generic product and expanding the \$35 out-of-pocket cost cap to generic fluticasone. These actions will ensure that patients of all ages and abilities can access life-saving asthma treatment.

Sincerely,

A handwritten signature in blue ink that reads "Maggie Hassan". The signature is fluid and cursive, with a long horizontal stroke at the end.

Margaret Wood Hassan
United States Senator

cc: Christopher Arington
Chief Executive Officer
Prasco Laboratories