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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

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June 27, 2025

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

Dear Ms. Walmsley:

Following the decision by GlaxoSmithKline (GSK) to discontinue the Flovent HFA inhaler in January 2024, children across the country have faced life-threatening medical challenges and families have grappled with more expensive or less effective alternative medications — when these options are available at all. In fact, reports over the past year noted significant increases in asthma-related hospitalizations and ICU admissions among the relevant patient population. Given these grave concerns, I write today to request documents and information about GSK's decision to discontinue Flovent HFA and the consequences of this decision.

My outreach today follows up on my letter from May 2024, in which I requested that GSK restore Flovent HFA — the most prescribed controller inhaler for young children with asthma — to the market.¹ I also requested that GSK work with Prasco Laboratories (Prasco) to lower the price of the authorized generic version of Flovent HFA that Prasco distributes to \$35. I noted that by discontinuing Flovent HFA, GSK appeared to have evaded payments that the company owed Medicaid for raising prices faster than the rate of inflation. Importantly, I explained that Flovent HFA was one of the only corticosteroid inhalers suitable for young children, elderly patients, people with developmental disabilities, and other adults with limited steroid options for treating asthma. Finally, I stressed that the discontinuation of Flovent HFA had created financial hardship for many families in New Hampshire and across the country who could not afford the new authorized generic product due to significant insurance coverage barriers.

¹ Letter from Senator Hassan to Emma Walmsley, Chief Executive Officer, GlaxoSmithKline (May 1, 2024).

Despite these concerns, GSK has not restored the Flovent HFA inhaler to the market or worked with Prasco to lower the price of the authorized generic. In its response to my previous letter, GSK also failed to offer a convincing explanation for why it decided to discontinue Flovent HFA while leaving other brand-name inhaler products on the market and capping their prices.² Notably, GSK also emphasized that Prasco “has control over pricing and contracting decisions” for the authorized generic and GSK “is not part of the process of negotiating or deciding formulary coverage, rebates or final net price.”³ Although GSK noted that the “wholesale acquisition cost for the [authorized generic] represents a 35 percent reduction from the branded Flovent,”⁴ previous rebates and discounts for Flovent HFA significantly reduced its list price and out-of-pocket costs for patients.⁵ GSK and Prasco have not offered these same discounts and rebates for the authorized generic — a fact that has led major insurers and pharmacy benefit managers (PBMs) to delay or deny coverage of the authorized generic.⁶

In fact, prior authorization requirements from PBMs and a lack of coverage from large insurers has limited patients’ access to the authorized generic alternative.⁷ Shortly after the discontinuation of Flovent HFA, for example, a spokesman for CVS Caremark explained that it would not carry the authorized generic because it “would be more expensive to include for its

² Letter from Amy Efantis, Vice President, Government Affairs, Public Policy & Patient Advocacy, to Senator Hassan (May 16, 2024).

³ *Id.*

⁴ *Id.*

⁵ *A Popular Asthma Inhaler is Leaving Pharmacy Shelves. Here’s What You Need to Know*, NPR (Dec. 30, 2023) (www.npr.org/sections/health-shots/2023/12/30/1222224197/a-popularasthma-inhaler-is-leaving-pharmacy-shelves-heres-what-you-need-to-know); STAT, *GSK is Replacing its Popular Flovent Inhaler with Authorized Generics, Raising Cost Concerns for Asthma Patients*, STAT (Jan. 5, 2024) (www.statnews.com/2024/01/05/flovent-asthma-inhaler-gsk-authorized-generic/); Stacie B. Dusetzina, Ameet Sarpatwari, and Michael A. Carrier, et al., *Patient and Payer Incentives to Use Patented Brand-Name Drugs vs Authorized Generic Drugs in Medicare Part D*, JAMA Internal Medicine (Oct. 18, 2021) (jamanetwork.com/journals/jamainternalmedicine/fullarticle/2785227) (explaining, in general, that plans “have limited incentives to encourage authorized generic drug use because rebates for brands likely exceed savings available with authorized generic drugs”).

⁶ *Discontinuation of Popular Asthma Medication, Flovent, Linked with Increased Hospitalization*, ABC News (Oct. 29, 2024) (<https://abcnews.go.com/Health/discontinuation-popular-asthma-medication-flovent-linked-increased-hospitalization/story?id=115267150>); *New Medicaid Rebate Rule Causes Problems for Asthma Patients on Flovent*, Forbes (Jan. 3, 2024) (www.forbes.com/sites/joshuacohen/2024/01/03/new-medicare-rebate-rule-causes-problems-for-asthma-patients-on-flovent/).

⁷ *As Childhood Asthma Worsens, Insurers Restrict Access to an Essential Medication*, STAT (May 16, 2024) (www.statnews.com/2024/05/16/asthma-medicine-discontinuation-flovent-children/).

clients than a brand name drug,” per STAT.⁸ Around the same time, another PBM, Optum Rx, stated that GSK introduced the authorized generic at a “much higher net price” than Flovent HFA and described this move as “put[ting] profits before patients.”⁹

Furthermore, alternative medications to the authorized Flovent HFA generic can pose their own challenges for patients with asthma. In a letter I received in March 2024, for example, the New England Pediatric Pulmonary Consortium explained:

Flovent HAD been THE #1 go-to preventive inhaler for asthma, prescribed by pediatric providers to millions of children for decades because it is one of very few inhaled corticosteroid “metered dose inhaler” (MDI) devices that can be used with a “spacer” attachment with a face mask for children as young as infancy.¹⁰

In addition, certain alternatives may not effectively treat eosinophilic esophagitis, a chronic allergic inflammatory condition for which Flovent HFA was the standard of care.¹¹ Even if patients can benefit from alternatives, shortages and coverage issues have limited access. One common alternative, Asmanex HFA, experienced substantial shortages throughout 2024,¹² and Alvesco, an alternative only available to older children, has lacked broad insurance coverage.¹³ As a result — despite GSK’s claim that it produces authorized generics “to facilitate...greater patient access”¹⁴ — the withdrawal of Flovent HFA, coverage dynamics for the authorized generic, and shortages of alternative drugs have created significant access barriers.

⁸ *‘It’s a Nightmare’: One of the Most Common Children’s Asthma Meds is No Longer Available, Leaving Families Scrambling*, STAT (Mar. 4, 2024) (www.statnews.com/2024/03/04/gsk-flovent-asthma/).

⁹ *Doctors and Parents are Scrambling After Asthma Inhaler Switch Takes Popular Medication Off the Market*, CNN (Feb. 13, 2024) (www.cnn.com/2024/02/13/health/asthma-medication-flovent/index.html).

¹⁰ Letter from the New England Pediatric Pulmonary Consortium to Senator Hassan (Mar. 26, 2024).

¹¹ Melissa Jenco, *Experts Call on Insurers to Prioritize Corticosteroid Medicines Appropriate for Children*, AAP News (Dec. 8, 2023) (publications.aap.org/aapnews/news/27474/Experts-call-on-insurers-to-prioritize).

¹² *A Top Inhaler for Children was Discontinued. Families and Doctors are Scrambling to Fill the Gap*, Boston Globe (June 12, 2024) (www.bostonglobe.com/2024/06/12/metro/asthma-inhaler-discontinued-children/).

¹³ *‘Kids Need to Breathe Just Like Adults Do’: \$35 Price Caps Don’t Apply to Asthma Meds Young Children Need, Doctors Say*, CNN (Apr. 17, 2024) (www.cnn.com/2024/04/17/health/asthma-inhaler-kids-price-cap/index.html).

¹⁴ Letter from Senator Hassan to Emma Walmsley, Chief Executive Officer, GlaxoSmithKline (May 1, 2024).

These barriers have continued since my May 2024 letter, which has resulted in life-threatening consequences for patients. According to a study published in October 2024, the patient population that has been prescribed fluticasone propionate — the active ingredient in Flovent HFA and alternatives — saw a 17.5 percent increase in asthma-related hospitalizations in the three months after the discontinuation of Flovent and a 24.1 percent increase in the following three to six months, compared to the average rates for the corresponding quarters in 2022 and 2023.¹⁵ Asthma-related ICU admission rates increased by similar percentages.¹⁶ In just one example, pediatricians at the Children’s Hospital of Philadelphia reported that asthma-related admissions increased by 50 percent in March and April 2024 compared to 2023, and intensive care admissions for children with asthma nearly doubled from the pre-pandemic baseline.¹⁷ Moreover, “[a]t least seven children have died due to uncontrolled asthma this year in the Philadelphia region, a dramatic increase from prior years.”¹⁸ In Kansas City, Missouri, one pediatric pulmonologist described the discontinuation of Flovent HFA as “just as big a disaster as we thought it was going to be.”¹⁹

GSK’s decision to discontinue Flovent HFA has also had far-reaching economic consequences. According to a November 2024 analysis from researchers at Johns Hopkins University, for example, GSK avoided an additional \$367.6 million in rebates to Medicaid in 2024 alone by discontinuing Flovent HFA.²⁰ Instead of receiving these rebates, Medicaid spent on net an estimated \$551.8 million on the authorized generic for 2024.²¹ At the patient level, physicians have also reported that even individuals with insurance coverage for the authorized generic have paid as much as \$150 for a single inhaler.²² In one example, an Ohio mother

¹⁵ Christopher Alban, Joe Deckert, and Nikki Carrico, et al., *Asthma Visits More Common After Flovent No Longer Manufactured*, Epic Research (Oct. 17, 2024) (www.epicresearch.org/articles/asthma-visits-more-common-after-flovent-no-longer-manufactured).

¹⁶ *Id.*

¹⁷ *As Childhood Asthma Worsens, Insurers Restrict Access to an Essential Medication*, STAT (May 16, 2024) (www.statnews.com/2024/05/16/asthma-medicine-discontinuation-flovent-children/).

¹⁸ *Id.*

¹⁹ *A Discontinued Asthma Medication Has Patients Scrambling, Some to the ER*, NPR (July 22, 2024) (www.npr.org/sections/shots-health-news/2024/07/22/nx-s1-5042364/a-discontinued-asthma-medication-haspatients-scrambling-some-to-the-er).

²⁰ Joseph F. Levy, Mariana P. Socal, and Jeromie M. Ballreich, *Strategic Manufacturer Response to the Medicaid Rebate Cap Removal*, JAMA Health Forum (Nov. 15, 2024) (jamanetwork.com/journals/jama-healthforum/fullarticle/2826158).

²¹ *Id.*

²² See Dr. Robyn Cohen and Dr. Christy Sadreameli, *Asthma Inhaler Chaos Leaves Us Doctors and the Children We Treat Out of Breath*, US News & World Report (Apr. 18, 2024)

learned she would pay \$70 a month for the authorized generic for her daughter compared to \$10 a month for Flovent — an unaffordable increase that left her “literally in tears.”²³ In addition, as I noted last year, 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 U.S. health care system an estimated \$6 billion per year.²⁴ By withdrawing Flovent HFA from the market, GSK has increased these existing economic and health care challenges.

To aid the Senate Finance Subcommittee on Health Care - Minority in understanding the factors that have led to these significant impacts on patients, the Medicaid program, and the U.S. economy, please provide responses to the following document and information requests:

1. The current version and any prior versions of the licensing agreement between GSK and Prasco for the authorized generic of Flovent HFA since January 1, 2020;
2. For both Flovent HFA and the authorized generic of Flovent HFA, the following information for each calendar year since January 1, 2020, if available:
 - a. The cost of goods sold;
 - b. The volume of goods manufactured and sold;
 - c. The net revenue generated from sales, broken out by payer type, including any lump sums, royalties, and licensing fees;
 - d. Average list price; and
 - e. Average net prices, after rebates and discounts, for the 10 largest commercial health plans, state Medicaid programs, and Medicare Part D plans;
3. Since product launch, net payments received annually from Medicaid for Flovent HFA and the authorized generic, including units, gross sales, and net sales, as well as rebates paid to Medicaid, disaggregated by inflationary rebates, best price rebates, and any supplemental rebates;
4. Any market analysis created since January 1, 2020, for Flovent HFA and the authorized generic, including but not limited to analyses concerning the products’ patient populations, the number and percentage of infants, children, and adults who used or use the products each year, and their utilization relative to other similar products;

(www.usnews.com/opinion/articles/2024-04-18/asthma-inhaler-chaos-leaves-us-doctors-and-the-children-we-treat-out-of-breath).

²³ Gerry Smith, *Asthma Patients Scramble for Alternatives to Popular Inhaler*, Bloomberg (Jan. 16, 2024) (www.bloomberg.com/news/newsletters/2024-01-16/flovent-inhaler-discontinued-where-to-find-alternatives-for-asthma).

²⁴ Richard Perry, George Braileanu, and Thomas Palmer, et al., *The Economic Burden of Pediatric Asthma in the United States: Literature Review of Current Evidence*, Pharmacoeconomics (Feb. 2019) ([pmc.ncbi.nlm.nih.gov/articles/PMC6386052/](https://pubmed.ncbi.nlm.nih.gov/articles/PMC6386052/)).

5. All documents, including but not limited to memoranda, presentations, spreadsheets, reports, studies, analyses, and forecasts, created since January 1, 2020, concerning:
 - a. The decision to license Prasco to sell an authorized generic of Flovent HFA and any alternatives considered;
 - b. Any potential generic competition for Flovent HFA;
 - c. Any discussion or analysis of the changes to the Medicaid Drug Rebate Program, including the impact of the cap removal, as applied to Flovent HFA;
 - d. The impact of discontinuing Flovent HFA on revenue, rebates, and costs, health outcomes, and access for patients;
 - e. Any options considered as alternatives to discontinuing Flovent HFA; and
 - f. The decision to lower the wholesale acquisition cost (WAC) for alternative medications Advair Diskus and Advair HFA instead of discontinuing these products;
6. The following information concerning GSK's patient assistance program for Flovent HFA for each calendar year since January 1, 2020:
 - a. The number of unique patients who received assistance through the program;
 - b. The number of inhaler products provided to patients at no or reduced cost, including the average number of inhaler products provided to each patient;
 - c. The total amount of financial assistance provided to patients and the average amount of financial assistance provided to each patient; and
 - d. The amount of any federal corporate tax deduction the company claimed in connection with the program;
7. Any settlement agreements between GSK and generic manufacturers concerning Flovent HFA since January 1, 2020; and
8. Any document productions concerning the issues outlined above made since January 1, 2020, to the U.S. Department of Justice, the U.S. Department of Health and Human Services Office of Inspector General, state attorneys general, any committee or subcommittee of the U.S. Congress, or any U.S. Attorney's office.

Please provide your responses as soon as possible but in no event later than July 18, 2025. If you have any questions related to this request, please contact Jasmine Masand at jasmine_masand@hassan.senate.gov or [REDACTED]. Please send any official correspondence relating to this request to jasmine_masand@hassan.senate.gov.

Sincerely,



Margaret Wood Hassan
Ranking Member
Senate Finance Subcommittee on Health Care

Emma Walmsley
June 27, 2025
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cc: Todd Young
Chairman