

March 11, 2025

Juliet T. Hodgkins
Principal Deputy Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Principal Deputy Inspector General Hodgkins,

I write to request that your office conduct an investigation into the outrageous profiteering by GlaxoSmithKline (GSK), whose brazen circumvention of the *American Rescue Plan Act's* (ARPA's) Medicaid rebates has raised drug costs for taxpayers and patients alike — while putting patients at grave risk. To avoid paying over \$350 million in penalties for rapidly hiking the price of Flovent HFA well above the inflation rate, GSK chose to discontinue the medication and, in its place, introduce an authorized generic alternative at an artificially high price, costing Medicaid nearly \$1 billion in 2024 alone.¹ These higher prices have also deterred private insurers from covering the generic, impeding access to the medication — one of a small number of inhaler products appropriate for children — and inducing a shortage of its primary alternative for pediatric patients.²

GSK increased the price of Flovent HFA by about 50% between 2013 and 2023 — far above the rate of inflation.³ To disincentivize such exorbitant price hikes and incentivize price drops, ARPA expanded the rebate that drugmakers must pay to Medicaid if they raise the price of a drug faster than the inflation rate.⁴ The Congressional Budget Office estimated that this expanded rebate will save taxpayers \$18.5 billion between 2021 and 2031.⁵ The expanded rebate came into effect on January 1, 2024, and would have required GSK to pay an estimated \$368 million penalty if it had kept Flovent HFA on the market without lowering the drug's price.⁶

¹ JAMA Health Forum, “Strategic Manufacturer Reponse to the Medicaid Rebate Cap Removal,” Joseph Levy, Mariana Social, and Jeromie Ballreich, November 15, 2024, <https://jamanetwork.com/journals/jama-healthforum/fullarticle/2826158>.

² 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/>.

³ NPR, “A popular asthma inhaler is leaving pharmacy shelves. Here’s what you need to know,” Sydney Lupkin, December 30, 2023, <https://www.npr.org/sections/health-shots/2023/12/30/1222224197/a-popularasthma-inhaler-is-leaving-pharmacy-shelves-heres-what-you-need-to-know>; U.S. Bureau of Labor Statistics, “CPI Inflation Calculator,” https://www.bls.gov/data/inflation_calculator.htm.

⁴ 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/>.

⁵ Congressional Budget Office, “Cost Estimate,” February 14, 2021, p. 16 <https://www.cbo.gov/system/files/2021-02/EnergyandCommerceReconciliationEstimate.pdf>.

⁶ JAMA Health Forum, “Strategic Manufacturer Response to the Medicaid Rebate Cap Removal,” Joseph Levy, Mariana Social, and Jeromie Ballreich, November 15, 2024, <https://jamanetwork.com/journals/jama-healthforum/fullarticle/2826158>.

However, instead of paying the rebate *or* lowering the drug’s price, GSK instead chose to discontinue Flovent HFA entirely on January 1, 2024 — the day the increased rebate took effect.⁷ At the same time, GSK licensed an authorized generic version of Flovent HFA — the same drug, marketed under a different label — to Prasco, a company that specializes in peddling authorized generics for brand-name drugmakers.⁸ Although generic drugs are typically cheaper than brand-name products, in this case GSK and Prasco are charging Medicaid and other insurers more for the authorized generic than GSK had been charging for Flovent HFA.⁹ This profiteering scheme has fleeced taxpayers and circumvented the intent of ARPA’s expanded inflation rebate. Indeed, when asked about how the maneuver impacted the company’s bottom-line, GSK CEO Emma Walmsley told investors the discontinuation of Flovent HFA “has been fully offset by the increased use of authorized generic versions of Advair and Flovent.”¹⁰

In addition to overcharging Medicaid, GSK’s greed may have had deadly impacts. Due to the authorized generic’s higher pricing, numerous private insurers have chosen not to cover it or to exclude it from their lists of preferred drugs — putting the medication financially out of reach for a large number of patients who had relied on it to treat their asthma or allergies.¹¹ This has particularly affected young children with asthma, who cannot tolerate most other inhaler medications.¹² To make matters worse, the primary alternative to Flovent HFA that is appropriate for young children, Asmanex, has faced a shortage due to increased demand from former Flovent HFA patients scrambling to find an alternative that is covered by their insurance.¹³ This crisis has created gaps in access to medically necessary treatment for patients who are unable to afford the authorized generic or access an alternative. In one STAT News article, a group of pediatricians wrote that due to Flovent HFA’s discontinuation, they “are now regularly seeing children who require repeat hospitalizations and ED visits because their needed controller medicine is not covered by insurance and therefore the asthma gets out of control.”¹⁴ These physicians continued, describing the consequences due to “families having to go without basic medications to control their child’s asthma.”:

At least seven children have died due to uncontrolled asthma this year in the Philadelphia region, a dramatic increase from prior years. ... admissions for intensive care to support children with asthma have nearly doubled ... and admissions for asthma are up 50% ... compared to last year.¹⁵

⁷ *Id.*

⁸ STAT, “GSK is replacing its popular Flovent inhaler with authorized generics, raising cost concerns for asthma patients,” January 5, 2024, Annalisa Merelli, <https://www.statnews.com/2024/01/05/flovent-asthma-inhaler-gsk-authorized-generic/>.

⁹ Letter from Senator Elizabeth Warren to GSK CEO Emma Walmsley, December 4, 2024, pp.2-3, https://www.warren.senate.gov/imo/media/doc/letter_to_gsk_on_flovent_hfa.pdf.

¹⁰ GSK, “GSK delivers continue strong performance and upgrades 2024 guidance,” July 31, 2024, p.6 <https://www.gsk.com/media/11412/q2-2024-results-announcement.pdf>

¹¹ 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/>.

¹² *Id.*

¹³ *Id.*; ColumbiaDoctors, “Helping Parents and Kids Find an Alternative to Flovent,” <https://www.columbiadoctors.org/news/helping-parents-and-kids-find-alternative-flovent>.

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.*

Several months after Flovent’s discontinuation, patients who had previously been using Flovent faced a 24% rise in hospitalizations.¹⁶ Sufficient access to affordable inhaler medications is a matter of life or death for many patients with asthma. Tragically, in January 2024 a Wisconsin man died from a severe asthma attack because he was unable to access his GSK inhaler after his insurance stopped covering it.¹⁷

To gather more information on the crisis caused by GSK’s discontinuation of Flovent HFA, I wrote to the drugmaker in March 2024 with a series of questions about its pricing decisions and patients’ access to the authorized generic.¹⁸ Disappointingly, GSK’s response failed to answer the majority of my questions and withheld the pricing data that I had requested.¹⁹

Several months later, a team of health economists at the Johns Hopkins Bloomberg School of Public Health estimated that the average net price GSK has charged insurers for the authorized generic is *four* times as high as the price that the drugmaker charged for Flovent HFA.²⁰ According to the researchers, GSK charged Medicaid an estimated net \$552 million in 2024, whereas the manufacturer would have needed to *pay* Medicaid a net \$368 million in price gouging penalties had they not discontinued Flovent HFA or lowered its price. This is a swing of nearly \$1 billion that will simply pad GSK’s profits with taxpayer dollars.

I wrote to GSK for a second time in December 2024 after reviewing the researchers’ findings.²¹ In response, the drugmaker again evaded my questions regarding its pricing decisions. GSK’s reply largely focused on its new patient assistance program targeted at uninsured patients, entirely sidestepping my concerns about its overcharging of Medicaid and insured patients’ loss of access to the medication.²² Two months later, Arizona Attorney General Kris Mayes sued GSK for its corrupt Flovent pricing scheme, alleging that the company violated the *Arizona Consumer Fraud Act* and that its “manipulation of the system has left countless patients without access to life-saving medication, caused a spike in emergency room visits, and likely contributed to preventable deaths.”²³

Given the ongoing budgetary consequences for Medicaid, and the deadly consequences for patients, I write to request that your office review the impacts of GSK’s choice to discontinue Flovent while replacing it with a more expensive authorized generic. This investigation should address the following questions:

¹⁶ ABC News, “Discontinuation of popular asthma medication, Flovent, linked with increased hospitalization,” Sejal Parekh and Sara Avery, October 29, 2024, <https://abcnews.go.com/Health/discontinuation-popular-asthma-medication-flovent-linked-increased-hospitalization/story?id=115267150>.

¹⁷ The Washington Post, “Man dies of asthma attack after inhaler cost skyrockets to more than \$500,” Jonathan Edwards, February 10, 2025, <https://www.washingtonpost.com/business/2025/02/10/inhaler-cost-death-optum-rx-walgreens/>.

¹⁸ 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

¹⁹ Letter from GSK CEO Emma Walmsley to Senator Warren, March 27, 2024, On file with the Office of Senator Elizabeth Warren.

²⁰ JAMA Health Forum, “Strategic Manufacturer Response to the Medicaid Rebate Cap Removal,” Joseph Levy, Mariana Social, and Jeromie Ballreich, November 15, 2024, <https://jamanetwork.com/journals/jama-healthforum/fullarticle/2826158>.

²¹ Letter from Senator Elizabeth Warren to GSK CEO Emma Walmsley, December 4, 2024, https://www.warren.senate.gov/imo/media/doc/letter_to_gsk_on_flovent_hfa.pdf.

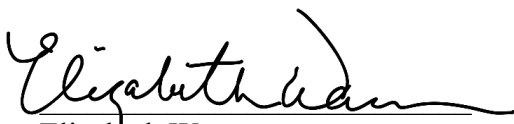
²² Letter from GSK CEO Emma Walmsley to Senator Warren, December 18, 2024, On file with the Office of Senator Elizabeth Warren.

²³ Arizona Attorney General Kris Mayes, “Attorney General Mayes Sues Pharmaceutical Company GlaxoSmithKline for Endangering Asthma Patients,” press release, February 6, 2025, <https://www.azag.gov/press-release/attorney-general-mayes-sues-pharmaceutical-company-glaxosmithkline-endangering-asthma>.

- 1) Has GSK or Prasco broken any Medicaid drug pricing laws or violated any federal drug pricing or payment rules with this scheme?
- 2) How have GSK's actions impacted Medicaid?
 - a) In 2024, what was the average net price, after rebates and discounts, for the authorized generic of Flovent HFA for state Medicaid agencies and Medicare Part D plans?
 - b) In 2023, what was the average net price, after rebates and discounts, for Flovent HFA for state Medicaid agencies and Medicare Part D plans?
 - c) By HHS OIG's estimation, how much did GSK's pricing scheme cost Medicaid, relative to an alternative scenario in which GSK did not discontinue Flovent HFA or introduce the authorized generic?
- 3) How have GSK's and Prasco's actions impacted insured patients?
 - a) To what extent have insured patients paid higher out-of-pocket costs due to GSK's pricing scheme?
 - b) To what extent have insured patients, including children with asthma, lost access to essential medication due to GSK's pricing scheme?
- 4) How have GSK's and Prasco's actions impacted uninsured patients?
 - a) To what extent have uninsured patients paid higher out-of-pocket costs due to GSK's pricing scheme?
 - b) To what extent have uninsured patients, including children with asthma, lost access to essential medication due to GSK's pricing scheme?
- 5) Have any other drugmakers evaded ARPA's expanded inflation rebate by discontinuing a drug, or otherwise engaging in a pricing scheme similar to GSK's? If so, how much did their actions cost Medicaid, how much did their actions cost patients out-of-pocket, and to what extent was access to care reduced?
- 6) What regulations could HHS implement to:
 - a) Prevent other drugmakers from following GSK's example by discontinuing an existing drug and reintroducing it as a more expensive authorized generic?
 - b) Mitigate the harms of GSK's pricing scheme or any similar pricing schemes implemented by drugmakers in the future?
- 7) What legislative fixes could Congress pass to:
 - a) Prevent other drugmakers from following GSK's example by discontinuing an existing drug and reintroducing it as a more expensive authorized generic?
 - b) Mitigate the harms of GSK's pricing scheme or any similar pricing schemes implemented by drugmakers in the future?

Thank you for your attention to this important matter.

Sincerely,



Elizabeth Warren
United States Senator