

December 4, 2024

Emma Walmsley
Chief Executive Officer
GlaxoSmithKline
9910 Belward Campus Dr
Rockville, Maryland 20850

Dear Ms. Walmsley,

On March 1, 2024, I wrote to GlaxoSmithKline (GSK) regarding its decision to discontinue its branded inhaler product, Flovent HFA – one of the two preferred products on the market that are safe for children with asthma – and, instead, introduce an authorized generic alternative at an artificially high price.¹ I was deeply disappointed that GSK’s March 27, 2024 response evaded the majority of my questions and failed to include information I requested regarding its pricing decisions for Flovent HFA and the authorized generic.² These omissions effectively obfuscated the true extent of GSK’s corporate profiteering and its effect on patients and taxpayers.

Since then, a study from researchers at Johns Hopkins University (JHU) has revealed that GSK’s scheme – designed to avoid accountability for years of outrageous price hikes on Flovent HFA – will cost state Medicaid programs nearly \$1 billion in 2024 alone.³ Even worse, recent reporting has confirmed pediatricians’ warnings that the discontinuation would “result in [more frequent] clinic visits, emergency department visits, hospitalization, or in some cases, loss of life.”⁴ According to one pediatric pulmonologist at a Kansas City, Missouri children’s hospital, GSK’s move “was just as big a disaster as we thought it was going to be.”⁵

GSK’s actions appear to be intended to circumvent new provisions passed by Congress to hold drug manufacturers accountable for years of historical price increases. Starting on January 1, 2024, drug manufacturers were required to begin paying increased penalties, or rebates, to Medicaid if

¹ Letter from Senator Warren to GSK CEO Emma Walmsley, March 1, 2024, https://www.warren.senate.gov/imo/media/doc/2024.03.01_Letter_to_GSK_on_Flovent_HFA.pdf.

² On file with the Office of Senator Elizabeth Warren.

³ JAMA Health Forum, “Strategic Manufacturer Response to the Medicaid Rebate Cap Removal,” Joseph Levy, Mariana Socal, and Jeromie Ballreich, November 15, 2024, <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2826158>.

⁴ Letter from the American Academy of Pediatrics to Payers, January 16, 2024, <https://downloads.aap.org/AAP/PDF/Flovent%20Formulary%20Replacements%20Letter.pdf>. 18 American College of Allergy Asthma and Immunology, “Facts and Stats – 8.3% of Americans Have Asthma,” <https://acaai.org/asthma/asthma-101/facts-stats/>.

⁵ NPR, “A discontinued asthma medication has patients scrambling, some to the ER,” Alan Yu, July 22, 2024, <https://www.npr.org/sections/shots-health-news/2024/07/22/nx-s1-5042364/a-discontinued-asthma-medication-has-patients-scrambling-some-to-the-er>.

they raised drug prices faster than the rate of inflation.⁶ In anticipation of the policy change, many of GSK’s largest rivals – including Eli Lilly, Novo Nordisk, and Sanofi – dramatically reduced prices for some of their best-selling products to avoid paying the increased penalties, delivering relief to millions of Americans.⁷ The Congressional Budget Office estimates that taxpayers and patients will save over \$18.5 billion from 2021 to 2031 thanks to these reforms.⁸

However, GSK chose a different path. Instead of lowering the price on the brand name Flovent HFA to avoid new penalties, as its competitors did, GSK took the drug off the market entirely on January 1, 2024 – the day the new penalties took effect. This maneuver allowed GSK to avoid up to \$367.6 million in rebates to Medicaid in 2024 alone.⁹

But GSK’s greed does not end there. In place of Flovent HFA, GSK pushed its own authorized generic – the same drug, marketed under a different label – in order to shield itself from increased penalties while remaining profitable. GSK has defended this move by pointing to the lower list price for its authorized generic – but the net price, which considers rebates and other discounts to insurers and government health programs, is much higher.

Indeed, your March 27, 2024, response confirmed that GSK offered a 90% discount on Flovent HFA in 2023, meaning that the average cost to insurers was just \$26:

[T]he average [2023] wholesale acquisition cost for all Flovent branded products was \$266 and the average net price was \$26. The difference between \$266 and \$26, that is, \$240, represents rebates, incentives, and other funds that inure to the benefit of other parties, such as pharmacy benefit managers (“PBMs”), not GSK.¹⁰

While you provided complete pricing information for Flovent HFA – including its net price after rebates and discounts – you hid behind your contract with Prasco, LLC (Prasco), and claimed it was impossible for your company to provide comparable information for the authorized generic. You also failed to detail any profit sharing between GSK and Prasco for the authorized generic, including whether Prasco pays GSK any royalties to distribute the drug, as Prasco has done with other brand name manufacturers.¹¹

⁶ Kaiser Family Foundation, “What Are the Implications of the Recent Elimination of the Medicaid Prescription Drug Rebate Cap,” January 16, 2024, <https://www.kff.org/policy-watch/what-are-the-implications-of-the-recent-elimination-of-the-medicaid-prescription-drug-rebate-cap/#:~:text=What%20are%20the%20implications%20of%20lifting%20the%20rebate%20cap%3F,avoid%20paying%20additional%20Medicaid%20rebates>.

⁷ Wall Street Journal, “How Lowering The Price of a Common Asthma Drug Made It Harder to Get,” Joseph Walker, December 29, 2023, <https://www.wsj.com/health/pharma/how-lowering-the-price-of-a-common-asthma-drug-made-it-harder-to-get-ee101bff>.

⁸ Congressional Budget Office, “Cost Estimate,” February 14, 2021, <https://www.cbo.gov/system/files/2021-02/EnergyandCommerceReconciliationEstimate.pdf>.

⁹ JAMA Health Forum, “Strategic Manufacturer Response to the Medicaid Rebate Cap Removal,” Joseph Levy, Mariana Socal, and Jeromie Ballreich, November 15, 2024, <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2826158>.

¹⁰ On file with the Office of Senator Elizabeth Warren.

¹¹ Santarus, INC., “Form 10-K,” <https://www.sec.gov/Archives/edgar/data/1172480/000119312513089895/d455826d10k.htm>.

Nevertheless, the JHU researchers confirmed the true extent of your corporate profiteering: After accounting for rebates and discounts, their analysis indicated that the average net price of the authorized generic is roughly *four* times more expensive than Flovent HFA. As a result, GSK and Prasco are on track to rake in \$551.8 million just from Medicaid in 2024 alone.¹²

In other words, by discontinuing Flovent HFA and peddling its own authorized generic, GSK will avoid \$367.6 million in rebate payments to Medicaid and, instead, *charge* Medicaid over \$551.8 million in 2024 – a nearly \$1 billion swing. Indeed, when asked about how the maneuver impacted GSK’s bottom-line, Emma Walmsley told investors the discontinuation of Flovent HFA “has been fully offset by the increased use of authorised generic versions of Advair and Flovent.”¹³

Furthermore, while many state Medicaid agencies have chosen to serve at-risk children by covering GSK’s more expensive authorized generic, many private insurers have not. As a result, doctors have scrambled to shift their patients over to the only other viable alternative for children with asthma, Asmanex, which has experienced shortages due to increased demand.¹⁴ At the Children’s Hospital of Philadelphia, for example, GSK’s maneuver contributed to a 50 percent increase in admissions for children with asthma in March and April, just three months after the discontinuation of Flovent HFA¹⁵ and likely when pharmacists ran out of reserves.¹⁶ In the Philadelphia region alone, at least seven children tragically died between January and July due to uncontrolled asthma, which is “significantly more than in previous years.”¹⁷

Patients, providers, and taxpayers deserve answers for your unconscionable profiteering. Since you failed to provide complete answers to the majority of my questions in your March 27, 2024, response, including key details regarding pricing decisions for the authorized generic and your contractual relationship with Prasco, I accordingly request a complete response to the following questions by no later than December 18, 2024:

1. What was the average net price, after rebates and discounts, for the authorized generic of Flovent HFA for the ten largest commercial health insurers in the country in 2023?
2. What was the average net price, after rebates and discounts, for the authorized generic of Flovent HFA for state Medicaid agencies and Part D plans?

¹² JAMA Health Forum, “Strategic Manufacturer Response to the Medicaid Rebate Cap Removal,” Joseph Levy, Mariana Socal, and Jeromie Ballreich, November 15, 2024, <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2826158>.

¹³ GSK, “GSK delivers continue strong performance and upgrades 2024 guidance,” July 31, 2024, <https://www.gsk.com/media/11412/q2-2024-results-announcement.pdf>.

¹⁴ STAT, “As childhood asthma worsens, insurers restrict access to an essential medication,” Chén Kenyon, Bianca Nfonoyim Bernhard, and Tyra Bryant-Stephens, May 16, 2024, <https://www.statnews.com/2024/05/16/asthma-medicine-discontinuation-flovent-children/>.

¹⁵ *Id.*

¹⁶ NBC Boston, “Popular asthma medication discontinued, leaving patients scrambling for alternatives,” Mary Markos, March 5, 2024, <https://www.nbcboston.com/news/local/a-popular-asthma-medication-was-discontinued-leaving-patients-scrambling-for-alternatives/3298604/>.

¹⁷ NPR, “A discontinued asthma medication has patients scrambling, some to the ER,” Alan Yu, July 22, 2024, <https://www.npr.org/sections/shots-health-news/2024/07/22/nx-s1-5042364/a-discontinued-asthma-medication-has-patients-scrambling-some-to-the-er>.

3. Will you supply a copy of the licensing agreement between GSK and Prasco for the authorized generic?
 - a. Does GSK charge Prasco a per-unit price to distribute its authorized generic, or is there an upfront cost?
 - b. Is Prasco required to pay any royalties to GSK on the annual net sales of the authorized generic? If so, what is the royalty percentage, and does the percentage tiered based on annual net sales of the authorized generic?
 - c. Specifically, for each unit of the authorized generic of Flovent HFA sold by Prasco, how much revenue does GSK earn? Please provide an answer for each size and formulation of Flovent HFA.
4. Please list the volume sales of Flovent HFA and the authorized generic for the last five years.
5. Has GSK expanded its low-income assistance programs for patients that are denied access to the authorized generic by their PBM or insurer?
6. Will you provide me with a copy of your licensing agreement or contract with Prasco?

Sincerely,



Elizabeth Warren
United States Senator

CC: E. Thomas Arington, Founder & Chairman Prasco Laboratories